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

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R4-23-110	Amend
R4-23-671	Amend
R4-23-674	New Section
R4-23-701	Amend
R4-23-701.01	Amend
R4-23-701.02	Amend
R4-23-701.03	Amend

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

Authorizing statutes: A.R.S. §§ 32-1904(A)(1) and (2) and 32-1904(B)(3)

Implementing statutes: A.R.S. §§ 32-1904(A)(1) and (2) and 32-1904(B)(3)

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

Notice of Rulemaking Docket Opening: 8 A.A.R. 1193, March 22, 2002

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

Name: Dean Wright, Compliance Officer

Address: Board of Pharmacy
4425 W. Olive, Suite 140
Glendale, AZ 85302

Telephone: (623) 463-2727, ext. 131

Fax: (623) 934-0583

E-mail: rxcop@msn.com

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

The Board's five-year rule review in September 1997 identified Sections R4-23-701, R4-23-701.01, R4-23-701.02, and R4-23-701.03 for amending. These Sections deal with pharmacy services to long-term care facilities. The proposed rule will incorporate relevant portions of these sections into a new Section R4-23-674. Section R4-23-674 will specify the requirements for limited-service long-term care pharmacies. Section R4-23-671 dealing with the general requirements of limited-service pharmacy will be amended to reference the new Section R4-23-674. Sections R4-23-701, R4-23-701.01, R4-23-701.02, and R4-23-701.03 will be further amended to increase the clarity, conciseness, and understandability of the Sections. Section R4-23-110 will be amended to include new definitions for "limited-service long-term care pharmacy" and "long-term care facility" or "LTCF" and an amended definition for "provider pharmacy". The amended rule will include format, style, and grammar changes necessary to comply with the current administrative rules of the Secretary of State and the Governor's Regulatory Review Council.

The Board believes that approval of these rules will benefit the public health and safety by establishing clear and current standards governing the practices of consultant pharmacists and limited-service long-term care pharmacies that provide pharmacy services to long-term care facilities.

6. A reference to any study relevant to the rule that the agency reviewed and either proposes to rely on in its evaluation of or justification for the rule or proposes 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 rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

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

The proposed rules will impact the Board, pharmacists, pharmacies, and long-term care facilities. Most of the changes to the rule have no economic impact, but rather provide more clear, concise, and understandable language.

The public, Board, pharmacists, and pharmacies benefit from rules that are clear, concise, understandable, and reflect current practice standards. A rule that reflects current practice standards is easier to enforce because there are fewer gray areas that require subjective interpretation by compliance staff. The proposed rules will not have an economic impact on the Board office.

The proposed rules will have no economic impact on pharmacists.

The proposed rules allow the use of a four to one technician to pharmacist ratio in a limited-service long-term care pharmacy. This will provide an economic benefit to those pharmacies by reducing payroll costs.

The Board believes that approval of these rules will benefit the public health and safety by establishing clear and current standards governing the practices of consultant pharmacists and limited-service long-term care pharmacies that provide pharmacy services to long-term care facilities.

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

Name: Dean Wright, Compliance Officer

Address: Board of Pharmacy
4425 W. Olive, Suite 140
Glendale, AZ 85302

Telephone: (623) 463-2727, ext. 131

Fax: (623) 934-0583

E-mail: rxcop@msn.com

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

Comments may be written or presented orally. Written comments must be received by 5:00 p.m., Monday, September 16, 2002. An oral proceeding is scheduled for:

Date: September 16, 2002

Time: 10:00 a.m.

Location: 4425 W. Olive, Suite 140
Glendale, AZ 85302

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

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

Not applicable

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

None

13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section
R4-23-110. Definitions

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section
R4-23-671. General Requirements for Limited-service Pharmacy
R4-23-674. ~~Reserved~~ Limited-service Long-term Care Pharmacy

ARTICLE 7. NON-PHARMACY LICENSED OUTLETS - GENERAL PROVISIONS

Section
R4-23-701. Long-term Care Facilities Pharmacy Services: Consultant Pharmacist
R4-23-701.01. Long-term Care Facilities Pharmacy Services: Provider ~~Pharmacist~~ Pharmacy
R4-23-701.02. Long-term Care Facilities Pharmacy Services: Emergency ~~Medications~~ Drugs
R4-23-701.03. Long-term Care Facilities Pharmacy Services: Emergency ~~Medication~~ Drug Prescription Order

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

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

"Active ingredient" No change
"Approved course in pharmacy law" No change
"Approved Provider" No change
"Authentication of product history" No change
"AZPLEX" No change
"Batch" No change
"Beyond-use date" No change
"Biological safety cabinet" No change
"Certified pharmacy technician" No change
"Class 100 environment" No change
"Community pharmacy" No change
"Component" No change
"Computer system" No change
"Computer system audit" No change
"Container" No change
"Continuing education" No change
"Continuing education activity" No change
"Continuing education unit" or "CEU" No change
"Contact hour" No change
"Correctional facility" No change
"CRT" No change
"Current good compounding practices" No change
"Current good manufacturing practice" No change
"Cytotoxic" No change
"Day" No change

"DEA" No change

"Delinquent license" No change

"Dispensing pharmacist" No change

"Drug sample" No change

"Extreme emergency" No change

"FDA" No change

"Immediate notice" No change

"Inactive ingredient" No change

"Internal test assessment" No change

"Limited-service correctional pharmacy" No change

"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" No change

"Limited-service nuclear pharmacy" No change

"Limited-service pharmacy permittee" No change

"Long-term care consultant pharmacist" No change

"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" No change

"Lot number" or "control number" No change

"Materials approval unit" No change

"Mediated instruction" No change

"MPJE" No change

"NABP" No change

"NABPLEX" No change

"NAPLEX" No change

"Other designated personnel" No change

"Outpatient" No change

"Outpatient setting" No change

"Patient profile" No change

"Pharmaceutical care" No change

"Pharmacy law continuing education" No change

"Pharmacy technician" No change

"Prepackaged drug" No change

"Provider ~~pharmacist~~ pharmacy" means a ~~pharmacist who supplies~~ pharmacy that contracts with a long-term care facility to supply prescription medication ~~to~~ or other services for residents of a long-term care facility ~~and maintains patient profiles~~.

"Radiopharmaceutical" No change

"Radiopharmaceutical quality assurance" No change

"Radiopharmaceutical services" No change

"Red C stamp" No change

"Remodel" No change

"Remote drug storage area" No change

"Resident" No change

"Responsible person" No change

"Score transfer" No change
"Sight-readable" No change
"Single-drug audit" No change
"Single-drug usage report" No change
"Sterile pharmaceutical product" No change
"Strength" No change
"Supervision" No change
"Supplying" No change
"Support personnel" No change
"Transfill" No change
"Wholesale distribution" No change
"Wholesale distributor" No change

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

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

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

B. The limited-service pharmacy permittee shall secure the limited-service pharmacy by conforming with the following standards:
1. Permit no one to be in the limited-service pharmacy unless the pharmacist-in-charge or a pharmacist authorized by the pharmacist-in-charge ~~pursuant to A.A.C. R4-23-672(B) or R4-23-673(E)~~ is present;
2. Require the pharmacist-in-charge to designate in writing, by name, title, and specific area, those persons who will have access to particular areas of the limited-service pharmacy;
3. Implement procedures to guard against theft or diversion of drugs, including controlled substances; and
4. Require all persons working in the limited-service pharmacy to wear badges, with their names and titles, while on duty.

C. To obtain permission to deviate from the minimum area requirement set forth in A.A.C. R4-23-609, ~~or~~ R4-23-673, or R4-23-682, a limited-service pharmacy permittee shall submit a written request to the Board and include documentation that the deviation will facilitate experimentation or technological advances in the practice of pharmacy as defined in A.R.S. § 32-1901. If the Board determines the requested deviation from the minimum area requirement will enhance the practice of pharmacy and benefit the public, the Board shall grant the requested deviation.

D. The Board shall require more than the minimum area in a limited-service pharmacy when the Board determines that equipment, personnel, or other factors in the limited-service pharmacy cause crowding that interferes with safe pharmacy practice.

E. Before dispensing from a limited-service pharmacy, the limited-service pharmacy permittee or pharmacist-in-charge shall:
1. Prepare and implement written policies and procedures for pharmacy operations and drug distribution,
~~2. Submit a copy of the written policies and procedures to the Board office with the original permit application,~~
~~3.~~2. Conduct a ~~biennial~~ review and revision of the policies and procedures ~~and submit a copy of any revision to the Board office,~~ and review biennially after that,
3. Document the review and revision process,
4. Assemble the policies and procedures as a written manual or by another method approved by the Board or its designee, and
~~4.~~5. Make the policies and procedures available in the pharmacy for employee reference and inspection by the Board or its designee.

R4-23-674. ~~Reserved~~ 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 A.A.C. R4-23-671;
2. The professional practice standards of A.A.C. Article 4, except R4-23-403(C); and
3. The permits and drug distribution standards of A.A.C. 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 long-term care consultant pharmacist and the pharmacist-in-charge of the limited-service long-term care pharmacy comply with A.A.C. R4-23-701, R4-23-701.01, R4-23-701.01, and R4-23-701.03 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 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:
1. Authorize only those individuals listed in R4-23-610(B) to be in the limited-service long-term care pharmacy, and
2. Allow no more than four pharmacy technicians or certified pharmacy technicians per pharmacist 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 shall develop 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 system, including development, review, modification, use, and documentation;
9. Patient profiles;
10. Patient education;
11. Prescription orders;
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. ~~Establish~~ Prepare, implement, review, and revise written policies and procedures for the safe and efficient receipt, distribution, and storage of pharmaceutical products by the long-term care facility in the manner specified in R4-23-671(E)~~.~~;
2. ~~Such documents shall be~~ Make the policies and procedures available ~~for review during inspections~~ in the provider pharmacy and long-term care facility for employee reference and inspection by the Board or its designee; and
3. ~~These~~ Ensure that the written policies and procedures ~~shall, at a minimum,~~ include the following:
   ~~1.~~a. Specification for the storage, distribution, and procurement of ~~medications~~ drugs and biologicals~~.~~;
   ~~2.~~b. Resident evaluation programs ~~which~~ that relate to monitoring the therapeutic response and utilization of all ~~medications~~ drugs and biologicals prescribed or administered to residents, utilizing as guidelines the most current indicators established by the ~~Health Care Financing Administration/~~ Centers for Medicare and Medicaid Services, United States Department of Health and Human Services as ~~provided in 42 CFR Part 431, et seq. pub-~~

~~lished in the Federal Register/Vol. 56, No. 187/September 26, 1991 page 48875 §~~ required in 42 CFR 483.60, published October 1, 2001, and no future amendments or editions, incorporated ~~herein~~ by reference and on file with the Board and the Office of the Secretary of State~~.~~;

~~3.~~c. Pharmacist assistance in ~~medication~~ 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 a 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 system procedures, including development, review, modification, use, and documentation;

~~4.~~k. Security and temperature control procedures for all ~~medications~~ drugs and biologicals~~.~~;

~~5. Key control of locked medication storage areas.~~

~~6.~~l. ~~Guidelines to ensure that all~~ Disposal procedures for discontinued or outdated, ~~prescription only medicines~~ drugs or containers with worn, illegible, or missing labels ~~are destroyed or disposed of under the supervision of either the long term care consultant or provider pharmacist, witnessed by the administrator or his designee. All medication destruction shall be done in a timely manner using procedures consistent with state and local requirements or regulations and subject to review by the Board of Pharmacy.~~ in compliance with subsection (D) of this Section; and

~~7.~~m. ~~Identifying~~ Procedures for identifying and reporting to proper authorities drug irregularities and dispensing errors.

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

1. A pharmacist ~~shall evaluate~~ evaluates and verifies the prescription ~~order, or a copy thereof~~ orders of a long-term care facility resident ~~and at a minimum verify the following:~~ in compliance with R4-23-402(A)(5) and (6);

~~1. Only medical practitioners as defined in A.R.S § 32-1901, authorized by law to prescribe medications, may prescribe for the practitioner's patient in a long term care facility.~~

~~2. Only symbols and abbreviations that are customarily used in the practice of medicine and pharmacy or those placed on an approved list agreed to by the long term care consultant pharmacist and medical staff shall be acceptable on long term care facility medical orders.~~

~~3.~~2. The prescription orders ~~for use by residents of the~~ of a long-term care facility resident ~~shall, at a minimum,~~ contain:

a. ~~resident's~~ Resident's name~~.~~;

b. ~~medication~~ Facility name or address;

c. Drug name~~, and~~ strength, and dosage form;

d. ~~directions~~ Directions for use~~.~~;

e. ~~date of order,~~ Date issued; and

f. ~~name~~ Name of prescriber~~.~~;

~~4.~~3. ~~That during such time at the long term care facility~~ When ~~the~~ a provider ~~pharmacist~~ pharmacy is not ~~available~~ open for business, arrangements ~~shall be~~ 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 ~~medications to the licensed nursing staff~~ emergency drugs for the licensed nursing staff to administer to the residents of the facility using an emergency ~~medication box~~ drug supply unit located at the facility~~.~~;

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

a. Store 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 accurate records of controlled substance administration or ultimate disposition.

~~5. Medications should be dispensed for a specific duration within the parameters defined by the policy and procedure manual developed by the long term care consultant pharmacist.~~

~~C. The long term care consultant pharmacist shall establish and implement procedures designed to assure that controlled substance accountability records are in conformity with requirements found in A.R.S. § 36-2501 et seq. and A.A.C. Chapter 23, Article 10. In addition to general accountability, the procedures shall address; the name of the persons administering the controlled substance, documentation and verification of any wasted doses or partial doses and exception reporting for refused doses.~~

~~D.~~**C.** The long-term care consultant pharmacist shall ~~assure that~~ ensure availability of records and reports ~~are~~ designed to provide the data necessary to evaluate the drug utilization of each long-term care facility resident~~.~~ that include the following ~~shall be included in such records and reports~~:

1. ~~Pharmacy medication~~ Provider pharmacy patient profiles and long-term care facility medication administration records~~.~~;
2. Reports of suspected adverse ~~medication~~ drug reactions~~.~~;
3. ~~Inspections~~ Inspection reports of ~~medication~~ drug storage ~~area~~ areas with emphasis on detecting outdated ~~medications.~~ drugs; and
4. Accountability reports, including all drug destruction forms ~~for controlled substance medications~~.

~~E. The label and packaging of all prescription and nonprescription medications intended for use within the facility shall comply with definitions as set forth in A.R.S. § 32-1901 and in accordance with state and federal regulations.~~

~~F. Pharmacists, when dispensing controlled substances, shall alert nursing home personnel that laws governing such medications require that long term care facilities keep them double locked in a separate cabinet, and accurate records be kept of their administration or ultimate disposition.~~

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 administrator or the administrator's designee;
   b. Using a list including drug name, strength, dosage form, and quantity; and
   c. In a timely manner using methods consistent with state and local requirements and subject to review by the Board or its designee; and
2. Drug containers with worn, illegible, or missing labels are:
   a. Identified; and
   b. Replaced or relabeled by a pharmacist employed by the pharmacy that dispensed the original drug container.

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

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

1. ~~provide medications~~ A prescription medication is provided only ~~pursuant to~~ by a valid prescription order for an individual long-term care facility resident, properly labeled for that resident, as ~~addressed in R4-23-701(E)~~ specified in this subsection, except for nonprescription ~~medications~~ drugs in nursing care institutions. Nothing in this ~~section~~ Section shall prevent ~~the~~ a provider ~~pharmacist~~ pharmacy from supplying emergency ~~medications~~ drugs using an emergency drug supply unit as ~~addressed~~ specified in R4-23-701.02~~.~~;

~~B.~~2. ~~The provider pharmacist shall affix labels to each container of medication for residents in long term care facilities, in compliance with~~ In addition to the labeling requirements of A.R.S. §§ 32-1963.01(C) and (I), ~~A.R.S. §~~ 32-1968, and ~~A.R.S. §~~ 36-2525 and the applicable parts of R4-23-658~~(E)~~(D), a prescription medication label for a long-term care facility resident contains:

   a. The drug name, strength, dosage form, and quantity; and
   b. A beyond-use-date;~~.~~

~~C.~~3. If a prescription medication label of a long-term care facility resident becomes damaged or soiled, only a pharmacist ~~shall, at their professional discretion, relabel medications. A pharmacist is permitted to label or relabel only medication originally dispensed from the provider pharmacy.~~ employed by the pharmacy that dispensed the prescription medication, through the exercise of professional judgement, relabels or alters the prescription medication label;

~~D.~~4. ~~The provider pharmacist shall develop~~ A ~~medication~~ drug recall policy and procedure is developed and implemented that protects the health and safety of ~~the resident~~ facility residents including immediate discontinuation of any recalled ~~medication~~ drug and notification of the prescriber and director of nursing of the facility~~.~~; and

~~E.~~5. The provider ~~pharmacist~~ pharmacy or any of its employees ~~shall~~ does not pay any rebate ~~pursuant to~~ under A.R.S. § 32-1932(D) and R4-23-404 ~~and A.R.S. § 32-1932(C)~~.

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

A. ~~Medications necessary to meet the immediate therapeutic needs of residents and which are not readily available shall be supplied by the provider pharmacist.~~ The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure that an emergency drug supply unit is available within the long-term care facility.

B. ~~In consultation with physicians from the facility, the long term care consultant pharmacist shall initially prepare and quarterly revise, a list of medications, by name, strength and quantity to be included in the emergency supply. Only properly packaged and labeled medications shall be available therein and only in quantities sufficient for immediate therapeutic needs of residents.~~ An emergency drug supply unit shall only contain a drug that meets the following criteria:

1. The drug is necessary to meet the emergent and immediate 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 drug is packaged 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. ~~Emergency medications shall be~~ 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 a temperature controlled ~~areas~~ area suitable to prevent unauthorized access;
2. Contains on the exterior of the unit a label to indicate that the contents are for emergency use only;
3. Contains on the exterior of the unit a complete list of the contents of the emergency drug supply 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 unit a label that indicates the date of and person responsible for the last inspection of the emergency drug supply unit.

D. ~~The exterior of an emergency medication storage unit shall be labeled to indicate that it is for emergency use only. Such label shall also contain a listing of the name, strength, expiration date and quantity of the medications, and the name of the provider pharmacy. Additionally, the exterior of the storage unit shall indicate the name of the provider pharmacist and the date of the last inspection. All medications included in the emergency supply shall be labeled to include the name, strength, manufacturer, lot number and expiration date.~~ The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall:

1. Prepare and implement written policies and procedures for the storage and use of an emergency drug supply unit in a long-term care facility in the manner specified in R4-23-671(E),
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
3. Ensure that the written policies and procedures include the following:
   a. Drug removal procedures that include receipt of a valid prescription order,
   b. Drug replacement procedures that include:
      i. Notifying the provider pharmacy after accessing the unit, and
      ii. Replacement of used or outdated drugs within 48 hours of the notification of need, and
   c. Security and inspection procedures, and
4. Educate pharmacy and long-term care facility personnel in the storage and use of an emergency drug supply unit.

~~**E.** Medications shall be removed from the emergency supply pursuant to a valid prescriber order.~~

~~**F.** Provider pharmacist shall replace used or outdated emergency medications within 48 hours of being notified of the need.~~

R4-23-701.03 Long-term Care Facilities Pharmacy Services: Emergency ~~Medication~~ Drug Prescription Order

~~In cases where an emergency medication order is written when pharmacy services are unavailable, the medication~~ The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall ensure that every emergency drug prescription order ~~shall be~~ is evaluated for legal and therapeutic appropriateness by a pharmacist within 72 hours of the first dose of drug administered under the emergency drug prescription order.

NOTICE OF PROPOSED RULEMAKING

TITLE 17. TRANSPORTATION

CHAPTER 4. DEPARTMENT OF TRANSPORTATION TITLE, REGISTRATION, AND DRIVER LICENSES

PREAMBLE

1. Sections Affected:	**Rulemaking Action:**
R17-4-501	Amend
R17-4-506	Amend
R17-4-507	Amend

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

Authorizing statute: A.R.S. § 28-366

Implementing statutes: A.R.S. §§ 28-3051, 28-2153(A)(11), 28-3165, and 28-3166

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

Notice of Rulemaking Docket Opening: 8 A.A.R. 3583, August 16, 2002

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

Name: George R. Pavia, Department Rules Supervisor

Address: Administrative Rules Unit
Department of Transportation, Mail Drop 507M
3737 N. 7th Street, Suite 160
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Please visit the ADOT web site to track progress of this rule and any other agency rulemaking matters at www.dot.state.az.us/about/rules/index.htm.

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

This rulemaking merely consolidates existing definitions into R17-4-501 from other Sections within the Article. There is no change in any substantive regulatory provisions in any of the affected Sections.

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

The agency will not rely on any study in this rulemaking.

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

Not applicable

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

This rulemaking merely consolidates existing definitions into R17-4-501 from other Sections within the Article. There is no change in any substantive regulatory provisions in any of the affected Sections. Therefore, the economic impact is unchanged from the last time Sections R17-4-506 and R17-4-507 were amended. The only impact this rule-making action will have is increased clarity and reduced possibility for confusion on the part of concerned persons.

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

An interested party may communicate with the agency official listed in item #4 concerning the economic impact statement.

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

No oral proceeding is scheduled for this rulemaking action. A request for an oral proceeding may be made to the agency official listed in item #4. If no request for an oral proceeding is made, the public record in this rulemaking will close at 4:30 p.m. on September 20, 2002.

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

None

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

None

13. The full text of the rules follows:

TITLE 17. TRANSPORTATION

CHAPTER 4. DEPARTMENT OF TRANSPORTATION
TITLE, REGISTRATION, AND DRIVER LICENSES

ARTICLE 5. SAFETY

Section
R17-4-501. Definitions
R17-4-506. Neurological Standards
R17-4-507. Driver License Identification Number

ARTICLE 5. SAFETY

R17-4-501. Definitions

~~In this Article~~ Unless otherwise indicated, the following definitions apply to this Article:

1. "Adaptation" means a modification of or addition to the standard operating controls or equipment of a motor vehicle.
2. "Applicant" or "licensee" means a person:
   a. Applying for an Arizona driver license or driver license renewal, or
   b. Required by the Division to complete an examination successfully or to obtain an evaluation.
3. "Application" means the Division form required to be completed by or for an applicant for a driver license or driver license renewal.
4. "Arizona Driver License Manual" or "manual" means the reference booklet for applicants, issued by the Division, containing non-technical explanations of the Arizona motor vehicle laws.
5. "Aura" means a sensation experienced before the onset of a neurological disorder.

~~5.~~6. "Certified substance abuse counselor" is defined in A.R.S. § 28-3005(C)(1).

~~6.~~7. "Director" means the Division Director or the Division Director's designee.

~~7.~~8. "Disqualifying medical condition" means a visual, physical, or psychological condition, including substance abuse that impairs functional ability.

~~8.~~9. "Division" means the Arizona Department of Transportation, Motor Vehicle Division.

~~9.~~10."Driver license" is defined in A.R.S. § 28-101(19).

~~10.~~11."Evaluation" means a medical assessment of an applicant or licensee by a specialist as defined under ~~(17)~~ (21) of this Section to determine whether a disqualifying medical condition exists.

~~11.~~12."Examination" means testing or evaluating an applicant's or licensee's:
   a. Ability to read and understand official traffic control devices,
   b. Knowledge of safe driving practices and the traffic laws of this state, and
   c. Functional ability.

~~12.~~13."Functional ability" means the ability to operate safely a motor vehicle of the type permitted by an Arizona driver license class or endorsement.

14. "Identification number" means a distinguishing number assigned by the Division to a person for a license or instruction permit.

~~13.~~15."Licensee" means a person issued a driver license by this state.

~~14.~~16."Licensing action" means an action by the Division to:
   a. Issue, deny, suspend, revoke, cancel, or restrict a driver license; or
   b. Require an examination or evaluation of an applicant or licensee.

~~15.~~17."Medical screening questions and certification" means the questions and certification on the application, as shown in Exhibit A following this Section.

18. "Neurological disorder" means a malfunction or disease of the nervous system.

~~16.~~19."Physician" means a person licensed to practice medicine or osteopathy in any state, territory, or possession of the United States or the Commonwealth of Puerto Rico.

20. "Seizure" means a neurological disorder characterized by a sudden alteration in consciousness, sensation, motor control, or behavior, due to an abnormal electrical discharge in the brain.

~~17.~~21."Specialist" means:
   a. A physician who is a surgeon or a psychiatrist;
   b. A physician whose practice is limited to:
      i. A particular anatomical or physiological area or function of the human body, or
      ii. Patients within a specific age range; or

c. A psychologist.

~~18.~~22. "Substance abuse" means:

a. Use of alcohol in a manner that makes the user an alcoholic as defined in A.R.S. § 36-2021(1), or

b. Drug dependency as described in A.R.S. § 36-2501(A)(5).

~~19.~~23. "Substance abuse evaluation" means an assessment by a physician, appropriate specialist, or certified substance abuse counselor to determine whether the use of alcohol or a drug impairs functional ability.

~~20.~~24. "Successful completion of an examination" means an applicant or licensee:

a. Establishes the visual ability, physical ability, and psychological ability to operate a motor vehicle safely, or

b. Achieves a score of at least 80 percent on a written test or road test.

R17-4-506. Neurological Standards

A. ~~Definitions.~~

~~1. "Aura" means a sensation experienced before the onset of a neurological disorder.~~

~~2. "Division" means the Arizona Department of Transportation, Motor Vehicle Division.~~

~~3. "Neurological disorder" means a malfunction or disease of the nervous system.~~

~~4. "Seizure" means a neurological disorder characterized by a sudden alteration in consciousness, sensation, motor control, or behavior, due to an abnormal electrical discharge in the brain.~~

~~B.~~ Driver license application.

1. A person who has had a seizure in the three months before the person applies for a driver license shall undergo medical examination as provided in R17-4-502.
2. After the medical examination at the time the person applies, the person or the person's physician shall submit the medical examination report to the Division.
3. The Division shall not issue a driver license to a person if the medical examination report shows that the person has a neurological disorder that affects the person's ability to operate a motor vehicle safely.

~~C.~~B. Driver license revocation.

1. A person with a driver license or non-resident driving privileges who experiences a seizure shall cease driving and:
   a. Undergo a medical examination as provided in R17-4-502;
   b. Submit the medical examination report to the Division; and
   c. Undergo a follow-up medical examination within one year after the occurrence of the seizure or within a shorter time, as recommended by a physician.
2. After each medical examination, the person or the person's physician shall submit the applicable medical examination report to the Division.
3. The Division shall revoke a person's driver license or nonresident driver privileges if any medical examination report shows the person has a neurological disorder that affects the person's ability to operate a motor vehicle safely.

~~D.~~C. Medical examination report. A medical examination report under this Section shall include the following information:

1. Age at onset of seizures, diagnosis, and history;
2. Aftereffects of seizures;
3. EEG findings, if any;
4. Description, cause, frequency, duration, and date of most recent seizure;
5. Current medications, including dosage, side effects, and serum level; and
6. A physician's medical opinion as to whether or not the neurological disorder will affect the person's ability to operate a motor vehicle safely.

~~E.~~D. Physician's medical opinion. A neurological disorder does not affect a person's ability to operate a motor vehicle safely if a physician concludes with reasonable medical certainty that:

1. Any seizure that occurred within the last three months was due to a change in anticonvulsant medication ordered by a physician and that seizures are under control after the change in medication;
2. Any seizure that occurred within the last three months was a single event that will not recur in the future;
3. Any seizure is likely to occur but has an established pattern of occurring only during sleep; and
4. There is an established pattern of an aura of sufficient duration to allow the person to cease operating a motor vehicle safely and immediately at the onset of the aura.

R17-4-507. Driver License Identification Number

A. ~~Definitions.~~

~~1. "Division" means the Motor Vehicle Division, Arizona Department of Transportation.~~

~~2. "Identification number" means a distinguishing number assigned by the Division to a person for a license or instruction permit.~~

~~B.~~ The Division shall assign an identification number to each person who receives a driver license, nonoperating identification license, or instruction permit. The Division shall place a person's identification number on the person's license, nonoperating identification, or instruction permit.

~~C.~~**B.** The Division shall not use a person's Social Security Number as the person's identification number unless:

1. The person's current driver license or nonoperating identification license has a Social Security Number as the identification number, or
2. The person requests that the person's Social Security Number be used as the identification number.