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
R4-23-651	Amend
R4-23-652	Amend
R4-23-653	Amend
R4-23-654	Amend
R4-23-655	Amend
R4-23-656	Amend
R4-23-657	Amend
R4-23-658	Amend
R4-23-659	Amend
R4-23-660	Amend
R4-23-661	Repeal
R4-23-662	Repeal
R4-23-663	Repeal
R4-23-664	Repeal

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) and (5)

Implementing statutes: A.R.S. §§ 32-1929, 32-1930, 32-1931, 32-1931, and 32-1934

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

Notice of Rulemaking Docket Opening: 7 A.A.R. 2014, May 4, 2001

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:

During the five-year rule review on September 9, 1997, the Board determined that the hospital pharmacy rules in R4-23-651 through R4-23-664 should be amended, including format, style, and grammar changes necessary to comply with the current Administrative Procedure Act and to provide a clear, concise, and understandable document. At the March 7, 2001 Board meeting, Board president Jerry Ritt appointed a subcommittee, chaired by Board member Bill Jones, to review the hospital pharmacy rules. The committee included five actively-practicing hospital pharmacists, Bill Jones, Linda McCoy, Larry Anderson, Larry Borggren, Michael Noel, the Board's Executive Director Llyn Lloyd, and Board Compliance Officer Dean Wright. The hospital rules were last updated in February 1990. The subcommittee was tasked to bring Arizona's hospital pharmacy rule language and concepts into the 21st century. The subcommittee completed its task and presented the first draft proposed hospital pharmacy rules to the Board on November 15, 2001.

The proposed rules amend the definition of "certified pharmacy technician" in R4-23-110 by adding language specific to hospital pharmacy. The proposed rules amend Sections R4-23-651 through R4-23-660 and repeal Sections R4-23-661 through R4-23-664. Language deemed necessary from the repealed Sections is incorporated into the amended Sections, where appropriate. The headings of R4-23-652, R4-23-653, R4-23-656, R4-23-659, and R4-23-660 are amended to reflect the amended content. R4-23-653 is amended to mandate the use of certified pharmacy technicians in all hospitals, including a one-year grace period for non-certified pharmacy technicians to become certified. The minimum number of hours of pharmacy services provided by a hospital is changed to 40 hours per week for all hospitals, except by specific permission of the Board. Previous rule allowed hospitals with one to 25 beds to provide a minimum of five hours per week of pharmacy services and 26 to 49 beds to provide a minimum of 20 hours per week of pharmacy services with the specific permission of the Board. The hospital pharmacy policy and procedure requirements are updated, and the technician policy and procedure requirements are expanded. In R4-23-654, the term "remote drug storage area" is used instead of "night cabinet." In R4-23-655, the minimum area of a hospital pharmacy is amended from 220 square feet to 500 square feet for any hospital pharmacy permit issued or hospital pharmacy remodeled after January 31, 2003. R4-23-656 through R4-23-660 are amended to reflect current practice standards regarding sanitation, equipment, security, drug distribution and control, drug administration, and investigational drug procedures.

The Board believes that approval of these rules will benefit the public health and safety by establishing clear and current standards governing hospital pharmacy practice.

6. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the rule and where the public may obtain or review the study, all data underlying each study, any analysis of the 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, technicians, and pharmacies. Most of the changes to the rule have no economic impact, but rather provide more clear, concise, and understandable language. The proposed rules include two changes that have possible economic impact on pharmacy technicians and hospital pharmacies: the requirement that all hospital pharmacy technicians have a certification recognized by the Board and the increase of the minimum hospital pharmacy area to 500 square feet.

The public, Board, pharmacists, technicians, 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 will economically impact hospital pharmacy technicians who are not already certified. The rule provides a one-year grace period in which a non-certified pharmacy technician may become certified. The minimum cost of certification is the $120 fee to take the Board-recognized Pharmacy Technician Certification Board examination. Three books to help a pharmacy technician prepare for the examination through self-study are available for $85. The Arizona Pharmacy Association provides a class to help pharmacy technicians prepare for the examination. The cost of the class is $250 which includes a quick-study guide or $300 which includes the quick-study guide and two other study books. The maximum cost of certification would be $420. Many of the pharmacies that employ pharmacy

technicians are reimbursing the pharmacy technician for the cost of certification after the pharmacy technician passes the certification examination. The majority of Arizona hospital pharmacies already use a large number of certified pharmacy technicians and have been encouraging technician certification through various methods. Certified pharmacy technicians benefit from a national certification that is portable throughout the country and an increase in salary.

The proposed increase in the minimum hospital pharmacy area may affect small and medium size hospitals. The proposed rules allow the Board to grant a variation to the minimum area requirement for out-of-the-ordinary conditions. The proposed minimum area requirement only affects new or remodeled hospital pharmacy permits issued after January 31, 2003. An existing hospital pharmacy with less than the proposed minimum pharmacy area is only affected by the increased minimum area requirement if the pharmacy is remodeled or changes ownership. When a remodel of the hospital pharmacy is desired, the hospital may request a variation from the minimum area requirements by showing out-of-the-ordinary conditions. The cost to increase a hospital pharmacy area from 220 square feet to 500 square feet could be several thousand dollars. The Board does not believe an Arizona hospital pharmacy will be forced to increase the minimum pharmacy area solely because of this rule. The pharmacy area of the majority of Arizona hospital pharmacies already exceeds 500 square feet.

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, July 29, 2002. An oral proceeding is scheduled for:

Date:	July 29, 2002
Time:	10:00 a.m.
Location:	Board of Pharmacy 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
R4-23-651. Definitions
R4-23-652. ~~Application/Registration~~ Hospital Pharmacy Permit
R4-23-653. Personnel: Professional~~, Supportive~~ or Technician
R4-23-654. Absence of Pharmacist
R4-23-655. Physical ~~Requirements~~ Facility
R4-23-656. ~~Other Standards~~ Sanitation and Equipment
R4-23-657. Security
R4-23-658. Drug Distribution and Control
R4-23-659. ~~Non-distributive Roles of the Pharmacist~~ Administration of Drugs
R4-23-660. ~~Administration of Drugs~~ Investigational Drugs
R4-23-661. ~~Drugs from Outside Sources~~ Repealed
R4-23-662. ~~Quality Assurance~~ Repealed
R4-23-663. ~~Investigational Drugs~~ Repealed
R4-23-664. ~~Inspections~~ Repealed

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" means:

~~an~~ An individual who receives a passing grade on a certification examination for pharmacy technicians recognized by the Arizona State Board of Pharmacy and meets the requirements of a pharmacy technician as defined in A.A.C. R4-23-110; or

An individual employed in a hospital pharmacy who meets the requirements in R4-23-653(F)(1) and performs, under the supervision of a pharmacist, activities related to the preparation, dispensing, or distribution of prescription medication consistent with the policies and procedures required in R4-23-653(G).

"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 mail-order pharmacy" No change
"Limited-service nuclear pharmacy" No change
"Limited-service pharmacy permittee" No change
"Long-term care consultant pharmacist" No change
"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" No change
"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

R4-23-651. Definitions

The following definitions apply to A.A.C. R4-23-651 through R4-23-659:

"Administration" means the giving of a ~~unit~~ dose of medication to a patient as a result of an order of a medical practitioner.

"Direct copy" means an electronic, facsimile or carbonized copy.

"Dispensing for hospital inpatients" means the ~~issuing to authorized hospital personnel of one or more doses of medication in a suitable container with appropriate label for subsequent administration to, or use by, an inpatient~~ interpreting, evaluating, and implementing a medication order including the preparation for delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient (hereinafter referred to as "dispensing").

"Drug distribution" means the delivery of drugs other than "administering" or "dispensing.".~~.~~

"Emergency medical situation" means a condition of emergency in which immediate drug therapy is required for the preservation of health, life, or limb of a person or persons.

"Floor stock" means a ~~minimum~~ supply of essential drugs not labeled for a specific patient ~~which is~~ and maintained and controlled by the pharmacy at a patient care area for the purpose of timely administration to a patient of the hospital.

"Formulary" means a continually revised compilation of pharmaceuticals (~~plus important~~ including ancillary information) that reflects the current clinical judgment of the medical staff.

"Hospital pharmacy" means a pharmacy, as defined in A.R.S. § 32-1901, that holds a current permit issued by the Board pursuant to A.R.S. § 32-1931, and is located in a hospital as defined in A.R.S. § 32-1901.

"Inpatient" means ~~a~~ any patient who ~~is registered as such~~ receives non-self-administered drugs from a hospital pharmacy for use while within a facility owned by the hospital.

"Intravenous admixture" means a sterile parenteral solution to which one or more additional drug products have been added ~~in the hospital~~.

"Medication order" means a written, electronic, or verbal order from a medical practitioner or ~~his~~ a medical practitioner's authorized agent for administration of a drug or device.

"On-call" means ~~to be~~ a pharmacist is available ~~for anything about, or for dispensing of, medications~~ to:

Consult or provide drug information regarding drug therapy or related issues; or

Dispense a medication order and review a patient's medication order for pharmaceutical and therapeutic feasibility under R4-23-653(E)(2) before any drug is administered to a patient, except as specified in R4-23-653(E)(1).

"Patient care area" means any area ~~whose~~ for the primary purpose ~~is to provide~~ of providing a physical environment~~,~~ that is owned by or operated in conjunction with a hospital, for ~~patients~~ a patient to obtain health care services, except those ~~places~~ areas where ~~physicians, dentists, veterinarians, osteopaths~~ a physician, dentist, veterinarian, osteopath, or other medical ~~practitioners engage~~ practitioner engages primarily in private practice.

"Repackaged drug" means a drug product ~~which~~ that is transferred by pharmacy personnel from an original manufacturer's container to another container properly labeled for subsequent dispensing.

"Satellite pharmacy" means a work area in a hospital setting under the direction of a pharmacist that is a remote extension of ~~the~~ a centrally licensed hospital pharmacy ~~but within the same facility~~ and owned by and dependent upon the centrally licensed hospital pharmacy for administrative control, staffing, and drug procurement.

"Single unit" means a package of medication ~~which~~ that contains one discrete pharmaceutical dosage form.

"Supervision" means the process by which a pharmacist ~~observes and~~ directs the activities of ~~a~~ hospital pharmacy ~~intern, technician or clerk~~ personnel to a sufficient degree to ensure that all ~~such~~ activities are performed accurately, safely, and without risk of harm to patients.

~~"Unit dose" means a package of medication which contains the particular dose of a drug ordered for the patient. A single unit package is a unit dose package if it contains that particular dose of drug ordered for the patient.~~

R4-23-652. ~~Application/Registration~~ Hospital Pharmacy Permit

A. The following rules are applicable to all ~~Hospitals~~ hospitals as defined by A.R.S. § 32-1901 and ~~Hospital Pharmacies~~ hospital pharmacies as defined by R4-23-651 ~~hereinabove~~.

B. ~~All hospital pharmacies shall obtain a pharmacy permit for which a biennial fee set by the Board shall be required and shall be collected in accordance with the provisions of A.R.S. § 32-1931. Renewals shall not be granted for a period of less than 24 months. Fees are not refunded under any circumstances.~~ Before opening a hospital pharmacy, a person shall obtain a pharmacy permit as specified in R4-23-602 and R4-23-606.

C. Discontinued hospitals. ~~:Whenever~~ If a hospital license is discontinued by the state Department of Health Services, the pharmacy ~~permit shall be returned to the Board of Pharmacy for cancellation and all drug signs removed from the premises. The drugs shall be adequately secured until legally disposed of. In addition, records and reports shall be furnished concerning drugs and prescription orders if required by the Board~~ permittee or pharmacist-in-charge shall follow the procedures described in R4-23-613 for discontinuing a pharmacy.

R4-23-653. Personnel: Professional~~, Supportive~~ or Technician

A. Each hospital pharmacy shall be directed by a pharmacist~~, hereinafter~~ who is licensed to engage in the practice of pharmacy in Arizona and is referred to as the Director of Pharmacy~~, who is licensed to engage in the practice of pharmacy in Arizona, and who is knowledgeable in and thoroughly familiar with the specialized functions of hospital pharmacies, as a result of satisfactory completion of a hospital pharmacy residency program or as a result of no less than two years experience in a hospital pharmacy~~. ~~The Director of a hospital pharmacy shall be a full-time employee of the hospital facility in which the pharmacy is located, except that the Director may be a part-time employee and may be exempt from the education and experience requirements above upon written request by the hospital and with express permission of the Board~~.

~~1.~~ The Director of Pharmacy shall be the pharmacist-in-charge, as defined in A.R.S. § 32-1901 or shall appoint a pharmacist-in-charge.

~~2.~~ The Director of Pharmacy and the pharmacist-in-charge, if a different individual, shall be responsible for all the activities of the hospital pharmacy and for meeting the requirements of the Arizona Pharmacy Act and these rules.

~~3. Contractual providers of pharmacy services shall meet the same requirements as for the Director of Pharmacy.~~

B. ~~Hospitals with 50 or more beds.~~ In all hospitals ~~with 50 beds or more~~, a pharmacist shall be in the hospital during the time the pharmacy is open for pharmacy services, except ~~in case of emergencies~~ for an extreme emergency as defined in R4-23-110. Pharmacy services shall be provided for a minimum ~~or~~ of 40 hours per week, unless an exception for less than the minimum hours is made upon written request by the hospital and with express permission of the Board or its designee.

C. ~~Hospital with less than 50 beds. In hospitals with less than 50 beds, a pharmacist shall be in the hospital during the time the pharmacy is open for pharmacy services. Upon written request by the hospital and with the express permission of the Board, the services of a pharmacist shall be required on a part-time basis, according to the needs of the hospital. The services of a pharmacist shall be required as follows: 1-25 beds - minimum of 5 hours per week 26-49 beds - minimum of 20 hours per week~~ In a hospital where the pharmacy is not open 24 hours per day for pharmacy services, a pharmacist shall be "on-call" as defined in R4-23-651 when the pharmacy is closed.

D. ~~Other personnel.~~ The Director of Pharmacy may be assisted by other personnel approved by the Director of Pharmacy in order to operate the pharmacy competently, safely, and adequately to meet the needs of the hospital's patients ~~of the hospital~~.

~~1.~~**E.** Pharmacists. ~~Pharmacists shall assist the Director of Pharmacy in meeting the responsibilities for all the activities of the hospital pharmacy and for meeting the requirements of the Arizona Pharmacy Act and these rules. The following professional practices shall be performed only by a~~ A pharmacist or a pharmacy intern or graduate intern under the supervision of a pharmacist shall perform the following professional practices:

~~a.~~1. ~~Receipt and transaction of all verbal medication orders other than refill approval by the prescriber.~~ Verify a patient's medication order before administration of a drug to the patient, except:

a. In an emergency medical situation; or

b. In a hospital where the pharmacy is open less than 24 hours a day for pharmacy services, a pharmacist shall verify a patient's medication order within four hours of the time the pharmacy opens for pharmacy services;

~~b.~~2. ~~Verification of the legal,~~ Verify a medication order's pharmaceutical and therapeutic feasibility ~~of dispensing, including an assessment of patient~~ based upon:
   a. The patient's medical condition,
   b. The patient's allergies,
   c. The pharmaceutical and therapeutic incompatibilities, ~~unusual quantities of dangerous drugs and controlled substances and frequency of refills.~~ and
   d. The recommended dosage limits;
   ~~e. Verification that the dosage is in proper limits.~~
   ~~d. Interpretation and evaluation of the medication order.~~

~~c.~~3. ~~Compounding, admixing, combining, measuring, counting~~ Compound, admix, combine, measure, count, or otherwise ~~preparing~~ prepare and ~~packaging~~ package the ~~medication~~ drug needed for dispensing, except ~~in accordance with~~ a certified pharmacy technician may compound, admix, combine, measure, count, or otherwise prepare and package the drug needed for dispensing under the supervision of a pharmacist according to written policies and procedures approved by the Board or its designee;

4. ~~, for pharmacy technicians, whereby~~ Verify the accuracy, correct procedure, ~~and preparation~~ compounding, admixing, combining, measuring, counting, preparing, packaging, and safety of ~~pharmaceutical constituents can be verified by the pharmacist.~~ a drug prepared and packaged by a certified pharmacy technician according to subsections (E)(3) and (G);

~~f.~~5. ~~Supervising the~~ Supervise drug repackaging ~~of drugs~~ and ~~checking~~ check the completed repackaging procedure and product~~.~~;

~~g.~~6. ~~Training~~ Supervise training and ~~educating~~ education in aseptic technique and drug incompatibilities for all personnel involved in the admixture of parenteral products within the hospital pharmacy~~. When any part of these processes is not under direct pharmacist supervision, the pharmacist shall have the responsibility for providing and approving written guidelines and procedures to assure that all pharmaceutical requirements are met.~~;

~~h.~~7. ~~Consultation~~ Consult with the ~~prescriber~~ medical practitioner regarding the patient's drug therapy or medical condition~~.~~;

~~i.~~8. ~~Consultation~~ When requested by the medical practitioner, patient, patient's agent, or when the pharmacist deems it necessary, provide consultation with ~~the~~ a patient regarding the medication order, patient's profile, and~~/or~~ overall drug therapy~~, both prior to and after the medication is delivered to the patient or patient's agent.~~;
   ~~j. Interpretation of data in the patient's medication profile and/or medical record.~~

~~k.~~9. ~~Determination of the factors necessary for the pharmacist monitoring and evaluating the patient's therapeutic response.~~ Monitor a patient's drug therapy for safety and effectiveness;

~~l.~~10.~~Provision of~~ Provide drug information to patients and health care professionals~~.~~;

~~m.~~11.~~Overseeing all of~~ Manage the activities of certified pharmacy technicians~~, clerks,~~ ~~and~~ other personnel, and systems to ~~insure~~ ensure that all ~~such~~ activities are performed accurately, safely, and without risk of harm to patients~~.~~;

~~n.~~12.~~Final checking and responsibility for~~ Verify the accuracy of all aspects of the original, completed medication order ~~including but not limited to the accuracy of drug, strength, labeling and appropriate container.~~; and

~~o.~~13.~~Compliance~~ Ensure compliance by pharmacy personnel with a quality assurance program developed by the ~~pharmacist in charge~~ hospital.

2.**F.** ~~Pharmacy~~ Certified pharmacy technicians.

~~a.~~1. ~~Pharmacy technicians shall not perform duties which may be performed only by a pharmacist.~~ Before working as a certified pharmacy technician, an individual shall:
   a. Be at least 18 years of age;
   b. Have a high school diploma or equivalent;
   c. Have a current pharmacy technician certificate recognized by the Arizona State Board of Pharmacy;
   d. Complete a training program, as specified in subsection (H), at the pharmacy of employment;
   e. Read and discuss with the pharmacist-in-charge of the pharmacy where employed, the Board rules concerning certified pharmacy technicians, the certified pharmacy technician job description, and the policy and procedure manual of that pharmacy; and
   f. Date and sign a statement affirming understanding of the Board rules for certified pharmacy technicians, the job description, and the policy and procedure manual.

~~b.~~2. ~~Pharmacy technicians,~~ Acting in compliance with all applicable statutes and rules and under the supervision of a pharmacist, a certified pharmacy technician may assist a pharmacist in ~~all~~ activities not defined as professional practices as outlined in ~~Section~~ R4-23-653(~~D~~E)~~(1) above~~.

~~c.~~3. ~~Pharmacy technicians must be 18 years or older and have a high school diploma or equivalent.~~ Nothing in subsection (F)(1) shall prevent additional off-site training of a certified pharmacy technician. Any currently employed hospital pharmacy technician who does not meet the requirement in subsection (F)(1)(c) before the effective date of this rule shall complete the requirement in subsection (F)(1)(c) within one year from the effective date of this rule.

d.**G.** ~~Pharmacy technicians shall complete a training program at the pharmacy of employment. The training program shall be developed by the pharmacist-in-charge and shall be based on the needs of the individual pharmacy. The training program shall include written guidelines that define the specific tasks the technician shall be expected to perform and how the technician's competency is to be assessed. A copy of the training guidelines shall be kept in the pharmacy at all times. The pharmacist-in-charge shall certify that the technician has successfully completed the training program. Pharmacy technicians may perform only those tasks for which they have been trained and in which competency has been demonstrated.~~ Technician policies and procedures. Before employing a certified pharmacy technician, a Director of Pharmacy or pharmacist-in-charge shall:

1. Develop policies and procedures that specify:
   a. The activities a certified pharmacy technician may perform, and
   b. The quality assurance methods used to ensure the accuracy and safety of a certified pharmacy technician's activities,
2. Implement the policies and procedures,
3. Review and revise the policies and procedures biennially,
4. Document the review and revision process,
5. Assemble the policies and procedures as a written manual or by another method approved by the Board or its designee, and
6. Make the policies and procedures available within the hospital pharmacy for reference by a certified pharmacy technician and inspection by the Board or its designee.

e.**H.** ~~Pharmacy technicians may prepare parenteral products in accordance with written policies and procedures, whereby the preparation, accuracy and safety of the final product is verified by the pharmacist prior to dispensing or administration to the patient.~~ Certified pharmacy technician training program.

1. A Director of Pharmacy or pharmacist-in-charge shall:
   a. Develop a training program for certified pharmacy technicians based on the needs of the hospital pharmacy;
   b. Implement the certified pharmacy technician training program;
   c. Include written training guidelines that:
      i. Define the specific tasks the certified pharmacy technician may perform;
      ii. Specify how the certified pharmacy technician's competency will be assessed; and
      iii. Provide a copy of the training program and guidelines in the hospital pharmacy for reference by a certified pharmacy technician and inspection by the Board or its designee; and
   d. Attest that a certified pharmacy technician successfully completes the training program.
2. A certified pharmacy technician shall:
   a. Perform only those tasks for which training and competency has been demonstrated; and
   b. Not perform professional practices reserved for a pharmacist, graduate intern, or pharmacy intern as specified in subsection (E).
   ~~f. The pharmacist in charge shall implement written policies and procedures to specify the duties to be performed by pharmacy technicians in that pharmacy, and the quality assurance procedures to be used to assure the accuracy and safety of the technician's activities.~~
   ~~g. Pharmacy technicians may perform the duties of a pharmacy clerk.~~
3. ~~Pharmacy clerk~~
   ~~a. Pharmacy clerks may not perform the tasks of a pharmacist, pharmacy intern or pharmacy technician.~~
   ~~b. Pharmacy clerks, under the supervision of a pharmacist, may perform clerical duties associated with the practice of pharmacy including but not limited to typing, filing, refiling, bookkeeping, pricing, stocking, delivery, non-professional telephone inquires and documentation of third party reimbursement.~~
4. ~~Secretarial personnel. Secretarial support may be provided as required to assist with recordkeeping, report submission and other administrative duties.~~

5.**I.** Supervision. ~~All~~ A hospital pharmacy's Director of Pharmacy and the pharmacist-in-charge, if a different individual, shall supervise all of the activities and operations of ~~the~~ a hospital pharmacy ~~shall be supervised by its Director or designee~~. ~~All~~ A pharmacist shall supervise all functions and activities of certified pharmacy technicians and other hospital pharmacy personnel ~~shall be supervised by pharmacists~~ to ~~insure~~ ensure that all ~~such~~ functions and activities are performed competently, safely, and without risk of harm to patients.

R4-23-654. Absence of Pharmacist

A. ~~Procedure in the absence of a pharmacist. During times that a pharmacist is not on duty in the hospital, arrangements shall be made in advance by the Director for provision of drugs to the medical staff and other authorized personnel of the hospital by use of night cabinets and in emergency circumstances, by access to the pharmacy.~~ If a pharmacist will not be on duty in the hospital, the Director of Pharmacy or pharmacist-in-charge shall arrange, before the pharmacist's absence, for the medical staff and other authorized personnel of the hospital to have access to drugs in the remote drug storage area

defined in R4-23-110 or, if a drug is not available in a remote drug storage area and is required to treat the immediate needs of a patient, in the hospital pharmacy. A pharmacist shall be ~~"on call"~~ on-call during all absences.

B. If a pharmacist will not be on duty in the hospital pharmacy, the Director of Pharmacy or pharmacist-in-charge shall arrange, before the pharmacist's absence, for the medical staff and other authorized personnel of the hospital to have telephone access to an on-call pharmacist.

C. The hospital pharmacy permittee shall ensure that the hospital pharmacy is not without a pharmacist on duty in the hospital for more than 72 consecutive hours.

~~1.~~**D.** ~~Night cabinets. If night cabinets are used when the pharmacist is not on duty in the hospital, the locked cabinets or other enclosures shall be constructed and located outside the Pharmacy area, accessed only by specifically authorized personnel and securely locked to deny access to unauthorized persons by force or otherwise.~~ Remote drug storage area. The Director of Pharmacy or pharmacist-in-charge shall, in ~~conjunction~~ consultation with the appropriate committee of the hospital~~,~~:

1. ~~develop~~ Develop and maintain an inventory listing of ~~those~~ the drugs to be included in ~~such cabinets~~ a.remote drug storage area; and ~~shall insure~~
2. Develop and implement policies and procedures in the same manner described in R4-23-653(G) that~~:~~ ensure proper storage, access, and accountability for drugs in a remote drug storage area.
   ~~a. Such drugs are available therein, properly labeled;~~
   ~~b. Only drugs packaged in amounts sufficient for immediate therapeutic requirements are available therein;~~
   ~~c. Whenever access to such cabinet shall have been gained, written physician's orders and a record of withdrawal are provided;~~
   ~~d. All drugs therein are inventoried no less than once per week;~~
   ~~e. A complete audit of all activity concerning such cabinets is conducted no less than once per month; and~~
   ~~f. Written policies and procedures shall be established to implement the requirements of this subsection.~~

~~B.~~**E.** Access to ~~Pharmacy~~ hospital pharmacy. ~~Whenever any~~ If a drug is not available from ~~night cabinets~~ a remote drug storage area and ~~such~~ the drug is required to treat the immediate needs of a patient whose health may ~~otherwise~~ be compromised, ~~such~~ the drug may be obtained from the hospital pharmacy ~~in accordance with~~ according to the requirements of this subsection. ~~One supervisory nurse in any given shift is responsible for removing drugs therefrom. The responsible nurse may, in times of emergency, delegate this duty to another nurse. The responsible nurse shall be designated by position in writing by the appropriate committee of the hospital and shall, prior to being permitted to obtain access to the Pharmacy, receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures required. Such education and training shall be given by the Director of Pharmacy.~~

1. The Director of Pharmacy or pharmacist-in-charge shall, in consultation with the appropriate committee of the hospital, develop and implement policies and procedures in the same manner described in R4-23-653(G) to ensure that access to the hospital pharmacy during the pharmacist's absence conforms to the following requirements:
   a. Access is delegated to only one supervisory nurse in each shift;
   b. The policy and name of supervisory nurse is communicated in writing to the medical staff of the hospital;
   c. Access is delegated only to a nurse who has received training from the Director of Pharmacy, pharmacist-in-charge, or Director's designee in the procedures required for proper access, drug removal, and recordkeeping; and
   d. Access is delegated by the supervisory nurse to another nurse only in an emergency.
2. If a nurse to whom authority is delegated to access the hospital pharmacy removes a drug from the hospital pharmacy, the nurse shall:
   a. Record the following information on a form or by another method approved by the Board or its designee:
      i. Patient's name,
      ii. Name of the drug and its strength and dosage form,
      iii. Quantity of drug removed, and
      iv. Date and time of removal;
   b. Sign or initial, if a corresponding signature is on file in the hospital pharmacy, the form recording the drug removal;
   c. Attach the original or a direct copy of the medication order for the drug to the form recording the drug removal; and
   d. Place the form recording the drug removal conspicuously in the hospital pharmacy.
3. Within four hours after a pharmacist's absence, a pharmacist shall verify all records of drug removal that occurred during the pharmacist's absence in accordance with R4-23-653(E).

~~C. Record of drug removal. Removal of any drug from the night cabinet or the Pharmacy by an authorized nurse shall be recorded on a suitable form showing:~~

~~1. Patient's name;~~
~~2. Name of the drug, strength and dosage form;~~
~~3. Dose prescribed;~~
~~4. Amount removed;~~

~~5. Time and date of removal;~~
~~6. Signature of the authorized nurse removing the drug; and~~
~~7. The original or a direct copy of the medication order. The record of drug removal shall be placed conspicuously in the night cabinet or pharmacy and must be verified within four hours of the pharmacist returning to duty in the hospital or a maximum of 72 hours.~~

R4-23-655. Physical ~~Requirements~~ Facility

A. General. ~~Each~~ A hospital pharmacy permittee shall ensure that the hospital pharmacy has ~~have~~ sufficient equipment and physical facilities for proper compounding, dispensing, and storage of drugs, including parenteral preparations.

B. Minimum area of hospital pharmacy. The minimum area of a hospital pharmacy shall depend on the type of hospital, the number of beds, and the pharmaceutical services ~~to be performed~~ provided. ~~The minimum floor space for any hospital pharmacy shall not be less than that required in Table 1. Plans for new construction shall be submitted to the Board for approval.~~

~~**Table 1.**~~

~~Bed Size of Hospital~~
~~Square Feet Per Bed for Pharmacy~~

	~~1 to 50 beds~~	~~51 to 100 beds~~	~~101 to 200 beds~~	~~201 to 500 beds~~	~~Over 500 beds~~
~~Dispensing~~	~~4.4~~	~~3.2~~	~~3.25~~	~~2.1~~	~~1.77~~
~~Storage~~	~~1.4~~	~~1.7~~	~~1.3~~	~~1.44~~	~~1.2~~
~~Preparation~~	~~0.6~~	~~1.85~~	~~1.0~~	~~0.6~~	~~0.6~~
~~Administrative~~	~~0.0~~	~~0.8~~	~~0.8~~	~~1.12~~	~~0.93~~
~~TOTAL SQUARE FEET PER BED~~	~~6.4*~~	~~7.55~~	~~6.35~~	~~5.26~~	~~4.5~~

~~*~~ Any hospital pharmacy permit issued or hospital pharmacy remodeled after January 31, 2003 shall provide a ~~The~~ minimum hospital pharmacy area ~~of any hospital pharmacy~~, the actual area primarily devoted to drug dispensing and preparation functions, exclusive of bulk drug storage, satellite pharmacy, and office areas ~~shall not be~~ that is not less than ~~220~~ 500 square feet. ~~Satellite pharmacy areas may be included in this minimum area upon the approval of the Board of Pharmacy. These are~~ The minimum area ~~requirements~~ requirement, not including ~~unutilizable~~ unusable area, ~~unless variations are approved~~ may be varied upon approval by the Board for out-of-the-ordinary conditions or for systems that require less space.

C. The Board may also require that a hospital pharmacy permittee or applicant provide:

1. More than the minimum area ~~in instances~~ where equipment, inventory, personnel, or other factors cause crowding to such a degree as to interfere with safe pharmacy practice~~.~~;
2. ~~Storage and dispensing areas may be required to be enlarged~~ Additional dispensing, preparation, or storage areas because of an increased number of specific drugs prescribed per day, the increased use of intravenous and irrigating solutions, and the increased use of disposable and prepackaged products~~.~~;
3. Additional ~~service areas may be required~~ dispensing, preparation, or storage areas to handle investigational drugs, emergency drug kits, chemotherapeutics, alcohol and other flammables, poisons, external preparations, and radioisotopes, and to accommodate quality control procedures~~.~~; and
4. ~~More~~ Additional office space ~~may be required~~ to provide for an increased number of personnel, a drug information library, a poison information library, ~~for~~ research support, teaching and conferences, and a waiting area.

~~Conversely, the Board may approve a reduction in the size of the pharmacy for innovative systems that require less space.~~

~~**C.**~~**D.** ~~Description of hospital~~ Hospital pharmacy area. ~~All of the required space for a hospital pharmacy, including adequate shelving and cabinets, shall lend itself to efficient pharmaceutical practice. The~~ A hospital pharmacy permittee shall ~~be~~ ensure that the hospital pharmacy area is enclosed by a permanent barrier or partition from floor to ceiling with entry doors that can be securely locked, constructed ~~similarly~~ according to R4-23-609~~(G)~~(F)(1)~~, for community pharmacies~~.

~~**D.**~~**E.** Hospital pharmacy storage areas. ~~All drugs, shall be~~ The hospital pharmacy permittee, Director of Pharmacy, or pharmacist-in-charge shall ensure that all undispensed or undistributed drugs are stored in designated areas within the hospital pharmacy or other locked areas under the control of ~~the~~ a pharmacist ~~which~~ that ~~are sufficient to insure~~ ensure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security.

~~**E.** Storage of alcohol and flammables. Alcohol and flammables shall be stored in areas that shall, at a minimum, meet basic local fire and building code requirements for volatiles and such other laws, ordinances or regulations that may apply.~~

R4-23-656. ~~Other Standards~~ Sanitation and Equipment

~~**A.** The~~ A hospital pharmacy permittee or Director of Pharmacy shall ensure that a hospital pharmacy:

1. ~~shall have~~ Has a professional reference library consisting of ~~at least one reference/text from each of the following subject areas; pharmacology/toxicology, theoretical and practical pharmacy, therapeutics, sterilization and disinfection in intravenous admixtures practice, drug compatibility/interaction and other references~~ hard-copy or electronic media appropriate for the scope of pharmacy services provided by the institution~~.~~;

~~**B.** The hospital pharmacy shall be arranged in an orderly fashion and shall be kept clean. All equipment shall be clean and in good condition.~~

~~**C.**~~2. ~~A~~ Has a sink, other than a sink in a toilet facility, that:

a. ~~With~~ Has hot and cold running water;
b. ~~shall be available to all pharmacy personnel and shall be~~ Is within the hospital pharmacy area for use in preparing drug products; and
c. Is maintained in a sanitary condition ~~at all times.~~ and in good repair;

~~**D.** The hospital pharmacy shall be properly lighted and ventilated.~~

~~**E.**~~3. ~~The temperature of the hospital pharmacy shall be maintained~~ Maintains a room temperature within a range compatible with the proper storage of drugs~~.~~;

4. ~~The temperature of the~~ Has a refrigerator and freezer ~~shall be~~ with a temperature maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing~~.~~; and

~~**F.** The hospital pharmacy shall have locked storage for Schedule II controlled substances and other controlled drugs requiring additional security.~~

~~**G.** The hospital pharmacy shall have~~ Has a designated area for ~~the~~ a laminar air flow hood and other supplies required for the preparation of sterile products as specified in R4-23-670. ~~This area shall include facilities for handwashing, be designed to minimize personnel traffic, have non-porous and cleanable surfaces, be ventilated to not interfere with air-flow of the laminar hood, and be cleaned and disinfected routinely.~~

~~**H.** The hospital pharmacy shall have a designated area for the storage of poisons and external preparations.~~

R4-23-657. Security

A. Personnel security standards. ~~No one~~ A Director of Pharmacy shall ~~be~~ ensure that:

1. No one is permitted in the pharmacy unless ~~the~~ a pharmacist is present except as provided in this ~~section~~ Section and R4-23-654. If ~~the~~ only one pharmacist is on duty in the pharmacy and that pharmacist must leave the pharmacy for an emergency or patient care duties, ~~pharmacy technicians~~ nonpharmacist personnel may remain in the pharmacy to perform duties as outlined in R4-23-653~~(D)(2)~~, provided that all C-II controlled ~~drugs~~ substances are secured ~~in such a manner as~~ to prohibit access by other than a pharmacist, and that the pharmacist remain available in the hospital~~.~~;

~~**B.**~~2. All hospital pharmacy areas ~~shall be capable of being~~ are kept locked by key or programmable lock~~, so as~~ to prevent access by unauthorized personnel~~.~~; and ~~The Director shall designate in writing, by title and specific area, those persons who shall have access to particular pharmacy areas.~~

~~**C.** Each pharmacist on duty shall be responsible for the security of the hospital pharmacy, including provisions for adequate safeguards against theft or diversion of drugs including controlled substances and the records thereof.~~

~~**D.**~~3. ~~Personnel identification.~~ Pharmacists, pharmacy or graduate interns, certified pharmacy technicians, and other personnel working in the pharmacy ~~shall~~ wear identification badges, including name and position, whenever on duty.

~~**E.**~~**B.** Prescription blank security. The Director of Pharmacy shall ~~be responsible for~~ develop and implement policies and procedures in the same manner described in R4-23-653(G) for the safe distribution and control of prescription blanks bearing identification of the hospital.

R4-23-658. Drug Distribution and Control

A. General. The Director of Pharmacy or pharmacist-in-charge shall:

1. ~~Establish~~ In consultation with the medical staff, develop and implement written policies and procedures for the effective operation of a drug distribution system ~~which~~ that optimize patient safety~~.~~;
2. ~~These~~ Make the policies and procedures ~~shall be~~ available in the pharmacy for reference by pharmacy employees and inspection by the Board or its designee~~.~~;
3. ~~These~~ Review and revise the policies and procedures ~~will be developed with the advice of the medical staff and shall be reviewed and revised at least~~ biennially~~.~~;
4. Document the review and revision process; and
5. ~~The written policies and procedures shall include, but not be limited to, the following:~~ Assemble the policies and procedures as a written manual or by another method approved by the Board or its designee.

~~1. Physicians orders~~
~~2. Authorized abbreviations~~
~~3. Formulary system~~
~~4. Procurement and distribution of inpatient medications~~

~~5. Controlled substances~~
~~6. Stop orders~~
~~7. Pass/Discharge medications~~
~~8. Adverse drug reaction reports~~
~~9. Drug recall~~
~~10. Outdated drugs~~
~~11. Medication error and dispensing error monitoring These policies and procedures shall be available in the pharmacy for inspection.~~

B. Responsibility. The Director of Pharmacy ~~shall be~~ is responsible for the safe and efficient procurement, dispensing, distribution, administration, and control of drugs~~. Other professional, technical and clerical staff may assist the Director in meeting this responsibility. The Director shall be responsible for, at a minimum~~, including the following:

~~1. Establishment of specifications for procurement of all materials, including drugs, chemicals and biologicals;~~
~~2.~~1. ~~Participation in the development of~~ In consultation with the appropriate department personnel and medical staff committee, develop a medication formulary for the hospital;
~~3. Compounding and repackaging of drugs;~~
~~4. Preparation and sterilization of parenteral medications within the hospital;~~
~~5. Admixture of parenteral products;~~
~~6. Filling and labeling all containers from which drugs are to be distributed, dispensed or administered;~~
~~7.~~2. Proper handling, distribution, and recordkeeping of investigational drugs; and
~~8. Dispensing and distribution of drugs to be administered to inpatients and outpatients;~~
~~9. Ensuring the availability of an effective and efficient means for transportation of medications and orders within the hospital;~~
~~10. Records of all transactions of the hospital pharmacy as may be necessary to maintain accurate control over and accountability for all pharmaceutical services;~~
~~11.~~3. ~~Inspection~~ Regular inspections of drug storage and preparation areas within the hospital~~;~~
~~12. Maintaining and making available a sufficient inventory of floor stock drugs, antidotes and other emergency drugs both in the pharmacy and in patient care areas;~~
~~13. Participation in those aspects of the hospital quality assurance program relevant to pharmaceutical services; and~~
~~14. Participation of pharmacy personnel in relevant training and education programs including orientation of new employees~~.

C. ~~Physicians~~ Physician orders. ~~Drugs shall be~~ A Director of Pharmacy or pharmacist-in-charge shall ensure that:

1. Drugs are dispensed from the hospital pharmacy only upon a written ~~orders~~ order, direct ~~copies~~ copy or ~~facsimiles thereof~~ facsimile of a written order, or verbal ~~orders~~ order of an authorized medical practitioner~~.~~; and
2. ~~The~~ A pharmacist ~~shall review~~ reviews the original, ~~order or~~ direct or facsimile copy, or verbal order before ~~the~~ an initial dose of medication is ~~dispensed~~ administered, except ~~in an emergency~~ as specified in R4-23-653(E)(1).

~~1. Authorization. The medical staff shall designate those medical practitioners who are authorized to prescribe medications for hospital patients.~~
~~2. Abbreviations. Orders employing abbreviations and chemical symbols shall be processed only if such abbreviations and symbols appear on a published approved list of accepted abbreviations for the hospital~~
~~3. Requirements - Orders for drugs for use by inpatients. Orders for drugs for use by inpatients at a minimum shall contain: patient name and location, drug name, dose, frequency, directions for use, date and medical practitioner's signature (or that of his authorized representative).~~
~~4. Requirements - Orders for drugs for self-administration by outpatients. Orders for drugs to be self-administrated by outpatients become prescriptions and shall meet all applicable requirements of the Arizona Pharmacy Act and these rules.~~

~~**D.** Formulary. Under the direction of the proper hospital committee, the pharmacist in charge shall be available for inspection by the Board or its designee a medication formulary that addresses such subjects as:~~
~~1. Information of hospital policies and procedures concerning drugs;~~
~~a. Categories of drugs,~~
~~b. Description of the hospital pharmacy and therapeutics committee,~~
~~c. Hospital regulations governing the prescribing, dispensing and administration of drugs,~~
~~d. Pharmacy operating procedures,~~
~~e. Information on using the formulary;~~
~~2. Drug products listing;~~
~~3. Formulary item entries;~~
~~4. Indexes to the drug products listing;~~
~~5. Special information;~~

~~**E.**~~**D.** Labeling. ~~All~~ A Director of Pharmacy or pharmacist-in-charge shall ensure that all drugs distributed or dispensed by a hospital pharmacy ~~shall be~~ are packaged in appropriate containers and labeled as follows:

1. For use inside the hospital;
   a. Labels for all single unit packages ~~shall~~ contain at a minimum, the following information:
      i. Drug name, strength, and dosage form;
      ii. Lot number and beyond-use-date ~~where applicable~~; and
      iii. Appropriate auxiliary labels~~.~~;
   b. Labels for repackaged ~~or compounded~~ preparations ~~shall~~ contain at a minimum the following information:
      ~~i. Identification of the hospital pharmacy;~~
      ~~ii~~i. Drug name, ~~identification, or list of active ingredients~~ strength, and dosage form;
      ~~iii. Strength of drug or amount of active ingredients;~~
      ~~iv.~~ii. Lot number and beyond-use-date ~~where applicable~~;
      ~~v.~~iii. Appropriate auxiliary labels; and
      ~~vi.~~iv. Mechanism to identify pharmacist accountability for ~~preparation or packaging.~~ repackaging;
   c. Labels for all intravenous admixture preparations ~~shall~~ contain at a minimum the following information:
      i. Patient's name and location;
      ii. Name and quantity of the basic parenteral ~~solutions~~ solution;
      iii. Name and amount of ~~drugs~~ drug added;
      iv. Date ~~and, if appropriate, time~~ of preparation;
      v. Beyond-use-date and time;
      vi. ~~Date, time and guidelines~~ Guidelines for administration;
      vii. ~~Ancillary labels~~ Appropriate auxiliary label or precautionary ~~statements as appropriate~~ statement; and
      viii. Initials of pharmacist responsible for admixture preparation~~.~~; and
2. For use outside the hospital~~.~~; ~~All drugs~~ Any drug dispensed to a patient by a hospital pharmacy ~~which are~~ that is intended for self-administration outside of the hospital ~~shall be~~ is labeled ~~with, at a minimum, the following information:~~ as specified in A.R.S. §§ 32-1963.01(C) and 32-1968(D) and A.A.C. R4-23-402.
   ~~a. Name, address and telephone number of hospital pharmacy;~~
   ~~b. Date and identifying serial number;~~
   ~~c. Full name of the patient;~~
   ~~d. Name of drug, strength and number of units;~~
   ~~e. Directions for use to the patient;~~
   ~~f. Name of prescribing physician;~~
   ~~g. Initials of pharmacist dispensing;~~
   ~~h. Required precautionary information regarding controlled substances;~~
   ~~i. Name of manufacturer or distributor of the dispensed generic equivalent drug or abbreviations of such information approved by the Board; and~~
   ~~j. Such other and further accessory cautionary information as may be required or desirable for proper use and safety to the patient.~~

~~**F.** Records. The Director shall maintain appropriate records which document the selection, repackaging, manufacturing, distribution, dispensing and quality assurance processes for drug products and physician medication orders. Such documentation shall be maintained as required by law or for a minimum of one year. All records and labeling shall be devised in such a manner that professional responsibility can be traced to a pharmacist.~~

~~**G.**~~**E.** Controlled substance accountability. ~~The hospital shall establish~~ A Director of Pharmacy or pharmacist-in-charge shall ensure that effective policies and procedures ~~and maintain adequate records~~ are developed and implemented in the same manner described in R4-23-653(G) regarding the use, ~~and~~ accountability, and recordkeeping of controlled substances~~. If controlled drugs are stored in patient care areas, there shall be~~ in the hospital, including the use of locked storage areas when controlled substances are stored in patient care areas.

~~**H.** Discontinued drugs. Discontinued or outdated drugs and containers or packages of drugs with worn, illegible or missing labels shall be returned to the pharmacy for proper and safe destruction in accordance with written policies and procedures.~~

~~**I.**~~**F.** Emergency ~~care center~~ services dispensing. If ~~the~~ a hospital permits dispensing of drugs from the ~~Emergency Care Center~~ emergency services department when the pharmacy is unable to provide these services, the Director of Pharmacy, in ~~conjunction~~ consultation with the appropriate department personnel and medical staff committee shall develop and ~~supervise~~ implement written policies and procedures ~~which shall be used~~ in the same manner described in R4-23-653(G) for dispensing drugs for outpatient use from ~~a hospital for outpatient use~~ the hospital's emergency services department. ~~Such~~ The policies and procedures shall include ~~but not be limited to~~ the following requirements:

1. ~~Drugs may~~ Drugs are only ~~be~~ dispensed to patients who have been admitted to the emergency ~~care center~~ services department;

2. ~~Drugs may~~ Drugs are only ~~be~~ dispensed by an authorized medical ~~practitioners~~ practitioner, not ~~their~~ a designee or agent;
3. The nature and type of drugs available for dispensing ~~shall be~~ are designed to meet the immediate needs of the patients treated within the hospital;
4. ~~Drugs shall~~ Drugs are only ~~be~~ dispensed in quantities sufficient to meet patient needs until such time as outpatient pharmacy services are available;
5. ~~Such drugs shall be~~ Drugs are prepackaged by a pharmacist in suitable containers and appropriately prelabeled with the drug name, strength, dosage form, quantity, manufacturer, lot number, beyond-use-date, and any ~~necessary~~ appropriate auxiliary labels~~.~~;
6. Upon dispensing, the authorized medical practitioner ~~shall complete~~ completes the label on the prescription container ~~which shall comply~~ that complies with the requirements of R4-23-658~~(E)~~(D)~~.~~; and
7. The hospital pharmacy maintains a dispensing log, hard-copy prescription, or electronic record, approved by the Board or its designee and includes the patient name and address, drug name, strength, dosage form, quantity, directions for use, medical practitioner's signature or identification code, and DEA registration number, if applicable.

R4-23-659. ~~Non-distributive Roles of the Pharmacist~~ Administration of Drugs

~~The non-distributive roles of the pharmacist may include, but are not limited to, chart review, audits, drug therapy monitoring, committee participation, drug information, in-service training of pharmacy and other health professionals, poison control and patient care area inspections.~~

A. Self-administration. If a hospital allows self-administration of medications by a patient, the Director of Pharmacy or pharmacist-in-charge shall, in consultation with the appropriate department personnel and medical staff committee, develop and implement policies and procedures in the same manner described in R4-23-653(G) specifying that self-administration of medications shall occur only when:
1. Specifically ordered by a medical practitioner; and
2. A patient is educated and trained in the proper manner of self-administration.

B. Drugs brought in by a patient. If a hospital allows a patient to bring a drug into the hospital, the Director of Pharmacy or pharmacist-in-charge shall, in consultation with the appropriate department personnel and medical staff committee, develop and implement policies and procedures in the same manner described in R4-23-653(G) for the disposition of the drug that include:
1. A patient-owned drug brought into the hospital is not administered to the patient unless:
   a. A pharmacist or medical practitioner identifies the drug; and
   b. A medical practitioner writes a medication order specifying administration of the identified patient-owned drug; and
2. If a patient-owned drug will not to be used during the patient's hospitalization, the hospital pharmacy's personnel shall:
   a. Package, seal, and give the drug to the patient's agent for removal from the hospital; or
   b. Package, seal, and store the drug for return to the patient at the time of discharge from the hospital.

C. Drug samples. The Director of Pharmacy or pharmacist-in-charge is responsible for the receipt, storage, distribution, and accountability of drug samples within the hospital, including developing and implementing specific policies and procedures in the same manner described in R4-23-653(G) regarding drug samples.

R4-23-660. ~~Administration of Drugs~~ Investigational Drugs

~~**A.** General. Drugs shall be administered at a hospital only upon the order of authorized medical practitioners. Drugs shall be administered only by authorized hospital personnel in accordance with policies and procedures developed in accordance with R4-23-660(B).~~

~~**B.** Policies. The Director of Pharmacy shall develop in conjunction with the medical staff and other disciplines in the hospital written policies and procedures that govern the safe administration of drugs.~~

~~**C.** Record of Administration. Each dose of medication administered shall be recorded in the patient's medication record and shall show the date, time, dosage and method of administration and a method of identifying the person who administered drug. When initials are used, the name identification shall be noted on each medication record.~~

~~**D.** Self-administration. If permitted in the hospital, self-administration of medications by patients shall be allowed only when specifically ordered by the physician and provided that patients are educated and trained in the proper manner of self-administration. If self-administration is allowed, policies and procedures shall be developed.~~ The Director of Pharmacy or pharmacist-in-charge shall ensure that an investigational drug is not dispensed before the drug is approved by the appropriate medical staff committee of the hospital.

R4-23-661. ~~Drugs from Outside Sources~~ Repealed

~~**A.** Drugs brought in by patients. If patients are permitted to bring their own drugs into the hospital, these drugs shall not be administered unless they can be identified by the pharmacist or medical practitioner and until the medical practitioner's order is written to administer these specific drugs. If the drug brought in by the patient is not to be used during the~~

~~patient's hospitalization, it shall be packaged and sealed and given to the patient's agent or stored and returned to the patient at the time of discharge.~~

~~**B.** Drug samples. Receipt, distribution and accountability of drug samples shall be under the direct control of the pharmacy department.~~

R4-23-662. ~~Quality Assurance~~ Repealed

~~**A.** General. The Director of Pharmacy shall be responsible for developing procedures for an ongoing Quality Assurance Program of pharmaceutical services that includes a mechanism for reviewing and evaluating dispensing, distribution, control and use of drugs in relation to patient care.~~

~~**B.** Sterile product preparation. The Director of Pharmacy shall be responsible for developing procedures for quality assurance in all areas where sterile product preparation takes place. Such procedures shall include the selection, education, training and evaluation of personnel, duties of personnel involved, handwashing technique, safe handling of antineoplastics, housekeeping of the intravenous admixture area, in-process controls and end-product verification. An annually certified laminar air flow hood is required for the preparation of sterile products by pharmacy personnel. Documentation of hood maintenance, including HEPA filter inspection, prefilter maintenance, disinfecting, and cleaning shall be kept in the pharmacy for a one-year period.~~

R4-23-663. ~~Investigational Drugs~~ Repealed

~~**A.** The pharmacist in charge shall obtain and make available to hospital personnel the following information concerning investigational drugs in use at the hospital:~~

~~1. Composition,~~
~~2. Pharmacology,~~
~~3. Adverse reactions,~~
~~4. Administration guidelines,~~
~~5. All other available information concerning the drug.~~

~~**B.** Investigational drugs shall be stored in the pharmacy and shall be properly labeled.~~

~~**C.** The pharmacist in charge shall not permit the dispensing of investigational drugs unless such drugs have been approved by the appropriate medical staff committee of the hospital.~~

R4-23-664. ~~Inspections~~ Repealed

~~Patient care area inspections. The pharmacist in charge or designee shall perform periodic inspections of all drug storage areas. These areas shall be well lighted and shall be located in a place where the nursing personnel are not interrupted when preparing drugs for administration to the patient. Records shall be maintained that verify compliance with current requirements as defined by the Board.~~

NOTICE OF PROPOSED RULEMAKING

TITLE 7. EDUCATION

CHAPTER 3. COMMISSION FOR POSTSECONDARY EDUCATION

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R7-3-501	Amend
R7-3-506	Amend
R7-3-507	Amend
R7-3-508	New Section

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

Authorizing statute: A.R.S. § 15-1852(A)

Implementing statutes: A.R.S. §§ 15-1871 through 15-1873

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

None

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

Name: Verna L. Allen, Executive Director

Address: 2020 N. Central Avenue, Suite 550
Phoenix, AZ 85004

Telephone: (602) 258-2435

Fax: (602) 258-2483

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

The Commission for Postseconday Education's purpose in promulgating the proposed rules and amendments is to bring the Arizona Family College Savings Program (Program) rules into conformity with federal H.R. 1836, Economic Growth and Tax Relief Reconciliation act of 2001, which was signed by President Bush on June 7, 2001, with § 529 of the Internal Revenue Code (Code) and IRS Notices promulgated pursuant to § 529 of the Code, and with amendments made by Arizona House Bill 2098 to A.R.S. § 15-1871 et seq.

6. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

No study is available or was relied upon.

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:

a. An identification of the proposed rulemaking: Arizona Family College Savings Plan, R7-3-501, R7-3-506, R7-3-507, and R7-3-508 adopted pursuant to A.R.S. §§ 15-1871 through 15-1877

b. An identification of the persons who will be directly affected by, bear the costs of, or directly benefit from the proposed rulemaking: Persons directly affected are account owners.

c. An analysis of the probable costs and benefits from the implementation and enforcement of the proposed rulemaking on the Commission, and on any political subdivision or business directly affected by the proposed rulemaking: The Commission will bear any administrative costs as a consequence of the proposed rulemaking.

d. The probable impact of the proposed rulemaking on employment in business, agencies, and political subdivisions of this state affected by the proposed rulemaking: None

e. A statement of the probable impact of the proposed rulemaking on small business: None

f. A statement of the probable effect on state revenues: No effect is anticipated as this Program is self-supported.

g. A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed rulemaking: Due to the nature of the various statutory requirements, less intrusive or less costly alternatives are not available.

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: Verna L. Allen, Executive Director

Address: 2020 N. Central Avenue, Suite 550
Phoenix, AZ 85004

Telephone: (602) 258-2435

Fax: (602) 258-2483

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:

Date:	August 7, 2002
Time:	9:30 a.m.
Location:	Commission for Postsecondary Education, 2020 N. Central Avenue, Suite 550 Phoenix, AZ 85004
Nature:	Oral Proceeding, Close of Record and Adoption of Rules

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. Incorporation by reference and their location in the rules:

Not applicable

13. The full text of the rules follows:

TITLE 7. EDUCATION

CHAPTER 3. COMMISSION FOR POSTSECONDARY EDUCATION

ARTICLE 5. ARIZONA FAMILY COLLEGE SAVINGS PROGRAM

Section

ARTICLE 5. ARIZONA FAMILY COLLEGE SAVINGS PROGRAM

R7-3-501. Definitions

A. No change

B. No change

C. "Cash" means currency, bills and coin in circulation, or converting a negotiable instrument to cash by endorsing and presenting to a financial institution for deposit. An automatic transfer, cashier's check, certified check, money order, payroll deposit, traveler's check, personal check, and wire transfer will be treated as cash. Deposits will also be accepted by credit card.

D. No change

E. No change

F. No change

~~**G.** "Direct the investment" means specifying or attempting to specify the particular financial instruments (such as certificates of deposit) or ownership interests (such as stock certificates or interests in mutual funds) either individually, or within a fund family or other group of financial instruments or ownership interests held as an investment group, into which the account holder's contributions or earnings will be invested. Direct the investment does not mean selecting an initial type of investment program if more than 1 program is offered.~~

~~H.~~G. "Higher education institution" means a higher education institution as defined in A.R.S. § 15-1871(7), provided that, solely for the purposes of determining whether a withdrawal or distribution is subject to a penalty under R7-3-506, the term shall not include any institution that is not also an "eligible educational institution" as defined in Code § 529(e)(5).

~~I.~~H. "Negotiable instrument" means negotiable instrument as defined in A.R.S. § 47-3104.

~~J.~~I. "Qualified Tuition Program" means a qualified tuition program as defined in § 529 of the Code.

R7-3-506. Withdrawals; Reporting of Non-qualified Withdrawals; Penalties

A. No Change

B. Withdrawals

1. Qualified Withdrawals.
   In order to make a qualified withdrawal, the account holder or the account holder's designee must complete a certification, on a form approved by the Commission, declaring that the funds will be used for the purposes set forth in A.R.S. § 15-1871(11). The form shall include a statement advising the designated beneficiary and account owner of

their obligations to report, in accordance with R7-3-506(B)(3)(c), refunds received from a higher education institution. In addition to the certification, a withdrawal shall be deemed qualified only if:

a. The financial institution is provided with a copy of an invoice from the higher education institution, and the distribution is made directly to the higher education institution; or
b. The financial institution is provided with a copy of an invoice from the higher education institution, and the distribution is made in the form of a check payable to both the designated beneficiary and the higher education institution; or
c. Within 30 days following the withdrawal, substantiation that the withdrawal was actually expended for qualified higher education expenses is submitted to the financial institution.

2. Withdrawal Based on Death, Disability, or Scholarship
A penalty-free withdrawal may be made as a result of the designated beneficiary's death, disability, or scholarship, if written substantiation thereof is provided. Such written substantiation must come from a party other than the designated beneficiary or the account owner. In the case of a scholarship, the withdrawal may not exceed the amount of the scholarship.
3. Non-Qualified or Unsubstantiated Withdrawals
Pursuant to A.R.S. §§ 15-1875(H), (I), and (J), the Commission has authority to assess penalties for non-qualified withdrawals. If an account holder fails to certify that a withdrawal is qualified or penalty-free, as defined in R7-3-506(B)(1) and (2), above, or if a financial institution has reason to believe that a withdrawal is non-qualified, the financial institution shall withhold from such withdrawal an amount equal to 10% of that portion of that withdrawal which constitutes income under § 72 of the Code. If an account holder seeks to make a withdrawal in accordance with R7-3-506(B)(1)(c) and does not provide the required substantiation at the time of the withdrawal, the withdrawal shall be limited so that the balance remaining in the account is sufficient to pay the 10% of earnings penalty. If the financial institution is not provided with the required substantiation within 30 days, the withdrawal shall be treated as a non-qualified withdrawal, the penalty shall be assessed at that time, and the financial institution shall withdraw the penalty from the account.
   a. If the withdrawal has not been declared, by the party making the withdrawal, to be non-qualified, the amount of any penalty shall be remitted to the Commission with the financial institution's 1st monthly report following the date that the withdrawal is determined to be non-qualified. If the withdrawal has been declared to be non-qualified, the amount of said withholding may be remitted to the Commission with the financial institution's required monthly report.
   b. If the withdrawal has not been declared, by the party making the withdrawal, to be non-qualified, the financial institution shall report any such withholding, in writing, to the Commission with the financial institutions's 1st monthly report following the date that the withdrawal is determined to be non-qualified. The report shall include identification of the account holder, beneficiary, date of withdrawal, amount of withdrawal, and a brief description as to why the financial institution believes the withdrawal to be non-qualified. If the withdrawal has been declared to be non-qualified, the report may be submitted to the Commission with the financial institution's required monthly report. The financial institution shall notify the account holder and beneficiary, in writing, of any withholding.
   c. If a qualified withdrawal is made from an account in any calendar year, within 60 days after the end of such year and within 60 days after the end of the following year, any designated beneficiary or account owner who received a partial or total refund from the higher education institution attended by the designated beneficiary or the higher education institution that the designated beneficiary had expected to attend shall provide to the financial institution a signed statement identifying the amount of any refunds received. In addition, the designated beneficiary or account owner shall provide an explanation as to what portion, if any, of the refund is allocable to a qualified withdrawal. If all or a portion of a refund is allocable to a qualified withdrawal, the designated beneficiary (or the account owner) may provide the financial institution with substantiation of qualified higher education expenses for which the refund was used or substantiation that the refund was made by reason of scholarship, or the death, or disability of the designated beneficiary. To the extent that a refund allocable to a qualified withdrawal was not used to pay qualified higher education expenses or made on account of death, disability, or scholarship of the designated beneficiary, it shall be considered a non-qualified withdrawal subject to the penalty described in R7-3-506(B)(3). The financial institution shall withdraw the penalty from the account from which the original qualified withdrawal was made, if sufficient funds are available in the account, or attempt to collect the penalty by billing the designated beneficiary or account owner for the penalty, if sufficient funds are not available in the account.
4. Substantiation Procedures
Before treating any withdrawal as qualified or penalty-free based on substantiation provided, the financial institution shall review the substantiation to confirm that substantiation is provided for the amount of a withdrawal that the account owner or designated beneficiary asserts is qualified or penalty-free, that the substantiation complies with the program rules, and, in the case of a withdrawal to pay qualified higher education expenses, that the substantiated

expenditures are of a nature and in amounts that can be treated as qualified higher education expenses. The financial institution may seek additional information from the account owner, the designated beneficiary, or the higher education institution before approving or rejecting substantiation, and the financial institution may seek guidance from staff of the Commission. If the financial institution determines that substantiation is inadequate, it shall promptly notify the account owner and defer making any distribution with respect to any inadequately substantiated request until proper substantiation is provided or the account owner instructs the financial institution to make the requested distribution and either withhold the penalty from the distribution or from other funds in the account.

5. Distributions Made after December 31, 2001
R7-3-506(B)(1) through (4) shall not apply to any withdrawals made after December 31, 2001, except to the extent that any provision contained therein is required for the Family College Savings Program to qualify as a qualified tuition program under § 529 of the Code. A financial institution shall not be required to collect a penalty on any withdrawal made after December 31, 2001. Withdrawals may be made pursuant to forms prepared or used by the financial institution and meeting the requirements of R7-3-501 through R7-3-507, if any, and any requirements for the Family College Savings Program to qualify as a qualified tuition program under § 529 of the Code. To the extent that A.R.S. § 15-1875 requires provisions that will generally enable the Commission to determine whether withdrawals are qualified or nonqualified withdrawals, a financial institution shall require an account owner to state whether the account owner expects that the withdrawal will be a qualified or nonqualified withdrawal.

C. The account holder may dispute any withholding made by a financial institution under subsection (B) by submitting written notice, to the Commission, within 30 days from the date of such withholding. The Commission shall make a written determination regarding the dispute within 30 days of the receipt of its notice from the account holder. If the account holder disagrees with the Commission's determination, the matter shall be adjudicated in accordance with A.R.S. § 41-1092 et seq.

R7-3-507. Oversight of Financial Institutions

A. No change
B. No Investment Direction. A financial institution shall not permit an account holder to move funds, once deposited, that in any way would result in investment direction under § 529(b)(5) of the Code ~~or A.A.C. R7-3-501(F)~~.
C. No change
D. No change
E. No change
F. No change

R7-3-508. IRS Regulations, Rulings, Notices and Other Guidance

A. If (i) the Internal Revenue Service issues on or after February 27, 2002, any regulation, ruling, notice or other precedential guidance on procedures or activities that a qualified tuition program may adopt or undertake without jeopardizing its exemption under § 529 of the Code, (ii) such guidance is less restrictive than any rule contained in Title 7, Chapter 3, Article 5, and (iii) the more restrictive rule was not mandated by A.R.S. §§ 15-1871 through 15-1877, then the more restrictive rule shall be deemed liberalized to the maximum extent possible without violating A.R.S. §§ 15-1871 through 15-1877 or any requirements for a program to qualify as a qualified tuition program under § 529 of the Code.
B. If (i) the Internal Revenue Service issues on or after February 27, 2002, any regulation, ruling, notice or other precedential guidance on procedures or activities that a qualified tuition program shall or shall not adopt or undertake to avoid jeopardizing its exemption under § 529 of the Code and (ii) the rules contained in Title 7, Chapter 3, Article 5 or the statutes contained in A.R.S. §§ 15-1871 through 15-1877 do not include such requirement or prohibition, then these rules shall be deemed amended to the maximum extent possible without violating A.R.S. §§ 15-1871 through 15-1877 to adopt such requirement or prohibition.