NOTICES OF PROPOSED RULEMAKING

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

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

Editor's Note: The following two Notices of Proposed Rulemaking were exempt from Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 319.)

[R13-22]

PREAMBLE

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

R4-23-110	Amend
R4-23-674	Amend
R4-23-701	Amend
R4-23-701.01	Amend
R4-23-701.02	Amend
R4-23-701.04	New Section
R4-23-702	New Section
R4-23-703	Amend
R4-23-704	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) and 32-1904(B)(3)

Implementing statute: A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3)

3. 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. 3263, December 14, 2012

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

Name:	Sandra Sutcliffe, Compliance Officer
Address:	Board of Pharmacy 1616 W. Adams Phoenix, AZ 85007
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	ssutcliffe@azpharmacy.gov
Web site:	www.azpharmacy.gov

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 An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

In August 2005 rules R4-23-701, R4-23-701.01, R4-23-701.02, R4-23-701.03, and R4-23-703 underwent the Five-Year Rule Review, and the Board identified that the rules needed to be amended. A task force was appointed by the Board in 2008 to review the rules and several meetings were held before the Governor's moratorium on rulemaking was implemented in March 2009. The rules were again due for the Five-Year Rule Review in August 2010, however

the rulemaking moratorium was still in effect through September 2011. The Board appointed another task force in 2012 to review the rules and is now ready to make changes to those rules.

The rulemaking will amend rule R4-23-110 Definitions by adding or amending definitions to support changes in Article 7 rules. These definitions include "assisted living facility", "automated dispensing system", "emergency drug supply unit", "hospice inpatient facility", "long-term care facility", and "resident".

The rulemaking will amend rule R4-23-674 Limited-service Long-term Care Pharmacy by removing the requirement that a long-term care consultant pharmacist be employed by or contracted with the provider pharmacy, and includes changes to the policies and procedures section. These changes are found in R4-23-674(B)(1)(2) and (F)(11).

The rulemaking will amend rule R4-23-701 Long-term Care Facilities Pharmacy Services: Consultant Pharmacist by including the requirement that a long-term care consultant pharmacist in an Arizona facility be licensed by the Board, and edits the long-term care consultant pharmacist's responsibilities to the facility. These changes are found in R4-23-701(A), (B), (C), and (D).

The rulemaking will amend rule R4-23-701.01 Long-term Care Facilities Pharmacy Services: Provider Pharmacy by clarifying the requirement that a provider pharmacy develops procedures for patient level drug recalls, and prohibits a provider pharmacy from repackaging previously dispensed drugs. These changes are found in R4-23-701.01(2)(3)(4) and (5).

The rulemaking will amend rule R4-23-701.02 Long-term Care Facilities Pharmacy Services: Emergency Drugs by editing the criteria for an emergency drug supply unit, revising the drug packaging, unit labeling and restocking requirements, and adding new subsections for the use of automation. These changes are found in R4-23-701.02(A), (B), (C), (D), (E), and (F).

The rulemaking will add a new rule section R4-23-701.04 Long-term Care Facilities Pharmacy Services: Automated Dispensing Systems to allow the use of automation within a long-term care facility.

The rulemaking will add a new rule section R4-23-702 Hospice Inpatient Facilities to outline the criteria for the provision of contracted pharmacy services in a hospice inpatient facility.

The rulemaking will amend rule R4-23-703 Assisted Living Facilities to prohibit the use of an emergency drug supply unit or an automated dispensing system in an assisted living facility, and also to prohibit the repackaging of previously dispensed drugs. These changes are found in R4-23-703(B)(2), (C), (F), and (G).

The rulemaking will add a new rule section R4-23-704 Customized Patient Medication Packages to allow the packaging of two or more prescribed drugs in a single container.

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.

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

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

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

Not applicable

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

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

The Board estimates most of the proposed rules will have no economic impact on pharmacies, pharmacists, and long-term care facilities.

The proposed rules allow for the restocking or replacement of an emergency drug supply unit on a weekly basis rather than every 48 hours. This will provide an economic benefit to pharmacies by reducing transportation and payroll costs.

The proposed rules allow for the use of automation in a long-term care facility, however the use of automation is discretionary not mandatory.

The Board estimates the remaining proposed rule changes would have no economic impact on pharmacies, pharmacists, and long-term care facilities.

The Board believes that approval of the rules benefits the public, pharmacies, pharmacists, and long-term care facilities by establishing standards governing the practice of consultant pharmacists and limited service long-term care pharmacies that provide pharmacy services to long-term care facilities.

9. The agency's contact person who can answer questions about the economic, small business and consumer impact

statement:

Name: Sandra Sutcliffe, Compliance Officer

Address: Board of Pharmacy
1616 W. Adams
Phoenix, AZ 85007

Telephone: (602) 771-2727

Fax: (602) 771-2749

E-mail: ssutcliffe@azpharmacy.gov

Web site: www.azpharmacy.gov

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

Comments may be written or presented orally. Written comments must be received by 5 p.m., Monday, March 25, 2013. An oral proceeding is scheduled for:

Date: March 25, 2013

Time: 11:00 a.m.

Location: 1616 W. Adams, 1st Floor Board Room
Phoenix, AZ 85007

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

11. 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:

The rule itself does not require a permit. However, the registration 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:

Yes, federal law is applicable, however the rule is not more stringent than 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

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

42 CFR 483.60, October 1, 2010, in R4-23-701(A)(4)

13. 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
R4-23-674. Limited-service Long-term Care Pharmacy

ARTICLE 7. NON-PHARMACY LICENSED OUTLETS-GENERAL PROVISIONS

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.

"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.

"Assisted living facility" means a residential care institution as defined in A.R.S. § 36-401.

"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 dispensing system" means a mechanical system in a long-term care facility that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information.

"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 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.
"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" 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.
"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.

"Emergency drug supply unit" means those drugs that may be required to meet the immediate and emergency therapeutic needs of long-term care facility residents and hospice inpatient facility patients, and which are not available from any other authorized source in sufficient time to prevent risk of harm to residents or patients.

"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.

"Hospice inpatient facility" means a health care institution licensed under A.R.S. § 36-401 and Article 8 that provides hospice services to a patient requiring inpatient services.

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

"Immunizations training program" means an immunization training program for pharmacists, pharmacy interns, and graduate interns that meets the requirements of R4-23-411(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 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.

"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.
"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" 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 identify-

ing 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 or an assisted living 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, 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.

"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; repack-

ers; 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 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-674. Limited-service Long-term Care Pharmacy

A. A limited-service pharmacy permittee shall ensure that the limited-service long-term care pharmacy complies with:
1. The general requirements of R4-23-671;
2. The professional practice standards of Article 4 and Article 11; and
3. The permits and drug distribution standards of R4-23-606 through R4-23-612, R4-23-670, and this Section.

B. If a limited-service long-term care pharmacy permittee contracts with a long-term care facility as a Provider Pharmacy, as defined in R4-23-110, the limited-service long-term care pharmacy permittee shall ensure that~~:~~
~~1. The limited-service long-term care pharmacy employs or contracts with a long-term care consultant pharmacist; and~~
~~2.~~ ~~The~~ the long-term care consultant pharmacist and the pharmacist-in-charge of the limited-service long-term care pharmacy comply with R4-23-701, R4-23-701.01, R4-23-701.02, ~~and~~ R4-23-701.03, R4-23-701.04, and this Section.

C. The limited-service long-term care pharmacy permittee or pharmacist-in-charge shall ensure that prescription medication is delivered to the patient's long-term care facility or locked in the dispensing area of the pharmacy when a pharmacist is not present in the pharmacy.

D. The pharmacist-in-charge of a limited-service long-term care pharmacy shall authorize only those individuals listed in R4-23-610(B) to be in the limited-service long-term care pharmacy.

E. In consultation with the long-term care facility's medical director and director of nursing, the long-term care consultant pharmacist and pharmacist-in-charge of the long-term care facility's provider pharmacy may develop, if necessary, a medication formulary for the long-term care facility that ensures the safe and efficient procurement, dispensing, distribution, administration, and control of drugs in the long-term care facility.

F. The limited-service long-term care pharmacy permittee or pharmacist-in-charge shall ensure that the written policies and procedures required in R4-23-671(E) include the following:
1. Clinical services and drug utilization management for:
   a. Drug utilization reviews,
   b. Inventory audits,
   c. Patient outcome monitoring,
   d. Drug information, and
   e. Education of pharmacy and other health professionals;
2. Controlled substances;
3. Drug compounding, dispensing, and storage;
4. Drug delivery requirements for:
   a. Transportation,
   b. Security,
   c. Temperature and other environmental controls, and
   d. Emergency provisions;
5. Drug product procurement;
6. Duties and qualifications of professional and support staff;
7. Emergency drug supply unit procedures;
8. Formulary, including development, review, modification, use, and documentation, if applicable;
9. Patient profiles;
10. Patient education;
11. Prescription orders~~:~~, including:
    a. Approved abbreviations,
    b. Stop-order procedures, and
    c. Leave-of-absence and discharge prescription order procedures;
12. Quality management procedures for:
    a. Adverse drug reactions,
    b. Drug recalls,
    c. Expired and beyond-use-date drugs,
    d. Medication or dispensing errors, and
    e. Education of professional and support staff;
13. Recordkeeping;
14. Sanitation; and
15. Security.

ARTICLE 7. NON-PHARMACY LICENSED OUTLETS - GENERAL PROVISIONS

R4-23-701. Long-term Care Facilities Pharmacy Services: Consultant Pharmacist

A. The long-term care consultant pharmacist as defined in R4-23-110~~, in cooperation with the pharmacist-in-charge of a provider pharmacy~~ shall:

1. ~~Prepare, implement, review, and revise in the same manner described in R4-23-671(E) and comply with written policies and procedures for the safe and efficient receipt, distribution, and storage of pharmaceutical products by the long-term care facility;~~ Possess a valid Arizona pharmacist license issued by the Board;
2. ~~Make the policies and procedures available in the provider pharmacy and long-term care facility for employee reference and inspection by the Board or its designee; and~~ Ensure the provision of pharmaceutical patient care services as defined in R4-23-110;
3. ~~Ensure that the written policies and procedures required under (A)(1) include the following:~~ Review the distribution and storage of drugs and devices and assist the facility in establishing policies and procedures for the distribution and storage of drugs and devices;
   - ~~a. Specification for the storage, distribution, and procurement of drugs and biologicals;~~
   - ~~b. Resident evaluation programs that relate to monitoring the therapeutic response and use of all drugs and biologicals prescribed or administered to residents, using as guidelines the most current indicators established by the Centers for Medicare and Medicaid Services, United States Department of Health and Human Services as required in 42 CFR 483.60, published October 1, 2001, and no future amendments or editions, incorporated by reference and on file with the Board and the Office of the Secretary of State.~~
   - ~~c. Pharmacist assistance in drug-related emergency situations on a 24-hour basis;~~
   - ~~d. Controlled substance accountability including:~~
     - ~~i. Date and time of administration,~~
     - ~~ii. Name of the person who administers the controlled substance,~~
     - ~~iii. Documenting and verifying of any wasted or partial doses, and~~
     - ~~iv. Exception reports for refused doses;~~
   - ~~e. Prescription order requirements;~~
   - ~~f. Approved abbreviations;~~
   - ~~g. Stop-order procedures;~~
   - ~~h. Pass and discharge prescription order procedures;~~
   - ~~i. Emergency drug supply unit procedures;~~
   - ~~j. Formulary procedures, including development, review, modification, use, and documentation, if applicable;~~
   - ~~k. Security and temperature control procedures for all drugs and biologicals;~~
   - ~~l. Disposal procedures that comply with subsection (D) for discontinued or outdated, prescription-only drugs or containers with illegible or missing labels; and~~
   - ~~m. Procedures for identifying and reporting to proper authorities drug irregularities and dispensing errors.~~
4. Provide resident evaluation programs that relate to monitoring the therapeutic response and utilization of all drugs and devices prescribed or administered to residents, using as guidelines the most current indicators established by the Centers for Medicare and Medicaid Services, United States Department of Health and Human Services as required in 42 CFR 483.60 (revised October 1, 2010, incorporated by reference and on file with the Board. This incorporated material contains no future editions or amendments.).
5. Serve as a resource for pharmacy-related education services within the facility;
6. Participate in quality management of resident care in the facility; and
7. Communicate with the provider pharmacy regarding areas of mutual concern and resolution.

B. A long-term care consultant pharmacist shall ensure that:

~~1. A pharmacist evaluates and verifies a prescription order of a long-term care facility resident in compliance with R4-23-402(A)(5) and (6);~~

~~2. The prescription order of a long-term care facility resident contains:~~
   - ~~a. Resident's name;~~
   - ~~b. Facility name or address;~~
   - ~~c. Drug name, strength, and dosage form;~~
   - ~~d. Directions for use;~~
   - ~~e. Date issued; and~~
   - ~~f. Name of prescriber;~~

~~3.~~1. When a provider pharmacy is not open for business, arrangements are made in advance by the long-term care consultant pharmacist, in cooperation with the pharmacist-in-charge of the provider pharmacy and the director of nursing and medical staff of the long-term care facility, for providing emergency drugs for the licensed nursing staff to administer to the residents of the facility using an emergency drug supply unit located at the facility;

~~4.~~2. The label and packaging of prescription-only and nonprescription drugs intended for use within a long-term care

facility complies with ~~R4-23-701.01 and~~ state and federal law; and

~~5.~~3. ~~A long-term care facility's personnel is informed that laws governing controlled substances require that a long-term care facility:~~ The long-term care facility:

a. ~~Store~~ Stores controlled substances listed in A.R.S. § 36-2513 in a separately locked and permanently affixed compartment, unless the facility uses a single-unit package medication distribution system~~,~~; and

b. ~~Maintain~~ Maintains accurate records of controlled substance administration or ultimate disposition.

C. The long-term care consultant pharmacist shall:

1. ~~ensure~~ Ensure availability of records and reports designed to provide the data necessary to evaluate the drug use of each long-term care facility resident that include the following:

~~1.~~a. Provider pharmacy patient profiles and long-term care facility medication administration records;

~~2.~~b. Reports of suspected adverse drug reactions;

~~3.~~c. Inspection reports of drug storage areas with emphasis on detecting outdated drugs; and

~~4.~~d. Accountability reports, ~~including all drug destruction forms.~~ that include:

i. Date and time of administration,

ii. Name of the person who administered the drug,

iii. Documentation and verification of any wasted or partial doses,

iv. Exception reports for refused doses, and

v. All drug destruction forms; and

2. Identify and report drug irregularities and dispensing errors to the prescriber, the director of nursing of the facility, and the provider pharmacy.

D. A long-term care consultant pharmacist or pharmacist-in-charge of a provider pharmacy shall ensure that:

1. Discontinued or outdated drugs, including controlled substances, are destroyed or disposed of~~:~~

~~a. Under the supervision of either a long-term care consultant pharmacist or a pharmacist employed by a provider pharmacy and witnessed by the long-term care facility administrator or the administrator's designee;~~

~~b. List by drug name, strength, dosage form, and quantity; and~~

~~c.~~ ~~In~~ in a timely manner using methods consistent with federal, state, and local requirements and subject to review by the Board or its ~~designee~~ staff; and

2. Drug containers with illegible or missing labels are:

a. Identified; and

b. Replaced or relabeled by a pharmacist employed by the pharmacy that dispensed the prescription medication.

R4-23-701.01. Long-term Care Facilities Pharmacy Services: Provider Pharmacy

The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure that:

1. A prescription medication is provided only by a valid prescription order for an individual long-term care facility resident, properly labeled for that resident, as specified in this subsection. Nothing in this Section shall prevent a provider pharmacy from supplying nonprescription drugs in a manufacturer's unopened container or emergency drugs using an emergency drug supply unit as specified in R4-23-701.02;
2. A prescription medication label for a long-term care facility resident complies with A.R.S. §§ ~~32-1963.01(C) and (I),~~ 32-1968~~,~~ and 36-2525 ~~and the applicable parts of R4-23-658(D),~~ and contains:
   a. The drug name, strength, dosage form, and quantity; and
   b. The beyond-use-date;
3. Only a pharmacist employed by the pharmacy that dispensed the prescription medication may, through the exercise of professional ~~judgement~~ judgment, relabel or alter a prescription medication label that is illegible or missing;
4. The ~~long-term care facility~~ provider pharmacy develops and implements drug recall policies and procedures that protect the health and safety of facility residents. The drug recall procedures shall include immediate discontinuation of any patient level recalled drug and notification of the prescriber and director of nursing of the facility;~~-~~and
5. ~~The provider pharmacy or any of its employees does not pay any rebate under A.R.S. § 32-1932(D) and R4-23-404.~~ Drugs previously dispensed to a resident of the long-term care facility by another pharmacy, and drugs previously dispensed by the provider pharmacy, are not repackaged.

R4-23-701.02. Long-term Care Facilities Pharmacy Services: Emergency Drugs

A. The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure that:

1. ~~an~~ An emergency drug supply unit is available within the long-term care facility~~.~~;
2. Drugs contained in an emergency drug supply unit remain the property of the provider pharmacy, and
3. Controlled substance drugs contained in an emergency drug supply unit are included in all inventories required under A.R.S. § 36-2523(B) and R4-23-1003(A).

B. An emergency drug supply unit shall ~~contain only a drug that meets~~ meet the following criteria:

1. The ~~drug is~~ drugs are necessary to meet the ~~emergent and immediate~~ immediate and emergency therapeutic needs of long-term care facility residents as determined by the provider pharmacy's pharmacist-in-charge in consultation with

the long-term care facility's medical director and nursing director; ~~and~~

2. The purpose of the emergency drug supply unit in a long-term care facility is not to relieve a provider pharmacy of the responsibility for timely provision of the resident's routine drug needs, but to ensure that an emergency drug supply unit is available for facility residents in need of immediate and emergency therapeutic drugs; and

~~2.~~3. The ~~drug is packaged~~ drugs are provided in a manufacturer's unit of use package or are prepackaged and labeled to include the drug name, strength, dosage form, manufacturer, lot number, and expiration date and provider pharmacy's name, address, telephone number, and pharmacist's initials.

C. The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure that an emergency drug supply unit:

1. Is stored in an area that:
   a. Is temperature controlled; and
   b. Prevents unauthorized access;
2. Contains on the exterior of the emergency drug supply unit a label to indicate that the contents are for emergency use only;
3. Contains on the exterior of the emergency drug supply unit a complete list of the contents of the unit by drug name, strength, dosage form, ~~expiration date~~, and quantity and the provider pharmacy's name, address, and telephone number; ~~and~~
4. Contains on the exterior of the emergency drug supply unit a label that indicates the date of the earliest drug expiration date; and

~~4.~~5. Contains on the exterior of the emergency drug supply unit a label that indicates the date of and ~~person~~ pharmacist responsible for the last inspection of the emergency drug supply unit~~.~~; and

6. Is secured with a tamper-evident seal, or is locked and sealed in a manner that obviously reveals when the unit has been opened or tampered with.

D. The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall:

1. Prepare, implement, review, and revise in the same manner described in R4-23-671(E) and comply with written policies and procedures for the storage and use of an emergency drug supply unit in a long-term care facility;
2. Make the policies and procedures available in the provider pharmacy and long-term care facility for employee reference and inspection by the Board or its ~~designee~~ staff; ~~and~~
3. Ensure that the written policies and procedures include the following:
   a. Drug removal procedures that requires:
      i. The long-term care facility's personnel receive a valid prescription order for each drug removed from the emergency drug supply unit,
      ii. The long-term care facility's personnel notify the provider pharmacy when a drug is removed from the emergency drug supply unit, ~~and~~
      ~~iii. The provider pharmacy's personnel restock the emergency drug supply unit within 48 hours of receiving the notification required in subsection (D)(3)(a)(ii),~~
   b. Outdated drug replacement procedures ~~that requires:~~, and
      ~~i. The provider pharmacy's personnel check for outdated drugs in the emergency drug supply unit once a month,~~
      ~~ii. The long-term care facility's personnel notify the provider pharmacy when an outdated drug is found in the emergency drug supply unit,~~
      ~~iii. The provider pharmacy's personnel remove an outdated drug from the emergency drug supply unit within 48 hours~~ seven days ~~of receiving the notification required in subsection (D)(3)(b)(ii), and~~
      ~~iv. The provider pharmacy's personnel restock the emergency drug supply unit within 48 hours of receiving the notification required in subsection (D)(3)(b)(ii), and~~
   c. Security and inspection procedures; ~~and~~
4. Exchange or restock the emergency drug supply unit weekly, or more often as necessary, to ensure the availability of an adequate supply of emergency drugs within the long-term care facility. Restocking of the emergency drug supply unit at the facility shall be completed by an Arizona licensed pharmacist employed by the provider pharmacy, or by an Arizona licensed intern, graduate intern, technician or technician trainee under the direct on-site supervision of an Arizona licensed pharmacist; and

~~4.~~5. Educate pharmacy and long-term care facility personnel in the storage and use of an emergency drug supply unit.

E. In addition to the requirements of subsections (A) through (D), an automated emergency drug supply unit may be used provided:

1. The pharmacy permittee or pharmacist-in-charge of the provider pharmacy notifies the Board or its staff in writing of the intent to use an automated emergency drug supply unit, including the name and type of unit;
2. The provider pharmacy is notified electronically when the automated emergency drug supply unit has been accessed;
3. All events involving the access of the automated emergency drug supply unit are recorded electronically and maintained for not less than two years;

4. The provider pharmacy is capable of producing a report of all transactions of the automated emergency drug supply unit including a single drug usage report as required in R4-23-408(B)(5) on inspection by the Board or its staff;
5. The provider pharmacy develops written policies and procedures for:
   a. Accessing the automated emergency drug supply unit in the event of a system malfunction or downtime,
   b. Authorizing and modifying user access,
   c. An ongoing quality assurance program that includes:
      i. Training in the use of the automated emergency drug supply unit for all authorized users,
      ii. Maintenance and calibration of the automated emergency drug supply unit as recommended by the device manufacturer; and
6. Documentation of the requirements of subsection (E)(5)(c)(ii) is maintained for inspection by the Board or its staff for not less than two years.

F. The Board may prohibit a pharmacy permittee or pharmacist-in-charge of a provider pharmacy from using an automated emergency drug supply unit if the pharmacy permittee or pharmacy permittee's employees do not comply with the requirements of subsections (A) through (E).

R4-23-701.04. Long-term Care Facilities Pharmacy Services: Automated Dispensing Systems

A. Before using an automated dispensing system as defined in R4-23-110, a pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall:
1. Notify the Board or its staff in writing of the intent to use an automated dispensing system, including the name and type of system;
2. Obtain a separate controlled substances registration at the location of each long-term care facility at which an automated dispensing system containing controlled substances will be located as required by federal law; and
3. Maintain copies of the registrations required under subsection (A)(2) at the provider pharmacy for inspection by the Board or its staff.

B. A pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure:
1. Drugs contained in an automated dispensing system remain the property of the provider pharmacy,
2. Controlled substance drugs contained in an automated dispensing system are included in all inventories required under A.R.S. § 36-2523(B) and R4-23-1003(A),
3. Schedule II drugs are not stocked in an automated dispensing system, and
4. A separate emergency drug supply unit is available in the long-term care facility to meet the requirements of R4-23-701.02.

C. A pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall:
1. Ensure that policies and procedures as required in subsection (D) for the use of an automated dispensing system in a long-term care facility are prepared, implemented, and complied with;
2. Review biennially and, if necessary, revise the policies and procedures required under subsection (D);
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 for employee reference and inspection by the Board or its staff within the pharmacy and at any location outside of the pharmacy where the automated dispensing system is used.

D. A pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure the written policies and procedures include:
1. Drug removal procedures that include the following:
   a. A drug is provided only by a valid prescription order for an individual long-term care facility resident;
   b. A drug is dispensed from an automated dispensing system only after a pharmacist has:
      i. Reviewed and verified the resident's prescription order as required by R4-23-402(A), and
      ii. Electronically authorized the access for that drug for that particular resident, and
   c. The automated dispensing system labels each individual drug packet with a resident specific label that complies with R4-23-701.01(2) and contains the resident's room number or facility identification number; and
2. Security procedures that include the following:
   a. The pharmacy permittee or pharmacist-in-charge of the provider pharmacy is responsible for authorizing user access, including adding and removing users and modifying user access;
   b. Each authorized user is a licensee of the Board or authorized licensed personnel of the long-term care facility; and
   c. The automated dispensing system is secured at the long-term care facility by electronic or mechanical means or a combination thereof designed to prevent unauthorized access;
3. Drug stocking procedures that include the following:
   a. Automated dispensing systems that use non-removable containers that do not allow prepackaging of the container as set out in subsection (D)(3)(b):
      i. Are stocked at the long-term care facility by an Arizona licensed pharmacist employed by the provider phar-

macy, or by an Arizona licensed intern, graduate intern, technician or technician trainee under the direct on-site supervision of an Arizona licensed pharmacist; and

ii. Utilize barcode or other technologies to ensure the correct drug is placed in the correct canister or container; and

b. Automated dispensing systems that use removable containers may be stocked at the long-term care facility by an authorized user provided:

i. The prepackaging of the container occurs at the provider pharmacy;

ii. A pharmacist verifies the container has been properly filled and labeled, and the container is secured with a tamper-evident seal;

iii. The individual containers are transported to the long-term care facility in a secure, tamper-evident shipping container; and

iv. The automated dispensing system uses microchip, bar-coding, or other technologies to ensure the containers are accurately loaded in the automated dispensing system; and

4. Record-keeping and report procedures that include the following:

a. All events involving the access of the automated dispensing system are recorded electronically and maintained for not less than two years;

b. The provider pharmacy is capable of producing a report of all transactions of the automated dispensing system including:

i. A single drug usage report that complies with R4-23-408(B)(5); and

ii. An authorized user history including date and time of access and type of transaction; and

c. The provider pharmacy has procedures to safeguard the storage, packaging, and distribution of drugs by monitoring:

i. Current inventory;

ii. Expiration dates;

iii. Controlled substance dispensing;

iv. Re-dispense requests; and

v. Wastage.

E. A pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall:

1. Ensure that an electronic log is kept for each container fill that includes:

a. An identification of the container by drug name and strength, and container number;

b. The drug's manufacturer or National Drug Code (NDC) number;

c. The expiration date and lot number from the manufacturer's stock bottle that is used to fill the container. If multiple lot numbers of the same drug are added to a container, each lot number and expiration date shall be documented;

d. The date the container is filled;

e. Documentation of the identity of the licensee who placed the drug into the container; and

f. If the licensee who filled the container is not a pharmacist, documentation of the identity of the pharmacist who supervised the non-pharmacist licensee; and

2. Maintain the electronic log for inspection by the Board or its staff for not less than two years.

F. A pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall:

1. Implement an ongoing quality assurance program that monitors performance of the automated dispensing system and compliance with the established policies and procedures that includes:

a. Training in the use of the automated dispensing system for all authorized users,

b. Maintenance and calibration of the automated dispensing system as recommended by the device manufacturer,

c. Routine accuracy validation testing no less than every three months, and

d. Downtime and malfunction procedures to ensure the timely provision of medication to the long-term care facility resident, and

2. Maintain documentation of the requirements of subsections (F)(1)(b) and (F)(1)(c) for inspection by the Board or its staff for not less than two years.

G. The Board may prohibit a pharmacy permittee or pharmacist-in-charge from using an automated dispensing system in a long-term care facility if the pharmacy permittee or the pharmacy permittee's employees do not comply with the requirements of subsections (A) through (F).

R4-23-702. ~~Repealed~~ Hospice Inpatient Facilities

A. If a pharmacy permittee contracts to provide pharmacy services to the patients of a hospice inpatient facility as defined in R4-23-110, the pharmacy permittee shall ensure that:

1. A prescription medication is provided only by a valid prescription order for an individual hospice inpatient facility patient, properly labeled for that patient, as specified in this subsection. Nothing in this section shall prevent a provider pharmacy from supplying non-prescription drugs in a manufacturer's unopened container;

2. A prescription medication label for a hospice inpatient facility patient complies with A.R.S. § 32-1968 and A.R.S. § 36-2525 and contains:
   a. The drug name, strength, dosage form, and quantity; and
   b. The beyond-use date; and
3. If the label on the hospice inpatient facility patient's drug container becomes damaged or soiled, a pharmacist employed by the pharmacy that dispensed the drug container, through the exercise of professional judgment, may relabel the drug container. Only a pharmacist is permitted to label a drug container or alter the label of a drug container.

B. A pharmacist may help hospice inpatient facility personnel develop written policies and procedures for the procurement, administration, storage, control, recordkeeping, and disposal of drugs in the facility.

C. The provider pharmacy may contract with the hospice inpatient facility to provide pharmacist services at the facility that include evaluation of the patient's response to medication therapy, identification of potential adverse drug reactions, and recommended appropriate corrective action.

D. A provider pharmacy that places an emergency drug supply unit at a hospice inpatient facility shall comply with the requirements of R4-23-701.02.

E. A pharmacy shall not place an automated dispensing system as defined in R4-23-701.04 in a hospice inpatient facility.

F. Drugs previously dispensed to a patient of the hospice inpatient facility by another pharmacy, and drugs previously dispensed by the provider pharmacy, shall not be repackaged.

R4-23-703. Assisted Living Facilities

A. Assisted living facilities are licensed by the state Department of Health Services.

B. A pharmacy shall:
1. Only dispense, sell, or deliver a prescription or nonprescription drug to an assisted living facility resident after receiving a prescription order for the drug from the resident's medical practitioner;
2. Label, in accordance with A.R.S. §§ 32-1963.01 ~~and,~~ 32-1968, and 36-2525, all drugs dispensed, sold, or delivered to an assisted living facility resident;
3. Obtain a copy of the current Arizona Department of Health Services license issued to an assisted living facility before dispensing drugs to that facility's resident; and
4. Maintain, for inspection by a Board compliance officer, a file containing the license copy required in subsection (B)(3).

C. In addition to the labeling requirements of A.R.S. §§ 32-1963.01, ~~and~~ 32-1968, and 36-2525, the label on a prescription medication for an assisted living facility resident shall include the name, strength, and quantity of the drug and a beyond-use date.

D. If the label on an assisted living facility resident's drug container becomes damaged or soiled, a pharmacist employed by the pharmacy that dispensed the drug container, through the exercise of professional judgment, may relabel the drug container. Only a pharmacist is permitted to label a drug container or alter the label of a drug container.

E. A pharmacist may help assisted living facility personnel to develop written policies and procedures for the procurement, administration, storage, control, recordkeeping, and disposal of drugs in the facility and provide other information concerning drugs that assisted living facilities should have for safe and effective supervision of drug self-administration.

F. ~~A pharmacist shall not pay any rebate to an assisted living facility according to R4-23-404 and A.R.S. § 32-1932(B)(1).~~ A pharmacy shall not place an emergency drug supply unit as defined in R4-23-701.02 or an automated dispensing system as defined in R4-23-701.04 in an assisted living facility.

G. Drugs previously dispensed to a resident of the assisted living facility by another pharmacy, and drugs previously dispensed by the provider pharmacy, shall not be repackaged.

R4-23-704. ~~Repealed~~ Customized Patient Medication Packages

In lieu of dispensing two or more prescribed drugs in separate containers, a pharmacist may, with the consent of the patient, the patient's caregiver, the prescriber, or the facility caring for the patient, provide a customized patient medication package. The pharmacist preparing a customized patient medication package shall abide by the guidelines set forth in the current edition of the official compendium for labeling, packaging, and record-keeping, and state and federal law.

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R13-21]

PREAMBLE

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

R4-23-601 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)

Implementing statute: A.R.S. §§ 32-1904(B)(3), 32-1931(B), and 32-1984(A) and (B).

3. 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: 19 A.A.R. 8, January 4, 2013

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

Name:	Sandra Sutcliffe, Compliance Officer
Address:	Board of Pharmacy 1616 W. Adams Phoenix, AZ 85007
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	ssutcliffe@azpharmacy.gov
Web site:	www.azpharmacy.gov

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

Rule R4-23-601(A) sets out the requirement that a current Board permit is required for all sales of drugs and regulated chemicals within Arizona and shipment of drugs and regulated chemicals into Arizona. It has come to the Board's attention through recent complaint review, that resident permit holders have purchased drugs from persons that do not have a current Board permit, then shipped those drugs into other states without obtaining a non-resident permit where required. The Board has determined that R4-23-601 needs to be amended to add the requirement that a resident permit holder verify they receive drugs and regulated chemicals only from persons that comply with subsection (A) of R4-23-601, and they comply with any non-resident permit or license requirements.

The rulemaking will amend R4-23-601 General Provisions by adding the requirement that a resident permit holder verify they receive drugs and regulated chemicals only from persons with a current Board permit. Those references are in R4-23-601(B).

The rulemaking will amend R4-23-601 General Provisions by adding the requirement that a resident permit holder selling or delivering drugs and regulated chemicals into other states or jurisdictions comply with the permit or license requirements of those states or jurisdictions. Those references are in R4-23-601(C).

The rulemaking will amend R4-23-601 General Provisions by adding the pedigree requirements found in A.R.S. § 32-1984. Those references are in R4-23-601(D).

The rulemaking will amend R4-23-601 General Provisions by adding the prorated permit fee requirements found in A.R.S. § 32-1931(B). Those references are in R4-23-601(F).

The rulemaking will amend R4-23-601 General Provisions by adding the DEA registration number requirement found in R4-23-1003(A). Those references are R4-23-601(G)(b) and (c).

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.

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

underlying each study, and any analysis of each study and other supporting material:

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

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

Not applicable

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

The proposed rules will impact the Board, pharmacies, wholesalers, manufacturers, compressed medical gas distributors, and compressed medical gas suppliers. The proposed rules' impact on the Board will be the usual rulemaking-related costs, which are minimal.

The Board estimates most of the proposed rules will have no economic impact on pharmacies, wholesalers, manufacturers, compressed medical gas distributors, and compressed medical gas suppliers.

The proposed rules require resident permit holders to comply with permit or license requirements if they choose to sell or deliver drugs or regulated chemicals into other states or jurisdictions. This will have an economic impact of permit or license fees for those resident permit holders selling or delivering into other states or jurisdictions.

The Board estimates the remaining proposed rule changes would have no economic impact on pharmacies, wholesalers, manufacturers, compressed medical gas distributors, and compressed medical gas suppliers.

The Board believes that approval of the rules benefits the public, pharmacies, wholesalers, manufacturers, compressed medical gas distributors, and compressed medical gas suppliers by clearly establishing standards for the receipt and sale or delivery of narcotic or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, and regulated chemicals.

9. The agency's contact person who can answer questions about the economic, small business and consumer impact statement:

Name:	Sandra Sutcliffe, Compliance Officer
Address:	Board of Pharmacy 1616 W. Adams Phoenix, AZ 85007
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	ssutcliffe@azpharmacy.gov
Web site:	www.azpharmacy.gov

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

Comments may be written or presented orally. Written comments must be received by 5 p.m., Monday, March 25, 2013. An oral proceeding is scheduled for:

Date:	March 25, 2013
Time:	10:00 a.m.
Location:	1616 W. Adams, 1st Floor Board Room Phoenix, AZ 85007

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

11. 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:

The rule itself does require a permit. The specific permit is required by A.R.S. § 32-1931.

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, federal law is applicable, however the rule is not more stringent than 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

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

13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section
R4-23-601. General Provisions

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-601. General Provisions

A. Permit required to sell a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical. A person shall have a current Board permit to:
1. Sell a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical in Arizona; or
2. Sell a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical from outside Arizona and ship the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into Arizona.

B. Before receiving a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, a resident permit holder shall verify that the person selling or delivering the narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical meets the requirements of subsection (A).

C. Before selling or delivering a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into another state or jurisdiction, a resident permit holder shall comply with the license or permit requirements of the other state or jurisdiction.

D. In addition to the records requirements of subsection (G), resident full-service wholesale permittees and resident pharmacies that engage in the wholesale distribution of prescription-only drugs shall maintain a pedigree as specified in A.R.S. § 32-1984 for all prescription-only drugs that leave the normal distribution channel as defined in A.R.S. § 32-1981.

~~**B.**~~**E.** A medical practitioner is exempt from subsection (A) to administer a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical for the emergency needs of a patient.

~~**C.**~~**F.** Permit fee. Permits are issued biennially on an odd- and even- year expiration based on the assigned permit number. The fee, specified in R4-23-205, is not refundable under any circumstances except the Board's failure to comply with the permit time-frames established in R4-23-602. The Board shall prorate the fee for new permits for the remaining full calendar months of the respective group to which the permit is assigned.

~~**D.**~~**G.** Record of receipt and disposal of narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals.
1. Every person manufacturing a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical, including repackaging or relabeling, shall prepare and retain for not less than three years the manufacturing, repackaging, or relabeling date for each narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical.
2. Every person receiving, selling, delivering, or disposing of a narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical shall record and retain for not less than three years the following information:
   a. The name, strength, dosage form, and quantity of each narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical received, sold, delivered, or disposed;
   b. The name, address, and ~~license or~~ permit number, and DEA registration number, if applicable, of the person from whom each narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is received;
   c. The name, address, and license or permit number, and DEA registration number, if applicable, of the person to whom each narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical is sold or delivered, or of the person who disposes of each narcotic or

other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical; and

d. The receipt, sale, deliver, or disposal date of each narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical.

3. The record required in this subsection shall be available for inspection by the Board or its compliance officer during regular business hours.
4. If the record required in this subsection is stored in a centralized recordkeeping system and not immediately available for inspection, a permittee, manager, or pharmacist-in-charge shall provide the record within four working days of the Board's or its compliance officer's request.

~~E.~~**H.** Narcotics or other controlled substances, prescription-only drugs or devices, nonprescription drugs, precursor chemicals, or regulated chemicals damaged by water, fire, or from human or animal consumption or use. No person shall sell or offer to sell any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical damaged by water, fire, or from human or animal consumption or use.

NOTICE OF PROPOSED RULEMAKING

TITLE 6. ECONOMIC SECURITY

CHAPTER 12. DEPARTMENT OF ECONOMIC SECURITY
CASH ASSISTANCE PROGRAM

Editor's Note: The following Notice of Proposed Rulemaking was reviewed per Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 319.) The Governor's Office authorized the notice to proceed through the rulemaking process on December 18, 2012.

[R13-20]

PREAMBLE

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

Article 14	New Article
R6-12-1401	New Section
R6-12-1402	New Section
R6-12-1403	New Section
R6-12-1404	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. §§ 41-1954(A)(3) and 46-134(A)(12)

Implementing statute: A.R.S. § 46-298

3. 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: 19 A.A.R. 50, January 11, 2013

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

Name:	Beth Broeker
Address:	Department of Economic Security P.O. Box 6123, Site Code 837A Phoenix, AZ 85005 or Department of Economic Security 1789 W. Jefferson, Site Code 837A Phoenix, AZ 85007
Telephone:	(602) 542-6555
Fax:	(602) 542-6000
E-mail:	bbroeker@azdes.gov
Web site:	http://www.azdes.gov

5. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an

explanation about the rulemaking:

This rulemaking will add rules pertaining to the Cash Assistance Grant Diversion program, to comply with Laws 2007, Ch. 120, § 1. The Grant Diversion cash benefit is a nonrecurring short term benefit intended to provide financial assistance to meet the critical needs of the assistance unit for a three calendar month period, which includes the initial month of Grant Diversion eligibility and the two months immediately following, in order for an adult assistance unit member to secure employment and support for the assistance unit. A.R.S. § 46-298 requires the Department to offer, and a Cash Assistance applicant may accept, the option of receiving a lump sum Grant Diversion cash benefit as an alternative to a monthly Cash Assistance benefit when all of the eligibility criteria in this Article are satisfied.

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

Not applicable

7. 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

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

For the 12-month period of July 1, 2011, through June 30, 2012, the Department of Economic Security issued $12,880,000 to 16,599 eligible TANF Cash Assistance applicants who chose the Grant Diversion option and were diverted from long-term assistance. The monthly average number of Grant Diversion option approvals was 1,383 and the average payment per case was $776. The Department's average monthly expenditure for the Grant Diversion option was $1,073,300. The rule has minimal impact to small business and consumers, because it explains current procedures in the Grant Diversion component of the Cash Assistance program.

9. The agency's contact person who can answer questions about the economic, small business and consumer impact statement:

Name:	Beth Broeker
Address:	Department of Economic Security P.O. Box 6123, Site Code 837A Phoenix, AZ 85005 or Department of Economic Security 1789 W. Jefferson, Site Code 837A Phoenix, AZ 85007
Telephone:	(602) 542-6555
Fax:	(602) 542-6000
E-mail:	bbroeker@azdes.gov
Web site:	http://www.azdes.gov

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

The Department does not plan to hold oral proceedings on this rule, unless a public hearing is requested within 30 days of the publication of this rule. All written comments on the rule and any requests for public hearing shall be made to the individual listed in item 4.

11. 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:

None

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:

Not applicable

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:

Not applicable

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:

Not applicable

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

13. The full text of the rules follows:

TITLE 6. ECONOMIC SECURITY

CHAPTER 12. DEPARTMENT OF ECONOMIC SECURITY
CASH ASSISTANCE PROGRAM

ARTICLE 14. GRANT DIVERSION

Section
R6-12-1401. Definitions
R6-12-1402. Eligibility Criteria for Grant Diversion
R6-12-1403. Amount of the Grant Diversion Cash Benefit
R6-12-1404. Treatment of Changes During the Grant Diversion Payment Period

ARTICLE 14. GRANT DIVERSION

R6-12-1401. Definitions
"Grant Diversion Payment Period" means the time period that begins the first day of the first eligible month and ends the last day of the third eligible month.

R6-12-1402. Eligibility Criteria for Grant Diversion
The Department shall offer a Cash Assistance applicant the option of receiving a lump sum Grant Diversion cash benefit when the applicant satisfies all of the following eligibility criteria:

A. The assistance unit includes an adult parent or non-parent caretaker relative;

B. The assistance unit meets all CA financial and non-financial eligibility criteria, except that the adult parent or non-parent caretaker relative is exempt from the following:
1. The Child Support requirements in R6-12-311;
2. The Jobs program participation requirements in R6-12-313;
3. The Personal Responsibility Agreement in R6-12-302; and
4. The TPEP Employment and Education requirements in R6-12-610;

C. The assistance unit is eligible for a CA cash benefit of at least one dollar in either the month of application or either of the two months following the month of application;

D. An adult assistance unit member is immediately available for full-time employment and the adult satisfies at least one of the following requirements:
1. Was employed in the month the application was received or in at least one of the 12 months preceding the month that the application was received;
2. Has a verified offer of full-time employment that will begin within the three month Grant Diversion payment period; or
3. Has successfully completed an educational, vocational, or job training program in the month the application was received or in one of the six months preceding the month that the application was received.

E. An adult parent or non-parent caretaker relative in the assistance unit completes and signs the Grant Diversion Applicant Agreement form, which includes the adult's agreement that the short term Grant Diversion cash benefit shall assist and support the adult in securing full-time employment within 90 days of the application date in order to enable the assistance unit to become self-sufficient.

F. The assistance unit has not received a Grant Diversion cash benefit in the 12 months preceding the month that the application was received; and

G. The assistance unit is not currently being sanctioned under R6-12-316.

R6-12-1403. Amount of the Grant Diversion Cash Benefit
The Department shall provide an eligible assistance unit a nonrecurring lump sum cash benefit in an amount equal to three times the maximum monthly cash benefit for which the assistance unit would be eligible in the Cash Assistance program, based on zero countable income. The Department shall provide the cash benefit to financially assist an adult assistance unit member in securing full-time employment within the three month Grant Diversion payment period.

R6-12-1404. Treatment of Changes During the Grant Diversion Payment Period

A. The Department shall exempt the assistance unit from the change reporting requirements in R6-12-901 during the three month Grant Diversion payment period.

B. When the Department receives a request to add a member to the assistance unit during the three month Grant Diversion payment period, the Department shall comply with subsections (B)(1) through (B)(3).

1. The Department shall redetermine eligibility including the added member. The Department shall add the new member, effective the date the request is received, only when the assistance unit remains eligible.
2. When the assistance unit remains eligible, the Department shall add the new member, effective the date the Department receives the request to add the member, and recalculate the assistance unit's Grant Diversion benefit amount. The Department shall issue the assistance unit a supplemental payment when the amount of the recalculated cash benefit amount exceeds the amount of the cash benefit that was issued to the assistance unit. The supplemental payment shall be a prorated amount from the date the Department received the request to add the member through the end of the three-month Grant diversion payment period.
3. When the recalculated Grant Diversion cash benefit amount is less than the cash benefit that was issued to the assistance unit, the Department shall not add the member to the assistance unit and shall not write an overpayment.