NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

Editor's Note: The following Notices of Final Rulemaking were exempt from Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 2688.)

[R12-198]

PREAMBLE

1. Articles, Parts, or Sections Affected (as applicable) — **Rulemaking Action**

R4-23-110	Amend
R4-23-620	New Section

2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. § 32-1904(A)(1)

Implementing statute: A.R.S. § 32-1973

3. The effective date of the rule:

December 2, 2012

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

Notice of Rulemaking Docket Opening: 14 A.A.R. 1241, April 18, 2008

Notice of Rulemaking Docket Opening: 18 A.A.R. 4, January 6, 2012

Notice of Proposed Rulemaking: 18 A.A.R. 564, February 24, 2012

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

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy P.O. Box 18520 Phoenix, AZ 85005
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	dwright@azpharmacy.gov

6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

During the 48th Legislative Session in 2007, the Legislature passed HB 2255 adding A.R.S. § 32-1973 to the Pharmacy Act. A.R.S. § 32-1973 requires each pharmacy to implement or participate in a continuous quality assurance program to review pharmacy procedures in order to identity methods for addressing pharmacy medication errors. The Board is required to make rules to implement the statute. The Board opened a docket on the rulemaking April 18, 2008, but the rulemaking was suspended during the rulemaking moratorium beginning in 2009. The Board is now ready to proceed with the rulemaking.

The rulemaking will include necessary new definitions added to R4-23-110 (Definitions) and a new Section R4-23-620 (Continuous Quality Assurance Program) to prescribe the program, policy and procedure, and recordkeeping requirements. 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 approval of these rules will benefit the public health and safety by clearly establishing standards that require pharmacies to implement or participate in a continuous quality assurance program to review pharmacy procedures in order to identify methods for addressing pharmacy medication errors.

7. A reference to any study relevant to the rules that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rules, 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.

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

Not applicable

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

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

The Board estimates the amended rules will have minimal economic impact on pharmacies. The statute establishes the requirement that pharmacies must implement or participate in a continuous quality assurance program. The rulemaking will establish the pharmacy procedures and record keeping requirements to assure the Board that a pharmacy has implemented or participated in a continuous quality assurance program. The Board will not be able to review the actual records of a pharmacy's quality assurance program, as those documents are considered peer review documents and not subject to subpoena or discovery in any arbitration or civil proceedings. The Board estimates that the majority of pharmacies already have some type of quality assurance program in place. The only thing lacking is satisfactory documentation of such programs. The rulemaking will establish necessary policy and procedure requirements for documenting compliance with the statutory requirement that a pharmacy must implement or participate in a continuous quality assurance program. The Board estimates the costs for the average pharmacy to implement a quality assurance program is minimal.

The approximate start up costs for a standard pharmacy quality assurance program using generic 2012 pharmacy market/employment compensation figures for Arizona is $627.50. The approximate annual maintenance costs for a standard pharmacy quality assurance program (CQA) using generic 2012 pharmacy market/employment compensation figures for Arizona in subsequent years after start up is $410.00. The costs breakdown includes:

Drafting of Policy and Procedures (P&P):

4 hours- $133/Start up Cost: Senior Pharmacy Technician Staff (Administrative Level $25/hour plus 30% Salary and Fringe);
1 hour- $84.50/Start up Cost: Senior Director, Pharmacy Operations Review and Edits for P&P, Final Approval (Senior RPh Staff, $65/hour plus S&F);

Annual Review and Update of P&P:

30 min - $16.25/Annual Expense: QA Staff Review of P&P and Update, if necessary;
30 min - $42.50/Annual Expense: Senior Pharmacy Operations RPh, Review and Approval of P&P Annual Update;

Annual Meeting on CQA Program:

2 hours - $143.00/Annual Expense: Pharmacist-in-charge at pharmacy ($55/hr plus 30% S&F);
2 hours - $91.00/Annual Expense: CQA Director (#35/hr plus 30% S&F);

Annual Training on CQA and P&P:

1 hour - $45.50/Annual Expense: CQA Director;
1 hour - $71.75/Annual Expense: Pharmacist-in-charge.

Total Start Up/ First Year: $627.50

Annual Cost (Subsequent Years): $410.00.

The Board believes that approval of these rules will benefit the public health and safety by clearly establishing standards that require pharmacies to implement or participate in a continuous quality assurance program to review pharmacy procedures in order to identify methods for addressing pharmacy medication errors.

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

There are no substantial changes in the final rules from the proposed rules. There are minor changes to style, format, grammar, and punctuation requested by GRRC staff.

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

A public hearing was held March 26, 2012. Janet Underwood representing the Arizona Community Pharmacy Committee attended the public hearing. Ms. Underwood provided written comment from the Arizona Community Pharmacy Committee voicing support for the rulemaking. No other comments were received.

12. All agencies shall list any other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:
The rule itself does not require a permit. However, the pharmacy permit required by statute arguably falls within the definition of general permit in A.R.S. § 41-1001.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:
No

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:
No

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rule:
None

14. Whether the rule was previously made, amended or repealed as an emergency rule. If so, cite the notice published in the *Register* as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:
No

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section
R4-23-110. Definitions

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section
R4-23-620. ~~Reserved~~ Continuous Quality Assurance Program

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to 4 A.A.C. 23:

"Active ingredient" No change

"AHCCCS" No change

"Alternate physician" No change

"Annual family income" No change

"Approved course in pharmacy law" No change

"Approved Provider" No change

"Authentication of product history" No change

"Automated storage and distribution system" No change

"Batch" No change

"Beyond-use date" No change

"Biological safety cabinet" No change

"Care-giver" No change

"Community pharmacy" No change
"Component" No change
"Compounding and dispensing counter" No change
"Computer system" No change
"Computer system audit" No change
"Contact hour" No change
"Container" No change
"Continuing education" No change
"Continuing education activity" No change
"Continuing education unit" or "CEU" No change
"Continuous quality assurance program" or "CQA program" means a planned process designed by a pharmacy permittee to identify, evaluate, and prevent medication errors.
"Correctional facility" No change
"CRT" No change
"CSPMP" No change
"Current good compounding practices" No change
"Current good manufacturing practice" No change
"Cytotoxic" No change
"Day" No change
"DEA" No change
"Declared disaster areas" No change
"Delinquent license" No change
"Dietary supplement" No change
"Digital signature" No change
"Dispensing pharmacist" No change
"Drug sample" No change
"Drug therapy management" No change
"Drug therapy management agreement" No change
"Earned income" No change
"Electronic signature" No change
"Eligible patient" No change
"Extreme emergency" No change
"Family unit" No change
"FDA" No change
"Health care decision maker" No change
"Health care institution" No change
"Immediate notice" No change
"Inactive ingredient" No change
"Internal test assessment" No change
"ISO Class 5 environment" No change
"ISO Class 7 environment" No change
"Licensed health care professional" No change
"Limited-service correctional pharmacy" No change
"Limited-service long-term care pharmacy" No change
"Limited-service mail-order pharmacy" No change
"Limited-service nuclear pharmacy" No change
"Limited-service pharmacy permittee" No change

"Limited-service sterile pharmaceutical products pharmacy" No change

"Long-term care consultant pharmacist" means a pharmacist providing consulting services to a long-term care facility.

"Long-term care facility" or "LTCF" No change

"Lot" No change

"Lot number" or "control number" No change

"Low-income subsidy" No change

"Materials approval unit" No change

"Mechanical counting device for a drug in solid, oral dosage form" No change

"Mechanical storage and counting device for a drug in solid, oral dosage form" No change

"Mediated instruction" No change

"Medical practitioner-patient relationship" No change

"Medicare" No change

"Medication error" means any unintended variation from a prescription or medication order. Medication error does not include any variation that is corrected before the medication is dispensed to the patient or patient's care-giver, or any variation allowed by law.

"Mobile pharmacy" No change

"MPJE" No change

"NABP" No change

"NABPLEX" No change

"NAPLEX" No change

"Order" No change

"Other designated personnel" No change

"Outpatient" No change

"Outpatient setting" No change

"Patient profile" No change

"Pharmaceutical patient care services" No change

"Pharmaceutical product" No change

"Pharmacist-administered immunizations training program" No change

"Pharmacy counter working area" No change

"Pharmacy law continuing education" No change

"Pharmacy permittee" No change

"Physician" No change

"Physician-in-charge" No change

"Poverty level" No change

"Precursor chemical" No change

"Prepackaged drug" No change

"Prep area" No change

"Primary care provider" No change

"Proprietor" No change

"Provider pharmacy" No change

"Radiopharmaceutical" No change

"Radiopharmaceutical quality assurance" No change

"Radiopharmaceutical services" No change

"Red C stamp" No change

"Refill" No change

"Regulated chemical" No change

"Remodel" No change

"Remote drug storage area" No change
"Resident" No change
"Responsible person" No change
"Score transfer" No change
"Security features" No change
"Shared order filling" No change
"Shared order processing" No change
"Shared services" No change
"Sight-readable" No change
"Single-drug audit" No change
"Single-drug usage report" No change
"Standard-risk sterile pharmaceutical product" No change
"State of emergency" No change
"Sterile pharmaceutical product" No change
"Strength" No change
"Substantial-risk sterile pharmaceutical product" No change
"Supervision" No change
"Supervisory physician" No change
"Supplying" No change
"Support personnel" No change
"Temporary pharmacy facility" No change
"Tourist" No change
"Transfill" No change
"Unearned income" No change
"Verified signature" or "signature verifying" No change
"Veteran" No change
"Wholesale distribution" No change
"Wholesale distributor" No change

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-620. ~~Reserved~~ Continuous Quality Assurance Program

A. Each pharmacy permittee shall implement or participate in a continuous quality assurance (CQA) program. A pharmacy permittee meets the requirements of this Section if it holds a current general, special or rural general hospital license from the Arizona Department of Health Services and is any of the following:
1. Certified by the Centers for Medicare and Medicaid Services to participate in the Medicare or Medicaid programs;
2. Accredited by the Joint Commission on the Accreditation of Healthcare Organizations; or
3. Accredited by the American Osteopathic Association.

B. A pharmacy permittee or the pharmacist-in-charge shall ensure that:
1. The pharmacy develops, implements, and utilizes a CQA program consistent with the requirements of this Section and A.R.S. § 32-1973;
2. The medication error data generated by the CQA program is utilized and reviewed on a regular basis, as required by subsection (D); and
3. Training records, policies and procedures, and other program records or documents, other than medication error data, are maintained for a minimum of two years in the pharmacy or in a readily retrievable manner.

C. A pharmacy permittee or pharmacist-in-charge shall:
1. Ensure that policies and procedures for the operation and management of the pharmacy's CQA program are prepared, implemented, and complied with;
2. Review biennially and, if necessary, revise the policies and procedures required under subsection (C)(1);
3. Document the review required under subsection (C)(2);
4. Assemble the policies and procedures as a written or electronic manual; and
5. Make the policies and procedures available within the pharmacy for employee reference and inspection by the Board or its staff.

D. The policies and procedures shall address a planned process to:
1. Train all pharmacy personnel in relevant phases of the CQA program;
2. Identify and document medication errors;
3. Record, measure, and analyze data collected to:
   a. Assess the causes and any contributing factors relating to medication errors, and
   b. Improve the quality of patient care;
4. Utilize the findings from subsections (D)(2) and (3) to develop pharmacy systems and workflow processes designed to prevent or reduce medication errors; and
5. Communicate periodically, and at least annually, with pharmacy personnel to review CQA program findings and inform pharmacy personnel of any changes made to pharmacy policies, procedures, systems, or processes as a result of CQA program findings.

E. The Board's regulatory oversight activities regarding a pharmacy's CQA program are limited to inspection of the pharmacy's CQA policies and procedures and enforcing the pharmacy's compliance with those policies and procedures.

F. A pharmacy's compliance with this Section shall be considered by the Board as a mitigating factor in the investigation and evaluation of a medication error.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R12-197]

PREAMBLE

1. Articles, Parts, or Sections Affected — **Rulemaking Action**

R4-23-110	Amend
R4-23-1005	Amend

2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. §§ 32-1904(A)(1) and 36-2521

Implementing statute: A.R.S. §§ 36-2512(B), 36-2513(B), 36-2514(B), 36-2515(B), and 36-2523

3. The effective date of the rule:

December 2, 2012

4. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the proposed rule:

Notice of Rulemaking Docket Opening: 18 A.A.R. 5, January 6, 2012

Notice of Proposed Rulemaking: 18 A.A.R. 996, May 4, 2012

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

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy P.O. Box 18520 Phoenix, AZ 85005
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	dwright@azpharmacy.gov

6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

During the Board's Five-Year Rule Review approved September 14, 2010, the Board determined that R4-23-1005 (Substances Excepted from the Schedules of Controlled Substances) needed to be amended to update citations in subsections (A), (B), and (C).

The rulemaking will include amending definitions in R4-23-110 (Definitions) that the Board has identified as due for update, such as, "continuing education" and "pharmacist-administered immunizations training program." The rulemaking will delete definitions identified after the repeal of the Drug Therapy Management rules in December 2011 that only relate to the repealed Drug Therapy Management rules and are no longer necessary. The rule 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 approval of these rules will benefit the public health and safety by clearly establishing those substances that are excepted from the schedules of controlled substances.

7. A reference to any study relevant to the rules that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rules, 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.

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

Not applicable

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

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

The Board estimates the amended rules will have no economic impact on pharmacist and pharmacies. The rulemaking is necessary to update citations in subsections (A), (B), and (C) of R4-23-1005 (Substances Excepted from the Schedules of Controlled Substances). The citations to federal law were last updated in August 2000 and need to be updated. The rulemaking includes amending definitions in R4-23-110 (Definitions) that the Board has identified as due for update, such as, "continuing education" and "pharmacist-administered immunizations training program." The rulemaking deletes definitions identified after the repeal of the Drug Therapy Management rules in December 2011 that only relate to the repealed Drug Therapy Management rules and are no longer necessary. The amending of these definitions will have no economic impact on pharmacists or pharmacies.

The Board believes that approval of these rules will benefit the public health and safety by clearly establishing those substances that are excepted from the schedules of controlled substances.

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

There are no substantial changes in the final rules from the proposed rules. There are minor changes to style, format, grammar, and punctuation requested by GRRC staff.

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

A public hearing was held June 5, 2012. Janet Underwood, representing the Arizona Community Pharmacy Committee, attended the public hearing. Ms. Underwood provided written comment from The Arizona Community Pharmacy Committee, voicing support for the rulemaking. No other comments were received.

12. All agencies shall list any other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

The rules do not require a permit.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

Yes, the rule specifically cites federal law. No, the rule is not more stringent than federal law. To ensure uniformity, the rule incorporates by reference federal law.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No

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

21 CFR 1308.22, April 1, 1012, in R4-23-1005(A)

21 CFR 1308.24, April 1. 2012, in R4-23-1005(B)

21 CFR 1308.32, April 1, 2012, in R4-23-1005(C)

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

No

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section
R4-23-110. Definitions

ARTICLE 10. UNIFORMED CONTROLLED SUBSTANCES AND DRUG OFFENSES

Section
R4-23-1005. Substances Excepted from the Schedules of Controlled Substances

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to 4 A.A.C. 23:

"Active ingredient" means any component that furnishes pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or that affects the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug, that are present in the finished drug product in a modified form, and that furnish the specified activity or effect.

"AHCCCS" means the Arizona Health Care Cost Containment System.

~~"Alternate physician" means a physician licensed under A.R.S. Title 32 Chapter 13 or 17 who signs a drug therapy management agreement to temporarily assume responsibility for supervision and evaluation of the drug therapy management performed by a pharmacist when the supervisory physician is unavailable by direct telecommunication or physical presence at the practice site.~~

"Annual family income" means the combined yearly gross earned income and unearned income of all adult individuals within a family unit.

"Approved course in pharmacy law" means a continuing education activity that addresses practice issues related to state or federal pharmacy statutes, rules, or regulations.

"Approved Provider" means an individual, institution, organization, association, corporation, or agency that is approved by the Accreditation Council for Pharmacy Education (ACPE) in accordance with ACPE's policy and procedures or by the Board as meeting criteria indicative of the ability to provide quality continuing education.

"Authentication of product history" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

"Automated storage and distribution system" means a mechanical system that performs operations or activities other than counting, compounding, or administration, relative to the storage, packaging, or distributing of drugs or devices and that collects, controls, and maintains all transaction information.

"Batch" means a specific quantity of drug that has uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

"Beyond-use date" means:

A date determined by a pharmacist and placed on a prescription label at the time of dispensing to indicate a time beyond which the contents of the prescription are not recommended to be used; or

A date determined by a pharmacist and placed on a compounded pharmaceutical product's label at the time of preparation as specified in R4-23-410(B)(3)(d), R4-23-410(I)(6)(e), or R4-23-410(J)(1)(d) to indicate a time beyond which the compounded pharmaceutical product is not recommended to be used.

"Biological safety cabinet" means a containment unit suitable for the preparation of low to moderate risk agents when there is a need for protection of the product, personnel, and environment, consistent with National Sanitation Foundation (NSF) standards, published in the National Sanitation Foundation Standard 49, Class II (Laminar Flow) Biohazard Cabinetry, NSF International P. O. Box 130140, Ann Arbor, MI, revised June 1987 edition, (and no future amendments or editions), incorporated by reference and on file with the Board.

"Care-giver" means a person who cares for someone who is sick or disabled or an adult who cares for an infant or child and includes a patient's husband, wife, son, daughter, mother, father, sister, brother, legal guardian, nurse, or medical practitioner.

"Community pharmacy" means any place under the direct supervision of a pharmacist where the practice of pharmacy occurs or where prescription orders are compounded and dispensed other than a hospital pharmacy or a limited service pharmacy.

"Component" means any ingredient used in compounding or manufacturing drugs in dosage form, including an ingredient that may not appear in the finished product.

"Compounding and dispensing counter" means a pharmacy counter working area defined in this Section where a pharmacist or a graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee under the supervision of a pharmacist compounds, mixes, combines, counts, pours, or prepares and packages a prescription medication to dispense an individual prescription order or prepackages a drug for future dispensing.

"Computer system" means an automated data-processing system that uses a programmable electronic device to store, retrieve, and process data.

"Computer system audit" means an accounting method, involving multiple single-drug usage reports and audits, used to determine a computer system's ability to store, retrieve, and process original and refill prescription dispensing information.

"Contact hour" means 50 minutes of participation in a continuing education activity sponsored by an Approved Provider.

"Container" means:

A receptacle, as described in the official compendium or the federal act, that is used in manufacturing or compounding a drug or in distributing, supplying, or dispensing the finished dosage form of a drug; or

A metal receptacle designed to contain liquefied or vaporized compressed medical gas and used in manufacturing, transfilling, distributing, supplying, or dispensing a compressed medical gas.

"Continuing education" means a structured learning process required of a ~~licensed pharmacist~~ licensee to maintain licensure that includes study in the general areas of socio-economic and legal aspects of health care; the properties and actions of drugs and dosage forms; etiology, characteristics and therapeutics of disease status; or pharmacy practice.

"Continuing education activity" means continuing education obtained through an institute, seminar, lecture, conference, workshop, mediated instruction, programmed learning course, or postgraduate study in an accredited college or school of pharmacy.

"Continuing education unit" or "CEU" means 10 contact hours of participation in a continuing education activity sponsored by an Approved Provider.

"Correctional facility" has the same meaning as in A.R.S. §§ 13-2501 and 31-341.

"CRT" means a cathode ray tube or other mechanism used to view information produced or stored by a computer system.

"CSPMP" means the Controlled Substances Prescription Monitoring Program established under A.R.S. Title 36, Chapter 28.

"Current good compounding practices" means the minimum standards for methods used in, and facilities or controls used for, compounding a drug to ensure that the drug has the identity and strength and meets the quality and purity characteristics it is represented to possess.

"Current good manufacturing practice" means the minimum standard for methods used in, and facilities or controls used for manufacturing, processing, packing, or holding a drug to ensure that the drug meets the requirements of the federal act as to safety, and has the identity and strength and meets the quality and purity characteristics it is represented to possess.

"Cytotoxic" means a pharmaceutical that is capable of killing living cells.

"Day" means a calendar day unless otherwise specified.

"DEA" means the Drug Enforcement Administration as defined in A.R.S. § 32-1901.

"Declared disaster areas" means areas designated by the governor or by a county, city, or town under A.R.S. § 32-1910 as those areas that have been adversely affected by a natural disaster or terrorist attack and require extraordinary measures to provide adequate, safe, and effective health care for the affected population.

"Delinquent license" means a pharmacist, pharmacy intern, graduate intern, or pharmacy technician license the Board suspends for failure to renew or pay all required fees on or before the date the renewal is due.

"Dietary supplement" means a product (other than tobacco) that:

Is intended to supplement the diet that contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients;

Is intended for ingestion in pill, capsule, tablet, or liquid form;

Is not represented for use as a conventional food or as the sole item of a meal or diet; and

Is labeled as a "dietary supplement."

"Digital signature" has the same meaning as in A.R.S. § 41-132(E).

"Dispensing pharmacist" means a pharmacist who, in the process of dispensing a prescription medication after the complete preparation of the prescription medication and before delivery of the prescription medication to a patient or patient's agent, verifies, checks, and initials the prescription medication label, as required in R4-23-402(A).

"Drug sample" means a unit of a prescription drug that a manufacturer provides free of charge to promote the sale of the drug.

~~"Drug therapy management" means any act or service provided by a pharmacist in compliance with a Board-approved drug therapy management agreement.~~

~~"Drug therapy management agreement" means a written protocol, approved and signed by a supervisory physician, alternate physician, and pharmacist that specifies the conditions under which a pharmacist:~~

~~Assesses patient status;~~

~~Orders and interprets laboratory tests; and~~

~~Modifies, implements, or monitors patient drug therapy.~~

"Earned income" means monetary payments received by an individual as a result of work performed or rental property owned or leased by the individual, including:

Wages,

Commissions and fees,

Salaries and tips,

Profit from self-employment,

Profit from rent received from a tenant or boarder, and

Any other monetary payments received by an individual for work performed or rental of property.

"Electronic signature" has the same meaning as in A.R.S. § 44-7002.

"Eligible patient" means a patient who a pharmacist determines is eligible to receive an immunization using professional judgment after consulting with the patient regarding the patient's current health condition, recent health condition, and allergies.

"Extreme emergency" means the occurrence of a fire, water leak, electrical failure, public disaster, or other catastrophe constituting an imminent threat of physical harm to pharmacy personnel or patrons.

"Family unit" means:

A group of individuals residing together who are related by birth, marriage, or adoption; or

An individual who:

Does not reside with another individual; or

Resides only with another individual or group of individuals to whom the individual is unrelated by birth, marriage, or adoption.

"FDA" means the Food and Drug Administration, a federal agency within the United States Department of Health and Human Services, established to set safety and quality standards for foods, drugs, cosmetics, and other consumer products.

"Health care decision maker" has the same meaning as in A.R.S. § 12-2291.

"Health care institution" has the same meaning as in A.R.S. § 36-401.

"Immediate notice" means a required notice sent by mail, facsimile, or electronic mail to the Board Office within 24 hours.

"~~Pharmacist-administered immunizations~~ Immunizations training program" means an immunization training program for pharmacists, pharmacy interns, and graduate interns that meets the requirements of R4-23-411~~(C)~~(E).

"Inactive ingredient" means any component other than an "active ingredient" present in a drug.

"Internal test assessment" means performing quality assurance or other procedures necessary to ensure the integrity of a test.

"ISO Class 5 environment" means an atmospheric environment that complies with the ISO/TC209 International Cameroon Standards, specifically ANSI/IEST/ISO-14644-1:1999: Cleanrooms and associated controlled environments--Part 1: Classification of air cleanliness, first edition dated May 1, 1999, (and no future amendments or editions), incorporated by reference and on file in the Board office.

"ISO Class 7 environment" means an atmospheric environment that complies with the ISO/TC209 International Cleanroom Standards, specifically ANSI/IEST/ISO-14644-1:1999: Cleanrooms and associated controlled environments--Part

1: Classification of air cleanliness, first edition dated May 1, 1999, (and no future amendments or editions), incorporated by reference and on file in the Board office.

"Licensed health care professional" means an individual who is licensed and regulated under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 18, 25, 29, or 35.

"Limited-service correctional pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that:

Holds a current Board permit under A.R.S. § 32-1931;

Is located in a correctional facility; and

Uses pharmacists, interns, and support personnel to compound, produce, dispense, and distribute drugs.

"Limited-service long-term care pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board-issued permit and dispenses prescription medication or prescription-only devices to patients in long-term care facilities.

"Limited-service mail-order pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board permit under A.R.S. § 32-1931 and dispenses a majority of its prescription medication or prescription-only devices by mailing or delivering the prescription medication or prescription-only device to an individual by the United States mail, a common or contract carrier, or a delivery service.

"Limited-service nuclear pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board permit under A.R.S. § 32-1931 and provides radiopharmaceutical services.

"Limited-service pharmacy permittee" means a person who holds a current limited-service pharmacy permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and A.A.C. R4-23-606.

"Limited-service sterile pharmaceutical products pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current Board permit under A.R.S. § 32-1931 and dispenses a majority of its prescription medication or prescription-only devices as sterile pharmaceutical products.

"Long-term care consultant pharmacist" means a pharmacist providing consulting services to a long-term care facility.

"Long-term care facility" or "LTCF" means a nursing care institution as defined in A.R.S. § 36-401 or an assisted living facility that:

Provides 24-hour, seven-day a week licensed nursing services to resident patients; and

Is licensed by the Arizona Department of Health Services.

"Lot" means a batch or any portion of a batch of a drug, or if a drug produced by a continuous process, an amount of drug produced in a unit of time or quantity in a manner that assures its uniformity. In either case, a lot is identified by a distinctive lot number and has uniform character and quality with specified limits.

"Lot number" or "control number" means any distinctive combination of letters or numbers, or both, from which the complete history of the compounding or manufacturing, control, packaging, and distribution of a batch or lot of a drug can be determined.

"Low-income subsidy" means Medicare-provided assistance that may partially or fully cover the costs of drugs and is based on the income of an individual and, if applicable, the individual's spouse.

"Materials approval unit" means any organizational element having the authority and responsibility to approve or reject components, in-process materials, packaging components, and final products.

"Mechanical counting device for a drug in solid, oral dosage form" means a mechanical device that counts drugs in solid, oral dosage forms for dispensing and includes an electronic balance when used to count drugs.

"Mechanical storage and counting device for a drug in solid, oral dosage form" means a mechanical device that stores and counts and may package or label drugs in solid, oral dosage forms for dispensing.

"Mediated instruction" means information transmitted via intermediate mechanisms such as audio or video tape or telephone transmission.

"Medical practitioner-patient relationship" means that before prescribing, dispensing, or administering a prescription-only drug, prescription-only device, or controlled substance to a person, a medical practitioner, as defined in A.R.S. § 32-1901, shall first conduct a physical examination of that person or have previously conducted a physical examination. This subdivision does not apply to:

A medical practitioner who provides temporary patient supervision on behalf of the patient's regular treating medical practitioner;

Emergency medical situations as defined in A.R.S. § 41-1831;

Prescriptions written to prepare a patient for a medical examination; or

Prescriptions written, prescription-only drugs, prescription-only devices, or controlled substances issued for use by a

county or tribal public health department for immunization programs, emergency treatment, in response to an infectious disease investigation, public health emergency, infectious disease outbreak or act of bioterrorism. For purposes of this subsection, "bioterrorism" has the same meaning as in A.R.S. § 36-781.

"Medicare" means a federal health insurance program established under Title XVIII of the Social Security Act.

"Mobile pharmacy" means a pharmacy that is self propelled or movable by another vehicle that is self propelled.

"MPJE" means Multistate Pharmacy Jurisprudence Examination, a Board-approved national pharmacy law examination written and administered in cooperation with NABP.

"NABP" means National Association of Boards of Pharmacy.

"NABPLEX" means National Association of Boards of Pharmacy Licensure Examination.

"NAPLEX" means North American Pharmacist Licensure Examination.

"Order" means either of the following:

A prescription order as defined in A.R.S. § 32-1901; or

A medication order as defined in A.A.C. R4-23-651.

"Other designated personnel" means a non-pharmacist individual who is permitted in the pharmacy area, for a limited time, under the direct supervision of a pharmacist, to perform non-pharmacy related duties, such as trash removal, floor maintenance, and telephone or computer repair.

"Outpatient" means an individual who is not a residential patient in a health care institution.

"Outpatient setting" means a location that provides medical treatment to an outpatient.

"Patient profile" means a readily retrievable, centrally located information record that contains patient demographics, allergies, and medication profile.

"Pharmaceutical patient care services" means the provision of drug selection, drug utilization review, drug administration, drug therapy monitoring, and other drug-related patient care services intended to achieve outcomes related to curing or preventing a disease, eliminating or reducing a patient's symptoms, or arresting or slowing a disease process, by identifying and resolving or preventing potential and actual drug-related problems.

"Pharmaceutical product" means a medicinal drug.

"Pharmacy counter working area" means a clear and continuous working area that contains no major obstacles such as a desktop computer, computer monitor, computer keyboard, external computer drive device, printer, facsimile machine, pharmacy balance, typewriter, or pill-counting machine, but may contain individual documents or prescription labels, pens, prescription blanks, refill log, pill-counting tray, spatula, stapler, or other similar items necessary for the prescription-filling process.

"Pharmacy law continuing education" means a continuing education activity that addresses practice issues related to state or federal pharmacy statutes, rules, or regulations, offered by an Approved Provider.

"Pharmacy permittee" means a person who holds a current pharmacy permit that complies with A.R.S. §§ 32-1929, 32-1930, 32-1931, 32-1934, and A.A.C. R4-23-606 and R4-23-652.

"Physician" means a medical practitioner licensed under A.R.S. Title 32, Chapter 13 or 17.

"Physician-in-charge" means a physician who is responsible to the Board for all aspects of a prescription medication donation program required in A.R.S. § 32-1909 and operated in the physician's office or in a health care institution.

"Poverty level" means the annual family income for a family unit of a particular size, as specified in the poverty guidelines updated annually in the Federal Register by the U.S. Department of Health and Human Services.

"Precursor chemical" means a precursor chemical I as defined in A.R.S. § 13-3401(26) and a precursor chemical II as defined in A.R.S. § 13-3401(27).

"Prepackaged drug" means a drug that is packaged in a frequently prescribed quantity, labeled in compliance with A.R.S. §§ 32-1967 and 32-1968, stored, and subsequently dispensed by a pharmacist or a graduate intern or pharmacy intern under the supervision of a pharmacist, who verifies at the time of dispensing that the drug container is properly labeled, in compliance with A.R.S. § 32-1968, for the patient.

"Prep area" means a specified area either within an ISO class 7 environment or adjacent to but outside an ISO class 7 environment that:

Allows the assembling of necessary drugs, supplies, and equipment for compounding sterile pharmaceutical products, but does not allow the use of paper products such as boxes or bulk drug storage;

Allows personnel to don personnel protective clothing, such as gown, gloves, head cover, and booties before entering the clean compounding area; and

Is a room or a specified area within a room, such as an area specified by a line on the floor.

"Primary care provider" means the medical practitioner who is treating an individual for a disease or medical condition.

"Proprietor" means the owner of a business permitted by the Board under A.R.S. §§ 32-1929, 32-1930, 32-1931, and 32-1934.

"Provider pharmacy" means a pharmacy that contracts with a long-term care facility to supply prescription medication or other services for residents of a long-term care facility.

"Radiopharmaceutical" means any drug that emits ionizing radiation and includes:

Any nonradioactive reagent kit, nuclide generator, or ancillary drug intended to be used in the preparation of a radiopharmaceutical, but does not include drugs such as carbon-containing compounds or potassium-containing salts, that contain trace quantities of naturally occurring radionuclides; and

Any biological product that is labeled with a radionuclide or intended to be labeled with a radionuclide.

"Radiopharmaceutical quality assurance" means performing and interpreting appropriate chemical, biological, and physical tests on radiopharmaceuticals to determine the suitability of the radiopharmaceutical for use in humans and animals. Radiopharmaceutical quality assurance includes internal test assessment, authentication of product history, and appropriate record retention.

"Radiopharmaceutical services" means procuring, storing, handling, compounding, preparing, labeling, quality assurance testing, dispensing, distributing, transferring, recordkeeping, and disposing of radiochemicals, radiopharmaceuticals, and ancillary drugs. Radiopharmaceutical services include quality assurance procedures, radiological health and safety procedures, consulting activities associated with the use of radiopharmaceuticals, and any other activities required for the provision of pharmaceutical care.

"Red C stamp" means a device used with red ink to imprint an invoice with a red letter C at least one inch high, to make an invoice of a Schedule III through IV controlled substance, as defined in A.R.S. § 36-2501, readily retrievable, as required by state and federal rules.

"Refill" means other than the original dispensing of the prescription order, dispensing a prescription order in the same quantity originally ordered or in multiples of the originally ordered quantity when specifically authorized by the prescriber, if the refill is authorized by the prescriber:

In the original prescription order;

By an electronically transmitted refill order that the pharmacist promptly documents and files; or

By an oral refill order that the pharmacist promptly documents and files.

"Regulated chemical" means the same as in A.R.S. § 13-3401(30).

"Remodel" means to alter structurally the pharmacy area or location.

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

"Resident" means:

An individual admitted to and living in a long-term care facility,

An individual who has a place of habitation in Arizona and lives in Arizona as other than a tourist, or

A person who owns or operates a place of business in Arizona.

"Responsible person" means the owner, manager, or other employee who is responsible to the Board for a permitted establishment's compliance with the laws and administrative rules of this state and of the federal government pertaining to distribution of drugs, devices, precursor chemicals, and regulated chemicals. Nothing in this definition relieves other individuals from the responsibility to comply with state and federal laws and administrative rules.

"Score transfer" means the process that enables an applicant to take the NAPLEX in a jurisdiction and be eligible for licensure by examination in other jurisdictions.

"Security features" means the attributes incorporated into the paper of a prescription order, referenced in A.R.S. § 32-1968(A)(4), that are approved by the Board or its staff and that includes one or more of the following features that attempt to prevent duplication or aid the authentication of a paper document: laid lines, enhanced laid lines, thermochromic ink, artificial watermark, fluorescent ink, chemical void, persistent void, penetrating numbers, high-resolution border, high-resolution latent images, micro-printing, prismatic printing, embossed images, abrasion ink, holograms, and foil stamping.

"Shared order filling" means the following:

Preparing, packaging, compounding, or labeling an order, or any combination of these functions, that are performed by:

A person with a current Arizona Board license, located at an Arizona pharmacy, on behalf of and at the request of another resident or nonresident pharmacy; or

A person, located at a nonresident pharmacy, on behalf of and at the request of an Arizona pharmacy; and

Returning the filled order to the requesting pharmacy for delivery to the patient or patient's care-giver or, at the request of this pharmacy, directly delivering the filled order to the patient.

"Shared order processing" means the following:

Interpreting the order, performing order entry verification, drug utilization review, drug compatibility and drug allergy review, final order verification, and when necessary, therapeutic intervention, or any combination of these order processing functions, that are performed by:

A pharmacist or intern, under pharmacist supervision, with a current Arizona Board license, located at an Arizona pharmacy, on behalf of and at the request of another resident or nonresident pharmacy: or

A pharmacist or intern, under pharmacist supervision, located at a nonresident pharmacy, on behalf of and at the request of an Arizona pharmacy; and

After order processing is completed, returning the processed order to the requesting pharmacy for order filling and delivery to the patient or patient's care-giver or, at the request of this pharmacy, returning the processed order to another pharmacy for order filling and delivery to the patient or patient's care-giver.

"Shared services" means shared order filling or shared order processing, or both.

"Sight-readable" means that an authorized individual is able to examine a record and read its information from a CRT, microfiche, microfilm, printout, or other method acceptable to the Board or its designee.

"Single-drug audit" means an accounting method that determines the numerical and percentage difference between a drug's beginning inventory plus purchases and ending inventory plus sales.

"Single-drug usage report" means a computer system printout of original and refill prescription order usage information for a single drug.

"Standard-risk sterile pharmaceutical product" means a sterile pharmaceutical product compounded from sterile commercial drugs using sterile commercial devices or a sterile pharmaceutical otic or ophthalmic product compounded from non-sterile ingredients.

"State of emergency" means a governmental declaration issued under A.R.S. § 32-1910 as a result of a natural disaster or terrorist attack that results in individuals being unable to refill existing prescriptions.

"Sterile pharmaceutical product" means a medicinal drug free from living biological organisms.

"Strength" means:

The concentration of the drug substance (for example, weight/weight, weight/volume, or unit dose/volume basis); or

The potency, that is, the therapeutic activity of a drug substance as indicated by bioavailability tests or by controlled clinical data (expressed, for example, in terms of unity by reference to a standard).

"Substantial-risk sterile pharmaceutical product" means a sterile pharmaceutical product compounded as a parenteral or injectable dosage form from non-sterile ingredients.

"Supervision" means a pharmacist is present, assumes legal responsibility, and has direct oversight of activities relating to acquiring, preparing, distributing, administering, and selling prescription medications by pharmacy interns, graduate interns, pharmacy technicians, or pharmacy technician trainees and when used in connection with the intern training requirements means that, in a pharmacy where intern training occurs, a pharmacy intern preceptor assumes the primary responsibility of teaching the intern during the entire period of the training.

~~"Supervisory physician" means a physician licensed under A.R.S. Title 32 Chapter 13 or 17 who:~~

~~Writes an order in a patient's medical record and signs a drug therapy management agreement authorizing a pharmacist to provide patient-specific drug therapy management, and~~

~~Assumes responsibility for the on-going supervision and evaluation of the drug therapy management performed by the pharmacist.~~

"Supplying" means selling, transferring, or delivering to a patient or a patient's agent one or more doses of:

A nonprescription drug in the manufacturer's original container for subsequent use by the patient, or

A compressed medical gas in the manufacturer's or compressed medical gas distributor's original container for subsequent use by the patient.

"Support personnel" means an individual, working under the supervision of a pharmacist, trained to perform clerical duties associated with the practice of pharmacy, including cashiering, bookkeeping, pricing, stocking, delivering, answering non-professional telephone inquiries, and documenting third-party reimbursement. Support personnel shall not perform the tasks of a pharmacist, pharmacy intern, graduate intern, pharmacy technician, or pharmacy technician trainee.

"Temporary pharmacy facility" means a facility established as a result of a declared state of emergency to temporarily provide pharmacy services within or adjacent to declared disaster areas.

"Tourist" means an individual who is living in Arizona but maintains a place of habitation outside of Arizona and lives outside of Arizona for more than six months during a calendar year.

"Transfill" means a manufacturing process by which one or more compressed medical gases are transferred from a bulk container to a properly labeled container for subsequent distribution or supply.

"Unearned income" means monetary payment received by an individual that is not compensation for work performed or rental of property owned or leased by the individual, including:

Unemployment insurance,

Workers' compensation,

Disability payments,

Payments from the Social Security Administration,

Payments from public assistance,

Periodic insurance or annuity payments,

Retirement or pension payments,

Strike benefits from union funds,

Training stipends,

Child support payments,

Alimony payments,

Military family allotments,

Regular support payments from a relative or other individual not residing in the household,

Investment income,

Royalty payments,

Periodic payments from estates or trusts, and

Any other monetary payments received by an individual that are not:

As a result of work performed or rental of property owned by the individual,

Gifts,

Lump-sum capital gains payments,

Lump-sum inheritance payments,

Lump-sum insurance payments, or

Payments made to compensate for personal injury.

"Verified signature" or "signature verifying" means in relation to a Board license or permit application or report, form, or agreement, the hand-written or electronic signature of an individual who, by placing a hand-written or electronic signature on a hard-copy or electronic license or permit application or report, form, or agreement agrees with and verifies that the statements and information within or attached to the license or permit application or report, form, or agreement are true in every respect and that inaccurate reporting can result in denial or loss of a license or permit or report, form, or agreement.

"Veteran" means an individual who has served in the United States Armed Forces.

"Wholesale distribution" means distribution of a drug to a person other than a consumer or patient, but does not include:

Selling, purchasing, or trading a drug or offering to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this Section, "emergency medical reasons" includes transferring a prescription drug by a community or hospital pharmacy to another community or hospital pharmacy to alleviate a temporary shortage;

Selling, purchasing, or trading a drug, offering to sell, purchase, or trade a drug, or dispensing a drug as specified in a prescription;

Distributing a drug sample by a manufacturers' or distributors' representative; or

Selling, purchasing, or trading blood or blood components intended for transfusion.

"Wholesale distributor" means any person engaged in wholesale distribution of drugs, including: manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions in the amount of at least 5% of gross sales.

ARTICLE 10. UNIFORMED CONTROLLED SUBSTANCES AND DRUG OFFENSES

R4-23-1005. Substances Excepted from the Schedules of Controlled Substances

A. All over-the-counter non-narcotic substances containing limited amounts of controlled substances that are excluded from all controlled substance schedules by 21 CFR ~~§~~ 1308.22, ~~April 1, 1999~~ (Revised April 1, 2012, ~~and no future editions or amendments~~, incorporated by reference and on file with the Board ~~and the Office of the Secretary of State,~~. This incorporated material contains no future editions or amendments.), are excluded from all controlled substance schedules in Arizona.

B. All chemical preparations or mixtures containing one or more controlled substances listed in any schedule that are exempted from all controlled substance schedules by 21 CFR ~~§~~ 1308.24, ~~April 1, 1999~~ (Revised April 1, 2012, ~~and no future editions or amendments~~, incorporated by reference and on file with the Board ~~and the Office of the Secretary of State,~~. This incorporated material contains no future editions or amendments.), are excluded from all controlled substance schedules in Arizona.

C. All prescription-only drugs that are exempted by 21 CFR ~~§~~ 1308.32, ~~April 1, 1999~~ (Revised April 1, 2012, ~~and no future editions or amendments~~, incorporated by reference and on file with the Board ~~and the Office of the Secretary of State,~~. This incorporated material contains no future editions or amendments.), are excluded from all controlled substance schedules in Arizona.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R12-199]

PREAMBLE

1. Articles, Parts, or Sections Affected — **Rulemaking Action**

R4-23-303	Amend
R4-23-304	Amend

2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

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

Implementing statute: A.R.S. § 32-1923

3. The effective date of the rule:

December 2, 2012

4. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the proposed rule:

Notice of Rulemaking Docket Opening: 17 A.A.R. 2421, December 2, 2011

Notice of Proposed Rulemaking: 18 A.A.R. 570, February 24, 2012

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

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy P.O. Box 18520 Phoenix, AZ 85005
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	dwright@azpharmacy.gov

6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

During the September 10, 2008, Board meeting, the Board discussed the need to update the intern rules as it relates to internship training hours and reports. The Governor imposed a rulemaking moratorium in 2009. We are now ready to proceed with this rulemaking. The amended rulemaking will amend R4-23-303 (Training Time) and R4-23-304 (Reports). R4-23-303 will be amended to reflect the internship hours received by a student in an Accreditation Council for Pharmacy Education (ACPE) accredited school of pharmacy and include specific requirements for graduates of a non-ACPE accredited school of pharmacy. R4-23-304(B)(1) will be amended to require annual intern training reports instead of quarterly reports for interns who attend a non-Board approved College of Pharmacy or Graduate Interns. R4-23-304 will be amended by removing subsection (B)(2), which requires reports for intern hours received outside an approved college or school of pharmacy's experiential training program. R4-23-304(B)(3) will be

amended to only require documentation that a pharmacy intern who is a graduate of a Board-approved college or school of pharmacy successfully completed the experiential training program. 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 clearly establishing standards for pharmacy internship training hours and reports.

7. A reference to any study relevant to the rules that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rules, 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.

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

Not applicable

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

The amended rules will impact the Board, pharmacy interns, and schools of pharmacy. The amended rule's impact on the Board will be the usual rulemaking-related costs, which are minimal.

The Board estimates the amended rules will have little or no economic impact on pharmacy interns. The rulemaking will reflect what is already happening in accredited schools of pharmacy where pharmacy interns perform a set number of internship hours as part of the school of pharmacy's curriculum. The number of hours (1720) required by the schools of pharmacy as a member of the Accreditation Council for Pharmacy Education (ACPE) exceeds the number of hours (1500) the Board requires of a pharmacy intern for licensure. The rule will require the pharmacy student's school of pharmacy to certify to the Board that the pharmacy intern completed the number of internship hours necessary for licensure. Pharmacy interns will no longer need to file intern hour reports or provide proof of internship training hours completed with the Board. Interns who attend a non-Board approved school of pharmacy or graduate interns will only be required to submit annual intern training reports instead of quarterly reports, which will save interns time and save the Board staff processing time and reduce record storage requirements.

The Board estimates the amended rules will have minimal impact on schools of pharmacy, as they have already been performing the function (reporting internship training hours to the Board) for several years.

The Board believes that approval of these rules will benefit the public health and safety by clearly establishing standards for pharmacy internship training hours and reports.

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

There are no substantial changes in the final rules from the proposed rules.

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

A public hearing was held March 26, 2012. No one attended the hearing and no written or oral comments were received.

12. All agencies shall list any other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

The rule itself does not require a permit. However, the license required by statute arguably falls within the definition of general permit in A.R.S. § 41-1001.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

No

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No

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

None

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

No

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTORS

Section
R4-23-303. Training Time
R4-23-304. Reports

ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTORS

R4-23-303. Training Time

A. Training. The minimum hours of internship training required for licensure by examination shall be 1,500. ~~A pharmacy intern shall accumulate all 1500 hours of internship training after~~
1. After enrolling in a Board-approved college or school of pharmacy as prescribed in R4-23-301(B) and receiving a Board-issued pharmacy intern license, a pharmacy intern shall complete all required internship training as part of the pharmacy intern's Board-approved college or school of pharmacy experiential training program. ~~The Board shall credit a pharmacy intern with no more than 500 hours of internship training per calendar quarter.~~
2. After receiving a Board-issued pharmacy intern license, an individual who is a graduate of a college or school of pharmacy that is not approved by the Board shall complete a minimum of 1,500 hours of internship training in a training site or sites as defined in R4-23-302(A).
3. After receiving a Board-issued graduate intern license, a graduate intern shall complete the number of internship training hours required by the Board in a training site or sites as defined in R4-23-302(A).

B. Start of training and limitation of credit. To receive credit as internship training, the practical experience shall take place in a pharmacy or an alternative training site as specified in R4-23-302(A) and under the supervision of a pharmacy intern preceptor, except for a non-pharmacy site either as part of a Board-approved college or school of pharmacy experiential training program or as approved by the Board or its designee. The Board shall credit no more than 500 hours internship training as a pharmacy or graduate intern in an alternative training site specified in R4-23-302(A)(2).

R4-23-304. Reports

A. Change of employment or mailing address. A pharmacy intern or graduate intern shall notify the Board within 10 days of change of employment or mailing address.

B. ~~Quarterly~~ Annual reports.
1. A pharmacy intern who is a graduate of a college or school of pharmacy that is not approved by the Board or is a graduate intern shall provide the Board ~~quarterly~~ annual intern training reports for the duration of training. The pharmacy intern shall file ~~a quarterly~~ an annual intern training report ~~October 1, January 1, April 1 and July 1 for the preceding quarter, regardless of whether the intern was in training during the quarter~~ on a report form provided by the Board by calendar year (January 1st through December 31st). ~~A quarterly~~ An annual intern training report ~~is delinquent if not~~ shall be received at the Board's office ~~30 days after the due date~~ no later than 30 days after the end of the calendar year. The Board shall write the intern to acknowledge receipt of the reports and notify the intern of the remaining hours of training necessary for licensure. Any intern training hours reported to the Board office more than 30 days after the end of the calendar year in which the training hours were performed shall not be credited toward the total intern training hours required for licensure. ~~A quarterly intern training report shall include:~~
   a. ~~Intern's name, address, and license number;~~
   b. ~~Training site name and address;~~
   c. ~~Pharmacy intern preceptor's name and license number;~~
   d. ~~Whether the report is for the first quarter (Jan. Mar.), second quarter (Apr. June), third quarter (July Sept.), or fourth quarter (Oct. Dec.);~~
   e. ~~Number of intern training hours per week, specified by week ending date (month, day, year) and total number of intern training hours for the quarter; and~~
   f. ~~Date signed and pharmacy intern preceptor's signature verifying that the pharmacy intern preceptor has been actively engaged in the practice of pharmacy for at least one year and that the pharmacy intern preceptor supervised the intern training of the pharmacy or graduate intern identified in the quarterly intern training report.~~
2. ~~A pharmacy intern seeking credit for intern training hours received outside an approved college or school of pharmacy's experiential training program shall provide the Board a quarterly intern training report as specified in subsection (B)(1).~~
3. After graduation and before sitting for the NAPLEX or MPJE, a pharmacy intern who is a graduate of a Board-

approved college or school of pharmacy shall ensure that the director of the Board-approved college or school of pharmacy's experiential training program provides the Board an intern training report that includes:

~~a. A list of all training sites where training occurred during any part of the entire training program including addresses and telephone numbers;~~

~~b.~~a. The dates and number of training hours experienced, by training site and total; and

~~c. The name of the pharmacy intern preceptor, if applicable, for each training site; and~~

~~d.~~b. The date signed and experiential training program director's signature verifying that the pharmacy intern successfully completed the experiential training program.

NOTICE OF FINAL RULEMAKING

TITLE 20. COMMERCE, FINANCIAL INSTITUTIONS, AND INSURANCE

CHAPTER 4. DEPARTMENT OF FINANCIAL INSTITUTIONS

Editor's Note: The following Notice of Final Rulemaking was reviewed per Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 2688.) The Governor's Office authorized the notice to proceed through the rulemaking process on June 24, 2011.

[R12-200]

PREAMBLE

1. Article, Part or Section Affected (as applicable) | **Rulemaking Action**

R20-4-102	Amend
Table A	Amend
R20-4-927	New Section
R20-4-928	New Section
R20-4-1813	New Section

2. Citations to the agency's statutory rulemaking authority to include both the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. § 6-123(2)

Implementing statute: A.R.S. §§ 6-949, 6-912, and 6-913

3. The effective date of the rule:

December 2, 2012

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

Notice of Rulemaking Docket Opening: 17 A.A.R. 1361, July 22, 2011

Notice of Proposed Rulemaking: 18 A.A.R. 881, April 13, 2012

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

Name:	Richard Fergus
Address:	2910 N. 44th St., Suite 310 Phoenix, AZ 85018
Telephone:	(602) 771-2783
Fax:	(602) 381-1225
E-mail:	rfergus@azdfi.gov
Web site:	www.azdfi.gov

6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

The purpose for initiating these rules is to implement legislative changes over the past three years. One of those legislative changes was the passage of HB2318 (mortgage bankers; loan originators; fees), which was signed by Governor Brewer on July 13, 2009. The bill amended A.R.S. § 6-949 to require that the Department establish the application process for converting a mortgage banker license to a mortgage broker license. R20-4-1813 is intended to provide this conversion process.

A second legislative change was the passage of HB2004 (commercial mortgage brokers; license conversion), which was signed by Governor Brewer on April 6, 2011. The bill added A.R.S. § 6-913, requiring that the Department

establish a process in rule that allows for mortgage brokers to convert their license to a commercial mortgage broker license. R20-4-927 is intended to provide this conversion process.

A third legislative change occurred with the passage of HB2296 (national banks; mortgage loan originators), which was signed by Governor Brewer on April 19, 2011. The Department is now authorized in A.R.S. § 6-912 to "…charge a fee for processing the original or renewal application for a certificate of exemption and for other costs incurred by the Department." The purpose of R20-4-928 is to implement the fees that the Department will charge in response to this statute, as well as provide the process for applying for and renewing a certificate of exemption. Further, R20-4-102 is being amended to define "exclusive contract" as it is used in A.R.S. §§ 6-912 and 6-991.02. Additionally, R20-4-102 is being amended to add a numbering system that will create ease in identifying definitions established by rule.

Finally, with these legislative changes, as well as the sunset of the deferred presentment company ("payday lender") statutes in 2010, and changes to the loan originator statutes in 2009, it was necessary to amend Table A. Licensing Time-frames to include new license type time frames and delete those which no longer exist.

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

The Department has not reviewed, and did not rely on, any study as an evaluation or justification for the proposed rules.

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

Not applicable

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

The Department's current projection is that there will be less than 5 entities that apply and qualify for the certificate of exemption to supervise loan originators; therefore it is unlikely that the addition of this registration will result in an increase to state revenues. However, even one applicant for the certificate of exemption, opens up the possibility for at least 200 individuals to obtain their loan originator license. This will have a minimal, yet notable impact on private employment in Arizona and could potentially raise the revenues generated from loan originator licensing.

The ability for a mortgage broker to be able to convert to a commercial mortgage broker license and only pay the applicable renewal fees for the newly acquired license type will be a substantial savings for the private business, not only financially but also with regard to their time. Rather than having to start as an original applicant for a commercial mortgage broker license and pay the original application and licensing fees, mortgage brokers will be permitted to pay only the renewal fees upon converting the license. This could result in an individual savings for each entity of $800 for the application fee, the applicable prorated licensing fee, and $250 for each branch. Further, there will be an additional savings by not having to pay for and attend continuing education courses every year. The overall economic impact of these rules on private and public business is projected to be minimal.

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

Only minor, non-substantive grammatical, formatting, and clarifying changes were made between the proposed and the final rulemaking at the request of GRRC staff.

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

No comments were submitted.

12. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

Licensees affected fall within the definition of general permit in A.R.S. § 41-1001(10).

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

The rules are promulgated under state law.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

None

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

There is no material incorporated by reference in these rules.

14. Whether the rule was previously made, amended or repealed as an emergency rule. If so, cite the notice published

in the *Register* as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:

Not applicable

15. The full text of the rules follows:

TITLE 20. COMMERCE, FINANCIAL INSTITUTIONS, AND INSURANCE

CHAPTER 4. DEPARTMENT OF FINANCIAL INSTITUTIONS

ARTICLE 1. GENERAL

Section
R20-4-102. Definitions
Table A. Licensing Time-frames

ARTICLE 9. MORTGAGE BROKERS

Section
R20-4-927. Conversion to Commercial Mortgage Broker License
R20-4-928. Certificate of Exemption Application and Renewal

ARTICLE 18. MORTGAGE BANKERS

Section
R20-4-1813. Conversion to Mortgage Broker License

ARTICLE 1. GENERAL

R20-4-102. Definitions

In this Chapter, unless otherwise specified:

1. "Active management" means directing a licensee's activities by a responsible individual, who:
   a. Is knowledgeable about the licensee's Arizona activities;
   b. Supervises compliance with:
      i. The laws enforced by the Department of Financial Institutions as they relate to the licensee, and
      ii. Other applicable laws and rules; and
   c. Has sufficient authority to ensure compliance.
2. "Affiliate" has the meaning stated at A.R.S. § 6-901.
3. "Attorney General" means the Attorney General or an assistant Attorney General of the state of Arizona.
4. "Branch office" means any location within or outside Arizona, including a personal residence, but not including a licensee's principal place of business in Arizona, where the licensee holds out to the public that the licensee acts as a licensee.
5. "Business of a savings and loan association or savings bank" means receiving money on deposit subject to payment by check or any other form of order or request or on presentation of a certificate of deposit or other evidence of debt.
6. "Compensation" means, in applying that term's definition in A.R.S. §§ 6-901, 6-941, and 6-971, anything received in advance, after repayment, or at any time during a loan's life. This subsection expressly excludes the following items from those definitions of compensation:
   a. Charges or fees customarily received after a loan's closing including prepayment penalties, termination fees, reinvestment fees, late fees, default interest, transfer fees, impound account interest and fees, extension fees, and modification fees. However, extension fees and modification fees are compensation if the lender advances additional funds or increases the credit limit on an open-end mortgage as part of the extension or modification;
   b. Out-of-pocket expenses paid to independent third parties including appraisal fees, credit report fees, legal fees, document preparation fees, title insurance premiums, recording, filing, and statutory fees, collection fees, servicing fees, escrow fees, and trustee's fees;
   c. Insurance commissions;
   d. Contingent or additional interest, including interest based on net operating income; or
   e. Equity participation.
7. "Commercial finance transaction," as that term is used in this Section's definitions of the terms "Engaged in the business of making mortgage loans" and "Engaged in the business of making mortgage loans or mortgage banking

loans," means a loan made primarily for other than personal, family, or household purposes.

8. "Control of a licensee," as used in A.R.S. §§ 6-903, 6-944, or 6-978, does not include acquiring additional fractional equity interests in a licensee by any person who already has the power to vote 51% or more of the licensee's outstanding voting equity interests.
9. "Correspondent contract," as that term is used in A.R.S. §§ 6-941, 6-943, 6-971, or 6-973, means an agreement between a lender and a funding source under which the funding source may fund, or is required to fund, loans originated by the lender.
10. "Cushion," as that term is used in R20-4-1811 or R20-4-1908, means funds that a servicer or lender may require a borrower to pay into an escrow or impound account before the borrower's periodic payments are available in the account to cover unanticipated disbursements.
11. "Directly or indirectly makes, negotiates, or offers to make or negotiate" and "Directly or indirectly making, negotiating, or offering to make or negotiate," as those phrases are used in A.R.S. §§ 6-901, 6-941, or 6-971, mean:
    a. Providing consulting or advisory services in connection with a mortgage loan transaction, mortgage banking loan transaction, or commercial mortgage loan transaction;
        i. To an investor, concerning the location or identity of potential borrowers, regardless of whether the person providing consulting or advisory services directly contacts any potential borrowers; or
        ii. To a borrower, concerning the location or identity of potential investors or lenders; or
    b. Providing assistance in preparing an application for a mortgage loan transaction, mortgage banking loan transaction, or commercial mortgage banking loan transaction, regardless of whether the person providing assistance directly contacts any potential investor or lender; and
    c. Processing a loan; but
    d. "Directly or indirectly makes, negotiates, or offers to make or negotiate" and "Directly or indirectly making, negotiating, or offering to make or negotiate" do not include:
        i. Providing clerical, mechanical, or word processing services to prepare papers or documents associated with a mortgage loan transaction, mortgage banking loan transaction, or commercial mortgage banking loan transaction;
        ii. Purchasing, selling, negotiating to purchase or sell, or offering to purchase or sell a mortgage loan, mortgage banking loan, or commercial mortgage banking loan already funded;
        iii. Making, negotiating, or offering to make additional advances on an existing open-ended mortgage loan, mortgage banking loan, or commercial mortgage loan including revolving credit lines;
        iv. Modifying, renewing, or replacing a mortgage loan, a mortgage banking loan, or a commercial mortgage loan already funded, if the parties to and security for the loan are the same as the original loan immediately before the modification, renewal, or replacement, and if no additional funds are advanced and no increase is made in the credit limit on an open-ended loan. Replacing a loan means making a new loan simultaneously with terminating an existing loan.
12. "Electronic record" has the meaning stated at A.R.S. § 44-7002(7).
13. "Employee" means a natural person who has an employment relationship with a licensee that is acknowledged by both the person and the licensee, and:
    a. The person is entitled to payment, or is paid, by the licensee;
    b. The licensee withholds and remits, or is liable for withholding and remitting, payroll deductions for all applicable federal and state payroll taxes;
    c. The licensee has the right to hire and fire the employee and the employee's assistants;
    d. The licensee directs the methods and procedures for performing the employee's job;
    e. The licensee supervises the employee's business conduct and the employee's compliance with applicable laws and rules; and
    f. The rights and duties under subsections ~~(a)~~ (13)(a) through (e) belong to the licensee regardless of whether another person also shares those rights and duties.
14. "Engaged in the business of making mortgage loans," as that phrase is used in A.R.S. § 6-902, and "engaged in the business of making mortgage loans or mortgage banking loans," as that phrase is used in A.R.S. § 6-942, mean the direct or indirect making of a total of more than five mortgage banking loans or mortgage loans, or both in a calendar year. Each loan counts only once as of its closing date. A person is not "engaged in the business of making mortgage loans or mortgage banking loans" if the person makes loans solely in commercial finance transactions in which no more than 35% of the aggregate value of all security taken by the investor on the closing date is a lien, or liens, on real property.
15. "Exclusive contract," as that term is used in A.R.S. §§ 6-912 and 6-991.02, means a written agreement in which a loan originator agrees to perform services as a loan originator subject to supervision and control by a person holding a certificate of exemption issued under A.R.S. § 6-912 on an exclusive basis. The agreement provides that the loan originator is expressly prohibited from performing loan origination or modification services for any other person during the time the agreement is in effect.

16. "Generally accepted accounting principles" has the meaning used by the Financial Accounting Standards Board or the American Institute of Certified Public Accountants.
17. "Holds out to the public," as used in this Section's definition of "branch office," means advertising or otherwise informing the public that mortgage banking loans, commercial mortgage loans, or mortgage loans are made or negotiated at a location. "Holds out to the public" includes listing a location on business cards, stationery, brochures, rate lists, or other promotional items. "Holds out to the public" does not include a clearly identified home or mobile telephone number on a business card or stationery.
18. "Loan," as that term is used in A.R.S. §§ 6-126(C)(6) and ~~6-126(C)(8),~~ (8), means all loans negotiated or closed, without regard to the location of the real property collateral or type of loan.
19. "Loan Processing" means obtaining a loan application's supporting documents for use in underwriting.
20. "Person" means a natural person or any legal or commercial entity including a corporation, business trust, estate, trust, partnership, limited partnership, joint venture, association, limited liability company, limited liability partnership, or limited liability limited partnership.
21. "Property insurance," as that term is used in A.R.S. §§ 6-909 and 6-947, does not include flood insurance as that term is used in the Flood Disaster Protection Act of 1973, as modified by the National Flood Insurance Reform Act of 1994. 42 U.S.C. 4001, et seq.
22. "Reasonable investigation of the background," as that term is used in A.R.S. §§ 6-903, 6-943, or 6-976 means a licensee, at a minimum:
    a. Collects and reviews all the documents authorized by the Immigration Reform and Control Act of 1986, 8 U.S.C. 1324a;
    b. Obtains a completed Employment Eligibility Verification (Form I-9);
    c. Obtains a completed and signed employment application;
    d. Obtains a signed statement attesting to all of an applicant's felony convictions, including detailed information regarding each conviction;
    e. Consults with the applicant's most recent or next most recent employer, if any;
    f. Inquiries regarding the applicant's qualifications and competence for the position;
    g. If for a loan officer, loan originator, loan processor, branch manager, supervisor, or similar position, obtains a current credit report from a credit reporting agency; and
    h. Investigates further if any information received in the above inquiries raises questions as to the applicant's honesty, truthfulness, integrity, or competence. An inquiry is sufficient after two attempts to contact a person, including at least one written inquiry.
23. "Record" has the meaning stated at A.R.S. § 44-7002(13).
24. "Registered to do business in this state" means:
    a. If an Arizona corporation, it is incorporated under A.R.S. Title 10, Chapter 2, Article 1;
    b. If a foreign corporation, it either transfers its domicile under A.R.S. Title 10, Chapter 2, Article 2, or obtains authority to transact business in Arizona under A.R.S. Title 10, Chapter 15, Article 1;
    c. If a business trust, it obtains authority to transact business in Arizona under A.R.S. Title 10, Chapter 18, Article 4;
    d. If an estate, it acts through a personal representative duly appointed by this state's Superior Court, under the provisions of A.R.S. Title 14, Chapter 3 or 4;
    e. If a trust, it delivers to the Superintendent an executed copy of the trust instrument creating the trust together with:
        All the current amendments, or
        A true copy of the trust instrument certified accurate and complete by a trustee of the trust before a notary public;
    f. If a general partnership, limited partnership, limited liability company, limited liability partnership, or limited liability limited partnership, it is organized under A.R.S. Title 29;
    g. If a foreign general partnership, limited partnership, limited liability company, limited liability partnership, or limited liability limited partnership, it is registered with the Arizona Secretary of State's office under A.R.S. Title 29;
    h. If a joint venture, association, or any entity not specified in this subsection, it is organized and conducts its business in compliance with Arizona law; or
    i. The entity is exempt from registration.
25. "Registered Exempt Person" means a person who is exempt from licensure pursuant to A.R.S. § 6-912 and A.R.S. Title 6, Chapter 9, Articles 1, 2 and 3 as a federally chartered savings bank that is registered with the nationwide mortgage licensing system and registry and holds a certificate of exemption.
26. "Resident of this state" means a natural person domiciled in Arizona.
27. "Responsible individual" or "responsible person", as those terms are used in A.R.S. §§ 6-903, 6-943, 6-973, and 6-976, means a resident of this state who:

a. Lives in Arizona during the entire period of designation as the responsible individual on a license;
b. Is in active management of a licensee's affairs;
c. Meets the qualifications listed in A.R.S. §§ 6-903, 6-943, or 6-973; and
d. Is an officer, director, member, partner, employee, or trustee of a licensed entity.

Table A. Licensing Time-frames

No.	License Type	Legal Authority	Administrative Completeness Review (Days)	Substantive Review (Days)	Overall Time-frame (Days)
1	*Bank*	A.R.S. § 6-203, et seq.			
	Initial Application	R20-4-211	45	45	90
2	*Bank Trust Dept.*	A.R.S. § 6-381			
	Initial Application	A.R.S. § 6-203, A.R.S. § 6-204(C)	45	45	90
3	*Savings & Loan*	A.R.S. § 6-401, et seq.			
	Initial Application	A.R.S. § 6-408, R20-4-327	75	75	150
4	*Credit Union*	A.R.S. § 6-501, et seq.			
	Initial Application	A.R.S. § 6-506(A)	60	60	120
5	*Trust Company*	A.R.S. § 6-851, et seq.			
	Initial Application	A.R.S. § 6-854(A)	75	75	150
6	*Consumer Lender*	A.R.S. § 6-601, et seq.			
	Initial Application	A.R.S. § 6-603(C)	60	60	120
7	*Debt Management*	A.R.S. § 6-701, et seq.			
	Initial Application	A.R.S. § 6-704(A), R20-4-602(A), ~~R20-4-620(A)~~	30	30	60
8	*Escrow Agent*	A.R.S. § 6-801, et seq.			
	Initial Application	A.R.S. § 6-814	60	60	120
9	*Mortgage Broker or Commercial Mortgage Broker*	A.R.S. § 6-901, et seq.			
	Initial Application	A.R.S. § 6-903(C) and (D)	60	60	120
10	*Mortgage Banker*	A.R.S. § 6-941, et seq.			
	Initial Application	A.R.S. § 6-943(D)	60	60	120
11	*Commercial Mortgage Banker*	A.R.S. § 6-971, et seq.			
	Initial Application	A.R.S. § 6-974(A)	60	60	120
12	*Acquisition of Control of Financial Institution*	R20-4-1602, R20-4-1702			
	Initial Application	A.R.S. 6-1104	30	30	60

13	*Money Transmitter*	A.R.S. § 6-1201, et seq.			
	Initial Application	A.R.S. § 6-1204(A)	60	60	120
14	*Advance Fee Loan Broker*	A.R.S. § 6-1301, et seq.			
	Initial Application	A.R.S. § 6-1303(A)	30	30	60
15	*Premium Finance Co.*	A.R.S. § 6-1401, et seq.			
	Initial Application	A.R.S. § 6-1402(C)	60	60	120
16	*Collection Agency*	A.R.S. § 32-1001, et seq.			
	Initial Application	A.R.S. § 32-1021, R20-4-1502	30	15	45
17	*Motor Vehicle Dealer*	A.R.S. § 44-281, et seq.			
	~~Dealer~~ Initial Application	A.R.S. § 44-282(B)	30	15	45
18	*Sales Finance Co.*	A.R.S. § 44-281, et seq.			
	~~Sales Finance~~ Initial Application	A.R.S. § 44-282(B)	30	15	45
19	~~*Deferred Presentment Company*~~ *Certificate of Exemption*	~~A.R.S. § 6-1259~~ A.R.S. § 6-912			
	Initial Application	~~A.R.S. § 6-1253~~ A.R.S. § 6-912(B)	45	45	90
20	*Loan Originators*	A.R.S. § 6-991, et seq.			
	Initial Application	A.R.S. § 6-991.04(A)	60	60	120

ARTICLE 9. MORTGAGE BROKERS

R20-4-927. Conversion to Commercial Mortgage Broker License

A. Under A.R.S. § 6-913, a mortgage broker licensee shall only be permitted to convert his or her license to a commercial mortgage broker license during the renewal period established by A.R.S. § 6-904.

B. The licensee seeking conversion shall not be subject to the 12 continuing education units as prescribed by A.R.S. § 6-903(V).

C. The licensee seeking conversion shall submit:

1. The renewal fees required by A.R.S. § 6-126 for commercial mortgage brokers, and
2. The information and documents required by A.R.S. § 6-903.

R20-4-928. Certificate of Exemption Application and Renewal

A. Under A.R.S. § 6-912(C), upon application for a certificate of exemption, an applicant shall pay a nonrefundable fee of $300.

B. A person holding a certificate of exemption shall pay a renewal fee of $150.00 on or before December 31 of each year. Certificates of exemption not renewed by December 31 are automatically suspended, and the certificate holder shall not act as a registered exempt person until the certificate is renewed or a new certificate is issued pursuant to A.R.S. § 6-912. While the certificate is suspended, the licensed loan originators sponsored by the registered exempt person may not transact business as a loan originator. A registered exempt person may renew an automatically suspended certificate by paying the renewal fee plus $25.00 for each day after December 31 that a renewal fee is not received by the Superintendent and applying for renewal as prescribed by the Superintendent. A certificate of exemption that is not renewed by January 31 expires. A certificate of exemption shall not be granted to the holder of an expired certificate of exemption except as provided in A.R.S. § 6-912 for the issuance of an original certificate of exemption. Each licensed loan originator that is sponsored by a registered exempt person whose certificate has expired shall have his or her license placed on inactive status and shall not transact business in Arizona as a loan originator pursuant to A.R.S. § 6-991.02(M).

C. In addition to the application fee, on issuance of the certificate of exemption, the Superintendent shall collect the first year's renewal fee prorated according to the number of quarters remaining until the date of the next annual renewal, as

required by A.R.S. § 6-126(B).

D. The following fees are payable to the Department:

1. To change the name of the federally chartered savings bank on a certificate of exemption: $250.00.
2. To change the responsible individual for the exempt entity: $250.00.
3. To issue a duplicate or replace a lost certificate of exemption: $100.00.
4. To change the address of the federally chartered savings bank on a certificate of exemption: $50.00.

ARTICLE 18. MORTGAGE BANKERS

R20-4-1813. Conversion to Mortgage Broker License

Under A.R.S. § 6-949 to apply for a conversion from a mortgage banker license to a mortgage broker license, the applicant shall submit during the renewal period all applicable renewal documents and renewal fees required by A.R.S. §§ 6-126 and 6-903 for mortgage brokers.