ARKANSAS REGISTER

Transmittal Sheet

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Secretary of State
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Little Rock, Arkansas 72201-1094
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For Office Use Only:

Effective Date _____ Code Number _____

Name of Agency ADH Division of Health Related Boards and Commissions

Department Board of Pharmacy

Contact John Clay Kirtley E-mail john.kirtley@arkansas.gov Phone 501-682-0190

Statutory Authority for Promulgating Rules 17-92-205(a)

Rule Title: 17 CAR Part 160. Arkansas State Board of Pharmacy Rules

Intended Effective Date

(Check One)

- ☐ Emergency (ACA 25-15-204)
- ☐ 10 Days After Filing (ACA 25-15-204)
- ☐ Other 10/10/25 (Must be at leaet 10 days after filing date.)

	Date
Legal Notice Published	7/13/2025
Final Date for Public Comment	8/13/2025
Reviewed by Legislative Council	9/26/2025
Adopted by State Agency	8/13/2025

Electronic Copy of Rule e-mailed from: (Required under ACA 25-15-218)

John Clay Kirtley — Contact Person
john.kirtley@arkansas.gov — E-mail Address
Date

CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted
In Compliance with the Arkansas Administrative Act. (istrative Act. (ACA 25-15-201 et. seq.)

John Clay Kirtley Digitally signed by John Clay Kirtley Date: 2025.09.29 09:32:31 -05'00'
Signature

501-682-0190 — Phone Number
john.kirtley@arkansas.gov — E-mail Address

Director, Arkansas State Board of Pharmacy
Title

9/29/2025
Date

Revised 7/2015 to reflect new legislation passed in the 2015 Regular Session (Act 1258). This act changed the effective date from 30 days to 10 days after filing the rule.

Form Revised 1/2025

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY.

DEPARTMENT ADH Division of Health Related Boards and Commissions
BOARD/COMMISSION State Board of Pharmacy
PERSON COMPLETING THIS STATEMENT John Clay Kirtley
TELEPHONE NO. (501) 682-0190 **EMAIL** john.kirtley@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the Financial Impact Statement and email it with the questionnaire, summary, markup and clean copy of the rule, and other documents. Please attach additional pages, if necessary.

TITLE OF THIS RULE 17 CAR Part 160. Arkansas State Board of Pharmacy Rules

1. Does this proposed, amended, or repealed rule have a financial impact?
   Yes ☐ No ☑

2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule?
   Yes ☑ No ☐

3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes ☑ No ☐

   If no, please explain:

   (a) how the additional benefits of the more costly rule justify its additional cost;

   (b) the reason for adoption of the more costly rule;

   (c) whether the reason for adoption of the more costly rule is based on the interests of public health, safety, or welfare, and if so, how; and

   (d) whether the reason for adoption of the more costly rule is within the scope of the agency's statutory authority, and if so, how.

4. If the purpose of this rule is to implement a *federal* rule or regulation, please state the following:

   (a) What is the cost to implement the federal rule or regulation?

Current Fiscal Year		**Next Fiscal Year**	
General Revenue	$0.00	General Revenue	$0.00
Federal Funds	$0.00	Federal Funds	$0.00
Cash Funds	$0.00	Cash Funds	$0.00
Special Revenue	$0.00	Special Revenue	$0.00
Other (Identify)		Other (Identify)	
Total	$0.00	Total	$0.00

(b) What is the additional cost of the state rule?

Current Fiscal Year		**Next Fiscal Year**	
General Revenue	$0.00	General Revenue	$0.00
Federal Funds	$0.00	Federal Funds	$0.00
Cash Funds	$0.00	Cash Funds	$0.00
Special Revenue	$0.00	Special Revenue	$0.00
Other (Identify)		Other (Identify)	
Total	$0.00	Total	$0.00

5. What is the total estimated cost by fiscal year to any private individual, private entity, or private business subject to the proposed, amended, or repealed rule? Please identify those subject to the rule, and explain how they are affected.

Current Fiscal Year	**Next Fiscal Year**
$ 0.00	$ 0.00

6. What is the total estimated cost by fiscal year to a state, county, or municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

Current Fiscal Year	**Next Fiscal Year**
$ 0.00	$ 0.00

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars ($100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

Yes ☐ No ☑

If yes, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

(1) a statement of the rule's basis and purpose;

(2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;

(3) a description of the factual evidence that:
(a) justifies the agency's need for the proposed rule; and
(b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;

(4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;

(5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;

(6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and

(7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
(a) the rule is achieving the statutory objectives;
(b) the benefits of the rule continue to justify its costs; and
(c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

Promulgated by:
Arkansas State Board of Pharmacy 10/10/2025

Title 17. Professions, Occupations, and Businesses
Chapter XXX. Arkansas State Board of Pharmacy, Department of Health
Subchapter A. Generally
Part 160. Arkansas State Board of Pharmacy Rules
Subpart 1. General Operations

17 CAR § 160-101. Description of the Arkansas State Board of Pharmacy.

(a) The Arkansas State Board of Pharmacy shall consist of six (6) pharmacist members as provided by Arkansas Code §§ 17-92-201(a)(1) and (a)(2) and Arkansas Code § 17-92-201(d), plus a consumer member and a senior citizen consumer member as provided by Arkansas Code § 17-92-201(a)(3).

(b) The qualifications, powers, and duties of the board shall be those enumerated by the provisions of Arkansas Code §§ 17-92-201 – 17-92-208.

17 CAR § 160-102. Location of Arkansas State Board of Pharmacy offices.

(a) The office of the Arkansas State Board of Pharmacy shall be located at 322 South Main Street, Suite 600, Little Rock, Arkansas 72201.

(b) All communications thereto may be addressed to:

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

17 CAR § 160-103. Requests for information.

(a) Any person or persons seeking information respecting the Arkansas State Board of Pharmacy or desiring to submit complaints or charges thereto or make request thereof shall do so by filing with the board an instrument in writing:

(1) Signed by the writer; and

(2) Containing a return address.

(b) Communications need not be typed but should be legible.

17 CAR § 160-104. Licensees governed by Pharmacy Practice Act.

Except wherein items of practice and procedure are specifically set out in this part, the practice and procedure before the Arkansas State Board of Pharmacy shall be governed by the provisions of the Pharmacy Practice Act.

17 CAR § 160-105. Certificates of licensure — Expiration.

(a) All retail pharmacy permits, out-of-state pharmacy permits, specialty pharmacy permits, and pharmacist licenses shall expire on December 31 of the first odd-numbered year following the date of their issuance.

(b) All preceptor permits shall expire on December 31 of the first odd-numbered year following the date of their issuance.

(c)(1) An intern license issued to a student intern shall expire six (6) months following graduation or when the intern is issued a pharmacist license, whichever occurs first.

(2) Intern licenses issued to foreign graduates shall expire on December 31 of the second calendar year following the date of issuance or when the intern is issued a pharmacist license, whichever occurs first.

(d) Nonrenewable provisional licenses and provisional registrations shall expire six (6) months after the date of issuance or upon issuance of a pharmacist, intern, or technician license, whichever comes first.

(e) All pharmacy technician permits, hospital pharmacy permits, ambulatory care center pharmaceutical services permits, wholesale distributors of legend or controlled substance permits, wholesale distributors of medical equipment, legend devices, and

medical gases permits, institutional pharmaceutical services permits, List I chemical permits, and charitable clinic permits shall expire on December 31 of the first even-numbered year following the date of the issuance of the:

(1) Permit;

(2) License;

(3) Registration; or

(4) Certificate.

(f) Charitable clinic permits shall expire on December 31 of the first even-numbered year following the date of the issuance of the:

(1) Permit;

(2) License;

(3) Registration; or

(4) Certificate.

(g)(1) Every license, permit, registration, and certificate not renewed within ninety (90) days after expiration thereof shall be null and void.

(2)(A) Every licensed pharmacist engaged in the active practice of pharmacy shall pay to the Arkansas State Board of Pharmacy a renewal fee as defined in 17 CAR § 160-107.

(B) If the renewal fee for any pharmacist license is unpaid by the first day of February following the date of expiration, the:

(i) Holder thereof must pay a penalty as defined in 17 CAR § 160-107 for each month thereafter, provided that if the renewal is unpaid by the first day of April following the date of expiration, such certificate shall be null and void; and

(ii) Holder must:

(a) Be reinstated as a licensed pharmacist by satisfying the board that he or she is competent and qualified to compound and fill prescriptions; and

(b) Pay a reinstatement fee as defined in 17 CAR § 160-107 for each delinquent year up to a maximum as defined in 17 CAR § 160-107 plus the current year's renewal fee.

(3)(A) Every registered pharmacy technician shall pay to the board a renewal fee as defined in 17 CAR § 160-107.

(B) If the renewal fee for any pharmacy technician registration is unpaid by the first day of February following the date of expiration, the holder thereof must pay a penalty as defined in 17 CAR § 160-107 for each month thereafter, provided that if the renewal is unpaid by the first day of April following the date of expiration, such registration shall be null and void.

(C) The pharmacy technician may be reinstated as a pharmacy technician upon payment of a reinstatement fee as defined in 17 CAR § 160-107 plus the renewal fee.

(4)(A) Every preceptor shall pay to the board a renewal fee as defined in 17 CAR § 160-107.

(B) If the renewal fee for the preceptor license is unpaid by the first day of July following the date of expiration, the holder thereof must pay a penalty as defined in 17 CAR § 160-107 for each month thereafter, provided that if the renewal is unpaid by the first day of September following the date of expiration, such registration shall be null and void.

(5)(A) Every licensed pharmacy, hospital, ambulatory care center, wholesale distributor, List I chemical or supplier of medical equipment, legend device, or medical gas shall pay to the board a renewal fee as defined in 17 CAR § 160-107.

(B) If the renewal fee for any pharmacy or business license is unpaid by the first day of February following the date of expiration, the holder thereof must pay a penalty as defined in 17 CAR § 160-107 for each month thereafter, provided that if the renewal is unpaid by the first day of April following the date of expiration, such license shall be null and void.

17 CAR § 160-106. Arkansas State Board of Pharmacy meeting requirements.

(a) The Arkansas State Board of Pharmacy shall meet the second Tuesday and Wednesday in February, the second Tuesday and Wednesday in June, or at the time of

the annual meeting of the Arkansas Pharmacists Association in June, and the second Tuesday and Wednesday in October of each year unless changed and announced in advance by the board.

(b) Examination of candidates for licensure to practice pharmacy shall be on dates and at times and places as determined by the board.

17 CAR § 160-107. Fees charged by the Arkansas State Board of Pharmacy.

(a) The fees charged by the Arkansas State Board of Pharmacy for the various examinations, permits, licenses, certificates, and books issued by the board shall be as follows:

(1) The fee for examination to become a licensed pharmacist upon examination shall be twenty-five dollars ($25.00) plus the actual cost of the examination;

(2) The fee for a license as a licensed pharmacist from another state by reciprocity (license transfer) shall be two hundred dollars ($200);

(3)(A) The fee for the initial issuance of a license as a licensed pharmacist shall be seventy-five dollars ($75.00).

(B) The fee for the renewal of a license as a licensed pharmacist shall be seventy-five dollars ($75.00) per year;

(4)(A)(i) The fee for issuance of a permit for the first time to operate an in-state pharmacy shall be three hundred dollars ($300).

(ii) The fee for renewal of a permit to operate an in-state pharmacy shall be one hundred fifty dollars ($150) per year.

(iii) When there is a change of ownership of an in-state pharmacy:

(a) A new permit must be obtained; and

(b) The fee shall be one hundred fifty dollars ($150).

(B)(i) The fee for issuance of a permit for the first time to operate a specialty pharmacy shall be three hundred dollars ($300).

(ii) The fee for renewal of a permit to operate a specialty pharmacy shall be one hundred fifty dollars ($150) per year.

(iii) When there is a change in ownership in a specialty pharmacy:

(a) A new permit must be obtained; and

(b) The fee shall be one hundred fifty dollars ($150).

(C)(i) The fee for issuance of a permit for the first time to operate an out-of-state pharmacy shall be three hundred dollars ($300).

(ii) The fee for renewal of a permit to operate an out-of-state pharmacy shall be one hundred fifty dollars ($150) per year.

(iii) When there is a change in ownership in an out-of-state pharmacy or drug store:

(a) A new permit must be obtained; and

(b) The fee shall be one hundred fifty dollars ($150);

(5) The fee for a certificate as a licensed pharmacist shall be ten dollars ($10.00);

(6) The fee for certifying grades in connection with an application for reciprocity (license transfer) shall be ten dollars ($10.00);

(7)(A) The fee for issuance of a hospital pharmaceutical service permit shall be three hundred dollars ($300), and the fee for the renewal of a hospital pharmaceutical service permit shall be one hundred fifty dollars ($150) per year.

(B) When there is a change of ownership of a hospital pharmacy:

(i) A new permit must be obtained; and

(ii) The fee shall be one hundred fifty dollars ($150).

(C)(i) The fee for issuance of an ambulatory care center pharmaceutical service permit shall be three hundred dollars ($300), and the fee for the renewal of an ambulatory care center pharmaceutical service permit shall be one hundred fifty dollars ($150) per year.

(ii) When there is a change in ownership of an ambulatory care center pharmacy:

(a) A new permit must be obtained; and

(b) The fee shall be one hundred fifty dollars ($150);

(8)(A) The fee for issuance of an institutional pharmaceutical services permit shall be thirty-five dollars ($35.00).

(B) The fee for the renewal of an institutional pharmaceutical services permit shall be thirty-five dollars ($35.00) per year;

(9) The fee for intern registration shall be forty-five dollars ($45.00);

(10) The fee for change of pharmacist-in-charge of any pharmacy or other facility as described at Arkansas Code § 17-92-403 shall be thirty-five dollars ($35.00);

(11) The fee for reinstatement of a pharmacist license shall be seventy-five dollars ($75.00) for each delinquent year up to a maximum of three hundred dollars ($300);

(12)(A) The fee for the board law book shall be twenty-five dollars ($25.00) except to interns on initial licensure and applicants for reciprocity on a one-time basis.

(B) A copy of each edition as revised shall be provided free to each pharmacy permit holder;

(13) The fee for a change of location inspection shall be one hundred dollars ($100);

(14) The penalty for late payment of renewal of any permit, license, registration, or certificate, unless specifically stated in this rule, shall be twenty dollars ($20.00) per month beginning the first day of the second month after expiration, provided that if the renewal is not paid by the first day of the fourth month after expiration, the license shall be null and void;

(15)(A) The fee for issuance of a wholesale distributor of legend drugs and/or controlled substances permit shall be three hundred dollars ($300), and renewal shall be one hundred fifty dollars ($150) per year.

(B) When there is a change in ownership of a wholesale distributor of legend drugs and/or controlled substances:

(i) A new permit must be obtained; and

(ii) The fee shall be one hundred fifty dollars ($150);

(16)(A) The fee for the original issuance of a pharmacy technician's permit shall not exceed thirty-five dollars ($35.00).

(B) The fee for the renewal of a pharmacy technician's permit shall not exceed thirty-five dollars ($35.00) per year.

(C) There shall be no fee for the original issuance and renewal of a restricted charitable clinic pharmacy technician's permit issued pursuant to 17 CAR § 160-1304(f);

(17) The reinstatement fee for a pharmacy technician's permit shall not exceed forty dollars ($40.00);

(18)(A) The application fee for a license to sell, rent, offer to sell, or rent directly to patients in this state any home medical equipment, legend devices, or medical gases shall not exceed two hundred fifty dollars ($250).

(B) The license renewal fee shall not exceed one hundred twenty-five dollars ($125).

(C) The change-of-ownership fee shall not exceed one hundred twenty-five dollars ($125);

(19) The fee for issuance of a temporary permit for a pharmacist on active duty in a branch of the armed forces:

(A) Shall not exceed twenty-five dollars ($25.00); and

(B) Shall be administered as defined in rule 02-00-0004;

(20) The fee for registration as a preceptor shall be twenty dollars ($20.00) every two (2) years; and

(21)(A) The fee for a permit for wholesale distributors of List I chemicals shall not exceed three hundred dollars ($300), and the renewal shall not exceed one hundred fifty dollars ($150) per year.

(B) When there is a change of ownership of a wholesale distributor of List I chemicals:

(i) A new permit must be obtained; and

(ii) The fee shall not exceed one hundred fifty dollars ($150).

(b)(1) All fees for examination for license:

(A) Shall be payable with the application; and

(B) Shall not be subject to refund.

(2) All other fees are only refundable if it is determined that there has been an overpayment.

(c)(1) Should any license, certificate, or registration not be renewed within ninety (90) days after expiration thereof, it may be reinstated by the board as authorized in this section upon payment of the renewal fee and reinstatement fee.

(2) However, the following are not subject to reinstatement if not renewed within ninety (90) days after expiration:

(A) Pharmacy permits;

(B) Out-of-state pharmacy permits;

(C) Specialty pharmacy permits;

(D) Hospital permits;

(E) Ambulatory care center pharmacy permits;

(F) Wholesale distributors of legend drugs and/or controlled substance permits, or both;

(G) Suppliers of medical equipment, legend devices, and/or medical gas licenses;

(H) Institutional pharmacy permits;

(I) List I chemical permits; and

(J) Charitable clinic permits.

(d)(1) All retail pharmacy permits, out-of-state pharmacy permits, specialty pharmacy permits, and pharmacist licenses expiring in odd-numbered years shall be renewed every two (2) years.

(2) All pharmacy technician permits, hospital pharmaceutical service permits, ambulatory care center pharmaceutical services permits, wholesale distributors of legend or controlled substance permits, wholesale distributors of medical equipment,

legend devices, and medical gases permits, wholesale distributors of List I chemicals, institutional pharmaceutical services permits, charitable clinic permits, and any other permit, license, registration, or certificate issued by the board expiring in even-numbered years and not covered in subdivision (d)(1) of this section shall be renewed every two (2) years.

(3) The fee for any biennial renewal term will be the amount of two (2) annual renewal fees for the applicable license, permit, registration, or certification as provided in subsection (a) of this section.

(4) If the initial licensure, permit, certificate, or registration occurs in the first year of a biennial renewal term, the applicant shall pay the appropriate initial fee and the applicable annual fee for the license, permit, certificate, or registration for the second year in the renewal term, as provided in subsection (a) of this section.

(5) If the initial licensure, permit, certificate, or registration occurs in the second year of the biennial renewal term, the applicant will only pay the original fee and will not be responsible for the renewal fee until the biennial renewal period for the:

(A) License;

(B) Permit;

(C) Certificate; or

(D) Registration.

17 CAR § 160-108. Declaratory order.

(a) **Scope.** When a rule, statute, or order enforced by the Arkansas State Board of Pharmacy or its application will injure or threatens to injure a person in his or her person, business, or property, that person may file a petition for a declaratory order as to the applicability of that rule, statute, or order pursuant to this rule.

(b) **Petition — Contents.** The petition for a declaratory order shall contain the following:

(1) The venue, a heading specifying the subject matter and name of the petitioner, and the name of the pleading;

(2) The name, address, and telephone number of the petitioner and whether the petitioner is licensed by the board under Arkansas Code § 17-92-101 et seq.;

(3) The name, address, and telephone number of the petitioner's attorney, if any;

(4) A statement of the injury to result from the rule, statute, or order or the application thereof to the petitioner;

(5) The declaratory ruling that the petitioner seeks;

(6) The rule, statute, or order that is the subject of the petition;

(7)(A) The facts relevant to the order that the petitioner seeks.

(B) Said statement of facts shall be complete, specific, and particularized to the issue presented;

(8) Memorandum of law and legal authorities in support of the order the petitioner seeks;

(9) The name, address, and telephone number of each person:

(A) Known to the petitioner who may have a specific personal interest in the application of the:

(i) Rule;

(ii) Statute; or

(iii) Order; or

(B) Who may be adversely affected by the declaratory order sought by the petitioner;

(10) The signature of the petitioner or the petitioner's attorney, if any; and

(11) All documents pertinent to the petition shall be attached thereto.

(c) **Filing of the petition.**

(1)(A) The original and three (3) copies of each petition shall be in writing and shall be delivered in person or by mail to the Executive Director of the Arkansas State Board of Pharmacy during regular business hours at the board's offices.

(B) The executive director shall:

(i) Mark said petition as having been received by the board; and

(ii) Return a file-marked copy to the petitioner.

(2) In order to determine whether to issue a declaratory order, the board will consider any pertinent issues, including without limitation the following:

(A) Whether the petition:

(i) Substantially conforms to subsection (b) of this section; or

(ii) Is not supported by a memorandum of law in support of the petition;

(B) Whether the petition is frivolous;

(C) Whether the matter is within the jurisdiction of the board;

(D) Whether there is a genuine controversy of material fact, the resolution of which is necessary before any declaratory order may issue;

(E) Whether the order will terminate a controversy or remove uncertainties as to the applicability to the petitioner of any rule, statute, or order by the board;

(F) Whether the petition involves any subject, question, or issue that is the subject of a formal or informal matter or investigation currently pending before:

(i) The board;

(ii) A court;

(iii) Another agency of this state; or

(iv) The federal government;

(G) Whether the petition:

(i) Seeks a ruling on a moot or hypothetical question or speculative facts; or

(ii) Will result in an advisory ruling or opinion;

(H) Whether the issue presented is of such complexity that the board has had insufficient opportunity or resources to develop a fully matured opinion;

(I) Whether a declaratory order would provide a broad interpretation of a rule, statute, or order applicable to an entire class of persons;

(J) Whether the promulgation of a rule or an adjudication would be more appropriate to resolve the question; and

(K) Any other pertinent matter.

(d) **Parties.**

(1) The petitioner, persons identified in subdivision (b)(9) of this section, and the board shall be parties to a proceeding for a declaratory order.

(2) Any other person may seek leave of the board to intervene in such proceeding and leave to intervene will be granted at the sole discretion of the board.

(3)(A) A petition to intervene shall be filed in the manner as set forth the same matters as required by subsection (b) of this section.

(B) Any reference to "petitioner" herein also refers to any person who has been granted leave to intervene, unless the context clearly indicates to the contrary.

(e) **Disposition of petition.** The board may:

(1)(A) Decide the issue solely upon the facts presented in the petition.

(B) In such case, the decision will apply only to the extent of the facts presented in the petition and amended to the petition;

(2)(A) Require that additional information be submitted before the petition will be considered.

(B) In such event, the additional facts will be considered as an amendment to the petition;

(3) Require the petitioner to provide notice of the pendency of the proceeding to persons who may be necessary parties as well as other persons;

(4)(A) Schedule a time, date, and place at which the board will conduct a hearing on the petition for the purpose of obtaining additional facts or inquiring into any facts set forth in the petition.

(B) Notice of the hearing and purpose therefor shall be provided to the petitioner;

(5) Schedule a date, time, and place at which the petitioner and other persons may make an oral presentation on the petition; and/or

(6) Consider the petition and any attachments without oral presentation.

(f) **Order.**

(1) The board shall state its decision in writing signed by:

(A) The President of the Arkansas State Board of Pharmacy; or

(B) Other person designated by the board.

(2)(A) The board's decision deciding the issue presented by the petition shall include findings of fact and conclusions of law supporting the declaratory order.

(B) The decision may be in the form of a letter or pleading.

(3) The board's decision shall be rendered and entered as promptly as reasonably practicable considering the facts, circumstances, complexity, and other factors pertinent to the proceeding.

(4) The order shall be served upon the petitioner and any other parties to the proceeding by certified mail, return receipt requested.

17 CAR § 160-109. Inspector's warning notice.

(a) **Purpose.** An inspector's warning notice protects public health by allowing registrants to:

(1) Expeditiously correct violations of laws and rules; and

(2) Report these corrections to the Arkansas State Board of Pharmacy in writing.

(b) **Recipient.** A warning notice may be issued to any person or facility holding a permit, license, registration, certificate, or credential issued by the board that is found to be violating any Arkansas Code provision pertaining to the practice of pharmacy or any rule of the board as well as any other applicable state or federal law, rule, or regulation.

(c) **Issuance.** An inspector may issue a warning notice at the time a violation is found.

(d) **Filing.** The warning notice shall become an integral part of a file.

(e) **Failure to respond.** A recipient's failure to satisfactorily respond to a warning notice may be referred by the Executive Director of the Arkansas State Board of Pharmacy for review and hearing.

(f) **Board review of two (2) warning notices.** Any registrant receiving two (2) or more warning notices within a twelve-month period may be referred to the board for review and hearing.

17 CAR § 160-110. Licensure for uniformed service members, returning military veterans, and spouses.

(a) The Arkansas State Board of Pharmacy shall allow the following individuals to secure employment with a temporary license, certificate, or permit while completing the application process for full licensure or registration if the individual is the holder in good standing of a license, certificate, or registration with a similar scope of practice issued by another state, territory, or district of the United States:

(1) A uniformed service member stationed in the State of Arkansas;

(2) A uniformed service veteran who resides in or establishes residency in the State of Arkansas; or

(3) The spouse of a:

(A) Person under subdivisions (a)(1) and (a)(2) of this section;

(B) Uniformed service member who is assigned a tour of duty that excludes the uniformed service member's spouse from accompanying the uniformed service member and the spouse relocates to this state; and

(C) Uniformed service member who is killed or succumbs to his or her injuries or illness in the line of duty if the spouse establishes residency in the state.

(b) The board shall expedite the process and procedures for full licensure or registration for the individuals under subdivisions (a)(1), (a)(2), and (a)(3) of this section.

(c) Extension of license expiration and continuing education requirements.

(1) The board shall extend the expiration date of any individual license or registration for a deployed uniformed service member or his or her spouse for one

hundred eighty (180) days following the date of the uniformed service member's return from deployment.

(2) The board shall allow a full or partial exemption from a continuing education requirement that is required as a component of occupational licensure for an individual who is listed in subdivision (a)(1) of this section until one hundred eighty (180) days following the date of the uniformed service member's return from deployment.

(3) Any uniformed service member or his or her spouse exercising the exemption shall provide evidence of completion of continuing education before renewal or granting of a subsequent license.

Subpart 2. Pharmacists — General Requirements for Pharmacists

17 CAR § 160-201. Changes in employment.

(a) Whenever any licensed pharmacist shall change his or her place of employment for any reason, it shall be the duty of the former and current employer and said licensed pharmacist to notify the Arkansas State Board of Pharmacy in writing of such change within five (5) days after such change of employment.

(b) Notification must:

(1) Be made by:

(A) Letter;

(B) Fax;

(C) Email; or

(D) Through the board website; and

(2) Contain the new place of employment of the licensed pharmacist and his or her license number.

17 CAR § 160-202. Replacement of pharmacist's certificate.

Any licensed pharmacist whose certificate has been lost or destroyed may procure a duplicate from the Arkansas State Board of Pharmacy by:

(1) Filing an affidavit that said certificate has been lost or destroyed; and

(2) Paying a fee as defined in 17 CAR § 160-107.

17 CAR § 160-203. Practice after inactivity when reciprocating or reinstating a license.

(a) To be reinstated and immediately practice without supervision, the pharmacist's license shall not have lapsed by more than two (2) calendar years.

(b) To be reciprocated and immediately practice without supervision, the pharmacist shall:

(1) Have practiced the profession of pharmacy, as defined by law, at least forty (40) hours per year in the previous two (2) calendar years; or

(2) Be granted a waiver by the Arkansas State Board of Pharmacy.

(c) If the pharmacist must practice under supervision, the pharmacist must:

(1) Appear before the Board for consideration and approval of their application and return to practice plan.

(2) Prior to resuming the unsupervised practice of pharmacy, practice forty (40) hours under direct pharmacist supervision of an Arkansas-licensed pharmacist for each year or part of year out of practice.

(3) Cause the supervising pharmacist to document in writing to the board that the pharmacist has completed the designated number of hours of supervised practice; and

(4) Meet with a board representative in a practice situation so that the board representative can, by observation, questioning, and other methods, ensure that the pharmacist is able to competently practice pharmacy.

Subpart 3. Pharmacists — Internship/Clerkship

17 CAR § 160-301. Definitions.

As used in this part:

(1) "Class A pharmacy" means a pharmacy that has:

(A) A pharmacy permit with a pharmacist on duty at least forty (40) hours per week;

(B) No unsatisfactory deficiency; and

(C) No more than three (3) noncompliant deficiencies noted on its last board inspection;

(2) "Graduation" means certification from a board-approved college of pharmacy that the student has fulfilled all requirements for graduation or has completed all foreign pharmacist requirements as set forth in 17 CAR § 160-401(1);

(3)(A) "Licensed intern" means a person licensed by the Arkansas State Board of Pharmacy as a licensed intern and who is a student accepted by and enrolled as a student in a college of pharmacy approved by the board, or who is a graduate of a foreign college of pharmacy and has successfully completed a transcript verification program and who, due to circumstances beyond his or her control, has not been able to successfully complete a college of pharmacy equivalency exam program, equivalent to graduation from a board-approved college of pharmacy as set forth in 17 CAR § 160-401(1).

(B)(i) Provided, however, the graduate may qualify as a licensed intern under this exception to the required college of pharmacy equivalency exam program set forth in 17 CAR § 160-401(1) only until the first offering of said equivalency.

(ii) "Extern" means:

(a) An intern prior to graduation; or

(b) A graduate who has taken and failed the board exam.

(iii) "Graduate intern" means an intern who has:

(a) Graduated or completed requirements for examination as set forth in 17 CAR § 160-401(1); and

(b) Completed the practical experience or training required under board-approved conditions; and

(4) "Supervision" means a licensed pharmacist and/or certified preceptor:

(A) Supervises the practical experience of a licensed intern with both personal and physical supervision; and

(B) Actually gives instruction to the intern obtaining the experience during the entire period of such experience.

17 CAR § 160-302. Internship required.

(a) Hereafter no extern, intern, or student of a pharmacy school shall be granted authority from the Arkansas State Board of Pharmacy to practice pharmacy in Arkansas and serve any internship period in Arkansas unless he or she:

(1) Is licensed with the board; and

(2) Undergoes a criminal background check:

(A) Pursuant to Subpart 31; and

(B) Conducted by the:

(i) Division of Arkansas State Police; and

(ii) Federal Bureau of Investigation.

(b) Applications for an intern's license and for criminal background checks will be furnished by the board.

(c) The applicant will be responsible for the payment of applicable fees for state and federal criminal background checks pursuant to written instructions provided by the board, and for applicable fees for an intern's license to the board.

17 CAR § 160-303. Arkansas State Board of Pharmacy regulates internship program.

(a)(1) The Arkansas State Board of Pharmacy is charged with regulating the internship program in Arkansas Code § 17-92-307.

(2) The board recognizes that in order to properly fulfill its obligation to the profession of pharmacy and general welfare and protection of the public health that it must implement and supervise an internship program in the State of Arkansas.

(b) From time to time, as is required to establish a viable internship program, the board will establish, publish, and disseminate criteria establishing requirements and

standards necessary for qualifications for licensure under Arkansas Code §§ 17-92-305 and 17-92-307.

(c)(1) Hereafter, every applicant for licensure by examination in Arkansas must have two thousand (2,000) hours of acceptable internship training obtained after beginning the professional college curriculum.

(2) Required hours may be obtained in a training program as part of school curriculum under board-approved conditions.

17 CAR § 160-304. Requirements for internship training.

(a)(1) Any extern or intern receiving internship training practice or experience in the State of Arkansas must be licensed as an intern with the Arkansas State Board of Pharmacy.

(2) No credit for internship training will be allowed prior to licensure as an intern.

(3) The intern license application can be obtained from the office of the board.

(4) The intern license fee is specified in 17 CAR § 160-107(a)(10).

(b) An applicant for an intern license shall:

(1) Submit an application on a form provided by the board; and

(2) Have the following qualifications:

(A) Be enrolled as a student in a college of pharmacy accredited by ACPE and approved by the board; or

(B) Be a graduate of a foreign college of pharmacy who has obtained Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification from NABP.

(c) All students enrolled in any college of pharmacy shall be licensed as interns by the board prior to any participation in the practice of pharmacy as defined in Arkansas Code §§ 17-92-101, 17-92-301, and 17-92-307 in Arkansas.

(d)(1) The intern license remains valid:

(A) As long as the intern maintains active student status in a board-approved college of pharmacy; and

(B) For up to six (6) months after graduation from a college of pharmacy or completion of foreign pharmacist requirements as set forth in 17 CAR § 160-401(1) upon request.

(2) At this time, the intern license becomes void.

(e) An intern may not practice pharmacy as a graduate intern until they have met all criteria for graduate intern status.

(f)(1) The licensed intern's certificate must be displayed in the drugstore or pharmacy in which the intern is being trained.

(2) Licensed interns shall not be left in sole charge of the prescription department at any time.

(3) Violation of this rule may result in:

(A) A cancellation of any and all internship hours toward licensure that may be accrued by the pharmacy intern; and

(B) Suspension, revocation, or other penalties of the:

(i) Pharmacist-in-charge;

(ii) Supervising pharmacist; and/or

(iii) Pharmacy permit.

(g)(1) For graduates of a foreign college of pharmacy, the first five hundred (500) hours of pharmacy practice as a pharmacy intern, for each pharmacy setting where an intern practices pharmacy, the intern shall complete and file with the board office, prior to any practice, a "Training Plan" that is signed by the pharmacist-in-charge for that particular work situation.

(2) Prior to completion of the first five hundred (500) hours of practical experience, the pharmacy intern may only work under the direct supervision of a certified preceptor.

(3) Hours of practical experience:

(A) Include only those hours worked under the direct supervision of a preceptor; and

(B) May not exceed forty (40) hours per week.

(4) The pharmacist-in-charge must approve and verify, by signing the affidavit of experience, that the intern has earned their hours of practical experience under the direct supervision of a certified preceptor.

(5) Training plans shall expire on May 31 of each year.

(6) Interns must file affidavits of experience prior to the expiration date of their training plan to get credit for these hours with the board.

(h)(1) An intern may practice pharmacy in any Class A pharmacy under the supervision of a licensed pharmacist provided that the intern notifies the board:

(A) In writing of his or her employment as a pharmacy intern within five (5) days of starting to work in any pharmacy; and

(B) Of any change in his or her employment for any reason within five (5) days of the change.

(2)(A) Notification:

(i) Is made in writing by letter, fax, email, or through the board website; and

(ii) Must contain the:

(a) Name of the intern;

(b) Name and address of the pharmacy; and

(c) Date of hire or date of change in employment.

(B) It is the intern's responsibility to verify that the notification has been received and processed by the board.

(i) Participation in a school or college of pharmacy curriculum extern or clerkship program, approved by the board, will be credited week-for-week as training.

(j) The board will not approve applicants for the NAPLEX until the applicant has provided proof of graduation from a college of pharmacy approved by the board or proof of completion of foreign pharmacist requirements as set forth in 17 CAR § 160-304(b).

(k)(1) A graduate intern:

(A) May practice pharmacy in the State of Arkansas under the supervision of a pharmacist in a Class A pharmacy; and

(B) Will not count in the pharmacist-to-support staff ratio.

(2) A graduate intern must sit for the NAPLEX within six (6) months of the date of graduation.

(3) If a graduate intern sits for the NAPLEX and does not make a passing grade, the graduate intern will:

(A) Be reduced to intern status; and

(B) Once again count in the pharmacist-to-support staff ratio.

(l) After presenting satisfactory proof of either graduation and receipt of the first professional undergraduate degree from an ACPE-accredited college of pharmacy approved by the board or Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification from NABP and submitting an affidavit of two thousand (2,000) hours of practical experience or training under board-approved conditions, the intern may be designated as a candidate suitable for full licensure if other conditions have been met.

(m)(1) If the pharmacy intern is suspected to have, or evidence exists that a pharmacy intern may have violated any law or rule regarding the practice of pharmacy, legend drugs, or controlled substances, the preceptor shall notify the board in writing, within ten (10) days or immediately, if any danger to the public health or safety may exist.

(2) Any other pharmacist, whether or not practicing in the same pharmacy, who has such knowledge or suspicion shall notify the board in a like manner.

(n)(1) The board may revoke, suspend, or refuse to issue a license, or impose other appropriate penalties pursuant to Arkansas Code § 17-92-315 against an intern for any of the acts or offenses set forth in Arkansas Code § 17-92-311.

(2) The provisions of 17 CAR § 160-601 regarding unprofessional or dishonorable conduct shall be applicable to interns, and all references therein to "pharmacist" shall be construed as "intern" for purposes of this subsection.

(3) The procedures set forth in Arkansas Code § 17-92-313 and board rules applicable to disciplinary proceedings against pharmacists shall be applicable to any proceeding against an intern in this subsection.

17 CAR § 160-305. Rules applying to preceptors who train interns.

(a) The Arkansas internship training program requires that a pharmacist, who has been duly certified by the Arkansas State Board of Pharmacy, may serve as preceptor for an intern or extern.

(b) A pharmacist must meet the following requirements to be certified as a preceptor by the board:

(1) Be an Arkansas pharmacist:

(A) Licensed for more than one (1) year; and

(B) Actively engaged in the practice of pharmacy for the year immediately preceding the application for certification as a preceptor;

(2) Be a pharmacist employed in a pharmacy that currently holds a Class A rating indicated by the Inspection Sheet for pharmacies as outlined by the board;

(3) For the initial application as preceptor, the applicant must satisfactorily complete a test on requirements and responsibilities of a preceptor as developed and administered by the board or its representatives;

(4) Have a pharmacy library (latest edition) that meets or exceeds the requirements of the Inspection Sheet for pharmacies;

(5)(A) At least one (1) preceptor from the internship site shall be a member of an appropriate national pharmaceutical organization.

(B) Preceptors shall be a member of at least one (1) professional state organization;

(6) Must not have been convicted of any violation of Arkansas Code § 17-92-311 unless the board officially grants exception;

(7) Must have attended at least one (1) professional meeting during each licensure biennium;

(8) Must agree to give immediate personal and direct physical supervision to the intern; and

(9) Preceptors must renew their certification every two (2) years by application and payment of fees specified in 17 CAR § 160-107.

17 CAR § 160-306. Penalty for violation.

Violation of any of the rules and requirements set forth in this subpart may:

(1) Cause the preceptor to lose his or her certification; and

(2) Also cause the intern to lose internship training credit.

17 CAR § 160-307. Accredited pharmacy degree program.

(a) An accredited pharmacy degree program shall be any program that meets at least the minimum standards established for a recognized Doctor of Pharmacy program by the Accreditation Council for Pharmacy Education.

(b)(1) At the October Arkansas State Board of Pharmacy Board meeting each year, the board shall adopt a specific list, by name, of approved colleges.

(2) Until the list is revised, the existing list shall remain valid.

Subpart 4. Pharmacists — Examination

17 CAR § 160-401. Requisites for examination.

Before being approved to take the NAPLEX examination for licensure in Arkansas, each applicant must meet the following requirements:

(1) Satisfactory proof of graduation and receipt of the first professional undergraduate degree from a college of pharmacy approved by the Arkansas State Board of Pharmacy or Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification from NABP with two thousand (2,000) hours of practical experience or training under board-approved conditions;

(2)(A) Applicants may request a blank application from the board, which must be completed and returned to the board office together with the fee as defined in 17 CAR § 160-107.

(B) The application must be received no later than the date designated by the board for receipt of applications;

(3) Each application must be accompanied by a:

(A) Recent three inches by two inches (3" x 2") picture; and

(B) Physical description stating age, height, weight, and color of hair, eyes, and complexion of the applicant;

(4)(A) Each applicant must undergo a state and federal criminal background check pursuant to Subpart 31, to be conducted by the:

(i) Division of Arkansas State Police; and

(ii) Federal Bureau of Investigation.

(B) The board will furnish the forms and instructions to applicants for the criminal background check.

(C) The applicant is responsible for the payment of fees for criminal background checks pursuant to written instructions provided by the board;

(5)(A) The examination will be held at a site and at a time or during a time period designated by NABP or its contracted testing vendor.

(B) Upon the receipt by the board of certification of the requirements as defined in subdivision (1) of this rule and an application for licensure by examination, such applicant may practice pharmacy as a graduate intern, pursuant to 17 CAR § 160-303, in the State of Arkansas temporarily until the occurrence of the first of the following events:

(i)*(a)* Failure to take the exam at the designated time for the individual applicant.

(b) Provided, however, the board may grant a similar temporary privilege to practice pharmacy as a graduate intern subject to the same terms and conditions herein in the event the applicant is reasonably unable, due to

circumstances beyond the applicant's control, to take the examination at the first designated time for the individual applicant;

(ii) Failure to receive a passing grade on the examination at the first designated time for the individual applicant; or

(iii)*(a)* The expiration of six (6) calendar months following the applicant's graduation date from a college of pharmacy approved by the board, or reaching the intern license expiration date on December 31 of the second calendar year following issuance for foreign pharmacy graduates.

(b) Foreign pharmacy graduates may request an extension for the expiration of their intern permits while making progress towards the two thousand (2,000) practice hours required for examination.

(c) Foreign pharmacy graduates must attain five hundred (500) initial practice hours in order to practice as graduate interns.

(C) The granting of status as a graduate intern:

(i) Shall in no way entitle the recipient thereof to any rights of tenure of permanent license; and

(ii) Is conferred gratuitously at the discretion of the board;

(6) The test or tests shall be graded and reported;

(7) No person except members of the board or their authorized representatives will be permitted to enter the testing site during the course of examination; and

(8) The applicant must make a score of seventy percent (70%) or more on the jurisprudence exam prior to making application for licensure as a pharmacist in the State of Arkansas.

17 CAR § 160-402. Score transfer.

(a) The Arkansas State Board of Pharmacy participates in the National Association of Boards of Pharmacy Score Transfer Program.

(b) If a candidate takes NAPLEX in another participating state, properly transfers the score to Arkansas, and completes other requirements for licensure including but not

limited to criminal background checks pursuant to Subpart 31, Arkansas will license the applicant by the examination process within twelve (12) months of receipt of the score transfer.

Subpart 5. Pharmacists — Reciprocity

17 CAR § 160-501. Requirements for reciprocity.

(a)(1) No temporary license shall be granted to a reciprocity applicant until the:

(A) Preliminary application has been received and approved by the National Association of Boards of Pharmacy; and

(B) Applicant has:

(i) Submitted the application to the Arkansas State Board of Pharmacy office;

(ii) Paid the reciprocity fee;

(iii) Undergone criminal background checks pursuant to Subpart 31;

(iv) Supplied a copy of the applicant's birth certificate;

(v) Submitted proof of required continuing education; and

(vi) Supplied a current photograph of the applicant.

(2) The temporary license shall expire at the next meeting of the Arkansas State Board of Pharmacy after the issuance of the temporary license.

(3) However, the temporary license will automatically expire one hundred eighty (180) days from the date of issue, and the holder of the temporary license must cease practicing pharmacy in the State of Arkansas until reciprocity has been granted by the Arkansas State Board of Pharmacy.

(b) Before issuing a temporary license, the Arkansas State Board of Pharmacy member must:

(1) Personally talk to the applicant; and

(2) Ascertain that he or she has passed the Arkansas Jurisprudence Exam.

(c)(1) A pharmacist is not eligible for an Arkansas license by reciprocity until he or she has been licensed six (6) months in his or her state of original licensure by examination.

(2) Any practice in Arkansas within this six-month period must be as an intern and under the requirements set out in this criteria unless:

(A) Consideration is made by the Arkansas State Board of Pharmacy; and

(B) An exception is approved.

(3) The application for reciprocity will become null and void if it has not been completed within one (1) year of the date of receipt in the Arkansas State Board of Pharmacy office.

Subpart 6. Pharmacists — Defining Unprofessional or Dishonorable Conduct

17 CAR § 160-601. Preamble.

(a)(1) In defining "unprofessional conduct" the definitions of professional conduct and a pharmacist's duty should be determined.

(2) Professional conduct may be defined as complying with all the laws and rules that apply to a given professional activity.

(b) A pharmacist's duty means:

(1) The practicing pharmacist has a general duty to qualify himself or herself by:

(A) Attaining and maintaining an acceptable level of professional competence; and

(B) Using such skill and precaution in the preparation, compounding, dispensing, labeling, and distribution of drugs and medical devices, whether on prescription or not, so as to prevent injury or death to all who are exposed to his or her professional services; and

(2) If the pharmacist is an owner, operator, or director of a pharmacy, he or she has:

(A) An additional duty to employ only qualified persons; and

(B) Such other duties as are incidental to the operation of a mercantile business establishment.

17 CAR § 160-602. Definition.

Unprofessional or dishonorable conduct by a pharmacist shall mean among other things, but not limited to:

(1) Violation of any provision of the Pharmacy Practice Act;

(2) Violation of the Arkansas State Board of Pharmacy rules;

(3) Violation of the Food, Drug, and Cosmetic Act, Arkansas Code § 20-56-201 et seq.;

(4) Violation of the Uniform Controlled Substances Act, Arkansas Code § 5-64-101 et seq.;

(5) Failure of a pharmacist to conduct himself or herself professionally in conformity with all applicable federal, state, and municipal laws and rules in his or her relationship with:

(A) The public;

(B) Other healthcare professions; and

(C) Fellow pharmacists;

(6) Failure to keep his or her pharmacy and/or area of professional practice clean, orderly, maintained, and secured for the proper performance of his or her professional duties;

(7) Acquiring prescription stock from unlicensed sources or buying or selling legend drugs in violation of local, state, or federal law;

(8)(A) Personal participation in the sale of alcoholic beverages while on duty as a pharmacist.

(B) Exempts pharmacies selling alcoholic beverages before June 1985;

(9) Failure to hold to the strictest confidences all knowledge concerning patrons, their prescriptions, and other confidences entrusted or acquired by him or her,

divulging in the interest of the patron only by proper release forms or where required for proper compliance with legal authority;

(10) Participation in a plan or agreement that compromises the quality or extent of professional services or facilities at the expense of the public health and welfare;

(11) Participation in any plan, agreement, or arrangement that eliminates or detrimentally affects the traditional relationship of physician, patient, pharmacist, and the patient's freedom of choice of professional services;

(12)(A) The distribution, promotion, or advertising of premiums, rebates, coupons, amounts off, etc., on prescription drugs unless the offer is given to all patients purchasing prescriptions in the same time period.

(B) Senior-citizen discounts shall not be considered a violation of this section;

(13) The solicitation of prescription business by providing prescribers with prescription blanks with the name of any licensed pharmacist or pharmacy printed thereon;

(14) Violation of rules and procedures governing payment to pharmacies for pharmaceutical services for eligible public assistance recipients and/or other third-party payment programs;

(15) The provision of medication carts, printing and maintenance of the database to produce the doctor's order sheet or medication administration record, consultation, and related services by provider pharmacists to long-term care facilities free of charge or obviously below cost;

(16) Falsifying contracts or agreements for legend drug purchases or violation of such contracts;

(17) Providing invalid or insufficient checks in payment for licenses or renewals;

(18)(A) Receiving more than three (3) noncompliant deficiencies on two (2) consecutive board inspections.

(B) The inspection is based on the board inspection form, which is available on request; and

(19) Dishonorable conduct shall include, without limitation, conduct involving fraud or dishonesty whether or not said conduct involves the practice of pharmacy.

Subpart 7. Pharmacists — Arkansas State Board of Pharmacy Actions

17 CAR § 160-701. Emergency suspension.

(a) Arkansas Code § 25-15-211(c) states, "[i]f the agency finds that public health, safety, or welfare imperatively requires emergency action and incorporates a finding to that effect in its order, summary suspension of a license may be ordered pending proceedings for revocation or other action, which proceedings shall be promptly instituted and determined."

(b)(1) Where the Executive Director of the Arkansas State Board of Pharmacy believes that the above condition exists, he or she shall call an emergency meeting with proper notifications of involved parties and media.

(2) Proper notifications shall be consistent with the Arkansas Administrative Procedure Act, Arkansas Code § 25-15-201 et seq.

(3) This emergency meeting may be via a conference telephone call to a quorum of Arkansas State Board of Pharmacy members.

(c)(1) The executive director shall introduce evidence:

(A) Of why he or she thinks an emergency exists; and

(B) That a violation of the pharmacy licensing law or rule has occurred.

(2)(A) The board shall determine whether the license should be summarily suspended.

(B) A hearing shall be scheduled promptly, for which notice shall be given pursuant to Arkansas Code § 17-92-313.

(3) If immediate action is requested, this hearing shall be within fourteen (14) days from the final board decision.

Subpart 8. Pharmacists — Continuing Education for Pharmacists

17 CAR § 160-801. Establishing an Arkansas Tripartite Committee on Continuing Pharmacy Education.

(a)(1) The Arkansas Tripartite Committee on Continuing Pharmacy Education, hereinafter referred to as the committee, is established to maintain professional competence through continuing education.

(2) The committee shall consist of the:

(A) Executive Director of the Arkansas State Board of Pharmacy, the dean or deans of the colleges of pharmacy approved by the Arkansas State Board of Pharmacy that are located within the State of Arkansas, and the Executive Vice President of the Arkansas Pharmacists Association; or

(B) Designated representatives of these individuals.

(b) The general areas of responsibility for the committee shall be the following:

(1) Plan and coordinate continuing education opportunities;

(2) Promote research in continuing pharmacy education;

(3) Develop information and record systems pertaining to the participation of pharmacists licensed in the State of Arkansas in continuing education; and

(4) Make recommendations to the board concerning continuing education rules.

(c) The committee will meet periodically to:

(1) Review and recommend changes in the criteria by which the continuing education will be approved; and

(2) Accomplish the above responsibilities.

(d) The executive director will carry out approval of continuing education according to the guidelines in this subpart.

(e) The executive director will act as chair of the committee.

17 CAR § 160-802. Accreditation guidelines.

(a) **Guidelines.**

(1)(A) The continuing education unit (CEU) shall be the basis for accreditation of offerings within the state.

(B) One-tenth (0.1) CEU is defined as one (1) contact hour.

(2) The Arkansas State Board of Pharmacy will accredit intrastate and interstate continuing education offerings that have been reviewed by an appropriate national agency.

(3) Continuing education programs shall be accredited for the total length of the program.

(4) Credit shall not be allowed for:

(A) "Banquet" meetings with no educational program;

(B) Unstructured demonstrations; and

(C) Unstructured question-and-answer sessions.

(5) Credit, hour-for-hour, shall be allowed for:

(A) Speakers;

(B) Panels;

(C) Structured:

(i) Discussions;

(ii) Workshops; and

(iii) Demonstrations; and

(D) Structured question-and-answer sessions.

(6) Keynote speakers and topics will be accredited on an individual basis.

(7) The Arkansas Tripartite Committee on Continuing Pharmacy Education reserves the right for members or designees to review programs in operation.

(b) **Accreditation mechanism.**

(1) Members of the Arkansas Tripartite Committee on Continuing Pharmacy Education shall be responsible for reviewing and recommending changes in the criteria for the accreditation of continuing education offerings.

(2) In the temporary absence of a designated Arkansas Tripartite Committee on Continuing Pharmacy Education member, a designated representative may review and offer recommendations for establishing and reviewing the criteria for the accreditation of continuing education offerings.

(3) The Executive Director of the Arkansas State Board of Pharmacy shall review all programs within seven (7) days of receipt of request for accreditation.

(4) All requests for accreditation must be received, in writing, in the board office at least seven (7) days before the offering is to occur.

(c) **Requirements for accreditation.**

(1) The organization shall have completed the appropriate program requirements specified in subsection (d) of this section.

(2) The organization shall have the proper personnel to plan and produce educational programs.

(3) The organization and personnel presenting the offering shall be qualified in the area of the presentation.

(4) The organization shall provide the proper administrative facilities, provide the proper physical facilities, and have the financial resources for the production of educational programs.

(d) **Program criteria for accreditation.**

(1) The program criteria shall be appropriate to meet the needs of the pharmacist.

(2) Beginning and ending times for each section of live programs must be indicated.

(3) A description of the program content:

(A) Shall accompany the request for accreditation; and

(B) Must be evaluated prior to its presentation.

(4) The program description, which is presented for accreditation, shall have a statement of objectives and goals.

(5)(A) The program outline shall indicate how performance and effectiveness by the pharmacist will be measured.

(B) Live programs in themselves shall be acceptable for accreditation.

(C) Audiovisual and correspondence programs shall require a live moderator or testing procedure.

(6) The program shall allow the pharmacist a method to evaluate the presentation.

(7)(A) The program shall demonstrate a quality educational process.

(B) Appropriate handout materials will be used with live presentations and correspondence courses.

(C) Appropriate audiovisual materials will be used with audiovisual presentations and correspondence courses when necessary.

(8)(A) The program administrator shall present accreditation certificates to pharmacists who satisfy requirements of the program.

(B) The application for approval shall specifically state how the accreditation certificates will be presented to participants.

(9) The executive director must approve changes in the date, starting time, or duration of the program being presented if said changes are made after initial accreditation.

(10) Changes in speakers are acceptable if the quality of the program being presented is not diminished.

(11) The executive director must receive any changes in topics to be presented at least seven (7) days before the program is to be presented.

(12) The organization presenting a continuing education program must provide reasonable notification to potential participants of any changes in:

(A) Date, time, or duration of the program;

(B) Speakers; or

(C) Topics to be presented.

(13) The program administrator shall require all participating pharmacists to sign in and out to show attendance during the entire CE session unit in order to be eligible for credit.

(14) The program administrator must keep a record of all attendees receiving credit for four (4) years for verification by the board.

(e) Programs sponsored and conducted by local pharmacists' associations will be accredited provided that the programs meet the criteria outlined in subsections (c) and (d) of this section in addition to the following procedures:

(1) The program shall be structured and shall be offered to all pharmacists who are members of the local association;

(2) Each program shall be a minimum of one (1) hour in length; and

(3) The local pharmacists' association shall provide a method of registration and verification of attendance as outlined in subsection (d) of this section.

(f) Failure to follow the guidelines and requirements of 17 CAR § 160-802 will disqualify the program administrator or other entity requesting CE accreditation from being eligible for approval of future program requests.

17 CAR § 160-803. Implementation of pharmacy continuing education.

(a) The Arkansas State Board of Pharmacy adopts the accreditation guidelines set out by the Arkansas Tripartite Committee on Continuing Pharmacy Education for establishment of acceptable continuing education.

(b) The requirements for continuing education will be as follows:

(1) Thirty (30) hours of continuing education each biennium, as approved by the Arkansas Tripartite Committee on Continuing Pharmacy Education;

(2) A minimum of twelve (12) continuing education hours of the thirty (30) required hours must be live contact hours as defined by the Arkansas Tripartite Committee on Continuing Pharmacy Education; and

(3) A minimum of twelve (12) continuing education hours of the thirty (30) required hours must be accredited by the Accreditation Council for Pharmacy Education.

(d) The Arkansas State Board of Pharmacy will accept continuing education credits, approved by state boards of pharmacy in other states, toward licensure as a pharmacist in Arkansas provided that:

(1) There is a reciprocal arrangement; and

(2) The requirements of this section are met.

(e)(1) Pharmacists are required to:

(A) Retain certificates of participation in continuing education for a period of four (4) years; and

(B) Certify completion of the required continuing education on a form furnished by the Arkansas State Board of Pharmacy with the license renewal forms.

(2) The pharmacist must present certificates of participation to any representative of the Arkansas State Board of Pharmacy if requested to do so.

(f)(1) Pharmacists who wish to retain their licenses, but do not want to meet the continuing education requirements, may go on inactive pharmacist status for an indefinite period.

(2) To reestablish active status and return to practice in Arkansas, or to reinstate their license, a pharmacist must acquire the continuing education hours missed plus the continuing education hours for the current licensure period.

(3) If the pharmacist has been on inactive status with regard to continuing education for two (2) calendar years or more and has not been actively practicing pharmacy in another state, said pharmacist shall also comply with all requirements in 17 CAR § 160-203.

(g) Certifications awarded by the Board of Pharmacy Specialties during any biennium will satisfy continuing education requirements for that biennium subject to approval by the Arkansas Tripartite Committee on Continuing Pharmacy Education.

(h) Completion of postgraduate health professional course work may satisfy continuing education requirements subject to approval by the Arkansas Tripartite Committee on Continuing Pharmacy Education.

Subpart 9. Pharmacy Technicians — Registration/Permit Required

17 CAR § 160-901. Definitions.

As used in this part:

(1) "Pharmacy technician" means those individuals, exclusive of pharmacy interns, who assist the pharmacist in pharmaceutical services; and

(2)(A) "Supervision" means that the responsible pharmacist must be physically present to observe, direct, and supervise the pharmacy technician at all times when the pharmacy technician performs acts specified in this rule.

(B) The supervising pharmacist is totally and absolutely responsible for the actions of the pharmacy technician.

17 CAR § 160-902. Registration required.

(a) A pharmacy technician shall:

(1) Register with the Arkansas State Board of Pharmacy on a form provided by the board; and

(2) Undergo a criminal background check pursuant to Subpart 31.

(b) The registration shall expire on December 31 biennially as provided in 17 CAR § 160-107.

(c) The registration fee for a pharmacy technician shall be defined in 17 CAR § 160-107.

(d)(1) No person shall work as a pharmacy technician prior to the board issuing a certificate of registration and a permit.

(2) The permit shall be prominently displayed for public perusal in any pharmacy where the technician is working.

(3) The pharmacist-in-charge shall determine that the person is registered as a pharmacy technician and that the board has issued a permit for the technician before the technician performs any tasks identified in 17 CAR § 160-905 or 17 CAR § 160-906.

(e) If there is a change of mailing address for the pharmacy technician, the pharmacy technician shall immediately notify the board, in writing, of the new address.

(f) When a pharmacy technician leaves the employment of a pharmacy, the pharmacist-in-charge shall notify the board, in writing, within fourteen (14) days.

(g)(1) Any concurrent or subsequent employment at any pharmacy shall be reported to the board by both the pharmacy technician and the pharmacist-in-charge of the pharmacy where the pharmacy technician will be working.

(2) The pharmacist-in-charge must notify the board, in writing, of the exact date when the pharmacy technician will begin working.

(3) The pharmacy technician shall not work at that location until the board has received said notification.

(h) A pharmacy technician shall identify himself or herself as such in any telephone conversation regarding the functions of a pharmacy technician while on duty in the pharmacy.

(i)(1) If the pharmacy technician is suspected to have, or evidence exists that a pharmacy technician may have violated any law or rule regarding the practice of pharmacy, legend drugs, or controlled substances, the pharmacist-in-charge shall notify the board in writing:

(A) Within ten (10) days; or

(B) Immediately if any danger to the public health or safety may exist.

(2) Any other pharmacist, whether or not practicing in the same pharmacy, who has such knowledge or suspicion shall notify the board in a like manner.

(j)(1) The board may, after notice and hearing, suspend or revoke the permit of a pharmacy technician upon a finding of the following:

(A) Violation of this part;

(B) Violation of any law or rule regarding the practice of pharmacy; or

(C) Violation of any law or rule related to legend drugs or controlled substances.

(2) The board shall follow the same procedures for hearings for pharmacy technicians as applicable to hearings for pharmacists as set forth in Arkansas Code § 17-92-101 et seq. and board rules.

17 CAR § 160-903. A pharmacy technician shall.

A pharmacy technician shall:

(1) Conduct himself or herself professionally in conformity with all applicable federal, state, and municipal laws and rules in his or her relationship with:

(A) The public;

(B) Healthcare professionals; and

(C) Pharmacists;

(2) Hold to the strictest confidences all knowledge concerning patrons, their prescriptions, and other confidences entrusted or acquired by him or her, divulging in the interest of the patron only:

(A) By proper release forms; or

(B) Where required for proper compliance with legal authority; and

(3) Provide valid and sufficient checks in payment for licenses or renewals.

17 CAR § 160-904. Qualifications.

(a) A high school graduate or a recognized graduate equivalency degree (GED).

(b)(1) The applicant must complete a criminal background check pursuant to Subpart 31.

(2) If the pharmacy technician has a past record of alcohol or drug addiction or past record of violation of any law related to controlled substances, registration must be prior-approved by the Arkansas State Board of Pharmacy.

17 CAR § 160-905. Tasks, responsibilities, and duties of the pharmacy technician.

(a)(1) A pharmacy technician may assist the pharmacist in performing the following specific tasks in accordance with specific written policy and procedures established by the pharmacist-in-charge covering the areas described in this section.

(2) The supervising pharmacist is responsible for all tasks performed by the pharmacy technician.

(3) All tasks performed by the pharmacy technician must be supervised, checked, and approved by the supervising pharmacist.

(4) If the pharmacy technician performs any other task that is defined as the practice of pharmacy, it will be considered a violation.

(b) Approved tasks:

(1)(A) Placing, packing, pouring, or putting in a container for dispensing, sale, distribution, transferring possession of, vending, or bartering any drug, medicine, poison, or chemical that, under the laws of the United States or the State of Arkansas, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe:

(i) Drugs;

(ii) Medicines;

(iii) Poisons; or

(iv) Chemicals.

(B) This shall also include the adding of water for reconstitution of oral antibiotic liquids;

(2) Placing in or affixing upon any container described in this part a label required to be placed upon drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those:

(A) Drugs;

(B) Medicines;

(C) Poisons; or

(D) Chemicals;

(3) Selecting, taking from, and replacing upon shelves in the prescription department of a pharmacy or apothecary drugs, medicines, chemicals, or poisons that are required by the law of the United States or the State of Arkansas to be sold or dispensed only on prescription of a practitioner authorized by law to prescribe them;

(4)(A) In a manual system, preparing, typing, or writing labels to be placed or affixed on any container described in Arkansas Code § 17-92-101 on which a

label is required to be placed upon drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those:

(i) Drugs;

(ii) Medicines;

(iii) Poisons; or

(iv) Chemicals.

(B)(i) In a computer system, a pharmacy technician may enter information into the pharmacy computer.

(ii) The pharmacy technician shall not make any judgment decisions that could affect patient care.

(iii) The final verification of prescription information entered into the computer shall be made by the supervising pharmacist prior to dispensing, who is then totally responsible for all aspects of the data and data entry;

(5)(A) A pharmacy technician may obtain prescriber authorization for prescription refills provided that nothing about the prescription is changed.

(B) A pharmacy technician shall not receive prescriber authorization for a new prescription by telephone or by other verbal communication;

(6)(A) Prepackaging and labeling of multi-dose and unit dose packages of medication.

(B) The pharmacist must:

(i) Establish the procedures, including selection of:

(a) Containers;

(b) Labels; and

(c) Lot numbers; and

(ii) Check the finished task;

(7) Dose-picking for unit dose cart fill for a hospital or for a nursing home patient;

(8)(A) Nursing unit checks in a hospital or nursing home.

(B) Pharmacy technicians may check nursing units for proper medication storage and other related floor stock medication issues.

(C) Any related medication storage problems or concerns shall be documented and initialed by a pharmacist;

(9) **Patient and medication records.** The recording of patient or medication information in a manual or electronic system for later validation by the pharmacist may be performed by pharmacy technicians; and

(10) The pharmacy technician shall not make any judgment decisions that could affect patient care.

(c)(1) A pharmacy technician may assist in the following tasks when the pharmacist-in-charge has established a specific written policy and procedure for reconstitution of prefabricated noninjectable medication, bulk compounding, and/or preparation of parenteral products that establishes the:

(A) Order of addition of ingredients; and

(B) Point at which the ingredients will be checked by the pharmacist, and the point at which the final product will be checked for:

(i) Integrity;

(ii) Correctness; and

(iii) Pharmaceutical elegance.

(2)(A) Prior to any of these tasks being carried out by a pharmacy technician:

(i) The technician shall successfully complete an initial training, assessment of skills program, and test pursuant to a written training and assessment procedure established by the pharmacist-in-charge as provided in 17 CAR § 160-906; and

(ii) The pharmacist supervising a technician who engages in the above-referenced reconstitution, bulk compounding, and/or preparation of parenteral product shall:

(a) Perform all calculations of ingredients; and

(b) Provide written directions for measurement of ingredients by the technician.

(B) Prior to dispensing any of said products for administration, the supervising pharmacist shall verify and approve in written form all ingredients as well as the final product.

(d)(1) Bulk reconstitution of prefabricated noninjectable medication may include addition of multiple additives.

(2) Bulk compounding may include such items as sterile bulk solutions for small volume injectables, sterile irrigating solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other products for the pharmacy or other departments of the facility.

(3) Preparation of parenteral products.

(4) Pharmacy technicians may:

(A) Reconstitute and withdraw any amount, i.e., partial or entire amount, of an injectable medication to be administered to a patient; and

(B) Reconstitute, withdraw, and add any amount, i.e., partial or entire amount, of one (1) or more injectable products to an IV solution to be administered to a patient.

17 CAR § 160-906. Duties of the pharmacist in the use of pharmacy technicians.

(a) A pharmacist-in-charge who utilizes a pharmacy technician to enter information into the pharmacy computer must develop and keep on file at the pharmacy written policies and procedures that describe the process by which the supervising pharmacist verifies the accuracy, validity, and appropriateness of the filled prescription or medication order.

(b)(1) A pharmacist-in-charge who utilizes a pharmacy technician for bulk reconstitution of prefabricated noninjectable medication, bulk compounding, and/or preparation of parenteral products shall develop written policies and procedures for training, testing, and competency assessment of any pharmacy technicians performing these tasks.

(2) These policies and procedures shall incorporate those standards developed in the American Society of Health-System Pharmacists (ASHP) Guidelines on Quality Assurance for Pharmacy-Prepared Sterile Products (copyright 2002) or an Arkansas State Board of Pharmacy-approved equivalent.

(c) The pharmacist-in-charge shall include in the policy and procedure manual:

(1) The specific scope of responsibilities for pharmacy technicians; or

(2) Procedures delegated to pharmacy technicians.

(d) In each instance in which a pharmacy technician prepares or processes any medication identified in 17 CAR § 160-905, the supervising pharmacist shall:

(1) Supervise the technician participating in those tasks as provided in 17 CAR § 160-901(2);

(2) Personally determine all medication dose calculations and drug compatibilities, maintain proper storage conditions, and verify the proper labeling of all finished products, to include:

(A) For bulk products, the:

(i) Product name;

(ii) Name and strength of each drug;

(iii) Name and volume of each vehicle;

(iv) Preparation and expiration dates; and

(v) Lot or equivalent numbers; and

(B) For individual products, the information required by law for individual prescriptions;

(3) Determine all medication dose calculations and drug compatibilities, maintain proper storage conditions, and verify the proper labeling of all finished products including appropriate expiration dates; and

(4) Record in written form his or her verification of the:

(A) Amount of each ingredient by:

(i) Volume;

(ii) Weight; or

(iii) Measure; and

(B) Final product by lot or equivalent number.

(e) The supervising pharmacist shall ensure that the pharmacy technician maintains confidentiality of all patient records.

(f) The pharmacist-in-charge shall:

(1) Maintain records of each drug product resulting from the procedures identified in subsection (b) of this section for a period of two (2) years; and

(2) Make said records available for inspection by the board to include:

(A) A copy of all individual training, testing, and competency assessments;

(B) The record of verification of ingredients and final drug product described in subdivision (d)(4) of this section; and

(C) Policies and procedures applicable to producing said drug products.

17 CAR § 160-907. Pharmacist-to-support staff ratio.

(a) Each pharmacist on duty in a permitted pharmacy may utilize up to four support staff members (pharmacy technicians, licensed interns or externs) to assist the pharmacist under direct supervision.

(b) Licensed intern(s) working as part of an experiential learning experience as assigned by an ACPE accredited, Board approved College of Pharmacy, and graduate interns shall not count in this ratio.

(c) This ratio shall also exclude supportive personnel whose functions are not directly related to the preparation or distribution of medication. Such persons include, but are not limited to, clerks, secretaries, messengers, and delivery personnel.

Subpart 10. General Rules Regarding Pharmacies

17 CAR § 160-1001. Equipment specifications.

(a) Prescription equipment appropriate for the pharmacy's specific scope of practice shall be maintained by the pharmacy and may include but is not limited to:

(1) Graduates capable of measuring from one-tenth of one milliliter (0.1 ml) to at least one hundred twenty milliliters (120 ml);

(2) Mortars and pestles, at least one (1), porcelain or glass;

(3) Hot and cold running water in the prescription department;

(4) Spatulas;

(5) Ointment slab or ointment papers;

(6) Exempt narcotic record book;

(7) Class III balance and weights or comparable electronic scale;

(8) Equipment for labeling; and

(9)(A) Refrigeration for the proper storage of biologicals and other medications.

(B) Medications shall be stored in a separate compartment or area from food.

(b) Each pharmacy shall maintain a pharmacy library available for use by the pharmacist and the patient, including:

(1) Either current drug information manuals or computers capable of printing current drug information for the pharmacist and patient drug information and monographs for patients; and

(2) Other pharmacy reference books and periodicals necessary for effective pharmacy practice.

(c) **Exceptions.** Pharmacies meeting the requirements of 17 CAR § 160-1209 or 17 CAR § 160-2201 shall be exempt from requirements of this part when not applicable.

17 CAR § 160-1002. Time requirements for pharmacies and for the pharmacist-in-charge.

(a)(1) Unless expressly provided otherwise in Arkansas State Board of Pharmacy rules, all pharmacies in Arkansas shall:

(A) Be open a minimum of forty (40) hours per week; and

(B) Have on duty an Arkansas-licensed pharmacist-in-charge.

(2) The pharmacist-in-charge shall be on duty in the pharmacy:

(A) A minimum of fifty percent (50%) of the pharmacy hours for pharmacies open sixty-four (64) hours per week or fewer; or

(B) At least thirty-two (32) hours per week for pharmacies open more than sixty-four (64) hours per week.

(b)(1) Upon written application and appearance by the owner of a pharmacy before the board, the board may approve a minimum number of hours fewer than forty (40) per week for the pharmacy to be open to the public when the board determines that the reduced number of hours would not be detrimental to the public health, safety, and welfare.

(2) For pharmacies approved to be open fewer than forty (40) hours per week, the pharmacist-in-charge shall be on duty in the pharmacy a minimum of fifty percent (50%) of the pharmacy hours.

(c)(1) In an emergency situation, the Executive Director of the Arkansas State Board of Pharmacy may determine that the health and welfare of the public might be in peril because of a community's limited access to pharmaceutical services if a pharmacy would be forced to close if it was required to remain open forty (40) hours per week.

(2) The executive director may approve a retail pharmacy operation for fewer than forty (40) hours per week for a limited period of time but not beyond the date of the next meeting of the board.

(3) Thereafter, the owner of the pharmacy may request an exemption as provided for in subsection (b) of this section.

(4) The executive director must take into consideration the ultimate health and welfare of the patients in the area in making the determination.

17 CAR § 160-1003. Vending machines.

The sale of any legend drugs or medicines by means of a coin-operated vending machine is expressly prohibited.

17 CAR § 160-1004. Reuse of drugs prohibited.

The reuse of returned portions of a prescription drug for human consumption is prohibited whether dispensed by order of a prescription or otherwise, except to allow:

(1) Patients in nursing facilities to donate unused medications to charitable clinic pharmacies as provided by:

(A) Arkansas Code § 17-92-1101 et seq.; and

(B) 17 CAR §§ 160-1304 and 160-1706; or

(2)(A) Return of oral medications packaged in unit dose or blister packs, oral liquids in sealed unit dose packaging, and injectables in sealed unit dose vials or sealed multi-dose vials that have been sent to a long-term care facility or correctional facility but have not been opened or partially used by that facility.

(B) The aforementioned medications may be returned to the dispensing pharmacy for reuse to another nursing home or correctional facility patient by relabeling the medication if the medication is returned to the pharmacy within seventy-two (72) hours of delivery to the facility provided that:

(i) The drugs were originally dispensed by that pharmacy to the facility;

(ii) Under the pharmacist's professional judgment, the drugs are appropriate for return and reuse;

(iii) Any pharmacist or pharmacy accepting eligible drugs for return or reuse must adopt written policies and procedures governing such drugs to ensure compliance with subdivision (2) of this section;

(iv) Medications meet all federal and state standards for product integrity to the satisfaction of the dispensing pharmacist;

(v) The pharmacist has the assurance from a healthcare professional responsible for the drugs at the facility that the drugs have been stored in accordance with the manufacturer's recommendations;

(vi) Medications requiring refrigeration cannot be returned for reuse; and

(vii) Controlled substances cannot be returned for reuse.

17 CAR § 160-1005. Pick-up stations.

(a) No person, firm, or business establishment shall offer to the public in any manner its services as a "pick-up station" or intermediary for the purpose of having prescriptions filled or delivered, whether for profit or gratuitously.

(b) Nor may the owner of any pharmacy or drug store authorize any person, firm, or business establishment to act for them in this manner, provided, however, intermediary delivery stations after approval by the Arkansas State Board of Pharmacy may be operated in clinics in which a practitioner is in attendance at least one (1) day per week and located in an area where pharmaceutical services are unavailable within ten (10) miles of the clinic provided the filled prescriptions are delivered to a designated representative of the pharmacist filling the prescription.

17 CAR § 160-1006. Emergency pharmacy services.

(a) Any pharmacy providing prescription drugs to one (1) or more patients in a nursing home or other institution shall provide:

(1) Emergency prescription services for those patients; and

(2) Information to the nursing home or institution indicating how the pharmacists can be reached after pharmacy hours.

(b) All pharmacies other than hospital and institutional that do not provide emergency drug services for noninstitutionalized patients shall post a sign at least eight and one-half inches by eleven inches (8 1/2" x 11") with letters of at least one inch (1") stating "This pharmacy will not provide emergency prescription drugs when the pharmacy is closed".

17 CAR § 160-1007. Applications for pharmacy permits.

(a) Pharmacies shall apply for licensure and renewal on forms provided by the Arkansas State Board of Pharmacy.

(b) The permit will be issued to qualified applicants in the name of the licensed pharmacist who shall be directly responsible to the board for the operation of the pharmacy.

17 CAR § 160-1008. Requirements for a new pharmacy permit.

(a) Applications for pharmacy permits, other than biennial renewal of existing permits, will be reviewed by the Arkansas State Board of Pharmacy staff.

(b) Applications for a pharmacy permit for a new pharmacy:

(1) Must have the name and license number of the pharmacist-in-charge at the time of submission; and

(2) Cannot be altered except by submission of an application for change of pharmacist-in-charge and the fee as defined in 17 CAR § 160-107.

(c) If a post office box is used as the address for the pharmacy, the actual location including street address must also be included on the application as all pharmacy permits are for a specific physical location.

(d) The Executive Director of the Arkansas State Board of Pharmacy may require that a representative of the owner or owners and the pharmacist-in-charge appear before the board to finalize the application.

17 CAR § 160-1009. Responsibility of pharmacist, intern, or pharmacy technician.

(a) Any pharmacist, intern, or pharmacy technician participating in the preparation of orders or dispensing of prescriptions and/or any pharmacist who is responsible for supervising pharmacy personnel participating in the preparation of orders or dispensing of prescriptions is responsible for the validity and legality of the order or prescription.

(b) Any pharmacist who is responsible for supervising pharmacy personnel is also responsible for any shortage of drugs classified as controlled drugs under state or federal law that occurs under their supervision.

(c) In a pharmacy's electronic data processing system that can delineate the individual steps in the prescription filling process, the pharmacist overseeing each step would be specifically responsible for that part of the process.

(d) In a pharmacy's electronic data processing system that is not capable of delineating the individual steps in the prescription filling process, the pharmacist or pharmacists involved in the process will share a corresponding liability for each prescription filled.

17 CAR § 160-1010. Pharmacist-in-charge.

(a)(1) When a pharmacist ceases to be employed as a pharmacist-in-charge (PIC) at a pharmacy licensed by the Arkansas State Board of Pharmacy, the pharmacist must immediately notify the board in writing.

(2) The former PIC must provide an inventory of controlled drugs as defined in 17 CAR § 160-1013 to the board within five (5) days of ceasing employment as the PIC.

(b) When a PIC ceases to be employed in that position, the pharmacy permit holder must submit the permit issued in the name of the former PIC to the board within five (5) days.

(c)(1) The PIC is responsible for the:

(A) Security and accountability of all drugs stored in a pharmacy; and

(B) Validity and legality of all prescriptions and/or orders upon which drugs are dispensed in a pharmacy.

(2) The PIC is responsible for ensuring that pharmacy staff has been appropriately trained to follow the pharmacy's policies and procedures.

(d)(1) Any pharmacist, when making his or her initial application to be licensed as PIC, must satisfactorily complete a test on the requirements and responsibilities of a PIC.

(2) The test shall be developed and administered by the board or its representatives.

(e) The PIC named on any licensed pharmacy permit or pharmacist on call as designated by the PIC:

(1) Shall have immediate access to the pharmacy at all times; and

(2) If requested by board inspectors, he or she shall show satisfactory proof of access.

(f) If the pharmacy fails to have on staff a licensed pharmacist acting as the PIC due to extended illness, death, resignation, or for any other reason, the pharmacy permit holder shall notify the board within five (5) days and must within thirty (30) days or such additional time at the discretion of the board:

(1) Either secure the services of an Arkansas-licensed pharmacist to serve as the PIC; or

(2)(A) Cease to operate as a pharmacy in the State of Arkansas.

(B) Operation of the pharmacy without a PIC beyond the time limits set by the board is a violation of law and each day so operated will be a separate offense.

17 CAR § 160-1011. Permit required.

(a)(1) The permit licenses the pharmacy to which it is issued and is not transferable.

(2) It is issued on the application of the owner and the licensed pharmacist-in-charge, on the sworn statement that it will be conducted in accordance with the provisions of law.

(b)(1) Pharmacies opening for business must first secure a permit and be licensed with the Arkansas State Board of Pharmacy before they may lawfully conduct or operate a pharmacy.

(2) A fee defined in 17 CAR § 160-107 is charged for issuing such original permit.

(3) All pharmacies must register with the board and secure a biennial permit and pay a renewal fee as defined in 17 CAR § 160-107.

(c)(1) Permits must be posted in a conspicuous place.

(2) This requirement is not met when a permit is:

(A) Locked in a safe;

(B) Placed in a desk drawer; or

(C) Otherwise hidden away.

(d) No pharmacy may open for business, nor may it be inspected for the purpose of obtaining a permit, prior to the approval by the board.

17 CAR § 160-1012. Change of ownership.

(a)(1) Upon a change of ownership of a pharmacy as set out herein, a new permit shall be secured by the new owner or owners.

(2) The new owner or owners can continue operation of the pharmacy for fourteen (14) days after the effective date of the change of ownership.

(3) After the said fourteen-day period:

(A) The permit issued to the prior owner shall be void; and

(B) Same shall be surrendered to the Executive Director of the Arkansas State Board of Pharmacy.

(b) A change of ownership of a pharmacy occurs under, but is not limited to, the following circumstances:

(1) A change of ownership of a pharmacy owned by a sole proprietor is deemed to have occurred when:

(A) The pharmacy is sold and the sale becomes final or the new owner assumes control of the pharmacy, whichever occurs first; and

(B) The proprietor enters into a partnership with another individual or business entity;

(2) A change of ownership of a pharmacy owned by a partnership is deemed to have occurred when:

(A) There is an addition or deletion of one (1) or more partners in a partnership to which a pharmacy license has been issued; and

(B) The pharmacy is sold and the sale becomes final or the new owner assumes control of the pharmacy, whichever occurs first;

(3) A change of ownership of a pharmacy owned by a corporation is deemed to have occurred when:

(A)(i) An individual or business acquires or disposes of twenty percent (20%) or more of the corporation's outstanding shares of voting stock.

(ii) This shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market;

(B)(i) The corporation merges with another business or corporation.

(ii) The corporation owning the pharmacy is required to notify the Arkansas State Board of Pharmacy if a change of ownership or merger occurs within the parent corporation of the corporation that owns the pharmacy;

(C) The corporation's charter expires or is forfeited; or

(D) The pharmacy is sold and the sale becomes final or the new owner assumes control of the pharmacy, whichever occurs first; and

(4) A change of ownership of a pharmacy is deemed to have occurred when the pharmacy is leased by another individual or entity that is wholly responsible for the operation of the pharmacy under the terms of the lease agreement.

(c) The responsibility to ensure compliance with this part rests both with the pharmacist and with the pharmacy permit holder if they are not the same.

17 CAR § 160-1013. Inventory required.

(a)(1) When there is a change of pharmacy permit because of a change of ownership of the pharmacy, an inventory of all drugs now or hereafter classified as Schedule II, III, IV, or V drugs under either federal or state statutes shall be made by the pharmacist-in-charge on the day the new owner takes possession of the pharmacy.

(2) A copy of that inventory signed by the pharmacist-in-charge shall be submitted with the application for change of ownership and the fee for change of ownership as defined in 17 CAR § 160-107.

(b)(1) When there is a change of pharmacy permit because of a change of pharmacist-in-charge only, an inventory of all drugs now or hereafter classified as Schedule II, III, IV, or V drugs under either federal or state statutes will be made by the exiting pharmacist-in-charge and a copy of that inventory signed by said pharmacist

shall be furnished to the Arkansas State Board of Pharmacy within seven (7) days after the pharmacist's last day to work at the pharmacy and a copy left with the Controlled Substance Records of the pharmacy.

(2) The new pharmacist-in-charge shall also immediately inventory all drugs now or hereafter classified as Schedule II, III, IV, or V drugs under federal or state statutes and a copy of that inventory signed by the new pharmacist-in-charge shall be provided to the board with the application to change the pharmacy permit's pharmacist-in-charge.

(c) It is acceptable and preferable if the inventory is made jointly by the exiting and the new pharmacist-in-charge, signed by both pharmacists, and supplied to the board with the application for change of pharmacist-in-charge.

(d) If a joint inventory is not provided, both copies of said inventory (exiting pharmacist-in-charge and new pharmacist-in-charge) must be received by the board before a new permit will be issued.

17 CAR § 160-1014. Owner's responsibility — Pharmacist is licensed.

No owner or owners of a drugstore, apothecary, pharmacy, etc., shall allow any of its employees to profess to the public in any manner that they are a licensed pharmacist when they are not licensed.

17 CAR § 160-1015. Responsibility for security of controlled drugs.

(a) The permit holder and the pharmacist-in-charge are jointly responsible for the security and accountability of all controlled drugs stored in and/or ordered by a pharmacy.

(b)(1) The permit holder shall provide diversion prevention and detection tools appropriate for the particular pharmacy setting and the pharmacist-in-charge shall implement and monitor the diversion control and detection tools provided by the permit holder.

(2) Appropriate tools may include:

(A) Perpetual inventory;

(B) Automatic or limited-access online ordering;

(C) Reports comparing drugs ordered versus drugs dispensed and drugs manually ordered or adjusted; and

(D) Individual passwords for each employee to enter the pharmacy or access the computer.

(c)(1) The pharmacist-in-charge and the permit holder shall also develop policies and procedures to prevent and detect diversion and the pharmacist-in-charge shall ensure that pharmacy staff is trained to follow the policies and procedures.

(2) Appropriate policies and procedures may include:

(A) Limiting access by nonpharmacists to controlled drug shipments;

(B) Performing quarterly audits on high-risk drugs;

(C) Confirming pill count before opening a new bottle of high-risk drugs;

(D) Tracking pill count on stock bottles; and

(E) Requiring staff to use the tools provided by the permit holder.

(d) Pharmacists, pharmacy interns, and pharmacy technicians shall implement the tools provided by the permit holder and follow the pharmacy's policies and procedures as instructed by the pharmacist-in-charge.

Subpart 11. Pharmacy Permit Fees

17 CAR § 160-1101. Permit fees.

(a) Any person, corporation, or partnership operating a pharmacy in this state desiring to continue such operation must pay a renewal fee for the permit as established by law and/or rule.

(b) If the fee is not paid on or before February 1 of any even-numbered year, a penalty as defined in 17 CAR § 160-107 shall be levied for each month the pharmacy permit fee is delinquent.

(c) If the permit fee is unpaid by April 1 of any even-numbered year, the:

(1) Licensed pharmacy shall be expunged from the records of the Arkansas State Board of Pharmacy; and

(2) Owner and/or pharmacist-in-charge thereof shall, within thirty (30) days:

(A) Remove all drug signs; and

(B) Legally dispose of all prescription legend drugs.

Subpart 12. Rules Regarding Retail Pharmacies

17 CAR § 160-1201. Applications for pharmacy permits.

(a) Retail pharmacies shall apply for licensure and renewal on forms provided by the Arkansas State Board of Pharmacy.

(b) The permit will be issued to qualified applicants in the name of the licensed pharmacist who shall be directly responsible to the board for the operation of the prescription department.

17 CAR § 160-1202. Requirements for a new retail pharmacy permit.

(a)(1) No retail pharmacy may open for business within thirty (30) days of submission of the original application.

(2) Applications for a pharmacy permit for a new retail pharmacy:

(A) Must have the name and license number of the pharmacist-in-charge at the time of submission; and

(B) Cannot be altered except by submission of an application for change of pharmacist-in-charge and the fee as defined in 17 CAR § 160-107.

(3) The pharmacist-in-charge of the new pharmacy application cannot be the pharmacist-in-charge of another pharmacy at the time of submission of the new pharmacy application.

(4) The Executive Director of the Arkansas State Board of Pharmacy may require that a representative of the owner or owners and the pharmacist-in-charge appear before the Arkansas State Board of Pharmacy to finalize the application.

(5) After review by the board staff, an Inspection Request Form will be sent to the mailing address of the pharmacy making application.

(6) The Inspection Request Form must be received in the board office at least one (1) week before the facility will be ready for inspection.

(b) Upon approval of the inspection of the physical facility by the board inspector, the:

(1) Executive director will complete the final approval of the application; and

(2) Permit number will be issued.

17 CAR § 160-1203. Leased operations — Pharmacy is a department of another business.

(a) In any building, firm, or place of business where the pharmacy is a leased operation, and/or in situations where the pharmacist-in-charge does not own a substantial part of the business and is not manager of the total operation, and/or where the pharmacy is a department in a larger business that is not a drugstore or pharmacy, the prescription department shall be:

(1) Completely separated from the remainder of the building by some type of partition; and

(2) Arranged and constructed so that the public will not have access to any legend drugs or medicine.

(b) The prescription area or department of any pharmacy, firm, or place of business must be constructed so that it may be locked to prevent unauthorized persons from entering it in the absence of a licensed pharmacist or other authorized prescription personnel.

(c) A copy of the signed lease must be submitted:

(1) With the application of the original permit; and

(2) At such other times as the original lease is changed or renewed.

17 CAR § 160-1204. Necessary equipment required.

No pharmacy permit shall be issued or continued for the conduct of a pharmacy unless the premises are:

(1) Equipped with the necessary appliances for maintenance of proper sanitation; and

(2) Kept in a clean, sanitary, and orderly manner.

17 CAR § 160-1205. Retail veterinary pharmacy.

(a) A pharmacy that provides a prescription directly to a veterinary patient in Arkansas may accept payment for the prescription for a contracted price that is less than the price paid by the patient, only if:

(1) The veterinarian:

(A) Collects payment from the patient; and

(B) Forwards the contracted price for the prescription to the pharmacy; or

(2) Payment from the patient is deposited into an account held jointly by the veterinarian and the pharmacy and payment for the contracted price is distributed to each party.

(b) Under no circumstances may a pharmacy:

(1) Provide any type of remuneration directly to a veterinarian in connection with a prescription; or

(2) Maintain a shared inventory with a veterinarian.

(c) A pharmacy may allow a veterinarian to place its icon or other logo on the veterinarian website only if the site prominently displays a notice that patients may obtain prescriptions and refills from the pharmacy of their choice.

17 CAR § 160-1206. Regulating the use of electronic data processing in lieu of present recordkeeping systems in pharmacies holding pharmacy permits.

(a)(1) This part shall be construed, if possible, so as not to be in violation of or in conflict with any federal regulation or requirement, and if any part hereof is held invalid

because of such conflict, such invalidity shall not affect other provisions or applications of this part that can be given effect without the invalid provisions and to this end, the provisions of this part are declared severable.

(2) In any event, Drug Enforcement Administration permission to use electronic data processing recordkeeping systems must be obtained.

(b) The Arkansas State Board of Pharmacy must approve the system prior to implementation.

(c)(1) Input of drug information into the system may be performed only by a pharmacist or by a pharmacy technician under the supervision of a pharmacist.

(2) The final verification of prescription information into the computer shall be made by the supervising pharmacist, who is then totally responsible for all aspects of the data and data entry.

(3) Any judgmental decision concerning patient utilization of drugs must be performed by a pharmacist.

(d) The original prescription order must be readily retrievable and filed according to all applicable rules.

(e)(1) An electronic data processing system:

(A) Must be readily retrievable electronically online or by hard copy; and

(B) Shall be capable of printing a hard copy record.

(2) Said hard copy record or electronic database record shall be available upon request by a board representative or other state or federal agencies with authority to obtain such records within forty-eight (48) hours of the request.

(3) The system must be capable of furnishing the following information:

(A)(i) Must provide online retrieval, electronic record or hard copy, of original prescription order information.

(ii) This shall include, but not be limited to, the following:

(a) Original prescription order number, date filled, full name and address of patient, and name, address, and Drug Enforcement Administration number, if applicable, of practitioner;

(b) Trade name, or generic name and manufacturer's name, strength, dosage form, and quantity of drug dispensed; and

(c) Number of authorized refills, or if not refillable, it must be so indicated;

(B) Must provide online retrieval, electronic record or hard copy, of refill history of each prescription order to include, in addition to information specified in this section but not limited to the following:

(i) Initials or code designation of dispensing pharmacist for each refill;

(ii) Date refilled; and

(iii) Number of authorized refills remaining;

(C) **Daily prescription record.** Must provide a daily prescription record, or hard copy printout of each day's prescription order activity, to include but not limited to the following:

(i) Date of record;

(ii) Prescription order number, patient's name, name of drug, quantity dispensed and dosage form of drug, practitioner's name and Drug Enforcement Administration number, if applicable, and dispensing pharmacist's designation or initials on each prescription;

(iii)*(a)* If the pharmacy is using a hard copy printout, it may be replaced by monthly log containing the same information.

(b) This information must be maintained at the pharmacy for a period of two (2) years;

(iv) Any electronic data processing system must ensure strict confidentiality of patient records;

(v) All required information must be entered on the records of all prescription orders filled at the pharmacy, including nonrefillable prescriptions, and must be maintained for a period of no fewer than two (2) years;

(vi) Must be capable of producing a patient profile, electronic record or hard copy, indicating all drugs being taken and dates of refills for the patient;

(vii)*(a)* A pharmacy shall make arrangements with a supplier of data processing services or materials to ensure continuing adequate and complete prescription orders and dispensing records.

(b) If for any reason the relationship with said supplier terminates, the pharmacy shall ensure the continuity of records; and

(viii)*(a)* The pharmacist-in-charge of the pharmacy shall maintain a bound log book in which each individual pharmacist or individual intern involved in dispensing of prescriptions shall sign a statement each day attesting to the fact that the prescription information entered into the computer that day has been reviewed by him or her and is correct as shown.

(b) The log shall identify the time of day at which the pharmacist or intern:

(1) Started filling prescriptions; and

(2) Stopped filling prescriptions.

(c) Said log book shall be maintained by the pharmacist-in-charge or his or her successor in the pharmacy for a period of two (2) years after the date of dispensing the appropriately authorized prescription;

(D) Must be capable of providing a refill-by-refill audit trail for any specific strength and dosage form of any drug in the system, to contain but not limited to the following:

(i) Practitioner's name;

(ii) Name and address of patient;

(iii) Name of drug (must include manufacturer's name if generic name used);

(iv) Quantity dispensed on original and each refill;

(v) Prescription order number;

(vi) Initials or code designation of dispensing pharmacist on original and each refill; and

(vii) Date of original and each refill;

(E)(i) If the pharmacy closes, it shall be the responsibility of the pharmacist-in-charge to ensure that all prescription records:

(a) Are readily retrievable; and

(b) Can be easily accessed.

(ii) The pharmacist-in-charge:

(a) At the date of closing, shall store said records; and

(b) Within fourteen (14) days of closing, shall notify the board where said records are located.

(iii) That pharmacist-in-charge shall ensure that a hard copy printout or a retrievable electronic record of any prescription records shall be produced and made available to:

(a) A board representative on his or her request; and

(b) Any other person authorized by law to examine or receive copies of prescription records.

(iv) The records must be kept in a readily retrievable format for a period of two (2) years from the official closing date of the pharmacy;

(F)(i) In the event of computer breakdown (down time), the pharmacy must have an approved auxiliary recordkeeping system.

(ii) This system must contain all necessary information to ensure prompt data entry into the system as soon as the computer is available; and

(G) If maintaining the Patient Daily Medication Record electronically, the data must be backed up at least daily, preferably continuously.

(f) In a pharmacy system that can delineate the individual steps in the prescription filling process, the pharmacist overseeing each step would be specifically responsible for that part of the process.

(g) In a system that is not capable of delineating the individual steps in the prescription filling process, the pharmacist or pharmacists involved in the process will share a corresponding liability for each prescription filled.

17 CAR § 160-1207. Central fill pharmacy.

(a) A retail pharmacy with a licensed pharmacy permit may also act as a central fill pharmacy if the following requirements are met.

(b) **Definition.** As used in this part:

(1) "Central fill pharmacy" means a pharmacy that is licensed by the Arkansas State Board of Pharmacy ("the board") to prepare legend and controlled substances orders for dispensing pursuant to a valid prescription transmitted to it by a licensed retail pharmacy and to deliver the labeled and filled prescriptions in accordance with federal and state law.

(2) Provided, however, the central fill pharmacy may deliver prescriptions for controlled substances only in accordance with Drug Enforcement Administration regulations.

(3) Such a central fill pharmacy shall be deemed authorized to fill prescriptions on behalf of a retail pharmacy only if the retail pharmacy and central fill pharmacy:

(A) Have a contractual relationship providing for such activities; or

(B) Share a common owner.

(4) Both the retail pharmacy and the central fill pharmacy involved in these activities share a corresponding responsibility regarding central fill prescriptions.

(c) **Recordkeeping.**

(1)(A) Every retail pharmacy that utilizes the services of a central fill pharmacy must keep a record of all central fill pharmacies, including name, address, and Drug Enforcement Administration number, that are authorized to fill prescriptions on its behalf.

(B) The retail pharmacy must also verify the registration for each central fill pharmacy authorized to fill prescriptions on its behalf at the beginning of each registration period for the central fill pharmacy.

(C) These records must be made available upon request for inspection.

(2)(A) Every central fill pharmacy must keep a record of all retail pharmacies, including name, address, and Drug Enforcement Administration number, for which it is authorized to fill prescriptions.

(B) The central fill pharmacy must also verify the registration for all retail pharmacies for which it is authorized to fill prescriptions at the beginning of each registration period for each retail pharmacy.

(C) These records must be made available upon request for inspection.

(d) **Provision of prescription information of Schedule II controlled substances.**

(1)(A) Prescriptions for controlled substances listed in Schedule II may be transmitted electronically from a retail pharmacy to a central fill pharmacy, including via facsimile.

(B) The retail pharmacy transmitting the prescription information must:

(i) Electronically record or write the word "CENTRAL FILL" on the face of the original prescription and record the:

(a) Name, address, and Drug Enforcement Administration registration number of the central fill pharmacy to which the prescription has been transmitted;

(b) Name of the retail pharmacy pharmacist transmitting the prescription; and

(c) Date of transmittal;

(ii) Ensure that all information required to be on a prescription pursuant to federal and state law is transmitted to the central fill pharmacy, either on the face of the prescription or in the electronic transmission of information;

(iii) Maintain the original prescription for a period of two (2) years from the date the prescription was filled; and

(iv) Keep a record of receipt of the filled prescription, including the:

(a) Date of receipt;

(b) Method of delivery (private, common, or contract carrier);

(c) Identity of carrier; and

(d) Name of the retail pharmacy employee accepting delivery.

(2) The central fill pharmacy receiving the transmitted prescription must:

(A) Keep a copy of the prescription, if sent via facsimile, or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and Drug Enforcement Administration registration number of the retail pharmacy transmitting the prescription;

(B) Keep a record of the:

(i) Date of receipt of the transmitted prescription;

(ii) Name of the pharmacist filling the prescription; and

(iii) Date of filling of the prescription;

(C) Track the prescription drug order during each step in the filling process and identify the name or names, initials, or identification code or codes, and specific activity or activities of each pharmacist or pharmacy technician who performed any portion of the process including:

(i) Transmission;

(ii) Filling;

(iii) Dispensing; or

(iv) Delivery; and

(D) Keep a record of the:

(i) Date the filled prescription was delivered to the retail pharmacy;

(ii) Method of delivery, i.e., private, common, or contract carrier; and

(iii) Identity of the carrier.

(3) Central fill pharmacies shall not be authorized to prepare prescriptions for a controlled substance listed in Schedule II upon receiving an oral authorization from a retail pharmacist or an individual practitioner.

(e) **Provision of prescription information for initial and refill prescriptions of legend or Schedules III, IV, or V controlled substances.**

(1)(A) Prescriptions for legend or controlled substances listed in Schedules III, IV, or V may be transmitted electronically from a retail pharmacy to a central fill pharmacy, including via facsimile.

(B) The retail pharmacy transmitting the prescription information must:

(i) Electronically record or write the words "CENTRAL FILL" on the face of the original prescription and record the:

(a) Name, address, and Drug Enforcement Administration registration number of the central fill pharmacy to which the prescription has been transmitted;

(b) Name of the retail pharmacy pharmacist transmitting the prescription; and

(c) Date of transmittal;

(ii) Ensure that all information required to be on a prescription pursuant to federal and state law is transmitted to the central fill pharmacy, either on the face of the prescription or in the electronic transmission of information;

(iii) Indicate in the information transmitted the number of refills already dispensed and the number of refills remaining;

(iv) Maintain the original prescription for a period of two (2) years from the date the prescription was last refilled; and

(v) Keep a record of receipt of the filled prescription, including the:

(a) Date of receipt;

(b) Method of delivery (private, common, or contract carrier);

(c) Identity of the carrier; and

(d) Name of the retail pharmacy employee accepting delivery.

(2) The central fill pharmacy receiving the transmitted prescription must:

(A) Keep a copy of the prescription, if sent via facsimile, or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and Drug Enforcement Administration registration number of the retail pharmacy transmitting the prescription;

(B) Keep a record of the:

(i) Date of receipt of the transmitted prescription;

(ii) Name of the licensed pharmacist filling the prescription; and

(iii) Dates of filling or refilling of the prescription;

(C) Track the prescription drug order during each step in the filling process and identify the name or names, initials, or identification code or codes, and specific activity or activities of each pharmacist or pharmacy technician who performed any portion of the process including:

(i) Transmission;

(ii) Filling;

(iii) Dispensing; or

(iv) Delivery; and

(D)(i) Keep a record of the:

(a) Date the filled prescription was delivered to the retail pharmacy;

(b) Method of delivery (i.e., private, common, or contract carrier); and

(c) Identity of the carrier.

(ii) Prescriptions for controlled substances that are prepared by the central fill pharmacy may only be delivered to the ultimate user in accordance with Drug Enforcement Administration regulations.

(f) **Carriers to transport filled prescriptions.**

(1)(A) Central fill pharmacies must comply with all federal and state requirements when using private, common, or contract carriers to transport filled prescriptions to:

(i) The ultimate user; or

(ii) A retail pharmacy for delivery to the ultimate user.

(B) When central fill pharmacies contract with private, common, or contract carriers to transport filled prescriptions to a retail pharmacy, the central fill pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a Drug Enforcement Administration Form 106.

(2)(A) Retail pharmacies must comply with all federal and state laws when using private, common, or contract carriers to retrieve filled prescriptions from a central fill pharmacy.

(B) When retail pharmacies contract with private, common, or contract carriers to retrieve filled prescriptions from a central fill pharmacy, the retail pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a Drug Enforcement Administration Form 106.

(g) **Labeling.** The central fill pharmacy shall:

(1) Affix to the package a label showing the retail pharmacy name and address and a unique identifier, which shall be the central fill pharmacy's Drug Enforcement Administration registration number or a board-assigned identifier, indicating that the prescription was filled at the central fill pharmacy;

(2) Indicate in some manner which pharmacy filled the prescription, e.g., "Filled by ABC Pharmacy for XYZ Pharmacy"; and

(3) Comply with all other labeling requirements of federal and state statutes.

(h) **Policies and procedures.**

(1) A policy and procedure manual as it relates to centralized filling shall be:

(A) Maintained at the filling, originating, and dispensing pharmacies; and

(B) Available for inspection.

(2) Each pharmacy is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy's operations.

(3) The manual shall:

(A) Outline the responsibilities of each of the filling, originating, and dispensing pharmacies;

(B) Include a list of the names, addresses, telephone numbers, and all license/registration numbers of the pharmacies involved in centralized prescription filling; and

(C) Include policies and procedures for:

(i) Notifying patients that their prescriptions may be outsourced to another pharmacy for centralized prescription filling, and the name of that pharmacy;

(ii) Protecting the confidentiality and integrity of patient information;

(iii) Dispensing prescription drug orders when the:

(a) Filled order is not received; or

(b) Patient comes in before the order is received;

(iv) Complying with federal and state laws and rules;

(v) Operating a continuous quality improvement program for pharmacy services designed to objectively and systematically:

(a) Monitor and evaluate the quality and appropriateness of patient care;

(b) Pursue opportunities to improve patient care; and

(c) Resolve identified problems; and

(vi) Annually reviewing the written policies and procedures and documenting such review.

17 CAR § 160-1208. Retail pharmacy off-site order entry.

(a) The purpose of this section is to provide standards for remote or off-site order entry in retail pharmacies within Arkansas licensed by the Arkansas State Board of Pharmacy ("the board").

(b) **Definitions.** As used in this part:

(1) "Drug regimen review" means an evaluation of prescription drug orders and patient profile records for:

(A) Known allergies;

(B) Rational therapy-contraindications;

(C) Reasonable dose and route of administration;

(D) Reasonable directions for use;

(E) Duplication of therapy;

(F) Drug-drug interactions;

(G) Drug-food interactions;

(H) Adverse drug reactions; and

(I) Proper utilization, including overutilization or underutilization;

(2) "Off-site order entry" does not include the dispensing of a prescription drug order but includes any of the following:

(A) Receiving, interpreting, or clarifying prescription drug orders;

(B) Data entering and transferring of prescription drug order information;

(C) Performing drug regimen review;

(D) Reconciling third-party insurance claims;

(E) Obtaining refill and substitution authorizations;

(F) Interpreting clinical data for prior authorization for dispensing;

(G) Performing therapeutic interventions; and

(H) Providing drug information concerning a patient's prescription; and

(3) "Off-site order entry pharmacy" means a retail pharmacy that is licensed by the board to process legend and controlled substance prescriptions that

remotely accesses another pharmacy's electronic database from outside the pharmacy in order to process prescription drug orders, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

(c)(1) The board may approve a request for off-site order entry where the retail pharmacy can demonstrate that the procedure will result in an improvement in patient care by increasing the amount of time for pharmacist involvement in the process of medication review for safety and efficacy prior to the administration of the medication to the patient.

(2) Off-site order entry shall be prohibited out of state for prescriptions dispensed in the State of Arkansas.

(d)(1) The pharmacist-in-charge or the permit holder of the retail pharmacy shall submit a written request for off-site order entry a minimum of thirty (30) days prior to the board meeting at which the pharmacist seeks board approval.

(2)(A) The request shall be accompanied by a policy and procedure manual for off-site order entry that shall be:

(i) Maintained at all pharmacies involved in off-site order entry; and

(ii) Available for inspection.

(B) Each pharmacy is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy's operations.

(C) The manual shall:

(i) Outline the responsibilities of each of the pharmacies;

(ii) Include a list of the names, addresses, and telephone numbers of the pharmacies involved in off-site prescription order entry; and

(iii) Include policies and procedures for:

(a) Patient confidentiality and full compliance with HIPAA requirements; and

(b) Maintenance of appropriate records to identify the:

(1) Name or names, initials, or identification code or codes, and specific activity or activities of each pharmacist or pharmacy technician who performed any processing; and

(2) The store it was processed in;

(iv) Specify that only a pharmacist or pharmacy technician holding a current Arkansas license or registration in good standing shall enter orders at a remote or off-site entry location that is a duly licensed pharmacy;

(v) Comply with federal and state laws and rules; and

(vi) Include procedures for annually reviewing the written policies and procedures for needed modification with documentation of such review.

(e) **General requirements.**

(1) A pharmacy may utilize the services of an off-site order entry pharmacy provided the pharmacies:

(A) Share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to process a nondispensing function and have the same owner; or

(B) Entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and rules.

(2) An off-site order entry pharmacy shall comply with the provisions contained in 17 CAR § 160-1206 and 17 CAR § 160-2009 to the extent applicable for the specific processing activity and this section, including:

(A) Duties that must be performed by a pharmacist; and

(B) Supervision requirements for pharmacy technicians.

(3) Off-site order entry may only be performed by a retail pharmacy as appropriately licensed by the board.

(f) **Notifications to patients.** A pharmacy that outsources off-site prescription order entry to another pharmacy shall, prior to outsourcing their prescription:

(1) Notify patients that prescription processing may be outsourced to another pharmacy; and

(2)(A) Give the name of that pharmacy, or if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may process the prescription, the patient shall be notified of this fact.

(B) Such notification may be provided through:

(i) A one-time written notice to the patient; or

(ii) Use of a sign in the pharmacy.

(g) **Records.**

(1) All pharmacies shall maintain appropriate records that identify, by prescription drug order, the name or names, initials, or identification code or codes of each pharmacist or pharmacy technician who performs a processing function for a prescription drug order.

(2) Any record generated in this process, whether in a hard copy or electronic format, shall be maintained for a minimum period of two (2) years from the last date of entry.

(3) Such records may be maintained:

(A) Separately by each pharmacy and pharmacist; or

(B) In a common electronic file as long as the records are maintained in such a manner that the data processing system can produce a printout that lists the functions performed by each pharmacy and pharmacist.

(h) In the operation of the off-site order entry, patient confidentiality and full compliance with HIPAA requirements shall be observed at all times.

17 CAR § 160-1209. Nuclear pharmacy.

(a)(1) The practice of nuclear pharmacy is hereby recognized as a specialty of pharmacy practice regulated by the Arkansas State Board of Pharmacy.

(2) As such, the following rules are included to address those areas specific or unique to this specialty practice.

(3) This part is intended to supplement the rules and regulations of other state and federal agencies.

(b) **Definitions.** As used in this part:

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

(2) "Nuclear pharmacy" means a pharmacy that:

(A) Provides radiopharmaceutical services; and

(B) Shall be licensed by the Arkansas State Board of Pharmacy;

(3) "Practice of nuclear pharmacy" means a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs;

(4) "Qualified nuclear pharmacist" means a pharmacist who holds a current license issued by the Arkansas State Board of Pharmacy and who is certified as a nuclear pharmacist by a certification board recognized by the Arkansas State Board of Pharmacy, or satisfies each of the following requirements:

(A) Meets minimal standards of training for status as an authorized user of radioactive material as specified by the Radiation Control Section of the Department of Health and federal Emergency Management of the Nuclear Regulatory Commission;

(B) Has successfully completed a minimum of two hundred (200) contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from a college of pharmacy approved by the Arkansas State Board of Pharmacy, or other training program recognized by the Arkansas State Board of Pharmacy, with the minimum two hundred (200) hours apportioned as follows:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiation biology; and

(v) Radiopharmaceutical chemistry;

(C) Has attained a minimum of five hundred (500) hours of clinical/practical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in, but not limited to, the following areas:

(i) Procuring radioactive materials;

(ii) Compounding radiopharmaceuticals;

(iii) Performing routine quality control procedures;

(iv) Dispensing radiopharmaceuticals;

(v) Distributing radiopharmaceuticals;

(vi) Implementing basic radiation protection procedures;

(vii) Consulting and educating:

(a) The nuclear medicine community;

(b) Pharmacists;

(c) Other health professionals; and

(d) The general public; and

(D) Has submitted an affidavit of experience and training to the Arkansas State Board of Pharmacy;

(5) "Quality assurance procedures" means all activities necessary to ensure the quality of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by pertinent regulatory agencies;

(6) "Quality control testing" means the:

(A) Performance of chemical, biological, and physical tests on compounded radiopharmaceuticals; and

(B) Interpretation of the resulting data to determine their suitability for use in humans and animals;

(7)(A) "Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of any such substance but that does not include drugs such as

carbon-containing compounds or potassium-containing salts that contain trace quantities of naturally occurring radionuclides.

(B) The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide; and

(8) "Radiopharmaceutical services" means the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, distribution, transfer, recordkeeping, and disposal of radiochemicals, radiopharmaceuticals, and ancillary drugs, and also includes quality assurance procedures, radiological health activities, and consulting activities associated with the use of radiopharmaceuticals, health physics, and any other activities required for provision of pharmaceutical care.

(c) **General requirements for pharmacies providing radiopharmaceutical services.**

(1)(A) A permit to operate a nuclear pharmacy providing radiopharmaceutical services shall only be issued to a facility employing a qualified nuclear pharmacist.

(B) All personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of a qualified nuclear pharmacist who shall be in personal attendance when the nuclear pharmacy is open for business.

(C) The pharmacist-in-charge shall be responsible for all operations of the nuclear pharmacy.

(2) The permit to operate a nuclear pharmacy is effective only so long as the nuclear pharmacy also holds a current Department of Health or Nuclear Regulatory Commission license.

(3)(A) Nuclear pharmacies shall have adequate space and equipment commensurate with the scope of services required and provided.

(B) All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas:

(i) Radiopharmaceutical preparation/dispensing area;

(ii) Radioactive material shipping/receiving area;

(iii) Radioactive material storage area; and

(iv) Radioactive waste decay area.

(C) The application for a permit to operate a nuclear pharmacy shall include detailed floor plans, and no material change may be made without the permission of the Arkansas State Board of Pharmacy.

(4) The nuclear pharmacy professional service area:

(A) Shall be secured from unauthorized personnel; and

(B) Must be totally enclosed and lockable.

(5) Nuclear pharmacies shall maintain records of acquisition, inventory, and disposition of all radioactive materials in accordance with Arkansas State Board of Pharmacy and Department of Health or Nuclear Regulatory Commission statutes and regulations.

(6)(A) Nuclear pharmacies shall compound and dispense radiopharmaceuticals in accordance with accepted standards of radiopharmaceutical quality assurance.

(B) The Arkansas State Board of Pharmacy recognizes that the preparation of radiopharmaceuticals involves the compounding skills of the nuclear pharmacist to ensure that the final drug product meets accepted professional standards.

(7)(A) A radiopharmaceutical shall be dispensed only to a licensed practitioner authorized by the Department of Health or Nuclear Regulatory Commission to possess, use, and administer such drug.

(B) A radiopharmaceutical shall be dispensed only upon receipt of a prescription or medication order from such licensed practitioner.

(C) Otherwise, a radiopharmaceutical may be transferred to a person who is authorized to possess and use such drug for nonclinical applications.

(8)(A) A nuclear pharmacy, upon receipt of an oral prescription order for a radiopharmaceutical, shall immediately have the prescription order reduced to writing or electronically documented.

(B) The written or electronic record shall contain at least the following:

(i) The name of the institution and prescriber or prescriber's agent;

(ii) The date of dispensing and the calibration time of the radiopharmaceutical;

(iii) The name of the procedure;

(iv) The name of the radiopharmaceutical;

(v) The dose or quantity of the radiopharmaceutical;

(vi) The serial number assigned to the order for the radiopharmaceutical;

(vii) Any specific instructions; and

(viii) The initials of the person who dispensed the order.

(C) Orders for routine diagnostic radiopharmaceuticals that have been previously established by the nuclear pharmacist with the physician may be:

(i) Taken by a pharmacy technician; and

(ii) Entered into the computer.

(D) The nuclear pharmacist shall verify the label with the written order.

(E) However, whenever an order is for a therapeutic or blood-product radiopharmaceutical, the:

(i) Prescription order must be received by a nuclear pharmacist; and

(ii) Patient's name must be obtained and recorded prior to dispensing.

(9)(A) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:

(i) The name and address of the pharmacy;

(ii) The name of the prescriber;

(iii) The date of dispensing;

(iv) The serial number assigned to the order for the radiopharmaceutical;

(v) The standard radiation symbol;

(vi) The words "Caution Radioactive Material";

(vii) The name of the procedure;

(viii) The radionuclide and chemical form;

(ix) The amount of radioactivity and the calibration date and time;

(x) If a liquid, the volume;

(xi) If a solid, the number of items or weight;

(xii) If a gas, the number of ampoules or vials;

(xiii) Molybdenum 99 content to USP limits; and

(xiv)*(a)* The name of the patient or the words "Per Physician's Order" in the absence of a patient name.

(b) The requirements of this subsection shall be met when the name of the patient is readily retrievable from the physician upon demand.

(B) When the prescription is for a therapeutic or blood-product radiopharmaceutical, the patient name shall appear on the label prior to dispensing.

(10) The immediate inner container label of a radiopharmaceutical to be dispensed shall be labeled with:

(A) The standard radiation symbol;

(B) The words "Caution Radioactive Material";

(C) The identity of the radionuclide;

(D) The chemical form;

(E) The name of the procedure; and

(F) Serial number of the radiopharmaceutical.

(11) When a radiopharmaceutical is dispensed under the authority of an Investigational New Drug Application, the nuclear pharmacy records shall include:

(A) An investigator's protocol for the preparation of the radiopharmaceutical;

(B) A copy of the Institutional Review Board approval form or letter; and

(C) A letter from the manufacturer (sponsor) indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

(12) Each nuclear pharmacy shall have a current copy of state and applicable federal rules and regulations governing the safe storage, handling, use, dispensing, transport, and disposal of radiopharmaceuticals.

(d) **Minimum equipment.** The professional area of the pharmacy shall have equipment appropriate for the pharmacy's specific scope of practice, which may include but is not limited to the following:

(1) Radionuclide dose calibrator;

(2) Refrigerator;

(3) Single-channel or multiple-channel scintillation counter with well-type Nal(TI) or Ge(Li) detector;

(4) Radiochemical fume hood and filter system with suitable air sampling equipment;

(5) At least two (2) GM survey meters, including one (1) high-range meter;

(6) Microscope and hemacytometer;

(7) Supplies to perform quality assurance testing;

(8) Syringe and vial radiation shields;

(9) Lead-shielded drawing station;

(10) Decontamination supplies;

(11) Supplies to perform quality assurance testing;

(12) Lead transport shields for syringes and vials; and

(13) Department of Transportation-approved USA Type A, 7A approved transport containers and other labels and supplies for shipping radioactive materials.

Subpart 13. Rules Regarding Retail Specialty Pharmacies

17 CAR § 160-1301. Specialty pharmacy permits.

(a) The Arkansas State Board of Pharmacy may issue a specialty pharmacy permit for a facility to provide unique aspects of pharmaceutical care to an identified patient population as provided in 17 CAR §§ 160-1301 – 160-1304.

(b) Said specialty pharmacies and the pharmacists practicing therein shall comply with applicable federal and state laws and rules, including Arkansas pharmacy law, Arkansas Code § 17-92-101 et seq., and this part, including without limitation 17 CAR § 160-1201 et seq., that are not expressly superseded by the rule or regulation applicable to the specific type of specialty pharmacy.

17 CAR § 160-1302. Methadone clinic specialty pharmacy permit.

(a) **Definitions.** As used in this part:

(1)(A) "Administering" means giving a single dose of methadone, buprenorphine, or other approved medications to a patient to consume onsite.

(B) A physician shall administer or supervise the administration of methadone and the clinic pharmacist shall retain appropriate methadone administration records;

(2)(A) "Dispensing" means the:

(i) Preparation of one (1) or more doses of methadone, buprenorphine, or other approved medications in properly labeled, patient-specific containers; and

(ii) Delivery of said drugs to the patient to consume away from the clinic.

(B) Only a licensed pharmacist or physician holding a dispensing permit issued by the Arkansas State Medical Board shall dispense methadone; and

(3) "Methadone clinic pharmacy" means the place in which a licensed professional prepares methadone, buprenorphine, or other approved medications to be administered and/or dispensed to a patient of the clinic.

(b) **Permit.**

(1) Applications for methadone clinic permits shall be submitted pursuant to 17 CAR § 160-1201.

(2) Any pharmacist shall notify the Arkansas State Board of Pharmacy in writing and ascertain that a methadone clinic pharmacy permit has been issued to the clinic before beginning practice in that clinic.

(c) **Pharmacy operations.**

(1) The pharmacist-in-charge shall provide written policies, procedures, and protocols for the operation of the pharmacy and shall obtain the approval of same by the Executive Director of the Arkansas State Board of Pharmacy prior to operation of said pharmacy.

(2) A methadone clinic pharmacy shall stock and dispense methadone or buprenorphine only unless permission is obtained from the Arkansas State Board of Pharmacy to utilize other medications for research purposes.

(d) **Physical facilities.**

(1) The pharmacy shall be a controlled area for the storage, safeguarding, preparation, and dispensing of methadone, a Schedule II narcotic, buprenorphine, a Schedule III controlled substance, and any other medications approved by the Arkansas State Board of Pharmacy for research purposes, and shall have adequate facilities for pharmaceutical services including the procurement, storage, distribution, security, and control of said drug consistent with all federal and state laws and rules.

(2)(A) The pharmacy shall have all equipment necessary to carry out the functions of the methadone clinic pharmacy and is otherwise exempt from 17 CAR § 160-1204.

(B) The equipment must be identified in the policies and procedures of each methadone clinic specialty pharmacy.

(e) **Licensed pharmacist personnel requirements.**

(1) A methadone pharmacy shall be open to serve its patients, with a pharmacist or pharmacists on duty, a minimum of ten (10) hours per week or, if necessary, a greater period of time in order to perform pharmacy duties necessary to ensure patient safety.

(2) The pharmacy's operating hours must be approved by the executive director.

17 CAR § 160-1303. Student health clinic pharmacy permit.

(a) **Definitions.** As used in this part:

(1) "Board" means the Arkansas State Board of Pharmacy; and

(2) "Student health clinic pharmacy" means a pharmacy located on a university or college campus for the purpose of filling prescriptions for students or employees or their spouses or dependents.

(b) **Permit.**

(1) Applications for student health clinic pharmacy permits shall be submitted pursuant to 17 CAR § 160-1201.

(2) Any pharmacist shall notify the board in writing and ascertain that a student health clinic pharmacy permit has been issued to the clinic before beginning practice in that clinic.

(c) **Pharmacy operations.**

(1) The pharmacist-in-charge shall provide written policies, procedures, and protocols for the operation of the pharmacy and shall obtain the approval of same by the board prior to operation of said pharmacy.

(2) A student health clinic pharmacy may stock and dispense legend and controlled substances.

(d) **Physical facilities.**

(1) The pharmacy shall be a controlled area for the storage, safeguarding, preparation, and dispensing of legend and controlled substances, and shall have adequate facilities for pharmaceutical services including the procurement, storage, distribution, security, and control of said drugs consistent with all federal and state laws and rules.

(2) The pharmacy shall have all equipment specified in 17 CAR § 160-1001.

(e) **Licensed pharmacist personnel requirements.**

(1) The pharmacy's minimum operating hours must be approved by the board prior to operation of said pharmacy.

(2) A pharmacist or pharmacists must be on duty during all hours of operation.

(3) The pharmacist-in-charge must work fifty percent (50%) of the hours of operation.

17 CAR § 160-1304. Permit for pilot program for donated prescription medications pursuant to Arkansas Code § 17-92-1101 et seq.

(a) The definitions in Arkansas Code § 17-92-1102 are applicable in this part unless the context otherwise requires.

(b) **Permit.**

(1)(A)(i) Application for a pilot program permit for the reuse of donated prescription medications authorized by Arkansas Code § 17-92-1101 et seq., shall be on a form provided by the Arkansas State Board of Pharmacy, signed by the pharmacist-in-charge, and submitted pursuant to board rule, but the fee for the application will be waived.

(ii) The application and documentation identified in the following subparagraph shall be delivered to the board's office thirty (30) days prior to the meeting at which the applicant desires to appear for consideration of its application.

(B) The application shall be accompanied by appropriate documentation including:

(i) That necessary to qualify the applicant as a charitable clinic as defined in Arkansas Code § 17-92-1102(1);

(ii) Written policies and procedures for the operation of the charitable clinic pharmacy;

(iii) Protocols to include the procedure for screening and determining that the patient qualifies on the basis of income below two hundred percent (200%) of the federal poverty level;

(iv) A depiction of the physical facilities for the pharmacy and a description of provisions for security for and access to the pharmacy;

(v) A statement of any fees charged to patients;

(vi) A list stating the pharmacy's:

(a) Hours of operation;

(b) Equipment; and

(c) Library materials; and

(vii) The proposed contract with a nursing home or nursing homes for donation of unused prescription medications.

(C) The pharmacist-in-charge and an appropriate officer or director of the organization shall appear before the board for its consideration of the application.

(D) The contract with the nursing home for supplying donated prescription drugs must be renewed biennially.

(E) Either volunteer or paid healthcare professionals shall deliver pharmaceutical services for the pharmacy.

(2) Prior to opening the charitable clinic pharmacy, the pharmacist-in-charge shall notify the board in writing identifying each pharmacist who will work at the pharmacy and, within ten (10) days thereafter, provide similar notice of any changes in pharmacists working in the pharmacy.

(c) **Pharmacy operations.**

(1)(A) A pharmacy holding a permit under this part shall stock and dispense purchased legend drugs, donated prescription drugs, samples, and medications received from manufacturer-sponsored prescription drug assistance programs or any other sources.

(B) Provided, however, that the pharmacy shall not stock or dispense any controlled substance.

(2) Pharmacists shall dispense all medications to patients on individual prescriptions, shall properly label all drugs dispensed, and shall comply with requirements for storing, safeguarding, preparing and keeping records for prescription drugs as described in 17 CAR § 160-1706.

(3) The pharmacist-in-charge shall cause the approved written policies, procedures, contracts with nursing homes, and protocols for the operation of the pharmacy to be maintained and available in the pharmacy for use by pharmacy staff and review by board inspectors.

(d) **Physical facilities.** The pharmacy shall:

(1) Be locked when a pharmacist is not present in the pharmacy; and

(2) Have adequate facilities for performing pharmaceutical services including the procurement, storage, distribution, security, and control of said drugs consistent with all federal and state laws and rules.

(e) **Changes in pharmacy operations.** The pharmacist-in-charge shall obtain approval by the Executive Director of the Arkansas State Board of Pharmacy prior to any change in any item identified in subdivisions (b)(1)(B)(i) – (vii) of this section.

(f) **Limited-use technician permit.** The board may issue a restricted charitable clinic pharmacy technician permit for the sole purpose of performing pharmacy technician duties as a volunteer in a prescription drug redispensing program permitted in accordance with subsection (b) of this section.

Subpart 14. Out-of-State Pharmacies

17 CAR § 160-1401. Out-of-state pharmacy regulation.

Out-of-state pharmacies shall comply with the following qualifications to be and remain licensed in Arkansas by the Arkansas State Board of Pharmacy:

(1)(A) The pharmacy holds a current license in good standing in the state or states in which it is located.

(B) Each pharmacist dispensing drugs into Arkansas shall be licensed as a pharmacist in Arkansas or in the state where he or she practices if that state has standards of licensure at least equivalent to those of Arkansas;

(2)(A) A pharmacist currently licensed in Arkansas shall be named in the application and shall serve as the:

(i) Pharmacy's pharmacist-in-charge for the Arkansas permit; and

(ii) Contact person for communications by the board.

(B) Said Arkansas pharmacist shall be an employee of the out-of-state pharmacy who shall be present at the pharmacy's physical location at least fifty percent (50%) of the number of hours per week the pharmacy is open up to a maximum of twenty (20) hours per week.

(C)(i) The pharmacist-in-charge for the Arkansas permit need not be the same person as the pharmacist-in-charge of the pharmacy pursuant to the law in the state in which the pharmacy is located.

(ii) That pharmacist will be responsible for receiving and maintaining publications distributed by the board.

(iii) If at any time the pharmacist so designated as the pharmacist-in-charge for the Arkansas permit shall leave that capacity or not be able to serve in that capacity, the pharmacy shall:

(a) Notify the board within ten (10) calendar days; and

(b) Designate another Arkansas-licensed pharmacist to perform this function by written notice to the board within thirty (30) calendar days;

(3)(A) The out-of-state pharmacy shall apply for licensure and renewal on forms provided by the board.

(B) The board may require such information as reasonably necessary to carry out the provisions of Arkansas Code § 17-92-401, including without limitation the name, address, and position of:

(i) Each officer and director of a corporation; or

(ii) The owners if the pharmacy is not a corporation.

(C) Provided, however, the board may grant an exemption from licensing under Arkansas Code § 17-92-401 upon application by any nonresident pharmacy that confines its dispensing activity to isolated transactions.

(D) In determining whether to grant an exemption, the board shall consider:

(i) The number of prescriptions dispensed or reasonably expected to be dispensed into Arkansas;

(ii) The number of patients served or reasonably expected to be served in Arkansas;

(iii) Whether the pharmacy has promoted its services in Arkansas;

(iv) Whether the pharmacy has a contract or contracts with any employer or employers or an organization or organizations to provide pharmacy services to employees or other beneficiaries in Arkansas;

(v) Medical necessity;

(vi) The effect on the health and welfare of persons in Arkansas; and

(vii) Any other relevant matters;

(4)(A) The pharmacy shall pay a biennial license fee as defined in 17 CAR § 160-107.

(B) When there is a change of Arkansas-licensed pharmacist-in-charge, the fee for said change shall be paid as defined in 17 CAR § 160-107.

(C) Final notification to the board of the new Arkansas-licensed pharmacist-in-charge shall be:

(i) On a form furnished by the board; and

(ii) Accompanied by the fee for said change;

(5)(A) The pharmacy shall maintain records of drugs dispensed to Arkansas addresses in such a manner so as to be readily retrievable upon request.

(B) These records shall be made available for inspection by the board or by Arkansas law enforcement authorities;

(6) The pharmacy shall timely respond to any request for information from the board or law enforcement authorities;

(7)(A) The pharmacy shall maintain an incoming toll-free telephone number for use by Arkansas customers to be answered by a pharmacist with access to patient records.

(B) This service shall be available a minimum of forty (40) hours a week, six (6) days per week during normal business hours.

(C) This telephone number plus others available for use shall be printed on each container of drugs dispensed into Arkansas.

(D) The toll-free number shall have sufficient extensions to provide reasonable access to incoming callers;

(8)(A) Generic drugs shall be dispensed into Arkansas pursuant to Arkansas Code § 17-92-501 et seq.;

(B) Provided, however, nothing herein shall be construed to mandate that an out-of-state pharmacy comply with Arkansas Code § 17-92-501 et seq., if such compliance would cause the out-of-state pharmacy to violate the generic substitution act of the state wherein the facility of the dispensing out-of-state pharmacy is located;

(9)(A) The facilities and records of the pharmacy shall be subject to inspection by the board.

(B) Provided, however, the board may accept in lieu thereof satisfactory inspection reports by the licensing entity using similar standards of the state where the pharmacy is located;

(10) Each out-of-state pharmacy doing business in Arkansas by dispensing and delivering or causing to be delivered prescription drugs to Arkansas consumers shall designate a resident agent in Arkansas for service of process;

(11)(A) Each out-of-state pharmacy doing business in Arkansas shall comply with 17 CAR § 160-2901.

(B) Nothing herein shall be construed to mandate that an out-of-state pharmacy comply with 17 CAR § 160-2901 if such compliance would cause the out-of-state pharmacy to violate law or regulation of the state wherein the facility of the dispensing out-of-state pharmacy is located;

(12)(A) Upon a change of ownership of a pharmacy as set out herein, a new permit shall be secured by the new owner or owners.

(B) The new owner or owners can continue operation of the pharmacy for fourteen (14) days after the effective date of the change of ownership.

(C) After the said fourteen-day period, the permit issued to the prior owner shall be void and same shall be surrendered to the Executive Director of the Arkansas State Board of Pharmacy;

(13) A change of ownership of a pharmacy occurs under but is not limited to the following circumstances:

(A) A change of ownership of a pharmacy owned by a sole proprietor is deemed to have occurred when:

(i) The pharmacy is sold and the sale becomes final or the new owner assumes control of the pharmacy, whichever occurs first; or

(ii) The proprietor enters into a partnership with another individual or business entity;

(B) A change of ownership of a pharmacy owned by a partnership is deemed to have occurred when:

(i) There is an addition or deletion of one (1) or more partners in a partnership to which a pharmacy license has been issued; or

(ii) The pharmacy is sold and the sale becomes final or the new owner assumes control of the pharmacy, whichever occurs first; and

(C) A change of ownership of a pharmacy owned by a corporation is deemed to have occurred when:

(i)*(a)* An individual or business acquires or disposes of twenty percent (20%) or more of the corporation's outstanding shares of voting stock.

(b) This shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market;

(ii)*(a)* The corporation merges with another business or corporation.

(b) The corporation owning the pharmacy is required to notify the board if a change of ownership or merger occurs within the parent corporation of the corporation that owns the pharmacy;

(iii) The corporation's charter expires or is forfeited; or

(iv) The pharmacy is sold and the sale becomes final or the new owner assumes control of the pharmacy, whichever occurs first; and

(14) The responsibility to ensure compliance with this part rests both with the Arkansas pharmacist-in-charge and with the pharmacy owner if they are not the same.

Subpart 15. Rules Regarding Hospital Pharmacies

17 CAR § 160-1501. Hospital pharmaceutical services permit.

(a)(1) Any pharmacist practicing in an Arkansas hospital must:

(A) So notify the Arkansas State Board of Pharmacy; and

(B) Ascertain that a hospital pharmaceutical services permit has been issued.

(2) The hospital pharmaceutical services permit shall be issued in the name of the hospital showing a pharmacist-in-charge.

(b) Any hospital holding a retail pharmacy permit as of February 15, 1975, upon application for renewal must separate the facilities, stocks, records, etc., in compliance with Arkansas Code §§ 17-92-403 – 17-92-405.

(c)(1) All hospitals shall have adequate provisions for pharmaceutical services regarding the procurement, storage, distribution, and control of all medications.

(2) All federal and state rules shall be complied with.

(d) **Definitions.** As used in this part:

(1) "Hospital employee" means any individual employed by the hospital whose compensation for services or labor actually performed for a hospital is reflected on the payroll records of a hospital;

(2)(A) "Hospital pharmacy" means the place or places in which drugs, chemicals, medicines, prescriptions, or poisons are prepared for distribution and administration for the use and/or benefit of patients in a hospital licensed by the Department of Health.

(B) "Hospital pharmacy" shall also mean the place or places in which drugs, chemicals, medicines, prescriptions, or poisons are compounded for dispensing to:

(i) Hospital employees;

(ii) Members of the immediate families of hospital employees;

(iii) Patients being discharged; and

(iv) Other persons in emergency situations.

(C) "Hospital pharmacy" shall also mean the provision of pharmaceutical services as defined in the Pharmacy Practice Act by a pharmacist to a patient of the hospital;

(3) "Licensed pharmacist" means any person licensed to practice pharmacy by the Arkansas State Board of Pharmacy who provides pharmaceutical services as defined in the Pharmacy Practice Act to patients of the hospital;

(4) "Qualified hospital personnel" means persons other than licensed pharmacists who perform duties in conjunction with the overall hospital pharmaceutical services for inpatients; and

(5)(A) "Unit dose distribution system" means a pharmacy-coordinated method of dispensing and controlling medications in hospitals in which medications are dispensed in single-unit packages for a specific patient on orders of a physician where not more than a twenty-four-hour supply of said medications is dispensed, delivered, or available to the patient.

(B) "Unit dose distribution system" also means a system that meets the requirement of a "unit dose distribution system", provided that up to a seventy-two-hour supply may be sent to the floor once a week if the system has been reviewed and approved administratively by the Arkansas State Board of Pharmacy.

(e) **Compounding, dispensing, and distributing.**

(1) Compounding is the act of selecting, mixing, combining, measuring, counting, or otherwise preparing a drug or medication.

(2) Dispensing is a function restricted to licensed pharmacists that involves the issuance of:

(A) One (1) or more doses of a medication in containers other than the original, with such new containers being properly labeled by the dispenser as to content and/or directions for use as directed by the prescriber;

(B) Medication in its original container with a pharmacy-prepared label that carries to the patient the directions of the prescriber as well as other vital information; and

(C)(i) A package carrying a label prepared for nursing station use.

(ii) The contents of the container may be for one (1) patient (individual prescription) or for several patients (such as a nursing station medication container).

(3)(A) Distributing, in the context of this part, refers to the movement of a medication from a central point to a nursing station medication center.

(B) The medication must be in the original labeled manufacturer's container or in a prepackaged container labeled according to federal and state statutes and rules by a pharmacist or under his or her direct and immediate supervision.

(f) **Administering.**

(1) An act, restricted to nursing personnel as defined in the Nurse Practice Act, in which a single dose of a prescribed drug or biological is given a patient.

(2) This activity includes the removal of the dose from a previously dispensed, properly labeled container, verifying it with the prescriber's orders, giving the individual dose to the proper patient, and recording the time and dose given.

(g) **Pharmacy and therapeutics committee.** There is a committee of the medical staff to confer with the pharmacist in the formulation of policies, explained as follows:

(1)(A) A pharmacy and therapeutics committee (P&T Committee), composed of at least one (1) physician, the administrator or representative, the director of nursing service or representative, and the pharmacist, is established in the hospital.

(B) It represents the organizational line of communication and the liaison between the medical staff and the pharmacist;

(2) The P&T Committee assists in the formation of broad professional policies regarding the evaluation, appraisal, selection, procurement, storage, distribution, use, safety procedures, and all other matters relating to drugs in hospitals; and

(3) The P&T Committee performs the following specific functions:

(A) Serves as an advisory group to the hospital medical staff and the pharmacist on matters pertaining to the choice drugs;

(B) Develops and reviews periodically a formulary or drug list for use in the hospital;

(C) Establishes standards concerning the use and control of investigational drugs and research in the use of recognized drugs;

(D) Evaluates clinical data concerning new drugs or preparations requested for use in the hospital;

(E) Makes recommendations concerning drugs to be stocked on the nursing unit floors and emergency drug stocks;

(F) Prevents unnecessary duplication in stocking drugs and drugs in combination having identical amounts of the same therapeutic ingredients;

(G) The P&T Committee:

(i) Meets at least quarterly; and

(ii) Reports to the medical staff by written report; and

(H)(i) Develops and routinely evaluates a hospital-wide Medication Error Reduction Plan (MERP) to identify actual or potential medication-related errors and to perform a concurrent and retrospective review of clinical care.

(ii) The MERP should address the areas of:

(a) Prescribing;

(b) Prescription;

(c) Order communication;

(d) Product labeling;

(e) Product packaging and nomenclature;

(f) Compounding;

(g) Dispensing;

(h) Distribution;

(i) Administration;

(j) Education; and

(k) Monitoring and use.

(h) **Pharmacy operations.**

(1) The hospital has a pharmacy directed by a licensed pharmacist.

(2) The pharmacy is administered in accordance with accepted professional principles.

(3) **Pharmacy supervision.** There is a pharmacy directed by a licensed pharmacist, defined as follows:

(A) The director of pharmacy is trained in the specialized functions of hospital pharmacy;

(B) The director of pharmacy is responsible to the administration of the hospital and the Arkansas State Board of Pharmacy for developing, supervising, and coordinating all the activities of the pharmacy department and all pharmacists providing professional services in the hospital; and

(C)(i) All licensed pharmacists who provide pharmaceutical services as defined by the Pharmacy Practice Act shall practice under policies, procedures, and protocols approved by the director of pharmacy.

(ii) These policies, procedures, and protocols shall be subject to review and approval by the Arkansas State Board of Pharmacy.

(i) **Physical facilities.** Facilities are provided for the storage, safeguarding, preparation, and dispensing of drugs, defined as follows:

(1) Drugs are issued to floor units in accordance with approved policies and procedures;

(2)(A) Drug cabinets on the nursing units are routinely checked by the pharmacist.

(B) All floor stocks are properly controlled;

(3)(A) A careful determination of the functions of a department will regulate the space to be allocated, the equipment necessary to carry out the functions, and the number of personnel required to utilize the equipment and to render a given volume of service, as these functions relate to the frequency or intensity of each function or activity.

(B) Adequate equipment should specifically relate to services rendered and functions performed by the hospital pharmacy.

(C) Equipment lists will relate to the following services and functions:

(i) Medication preparation;

(ii) Library reference facilities;

(iii) Record and office procedures;

(iv) Sterile product manufacturing;

(v) Bulk compounding (manufacturing);

(vi) Product control (assay, sterility testing, etc.); and

(vii) Product development and special formulations for medical staff;

(4) Equipment appropriate for the hospital pharmacy's specific scope of practice shall be maintained by the pharmacy and may include but is not limited to:

(A) Graduates capable of measuring from one-tenth of a milliliter (0.1 ml) up to at least five hundred milliliters (500 ml);

(B) Mortars and pestles;

(C) Hot and cold running water;

(D) Spatulas, steel and nonmetallic;

(E) Funnels;

(F) Stirring rods;

(G) Class A balance and appropriate weights;

(H) Typewriter or other label printer;

(I) Suitable apparatus for production of small-volume sterile products; and

(J) Suitable containers and labels;

(5) Each hospital pharmacy shall maintain a pharmacy library available for use by the pharmacist and the patient, including:

(A) Either current drug information manuals or computers capable of printing current drug information for the pharmacist and patient drug information and monographs for patients; and

(B) Other pharmacy reference books and periodicals necessary for effective pharmacy practice; and

(6) Special locked storage space is provided to meet the legal requirements for storage of:

(A) Controlled drugs;

(B) Alcohol; and

(C) Other prescribed drugs;

(j) **Personnel.** Personnel competent in their respective duties are provided in keeping with size and activity of the department, explained as follows:

(1) The director of pharmacy is assisted by an adequate number of additional licensed pharmacists and such other personnel as the activities of the pharmacy may require to ensure quality pharmaceutical services; and

(2) The pharmacy, depending upon the size and scope of its operations, is staffed by the following categories of personnel:

(A) Chief pharmacist (director of pharmacy);

(B) One (1) or more assistant chief pharmacists (assistant director of pharmacy);

(C) Staff pharmacists;

(D) Pharmacy residents, where program has been activated;

(E) Trained nonprofessional pharmacy helpers (qualified hospital personnel); and

(F) Clerical help.

(k) **Emergency pharmaceutical services.** Through the administrator of the hospital, the P&T Committee shall establish policies and procedures that include but are not limited to the following:

(1) Upon admission to the emergency room on an outpatient basis and when examined by the physician where medications are prescribed to be administered, a record must be kept on file in the emergency room admission book or a copy of the emergency room medication order must be kept by the pharmacist to be readily accessible, for control and other purposes, as required by this part;

(2)(A) If the physician wishes the patient to have medication to be taken with them from the emergency room supplies, the amounts to be taken shall be sufficient to last until medication may be obtained from local pharmacies, in any case not to exceed a forty-eight-hour supply.

(B) All state and federal laws must be observed concerning all records, labeling, and outpatient dispensing requirements; and

(3) Take-home prescriptions for anti-infectives issued to patients at the time of discharge from the emergency room, filled by a pharmacist, shall be quantities consistent with the medical needs of the patient.

(l) **Pharmacy records and labeling.**

(1) Records are:

(A) Kept of the transactions of the pharmacy; and

(B) Correlated with other hospital records where indicated.

(2) All medication shall be properly labeled.

(3) Such record and labeling requirements are as follows:

(A) The pharmacy establishes and maintains, in cooperation with the accounting department, a satisfactory system of records and bookkeeping in accordance with the policies of the hospital for:

(i) Maintaining adequate control over the requisitioning and dispensing of all drugs and pharmaceutical supplies; and

(ii) Charging patients for drugs and pharmaceutical supplies;

(B) A record of procurement and disbursement of all controlled drugs is maintained in such a manner that the disposition of any particular item may be readily traced;

(C) The pharmacist shall receive and provide service pursuant to the perusal of the physician's original order or a direct copy thereof, except in emergency situations wherein the pharmacist may provide service pursuant to a verbal order or to an oral or written transcription of the physician's order provided that the pharmacist shall receive and review the original or direct copy within twenty-four (24) hours of the time the service is provided;

(D) A record shall be maintained by the pharmacy and stored separately from other hospital records for each patient, inpatient or outpatient, containing the:

(i) Name of the patient;

(ii) Prescribing physician;

(iii) Name and strength of drugs prescribed; and

(iv) Name and manufacturer or trademark of medication dispensed;

(E)(i) The label of each medication container prepared for administration to inpatients shall bear the:

(a) Name and strength of the medication;

(b) Expiration date; and

(c) Lot and control number.

(ii) The label on the medication, or the container into which the labeled medication is placed, must bear the name of the patient; and

(F) The label of each outpatient's individual prescription medication container bears the name of the patient, prescribing physician, directions for use, and

the name and strength of the medication dispensed, unless directed otherwise by the physician.

(m) **Control of toxic or dangerous drugs.** Policies are established to control the administration of toxic or dangerous drugs with specific reference to the duration of the order and the dosage, explained as follows:

(1) The medical staff has established a written policy that all toxic or dangerous medications not specifically prescribed as to time or number of doses will be automatically stopped after a reasonable time limit set by the staff;

(2) The classifications ordinarily thought of as toxic or dangerous drugs are:

(A) Controlled substances;

(B) Anticoagulants;

(C) Antibiotics;

(D) Oxytoxics; and

(E) Cortisone products;

(3) Except for controlled drugs, all deteriorated nonsterile, nonlabeled, or damaged medication shall be destroyed by the pharmacist; and

(4) All controlled drugs (Schedules II, III, IV, and V) should be listed and a copy sent along with the drugs to the Department of Health by registered mail or delivered in person for disposition.

(n) **Drugs to be dispensed.** Therapeutic ingredients of medications dispensed are included, or approved for inclusion, in the USP-NF and Homeopathic Pharmacopoeia of the United States, or Accepted Dental Remedies, except for any drugs unfavorably evaluated therein, and drugs approved by provisions of Acts 1975, No. 436, or are approved for use by the P&T Committee of the hospital staff, explained as follows:

(1) The pharmacist, with the advice and guidance of the P&T Committee, is responsible for specifications as to quality, quantity, and source of supply of all drugs; and

(2) There is available a formulary or list of drugs accepted for use in the hospital that is developed and amended at regular intervals by the P&T Committee with the cooperation of the pharmacist and the administration.

(o) **Policy and procedure manual.**

(1) A policy and procedure manual pertaining to the operations of the hospital pharmacy with updated revisions adopted by the P&T Committee of each hospital shall be prepared and maintained at the hospital.

(2) The policy and procedure manual should include at a minimum the following:

(A) Provisions for procurement, storage, distribution, and drug control for all aspects of pharmaceutical services in the hospital;

(B) Specialized areas such as surgery, delivery, ICU and CCU units, and emergency room stock and usage of medication shall be specifically outlined;

(C) A system of requisitioning supplies and medications for nurses' stations stock shall be in written procedural form as to limits of medications to be stocked in each nursing unit;

(D) Detailed job descriptions and duties of each employee by job title working in the pharmacy department must be developed and made a part of these policies and procedures; and

(E) The pharmacy policy and procedure manual shall be subject to review and approval by the Arkansas State Board of Pharmacy on request from the Arkansas State Board of Pharmacy.

(p) **Employee prescription medication.**

(1)(A) There will be a prescription on file for all prescription drugs dispensed to hospital employees and their immediate families.

(B) These records will be kept separate from all inpatient records.

(2) The only person or persons entitled to have employee prescriptions filled will be the employee listed on the hospital payroll and members of his or her immediate family.

(q) **Patient discharge medication.** Any take-home prescription dispensed to patients at time of discharge from the hospital shall be for drugs and quantities consistent with the immediate medical needs of the patient.

(r) **Licensed pharmacist personnel requirements.** The minimum requirements for licensed pharmacists in hospitals are:

(1)(A) A general hospital, surgery, and general medical care maternal and general medical care hospital, chronic disease hospitals, psychiatric hospitals, and rehabilitative facilities licensed for greater than fifty (50) beds, as determined by the institution's license issued by the Department of Health, shall require the services of a pharmacist-in-charge, who shall be responsible for duties defined in 17 CAR § 160-1010.

(B) Additional pharmacists shall be employed as are necessary to perform required pharmacy duties in keeping with the size and scope of the services of the hospital pharmacy's safe and efficient operation in the opinion of the Arkansas State Board of Pharmacy.

(C) Hospitals providing specialized or unique patient care services may request approval from the Arkansas State Board of Pharmacy to be exempt from the requirement of a pharmacist on duty forty (40) hours per week.

(D) The request for exemption must provide adequate written documentation to justify the services of a pharmacist for as many hours as are necessary to perform required pharmacy services, followed by an appearance before the Arkansas State Board of Pharmacy for final approval of the request;

(2)(A) The above classified hospitals, licensed for fifty (50) beds or fewer, as determined by the institution's license issued by the Department of Health, shall require the services of a pharmacist or pharmacists including a pharmacist-in-charge, for as many hours as, in the opinion of the Arkansas State Board of Pharmacy and the State Board of Health, are necessary to perform required pharmacy duties in keeping with the size and scope of the services of the hospital pharmacy's safe and efficient operation.

(B) The pharmacist or pharmacists shall be on site at least five (5) days per week to perform and review pharmacy dispensing, drug utilization, and drug distribution activities.

(C) A pharmacist shall be available to provide emergency services to the staff when the pharmacy is closed;

(3) **Recuperative centers, outpatient surgery centers, and infirmaries.**

(A) If the infirmary, recuperative center, or outpatient surgery center has a pharmacy department, a licensed pharmacist must be employed to administer the pharmacy in accordance with all state and federal laws regarding drugs and drug control.

(B) If the infirmary, recuperative center, or outpatient surgery center does not have a pharmacy department, it has provisions for promptly and conveniently obtaining prescribed drugs and biologicals from a community or institutional pharmacy.

(C)(i) If the infirmary, recuperative center, or outpatient surgery center does not have a pharmacy department but does maintain a supply of drugs, a licensed pharmacist shall:

(a) Be responsible for the control of all bulk drugs; and

(b) Maintain records of their receipt and disposition.

(ii) The pharmacist shall dispense drugs from the drug supply, properly labeled, and make them available to appropriate nursing personnel.

(D) All medication for patients shall be on individual prescription basis; and

(4) A pharmacist-in-charge, who is employed at any facility permitted by the Arkansas State Board of Pharmacy where a forty-hour work week is required, may also be the pharmacist-in-charge at a hospital licensed for fifty (50) beds or fewer by the Department of Health.

(s) **Responsibility of a pharmacist in a hospital pharmacy.**

(1) The pharmacist-in-charge is responsible for the:

(A) Control of all medications distributed in the hospital where he or she practices; and

(B) Proper provision of all pharmaceutical services.

(2) The following aspects of medication distribution and pharmaceutical service are functions involving professional evaluations of judgments and may not be performed by supportive personnel:

(A) Selection of the brand and supplier of medication;

(B)(i) Interpretation and certification of the medication order.

(ii) This involves a number of professional responsibilities such as the determination of:

(a) Accuracy and appropriateness of dose and dosage schedule;

(b) Such items as possible drug interactions, medication sensitivities of the patient, and chemical and therapeutic incompatibilities; and

(c) Accuracy of entry of medication order to patient's medication profile; and

(3) Final certification of the prepared medication.

(t) **Operation of pharmacy department without a pharmacist.** At no time will the hospital pharmacy be open and in operation unless a licensed pharmacist is physically present except:

(1) Entrance may be obtained for emergency medication as set forth in the pharmacy policy and procedure manual when the pharmacy is closed outside its normal operation hours; or

(2) When the pharmacist is summoned away from the pharmacy and there are other qualified personnel left in the pharmacy, the personnel left in the pharmacy could perform only those functions authorized within this part.

(u) **The American Society of Health-System Pharmacists Guidelines.** The American Society of Health-System Pharmacists' most recent statement on hospital

drug control systems and Guidelines for Institutional Use of Controlled Substances shall be required reading by hospital pharmacists.

17 CAR § 160-1502. Mechanical storage and delivery.

(a) Hospitals using mechanical storage and delivery machines for legend drugs must secure a hospital pharmaceutical services permit, and these machines shall be stocked only by a licensed pharmacist under this permit.

(b) Drugs may be obtained from these machines only by a physician, registered or licensed professional nurse or student nurse, an intern or resident physician, or a licensed pharmacist acting under the prescribed rules of safety procedures as promulgated by the individual hospital or institution using the machine.

(c) Use of these machines shall not be to circumvent adequate pharmaceutical services.

17 CAR § 160-1503. Regulating the use of electronic data processing in lieu of present recordkeeping systems in hospital pharmacies holding hospital pharmacy permits.

(a)(1) This part shall be construed, if possible, so as not to be in violation of, or in conflict with, any federal regulation or requirement.

(2) If any part hereof is held invalid because of such conflict, such invalidity shall not affect other provisions or applications of this part that can be given effect without the invalid provisions of this part are declared severable.

(b) The Arkansas State Board of Pharmacy must approve the system prior to implementation.

(c)(1) Input of drug information into the system shall be performed by a pharmacist or pharmacy technician.

(2) The final verification of prescription information entered into the computer shall be made by the supervising pharmacist who is then totally responsible for all aspects of the data and data entry.

(3) Any judgmental decision concerning patient utilization of drugs must be performed by a pharmacist.

(d)(1) An electronic data processing system:

(A) Must be readily accessible electronically online or by hard copy; and

(B) Shall be capable of printing a hard copy record.

(2) The hard copy record or electronic database record shall be available upon request by a board representative or other state or federal agencies with authority to obtain such records within forty-eight (48) hours of the request.

(3) The system must be capable of furnishing the following information:

(A)(i) Patient Medication Profile, accessible electronically online or by hard copy.

(ii) **Definition.** As used in this part, "Patient Medication Profile" means the basic document used by the hospital pharmacist to monitor a patient's:

(a) Medication regimen;

(b) Drug compliance;

(c) Drug interactions;

(d) Allergies; and

(e) Drug usage.

(iii) The Patient Medication Profile must contain, at a minimum, the following:

(a) Patient name, patient identification number, practitioner's name, drug name, drug strength and dosage form, number of doses issued, initials, name or identification number of pharmacist approving original order into the system, and date original order was entered into the system; and

(b) The Final Patient Medication Profile must be maintained by the pharmacy;

(B) **Patient Daily Medication Record.**

(i) The Patient Daily Medication Record is a document, whether electronic or hardcopy, which supports the Patient Medication Profile.

(ii) The Patient Daily Medication Record provides a daily refill-by-refill audit trail on all drugs dispensed and supplements the base document, the Patient Medication Profile.

(iii)*(a)* This record is produced on a daily basis.

(b) It may be used to fill patient medication orders for transport to the patient care area.

(c) This record must show all medications dispensed on any given day.

(iv) The Patient Daily Medication Record must contain, at a minimum, the following:

(a) Date of record;

(b) Patient name;

(c) Patient identification number;

(d) Drug name;

(e) Drug strength and dosage form; and

(f) Number of doses issued on that day.

(v)*(a)* The initials of the pharmacist who checked and verified the doses dispensed must appear on the Patient Daily Medication Record if not shown on the Patient Medication Profile described in this section.

(b) Since the Patient Daily Medication Record supports the Patient Medication Profile, some information such as practitioner's name, initials, name or identification number of pharmacist entering the original order into the system, and the date of the original order may or may not be duplicated because the information is readily retrievable from the base document.

(vi)*(a)* The Patient Daily Medication Record must be kept and a bound log book must be signed by all pharmacists filling orders for that day.

(b)(1) If a printed hard copy is used, the printout may be replaced by a monthly log containing the same information.

(2) This information must be maintained at the pharmacy for a period of two (2) years.

(vii)*(a)* The pharmacist-in-charge of the hospital pharmacy will maintain a bound log book in which each individual pharmacist and intern involved in the dispensing of medications will sign the log book each day, attesting to the fact that the prescription information entered into the computer that day:

(1) Has been reviewed by him or her; and

(2) Is correct as shown.

(b) The log shall identify the time of day at which the pharmacist started filling and stopped filling prescriptions.

(c) The log book shall be maintained by the pharmacist-in-charge or his or her successor in the hospital pharmacy employing such a system for a period of two (2) years after the date of dispensing the appropriately authorized prescription;

(C) Ensure strict confidentiality of all patient records;

(D)(i) If the hospital pharmacy closes, the pharmacist-in-charge:

(a) At the date of closing shall store said records; and

(b) Within fourteen (14) days of closing shall notify the board where said records are located.

(ii) A hard copy printout or electronic database of any daily log or logs shall be produced and made available to:

(a) A board representative on their request; and

(b) Any other person authorized by law to examine or receive copies of prescription records; and

(E) If maintaining the Patient Daily Medication Report electronically, the data must be backed up at least daily, preferably continuously.

(e)(1) Hospital pharmacies that make arrangements with outside suppliers of data processing services or materials must assure themselves of continuing, adequate, and complete drug information data and issuing records.

(2) If for any reason the relationship with said supplier terminates, the pharmacy shall ensure the continuity of records.

(f)(1) In the event of computer breakdown (down time), the pharmacy must have an auxiliary recordkeeping system.

(2) The backup system must contain all necessary information to ensure prompt data entry into the system as soon as the computer is again available.

(g) Registrants holding a hospital pharmaceutical services permit who fill outpatient prescriptions and who wish to utilize electronic data processing equipment as a recordkeeping system must then comply with all the requirements of 17 CAR § 160-1206.

(h) The electronic data processing systems described in this part are acceptable as the disposition records for all drugs, except that the actual signed disposition (proof of use) records for Schedule II controlled substances must be retained separate from other records for a period of two (2) years.

17 CAR § 160-1504. Off-site order entry.

(a) The purpose of this section is to provide standards for remote or off-site order entry in hospital pharmacies within the State of Arkansas.

(b) The Arkansas State Board of Pharmacy may approve a request for off-site order entry where the hospital pharmacy can demonstrate that the procedure will result in an improvement in patient care by increasing the amount of time of pharmacist involvement in the process of medication review for safety and efficacy prior to the administration of the medication to the patient.

(c)(1) The pharmacist-in-charge of the hospital pharmacy shall submit a written request for off-site order entry a minimum of thirty (30) days prior to the board meeting at which the pharmacist seeks board approval.

(2) The request shall be accompanied by policies and procedures for off-site order entry to include:

(A) Only a pharmacist holding a current license in good standing shall enter orders at a remote or off-site entry location;

(B) The pharmacist-in-charge at the hospital shall ascertain and maintain on-site documentation that all pharmacists that participate in the order entry process are:

(i) Licensed with the board; and

(ii) Competent to enter faxed or scanned orders for patients in that facility, including but not limited to the ability to accurately:

(a) Receive, interpret, and accurately enter medication orders from any physician on staff at that facility;

(b) Access and interpret clinical data as it pertains to that patient's drug regimen;

(c) Perform therapeutic interventions;

(d) Perform cross checks for known:

(1) Drug allergies;

(2) Adverse drug reactions; and

(3) Contraindications;

(e) Perform drug-drug interaction as well as drug-food interaction review;

(f) Identify any overutilization or underutilization; and

(g)(1) Be available via telephone for any questions or issues from nursing staff as well as from staff physicians.

(2) This number shall be posted in a visible place:

(A) At each nursing station;

(B) In all dictation rooms; and

(C) In all other areas within the facility that a:

(i) Physician might write orders; or

(ii) Nurse might fax or scan orders;

(C)(i) A clearly defined backup system in the event of:

(a) Connection or communication failure; and/or

(b) The need for on-site pharmacist is deemed necessary.

(ii) The above competencies shall be in written policy and procedure and shall include training, testing, and ongoing assessment of skills;

(D) Documentation that any remote or off-site order entry facility shall:

(i) Have compatible systems utilized at both the hospital as well as the facility itself; and

(ii) Include:

(a) Software;

(b) Hardware; and

(c) Connectivity; and

(E) Documentation that the remote or off-site order procedures and other requirements of this part have been approved by medical staff and/or P&T Committee at that hospital as reflected in the minutes or comparable record.

(d) In the operation of the off-site order entry, patient confidentiality and full compliance with HIPAA requirements shall be observed at all times.

Subpart 16. Institutional Pharmaceutical Services Permit

17 CAR § 160-1601. Class #1 institutional permit.

(a)(1) If a pharmacy is funded primarily by state or federal funds and/or if prescription drugs are to be purchased, maintained, or dispensed by a pharmacist in a facility that purchases drugs from Arkansas state contracts, and that facility does not meet the requirements set by the Arkansas State Board of Pharmacy to obtain a licensed pharmacy permit, a hospital pharmaceutical services permit, or a nursing home consultant's permit, then an exception may be made to issue an institutional pharmaceutical services permit.

(2) The institutional pharmaceutical services may be in facilities that:

(A) Provide extended health care to resident patients; and

(B) Are funded primarily by state or federal funds.

(3) The permit shall be issued in the name of the licensed pharmacist-in-charge.

(b) A licensed pharmacist employed or otherwise engaged to provide pharmaceutical service may have a flexible schedule of attendance in the institution, provided, however, the pharmacist must be physically present in the institution for a sufficient number of hours weekly to:

(1) Maintain an adequate supply of medications at the service area from which medications are administered;

(2) Maintain all records;

(3) Perform other pharmaceutical services authorized by law; and

(4) Provide adequate control and accountability of all drugs under his or her responsibility.

(c) Medication for patients shall be on an individual prescription basis by order from a licensed physician and the pharmacist shall dispense drugs, properly labeled, to be used for patients being treated at the facility.

(d)(1) Facilities are to be provided for the storage, safe-guarding, preparation, and dispensing of drugs.

(2) Equipment and supplies necessary to the facilities' safe and economical operation shall be provided.

(3) Special locked storage space is to be provided to meet all requirements for storage of controlled drugs and other prescription drugs.

(e) All policies and procedures related to the institutional pharmaceutical services must first be approved by the board before a permit will be issued.

(f)(1) Special floor stock or backup to meet emergency needs such as when the pharmacy is closed will be permitted only when specifically outlined in the policies and procedures.

(2) The policies and procedures shall include:

(A) Lists establishing quantity limits of these emergency drugs;

(B) The method of replacement;

(C) Maintenance of records accounting for drugs used; and

(D) Proper preparation and labeling by the pharmacist.

(g) With recognition of the Drug Enforcement Administration's statement of policy regarding emergency kits for long-term care facilities, and recognizing the Drug Enforcement Administration's definition of long-term care facilities, the following requirements must be met for facilities with institutional pharmaceutical services permits to store emergency kits containing controlled substances and/or other legend drugs in these facilities in Arkansas:

(1) All contents of the emergency kit will be provided by one (1) pharmacy designated by the facility;

(2) The facility holding an institutional permit with the board must have resident patients to which the facility provides extended health care;

(3) The controlled and legend drugs must remain the property of and under the responsibility of the pharmacy, which must have an Arkansas permit;

(4) All medications must be administered only on the order of a practitioner, and medications administered from the nurse's supply must be recorded as a prescription by the pharmacy prior to the pharmacy's replacement of the drug in the emergency supply;

(5) All medication records must be maintained as required by law, and out-of-date drugs must be properly destroyed by the pharmacy;

(6) Careful patient planning should be a cooperative effort between the pharmacy and the nursing department at the facility to make all medications available, and the emergency supply:

(A) Should only be used for emergency or unanticipated needs; and

(B) Shall not become a routine source or supply;

(7) The pharmacy is responsible to ensure compliance with this part, and any abuse or misuse of the intent of this part shall be immediately reported to the board; and

(8)(A) Storage conditions for the emergency kit shall meet all state and federal requirements.

(B) The storage conditions shall be set out in the policy and procedures of the facility.

(h) **Drug categories for emergency kits in facilities with institutional pharmaceutical services permits.** The following is a list of categories of drugs that are acceptable in emergency kits in facilities with institutional pharmaceutical services permits in accordance with this part:

(1)(A) Analgesics and controlled drugs.

(B)(i) Schedule II injectable.

(ii) Limit: one (1).

(iii) Maximum quantity: two (2);

(2)(A) Schedule III, IV, or V injectable.

(B) Limit: one (1).

(C) Maximum quantity: ten (10);

(3)(A) Schedule III, IV, or V oral medications.

(B) Limit: two (2).

(C) Maximum quantity: six (6);

(4)(A) Anticonvulsants, injectable controlled drugs.

(B) Limit: one (1).

(C) Maximum quantity: four (4); and

(5)(A) Anxiolytics, injectable controlled drugs.

(B) Limit: one (1).

(C) Maximum quantity: four (4).

17 CAR § 160-1602. Class #2 institutional pharmaceutical services permit.

(a) When controlled drugs are needed for research or instruction by a licensed pharmacist, and these drugs are not to be sold or dispensed on prescriptions, an

institutional pharmaceutical services permit for research or instruction (Class #2) may be issued.

(b) Total responsibility for such drugs is placed on the licensed pharmacist in whose name the permit is issued.

17 CAR § 160-1603. Class #3 institutional pharmaceutical services permit — Correctional facilities.

(a) **Definitions.** As used in this part:

(1) "Correctional facility" means any place used for the confinement of persons:

(A) Charged with or convicted of an offense; or

(B) Otherwise confined under a court order;

(2)(A) "Dispensary" means a correctional facility providing limited medical services by licensed personnel.

(B) This type of facility:

(i) Is not licensed by the Department of Health as an infirmary; and

(ii) Does not have patient beds; and

(3) "Infirmary" means a correctional facility with an infirmary licensed by the Department of Health having patient beds.

(b)(1) If a correctional facility is funded primarily by city, county, state, or federal funds, and/or if prescription drugs are to be purchased, maintained, or dispensed in a facility that purchases drugs from Arkansas state contracts, and that facility does not meet the requirements set by the Arkansas State Board of Pharmacy to obtain a licensed pharmacy permit, a hospital pharmaceutical services permit, or a nursing home consultant's permit, then the board may issue an institutional pharmaceutical services permit.

(2) The institutional pharmaceutical services may be in facilities that:

(A) Provide extended health care to resident patients; and

(B) Are funded primarily by city, county, state, or federal funds.

(3) The permit shall be issued in the name of the pharmacist providing consultant services to the facility.

(4) Any time there is a change in the pharmacist consultant for the facility, a new permit in the name of the new pharmacist shall be obtained.

(c) Medication for patients shall be on an individual prescription basis by order from a licensed prescriber, and the supervising nurse or other licensed nursing personnel shall administer properly labeled medications to be used for patients being treated at the correctional facility.

(d) A licensed pharmacist named on the permit shall be employed or otherwise engaged to provide consultant pharmaceutical service at the correctional facility.

(e)(1) Institutional pharmaceutical services permits may be issued to correctional infirmaries and dispensaries.

(2) **Correctional infirmaries.**

(A)(i) All policies and procedures related to the institutional pharmaceutical services permit must first be approved by the board staff before a permit will be issued to ensure compliance with all existing laws and rules.

(ii) Any changes to the policies and procedures related to the procurement, administration, distribution, or storage of prescription medications shall be reported to the board within thirty (30) days.

(B) Policies and procedures for obtaining, dispensing, and administering drugs and biologicals shall be developed with the:

(i) Consultation of an Arkansas-licensed pharmacist; and

(ii) Approval of medical staff.

(C)(i) Special floor stock or backup medications to meet the emergency needs of the patients in the correctional facility will be permitted only when specifically outlined in the policies and procedures manual.

(ii) The policies and procedures manual shall at a minimum include:

(a)(1) Lists of emergency medications that establish quantity limits for each medication.

(2) Said list shall be subject to the approval of the board;

(b) The method of replacement;

(c) Maintenance of records accounting for medications used; and

(d) Proper preparation and labeling by the pharmacy services provider.

(D) The pharmacist consultant:

(i) Must conduct monthly site visits; and

(ii) Will be responsible for the supervision of pharmacy services.

(3) **Correctional dispensaries.**

(A) Pharmaceutical services shall be provided under supervision of licensed nursing personnel.

(B) The dispensary shall maintain medical records on each patient.

(C)(i) All policies and procedures related to the institutional pharmaceutical services permit must first be approved by the board staff before a permit will be issued to ensure compliance with all existing laws and rules.

(ii) Any changes to the policies and procedures related to the procurement, administration, distribution, or storage of prescription medications shall be reported to the board within thirty (30) days.

(D) Policies and procedures for obtaining, dispensing, and administering drugs and biologicals shall be developed with the consultation of an Arkansas-licensed pharmacist and the approval of medical staff.

(E)(i) Special floor stock or backup medications to meet the emergency needs of the patients in the correctional facility will be permitted only when specifically outlined in the policies and procedures manual.

(ii) The policies and procedures manual shall at a minimum include:

(a)(1) Lists of emergency medications that establish quantity limits for each medication.

(2) Said list shall be subject to the approval of the board;

(b) The method of replacement;

(c) Maintenance of records accounting for medications used; and

(d) Proper preparation and labeling by the pharmacy services provider.

(F) The pharmacist consultant:

(i) Shall conduct quarterly site visits; and

(ii) Will be responsible for the supervision of pharmacy services.

(f) **Pharmacist consultant responsibilities.** Pharmacist consultants in correctional facilities are involved in the following areas of pharmaceutical care that include drug storage, distribution, and utilization in that correctional facility:

(1) **Supervision of services.** The pharmacist consultant shall:

(A)(i) Develop, coordinate, and supervise all pharmaceutical services.

(ii) The pharmacist consultant for the correctional facility must ensure that pharmacist consultation is available on a twenty-four-hours-per-day, seven-days-per-week basis.

(iii) A pharmacist consultant or consultants shall devote a sufficient number of hours based upon the needs of the facility during regularly scheduled visits to carry out these responsibilities;

(B) Assist the correctional facility in developing procedures to ensure the provision of emergency drugs, and shall report to the board any pharmacy refusing to provide medication for the pharmacy's regular patients in the facility on a twenty-four-hours-per-day, seven-days-per-week basis;

(C) Provide written consultation on compliance with federal and state laws governing legend drugs, including controlled substances;

(D) Be knowledgeable of all laws and rules pertaining to correctional facilities, and shall communicate with the state agencies involved with enforcement and regulation of these facilities;

(E)(i) Spend sufficient time to:

(a) Evaluate discontinued or other unused medication for return or destruction;

(b) Destroy unused medication;

(c) Check entries in a bound and numbered controlled drugs book; and

(d) Make general observations at the dispensing stations.

(ii) Medications may only be returned from a correctional facility in accordance with 17 CAR § 160-1004; and

(F) Indicate the day the pharmacist consultant or consultants visited the correctional facility and a brief statement of purpose, finding, and actions for each resident record reviewed;

(2) **Control and accountability of all legend drugs, including controlled substance.**

(A)(i) The pharmacist consultant shall check to see that only approved drugs and biologicals are used in the facility and shall be administered in compliance with federal and state laws.

(ii) Records of receipt and disposition of all controlled drugs shall be maintained in sufficient detail to enable an accurate reconciliation.

(iii) The pharmacist consultant shall determine that:

(a) Drug records are in order; and

(b) An account of all controlled drugs is maintained and reconciled;

(3) **Patient drug regimen review.**

(A) The primary duty of the pharmacist consultant or consultants to the patients' concerns is to apply his or her expertise regarding drugs to the patient's specific situation.

(B) State and federal rules shall be the minimum standards for an adequate drug regimen review.

(C) Additionally, the pharmacist consultant shall routinely review patient charts in accordance with state and federal rules and:

(i) Ascertain that patient history and drug utilization is being properly recorded;

(ii) Review drug usage, including O.T.C. and prescriptions;

(iii) Review patient compliance with drug regimen;

(iv) Review drug allergies or sensitivities;

(v) Determine whether the patient is predisposed to side effects due to:

(a) Disease;

(b) Illness; or

(c) Age;

(vi) Determine whether potential exists for significant drug interaction;

(vii) Develop procedures to monitor patients' records for signs that indicate abuse or misuse of drugs by the patient or individuals;

(viii) Make recommendations regarding drug therapy to:

(a) The physician;

(b) Nurse; or

(c) Other persons involved in the patient's care;

(ix) Communicate to the facility procedures that ensure adequate pharmacy services are available for emergencies that might develop in the correctional facility for a specific patient;

(x) Promote pharmacists' ability and knowledge to:

(a) All persons involved in patient care; and

(b) Offer assistance in solving specific problems relating to patient drug regimen; and

(xi) A pharmacist consultant or consultants shall quarterly in dispensaries and monthly in licensed correctional infirmaries:

(a) Review patient medication records in accordance with state and federal rules; and

(b) Consult with and provide a written report of findings to the director of nursing or the patient's physician; and

(4) **Labeling of drugs and biologicals and proper storage.** It is the duty of the pharmacist consultant or consultants to ascertain during each visit to the correctional facility that:

(A) Medications are:

(i) Properly labeled;

(ii) Properly stored; and

(iii) Refrigerated when needed;

(B) Expiration dates are routinely checked; and

(C) Appropriate accessory and cautionary instructions are on all medications when required.

Subpart 17. Charitable Clinic Permit

17 CAR § 160-1701. Issuance of charitable clinic permit.

The Arkansas State Board of Pharmacy may provide for the issuance of a charitable clinic pharmacy permit to clinics and facilities furnishing medical care and dental care to poor and underprivileged persons:

(1) In which drugs are dispensed without charge to such persons on orders or prescriptions of practitioners authorized by law to prescribe or administer said drugs; and

(2) To which the requirements of a licensed pharmacist on duty for a minimum of forty (40) hours shall not apply.

17 CAR § 160-1702. Prescriptions.

All medication for patients shall be on an individual prescription basis, and the pharmacist shall dispense drugs, properly labeled, and adhere to the requirements for proper storage, safeguarding, preparation, and recordkeeping for prescription drugs.

17 CAR § 160-1703. Policies and procedures for clinics.

All policies and procedures related to the charitable clinic pharmacy permit must first be approved by the Arkansas State Board of Pharmacy staff before a permit will be issued to ensure compliance with all existing laws and rules.

17 CAR § 160-1704. Categories for permits.

The staff of the Arkansas State Board of Pharmacy is authorized to approve and issue charitable clinic permits for:

(1) **Clinics of the Department of Health.**

(A) Recognizing that medications:

(i) Are provided to patients in the absence of a pharmacist; and

(ii) Dispensed in these clinics are limited to birth control medications, drugs to treat tuberculosis, and drugs to treat sexually transmitted disease treatment program.

(B)(i) Packaged and labeled prescription drugs shall be initialed by the pharmacist to ensure accuracy and appropriateness.

(ii) The prescribing practitioner or a licensed nurse may issue these predispensed prescription drugs by placing the patient's name, date of issue, and prescription number on the label at the time of issue to patients on order of the prescriber.

(C)(i) The prescription number, as placed on the label of the dispensed prescription drug, is to be placed with the prescribing practitioner's order in the patient's medical record.

(ii) The pharmacist shall monitor patients' medical records to ensure that medication profiles and prescription orders are maintained and utilized.

(D) Since the pharmacist is not present when the patient receives the medication, the pharmacist shall develop protocol to ensure that the patient is monitored and counseled by the prescribing practitioner or nurse consistent with the requirements of 17 CAR § 160-2901.

(2)(A) Other facilities meeting the requirements of this part, provided that, if a pharmacist is not present, there shall be a limited formulary negotiated by the Executive Director of the Arkansas State Board of Pharmacy and approved by the board at its next meeting.

(B) The dispensing medication distribution provisions of this section shall apply.

17 CAR § 160-1705. Pharmacist present when medication provided.

Other facilities meeting the requirements of this part and where a pharmacist is present when medications are provided to the patient shall not be restricted to a medication formulary.

17 CAR § 160-1706. Rule regarding charitable clinic pharmacies procuring and dispensing donated prescription medication.

(a) **Purpose.**

(1) This part is to implement a state pilot program whereby Arkansas nursing facilities donate unused prescription medications to charitable clinic pharmacies to be dispensed to medically indigent Arkansas residents as authorized under Arkansas Code § 17-92-1101 et seq.

(2) No controlled substance shall be donated or transferred by a nursing facility to or accepted by a charitable clinic pharmacy under this section or 17 CAR § 160-1304.

(b) **Definitions.**

(1) The words defined in Arkansas Code § 17-92-1102 shall have the same meanings in this part unless the context otherwise requires.

(2) As used in this section:

(A) "Charitable clinic pharmacy" means a pharmacy holding a permit issued under 17 CAR § 160-1304; and

(B) "Manifest" means a list of drugs being transferred or destroyed.

(c) **Donation of prescription drugs.**

(1) A charitable clinic pharmacy shall accept donations of unused prescription medications only from Arkansas nursing facilities licensed with the Department of Human Services' Office of Long-Term Care.

(2) A charitable clinic pharmacy shall accept from such a nursing facility only those unused prescription medications identified in a contract with the nursing facility that has been approved by the Arkansas State Board of Pharmacy in cooperation with the:

(A) Department of Human Services' Office of Long-Term Care; and

(B) Department of Health.

(3) The charitable clinic pharmacy shall accept only those prescription drugs that the nursing facility has maintained in compliance with the applicable Department of Health rules.

(d) The consultant pharmacist for the nursing facility shall be responsible for verifying or causing the following to be performed regarding delivery of unused prescription medication to a charitable clinic pharmacy:

(1) Determine quality and suitability of the unused prescription drugs for reuse by verifying the following:

(A) Healthcare professionals have maintained the drugs in compliance with applicable Department of Health rules;

(B) The drugs can be identified;

(C) The drugs are not adulterated or mutilated; and

(D) The expiration dates are more than thirty (30) days after the date the drugs are to be delivered to the charitable clinic pharmacy;

(2) A manifest has been properly completed to include the following:

(A) Names of the:

(i) Consultant pharmacist and director of nursing or designee;

(ii) Nursing home; and

(iii) Receiving pharmacy; and

(B) Name, strength, expiration date, and quantity of each prescription drug to be donated;

(3) A copy of the manifest is delivered to the charitable clinic pharmacist and pharmacy;

(4) Deliver the unused drugs only to a pharmacist designated by the charitable clinic pharmacy;

(5) The name of the patient and any identifying information has been redacted or otherwise removed from the drug packaging before the drugs are delivered to the charitable clinic pharmacy;

(6) Sign and date each manifest before delivery of the unused prescription medications to the charitable clinic pharmacy certifying that he or she has complied with the provisions of this subsection; and

(7)(A) Maintain a copy of the manifest signed and dated by the charitable clinic pharmacist in the nursing facility for a minimum of two (2) years.

(B) Said document shall be made available upon request by board inspectors.

(e) **Eligible prescription drugs.**

(1)(A) A charitable clinic pharmacy shall accept from a nursing facility only those unused prescription medications identified in the contract identified in subdivision (c)(2) of this section.

(B) The charitable clinic pharmacy shall not accept any unused prescription medication identified in said contract for which the charitable clinic pharmacy does not have or reasonably anticipate a patient need.

(2) Eligible prescription drugs are:

(A) Those packaged in single-unit doses or blister packs provided that the outside packaging can be opened if the single-unit dose packaging remains intact; or

(B) The manufacturer's original sealed or tamper-evident packaging.

(3) The expiration date placed on the medication by the original pharmacy dispensing to the nursing home patient, consistent with USP standards, shall become the actual expiration date for the eligible medication.

(4) No lost-identity or unknown drugs shall be accepted by a charitable clinic pharmacy.

(5) No adulterated or misbranded drugs shall be accepted by a charitable clinic pharmacy.

(6) Only those drugs that have physically been in the nursing facility at all times since being dispensed by the originating pharmacy shall be accepted by a charitable clinic pharmacy.

(7) Compounded drugs shall not be accepted by a charitable clinic pharmacy.

(f) **Patients eligible for donated prescription drugs.** The charitable clinic pharmacy shall dispense donated prescription medications only to indigent patients as defined in Arkansas Code § 17-92-1102(4).

(g) **Pharmacies eligible to accept and dispense unused prescription medications from nursing homes.**

(1) A pharmacy shall hold a permit in good standing under 17 CAR § 160-1304.

(2) Prescription medications donated under this section shall not be sold, resold, offered for sale, traded, or transferred to another charitable clinic pharmacy.

(h) **Procedures for charitable clinic pharmacies to dispense donated prescription drugs.**

(1)(A) A pharmacist on staff at the charitable clinic pharmacy shall verify, utilizing an appropriate reference resource, that the drug name and strength noted on the label of each unit of the packaged donated medication is correct.

(B) The pharmacist verifying the drug shall place his or her initials on the medication label.

(C) If the identity of the drug cannot be verified, the pharmacist:

(i) Shall segregate the unidentified drug for destruction; and

(ii) Shall not dispense the medication.

(D)(i) Medications shall not be removed from the donor's original packaging until after verification by the charitable clinic pharmacist.

(ii) A pharmacist shall then relabel the medication with the name and strength of the medication and the expiration date from the donor's original drug package.

(2) Pharmacists shall dispense unused prescription drugs only upon the valid prescription of an Arkansas-licensed healthcare practitioner.

(3)(A) Pharmacists shall label each medication to be dispensed according to Arkansas Code § 17-92-505.

(B) Pharmacists shall redact or otherwise remove any labeling on an unused prescription drug identifying the original patient or pharmacy, not removed at the nursing home, prior to delivering the medication to a patient.

(C) Pharmacists shall:

(i) Label all donated drugs dispensed with the name of the charitable clinic pharmacy; and

(ii) Deliver the current drug information to the patient or caregiver.

(D)(i) Pharmacists shall label all donated drugs dispensed with an expiration date.

(ii) If multiple packages of unused prescription drugs with varied expiration dates are used to fill a single prescription, the earliest expiration date shall be used for the dispensed prescription.

(E) Pharmacists dispensing donated medications shall comply with all aspects of 17 CAR § 160-2901 regarding patient counseling.

(4) **Storage.**

(A)(i) The room in which the medications are stored shall be locked at all times except during clinic hours or other times when a licensed pharmacist is physically present in the pharmacy.

(ii) A pharmacist shall be on duty during all hours of pharmacy operation.

(B) The room in which the medications are stored shall have proper environmental controls to ensure the integrity of the medication in accordance with the drug manufacturer's recommendations.

(i) **Responsibilities of pharmacist-in-charge of charitable clinic pharmacy.**

(1) Accept delivery of the donated unused prescription drugs from the nursing home in person or cause another pharmacist at the charitable clinic to do so.

(2) Verify that the unused prescription drugs offered by the nursing facility are those identified in the contract described in subdivision (c)(2) of this section and are accurately identified in the manifest provided by the nursing home and resolve any discrepancy before accepting and signing for the medication.

(3) Retain a copy of the nursing facility's manifest in the pharmacy records for a minimum of two (2) years and make said documents available to board inspectors.

(4)(A) Cause the unused prescription drugs to be taken directly from the nursing home to the clinic pharmacy to be properly stored.

(B) At no time are the medications to be out of the direct control of a licensed pharmacist.

(5)(A) Cause expired, adulterated, and lost-identity drugs to be segregated from other medications in the pharmacy and then to be destroyed.

(B) Pharmacists shall not dispense such drugs.

(6) Upon receipt of notice of the recall of a drug, cause a uniform destruction on all of said drugs in the inventory of the charitable clinic, irrespective of lot numbers.

(7) **Destruction of drugs.**

(A) Create a manifest to be made of expired, adulterated, recalled, and/or other unused prescription drugs, and then cause said drugs to be destroyed.

(B) Observe the destruction of said drugs in the company of a witness, thereafter both of whom sign the manifest verifying the destruction of said drugs.

(C) Maintain a copy of each drug destruction manifest in the files of the pharmacy for a minimum of two (2) years and make said records available for review by board inspectors.

Subpart 18. Long-Term Care Facilities — Consultants

17 CAR § 160-1801. Definition.

Consultant pharmacist. As used in this part:

(1) "Consultant pharmacist" means a pharmacist who assumes the ultimate responsibility to ensure adherence to all laws and rules concerning pharmacy services for a nursing home or other facility requiring consultant pharmacist services.

(2) The consultant pharmacist:

(A) Is required to perform the consultative services provided in the nursing home or other facility; and

(B) Must abide by:

(i) Pharmacy law and rules; and

(ii) The policy and procedures of the facility.

17 CAR § 160-1802. General requirements.

Any pharmacist desiring to serve as a consultant pharmacist for a nursing home or other facility must post a copy of his or her Arkansas Pharmacist License in the facility for which they are consulting.

17 CAR § 160-1803. Responsibilities.

Consultant pharmacists in a facility are involved in the following areas of pharmaceutical care that include drug storage, distribution, and utilization in that facility:

(1) **Supervision of services.**

(A)(i) The consultant pharmacist or pharmacists shall develop, coordinate, and supervise all pharmaceutical services.

(ii) The consultant pharmacist for the facility must ensure that pharmacist consultation is available on a twenty-four-hours-per-day, seven-days-per-week basis.

(iii) Consultant pharmacists shall devote a sufficient number of hours based upon the needs of the facility during regularly scheduled visits to carry out these responsibilities.

(B) Consultant pharmacists shall assist the facility in developing procedures to ensure the provision of emergency drugs, and shall report to the Arkansas State Board of Pharmacy any pharmacy refusing to provide medication for the pharmacy's regular patients in the facility on a twenty-four-hours-per-day, seven-days-per-week basis.

(C) The consultant pharmacist or pharmacists shall provide written consultation on compliance with federal and state laws governing legend drugs, including controlled substances.

(D) The consultant pharmacist or pharmacists shall:

(i) Be knowledgeable of all laws and rules pertaining to the facility; and

(ii) Communicate with the state agencies involved with enforcement and regulation of the facility.

(E) The consultant pharmacist or pharmacists shall spend sufficient time to:

(i) Evaluate discontinued or other unused medication for destruction or donation;

(ii) Check entries in a bound, numbered controlled drugs book;

(iii) Process unused medication for donation as provided in:

(a) Arkansas Code § 17-92-1101 et seq.; and

(b) 17 CAR § 160-1706; and

(iv) Make general observations at the nursing stations.

(F) Records shall indicate the day the consultant pharmacist or pharmacists visited the home and a brief statement of:

(i) Purpose;

(ii) Finding; and

(iii) Actions;

(2) **Control and accountability of all legend drugs, including controlled substances.**

(A) The consultant pharmacist:

(i) Develops written procedures for control and accountability of all drugs and biologicals throughout the facility; and

(ii) Supervises the implementation of these procedures.

(B)(i) Only approved drugs and biologicals are used in the facility and shall be dispensed in compliance with federal and state laws.

(ii) Records of receipt and disposition of all controlled drugs shall be maintained in sufficient detail to enable an accurate reconciliation.

(iii) The consultant pharmacist shall determine that:

(a) Drug records are in order; and

(b) An account of all controlled drugs is maintained and reconciled.

(C) The consultant pharmacist or pharmacists shall establish procedures to ensure that:

(i) All legend drugs and controlled substances must be stored in a secured location and appropriately locked;

(ii) Proper records of receipt and administration of controlled drugs must be maintained for review by the consultant pharmacist;

(iii) **Noncontrolled legend drugs.**

(a) Drugs to be destroyed shall be handled in accordance with state and federal requirements.

(b) **Drugs to be donated.** The consultant pharmacist shall cause all drugs that are designated for donation to charitable clinics licensed by the board under 17 CAR § 160-1304 and Arkansas Code § 17-92-1101 et seq., to be processed in accordance with 17 CAR § 160-1706; and

(iv) Controlled drugs shall be handled in accordance with state and federal requirements;

(3) **Patient drug regimen review.**

(A) The primary duty of the consultant pharmacist or pharmacists to the patients' concerns is to apply his or her expertise on drugs to the patient's specific situation.

(B) State and federal rules shall be the minimum standards for an adequate drug regimen review.

(C) Additionally, the consultant pharmacist shall routinely review each patient's medical records and:

(i) Ascertain that patient history and drug utilization is being properly recorded;

(ii) Review drug usage, including O.T.C. and prescriptions;

(iii) Review patient compliance with drug regimen;

(iv) Review drug allergies or sensitivities;

(v) Determine whether the patient is predisposed to side effects due to:

(a) Disease;

(b) Illness; or

(c) Age;

(vi) Determine whether potential exists for significant drug interaction;

(vii) Develop procedures to monitor patients' records for signs that indicate abuse or misuse of drugs by the patient or individuals;

(viii) Make recommendations regarding drug therapy to:

(a) The physician;

(b) The nurse; or

(c) Other persons involved in the patient's care;

(ix) Communicate to the facility procedures that ensure adequate pharmacy services are available for emergencies that might develop in the facility for a specific patient; and

(x) Promote pharmacists' ability and knowledge to:

(a) All persons involved in patient care; and

(b) Offer assistance in solving specific problems relating to a patient drug regimen.

(D) A consultant pharmacist or pharmacists shall quarterly in ICF/IID and assisted living (level II) facilities and monthly in nursing homes:

(i) Review each patient's medication record; and

(ii) Consult with and provide a written report of findings to the director of nursing or the patient's physician;

(4) **Labeling of drugs and biologicals and proper storage.**

(A) All legend drugs, including controlled substances, on the premises of a nursing home, except for the emergency kit maintained pursuant to 17 CAR § 160-1804 and 17 CAR § 160-1805, shall:

(i) Be stored under lock pursuant to Department of Health rules; and

(ii) Always be in a properly labeled container as dispensed upon a prescription by the pharmacy of the patient's choice.

(B) It is the duty of the consultant pharmacist or pharmacists to ascertain that:

(i) Medications are:

(a) Properly labeled;

(b) Properly stored; and

(c) Refrigerated when needed;

(ii) Expiration dates are routinely checked; and

(iii) Appropriate accessory and cautionary instructions are on all medications when required; and

(5) **Quality assurance and patient assessment committee.**

(A) A consultant pharmacist or pharmacists shall be a member of the quality assurance and patient assessment committee or its equivalent and make official reports to this committee as often as needed to ensure quality pharmaceutical care.

(B) The consultant pharmacist shall ensure that there are written policies and procedures for safe and effective drug:

(i) Therapy;

(ii) Distribution;

(iii) Control; and

(iv) Use.

(C) The policies and procedures shall include and are not limited to:

(i) Stop order policies or other methods to ensure appropriateness of continued drug therapy;

(ii) Maintaining the contents of the emergency kit in compliance with 17 CAR § 160-1805; and

(iii) Policies for the safe procurement, storage, distribution, and use of drugs and biologicals.

17 CAR § 160-1804. Emergency kits for long-term care and other approved institutional facilities.

(a) With recognition of the Drug Enforcement Administration's statement of policy regarding emergency kits for long-term care facilities and other law applicable to noncontrolled legend drugs, the following section is adopted to permit controlled substances and noncontrolled legend drugs to be stored in emergency kits in long-term care facilities in Arkansas.

(b) **Requirements.**

(1)(A) All contents of the emergency kit will be provided by one (1) pharmacy designated by the long-term care facility.

(B) This pharmacy must be properly registered with the Drug Enforcement Administration.

(2) The emergency kit shall be:

(A) Properly sealed and stored; and

(B) Accessible only to authorized personnel.

(3) The emergency kit contents shall only be administered by authorized personnel acting on order of a physician in compliance with 21 C.F.R. § 1306.11 and 21 C.F.R. § 1306.21.

(4)(A) The categories of drugs that may be contained in an emergency kit are identified in 17 CAR § 160-1805.

(B) The contents of the kit shall be determined by the medical director, director of nurses, and consultant pharmacist at the long-term care facility.

(C) Any exceptions to the established standard categories must be approved by the Arkansas State Board of Pharmacy.

(D) A list of contents shall be kept in the kit.

(5) The facility's licensed consultant pharmacist shall be responsible for maintaining the nursing home's emergency kit contents in compliance with 17 CAR § 160-1805 and the facility's licensed consultant pharmacist shall check the kit monthly for outdated drugs, etc.

(6) All drugs administered from the kit will be replaced within seventy-two (72) hours by the designated provider pharmacy based on a prescription for the patient to whom the drugs were administered.

(7) Violation of 17 CAR §§ 160-1801 – 160-1805 shall be just cause for the board to impose appropriate disciplinary action.

(8) Emergency kit drugs shall be of such a nature that the absence of such drugs would detrimentally affect the health of the patient.

(9)(A) Before an out-of-state pharmacy may supply an emergency kit to an Arkansas long-term care facility, it must provide an affidavit on a form supplied by the board that it will comply with Arkansas law regarding emergency kits.

(B) If applicable, an out-of-state pharmacy will also be subject to reciprocal restrictions as are imposed by its home state on out-of-state pharmacies.

(c) Recognizing the emergency and or unanticipated need for certain legend (noncontrolled) drugs to be available to nurses employed by Arkansas-licensed home health agencies, an Arkansas-licensed pharmacy may provide certain medications under the following conditions:

(1) A written contract must:

(A) Exist between the Arkansas-licensed home health agency and the Arkansas-licensed pharmacy; and

(B) Be available for review by the board upon request;

(2) The legend drugs remain the property of, and under the responsibility of, the Arkansas-licensed pharmacy;

(3) All medications shall be administered only on physician's orders and any medication administered from the nurse's supply must be recorded as a prescription by the pharmacy prior to the pharmacy's replacement of the drug in the emergency supply;

(4) All medication records must be maintained as required by law, and out-of-date drugs must be properly destroyed by the pharmacy;

(5) The emergency supply may be carried by each nurse or an emergency kit may be provided for each patient's home;

(6) Careful patient planning shall be a cooperative effort between the pharmacy and the nursing agency to make all medications available, and this emergency supply:

(A) Shall only be used for emergency or unanticipated needs; and

(B) Shall not become a routine source or supply;

(7)(A) Only the following medications can be supplied for emergency use by licensed home health agencies under this section by the pharmacy in sufficient but limited quantities:

(i) Heparin flush, pediatric (one (1) strength);

(ii) Heparin flush, adult (one (1) strength);

(iii) Sterile water for injection, small volume;

(iv) Sodium chloride for injection, small volume;

(v) Adrenalin (epinephrine) injection, single dose only; and

(vi)*(a)* Benadryl (diphenhydramine) injection, single dose only.

(b) **Note.** For heparin, adrenaline, and benadryl, all patients shall have a precalculated dose.

(B) If a container is opened and partially used, the unused portion shall be immediately discarded;

(8) The pharmacy is responsible for ensuring compliance with this part, and any abuse or misuse of the intent of this part shall be immediately reported to the board; and

(9) The pharmacy and the agency shall develop policy and procedures to address storage conditions for medications.

17 CAR § 160-1805. Drug categories for emergency kits in long-term care facilities.

(a) The following is a list of categories of drugs that are acceptable in emergency kits in long-term care facilities in accordance with this part.

(b) The Arkansas State Board of Pharmacy shall set guidelines for specific quantities of approved medications, which will be reviewed biennially or periodically as needed.

(c) The provision or presence of an emergency kit in long-term care facilities does not waive the requirements of 17 CAR § 160-1706, which requires any pharmacy providing prescription drugs to one (1) or more patients in a nursing home or other institution to provide:

(1) Emergency prescription services for those patients; and

(2) Information to the nursing home or institution indicating how the pharmacists can be reached after pharmacy hours.

(d) In every instance where injectables are indicated, only single-dose injectables are acceptable:

(1) Analgesics, controlled drugs;

(2) Anti-infectives;

(3) Anticholinergics;

(4) Anticoagulants;

(5) Antidiarrheals;

(6) Antihistamine injectables;

(7) Antinauseants;

(8) Antipsychotic injectables;

(9) Anti-hyperglycemics;

(10) Anxiolytics;

(11) Cardiac life support medications;

(12) Coagulants;

(13) Corticosteroids;

(14) Hypoglycemics;

(15) Seizure control medications;

(16) Large volume parenterals;

(17) Poison control;

(18) Respiratory medications;

(19) GI medications; and

(20) Other medications as approved by the board.

17 CAR § 160-1806. Drug categories for emergency kits in hospice care facilities.

(a) The following is a list of categories of drugs that are acceptable in emergency kits in licensed in-patient hospice facilities in accordance with this part.

(b) The board shall set guidelines for specific quantities of approved medications, which will be reviewed periodically.

(c) The provision or presence of an emergency kit in an in-patient hospice facility does not waive the requirements of 17 CAR § 160-1006 that requires any pharmacy providing prescription drugs to one (1) or more patients in a nursing home or other institution to provide emergency prescription services for those patients and to provide information to the nursing home or institution indicating how the pharmacists can be reached after pharmacy hours:

(1) Analgesics, controlled drugs;

(2) Antihistamine injectables;

(3) Antinauseants;

(4) Antipsychotic medications;

(5) Anxiolytics;

(6) Seizure control medications;

(7) Corticosteroids;

(8) Anticholinergic medications;

(9) Opioid antagonists; and

(10) Other medications as approved by the board.

17 CAR § 160-1807. Drug categories for emergency kits in crisis stabilization units.

(a) The following is a list of categories of drugs that are acceptable in emergency kits for facilities that are certified by the Department of Human Services as a crisis stabilization unit.

(b) The Arkansas State Board of Pharmacy shall set guidelines for specific quantities of approved medications, which will be reviewed periodically.

(c) The provision or presence of an emergency kit in a crisis stabilization unit does not waive the requirements of 17 CAR § 160-1006 that requires any pharmacy providing prescription drugs to one (1) or more patients in a nursing home or other institution to provide:

(1) Emergency prescription services for those patients; and

(2) Information to the nursing home or institution indicating how the pharmacists can be reached after pharmacy hours:

(A) Analgesics, controlled drugs;

(B) Antihistamine injectables;

(C) Antinauseants;

(D) Antipsychotic medications;

(E) Anxiolytics;

(F) Cardiac life support medications;

(G) Injectable seizure control medications;

(H) Anticholinergic medications;

(I) Opioid antagonists; and

(J) Other medications as approved by the board.

Subpart 19. Disciplinary Procedures

17 CAR § 160-1901. Procedures for disciplinary action.

(a) Before revoking the certificate of licensure of any licensed pharmacist or licensed pharmacy permit, the Arkansas State Board of Pharmacy shall give the licensee proper notice in writing to appear before the board, at such time and place as the

board may direct, to show cause, if any, why the certificate or permit should not be revoked.

(b) Said notice shall:

(1) Be signed by the Executive Director of the Arkansas State Board of Pharmacy; and

(2) Set forth in clear, concise language the nature of the charge against the licensee.

(c) Mailing a copy of such notice by registered mail, addressed to the licensee at the address appearing upon the records of the board, concerning the issuance of the certificate or permit or the last renewal thereof, shall be sufficient service of such notice.

(d) At such hearing, the:

(1) Board shall have power to subpoena witnesses;

(2) President or chair of the Arkansas State Board of Pharmacy shall have the power to administer oaths; and

(3) Board shall hear evidence.

(e) If the board finds after such hearing that the certificate of licensure or permit of the licensee should be revoked, the same shall be done forthwith.

Subpart 20. Drug Products/Prescriptions — General Rules Regarding Drugs/Prescriptions

17 CAR § 160-2001. Definitions.

As used in this part:

(1)(A) "Prescription" means an order for medicine or medicines usually written as a formula by a:

(i) Physician;

(ii) Optometrist;

(iii) Dentist;

(iv) Veterinarian; or

(v) Other licensed medicinal practitioner.

(B) It:

(i) Contains the names and quantities of the desired substance, with instructions to the pharmacist for its preparation and to the patient for the use of the medicine at a particular time; and

(ii) May authorize the pharmacist to substitute a therapeutically equivalent drug that is at an equal or lower cost to the patient and communicate that authorization by any generally accepted means of communication of a prescription from a prescriber to a pharmacist;

(2) "Prescription drug order" means a lawful order of a practitioner for a drug or device for a specific patient that is communicated to a pharmacist;

(3) "Therapeutic class" means a group of similar drug products that:

(A) Have the same or similar mechanisms of action; and

(B) Are used to treat a specific condition;

(4) "Therapeutically equivalent" means drug products from the same therapeutic class that if administered in appropriate amounts will provide the same therapeutic effect, identical in duration and intensity; and

(5) "Written prescription" means a prescription that is presented to an apothecary, pharmacy, or pharmacist in compliance with federal law and regulations, including a written, oral, faxed, or electronic prescription.

17 CAR § 160-2002. Facsimile (fax) prescription drug order.

(a) A prescription drug order that is transmitted by an electronic device which sends an exact copy image to the receiver (pharmacy) over telephone lines.

(b) **Faxing Schedule II prescriptions.**

(1)(A) **Faxing a Schedule II prescription for a home infusion or intravenous pain therapy patient, or both.** A prescription written for a Schedule II narcotic substance to be compounded for direct administration to a home infusion patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion

may be transmitted directly from the prescribing practitioner, by the practitioner or the practitioner's agent, to the pharmacy by facsimile.

(B)(i) The facsimile serves as the original written prescription.

(ii) This exception does not apply to oral dose medications.

(iii) Also see 17 CAR § 160-2401.

(2)(A) **Faxing a Schedule II prescription for a long-term care patient.** A prescription written for a Schedule II substance for a resident of a long-term care facility may be transmitted directly from the prescribing individual practitioner, or the practitioner's agent, to the provider pharmacy by facsimile.

(B) The facsimile serves as the original written prescription.

(C) See also 17 CAR § 160-2401.

(3)(A) A prescription written for a Schedule II substance for a home hospice patient may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile.

(B) It must be noted on the prescription that this is a hospice patient.

(C) The facsimile serves as the original written prescription.

(D) See 17 CAR § 160-2401.

(c) **Faxing from a long-term care facility to a pharmacy.** A pharmacist may accept a fax prescription from a long-term care facility provided that:

(1) For Schedule II drugs, all requirements of a written prescription are met including:

(A) The prescriber's signature on the faxed order;

(B) It is faxed by the nurse/person the physician and the long-term care facility has designated as his or her agent to transmit the order; and

(C) It must contain the nurse/person's signature;

(2) For drugs other than Schedule II, the order:

(A) Is faxed by the nurse/person the physician and the long-term care facility has designated as his or her agent to transmit the order; and

(B) Must contain the nurse/person's signature; and

(3) The pharmacist verifies the fax is from the machine in the long-term care facility.

(d) **Faxed prescriptions.**

(1) A pharmacist may dispense directly a controlled substance listed in Schedules III, IV, or V that is a prescription drug, or any legend drug, only pursuant to either a written prescription signed by a prescribing individual practitioner or a facsimile of a written signed prescription transmitted directly by the prescribing practitioner, or the practitioner's agent, to the pharmacy or pursuant to an oral prescription made by a prescribing individual practitioner, or the practitioner's agent, and either entered into the pharmacy's electronic prescription system or promptly reduced to writing by the pharmacist.

(2) All laws, rules, and regulations applicable to oral prescription drug orders shall also apply to all facsimile orders, including but not limited to generic substitution, maintenance of records, information required, etc.

(3) A prescription order transmitted by facsimile device shall contain all prescription information required by federal and state law.

(4)(A) A pharmacist may dispense new prescription orders transmitted by fax only when signed by the prescribing practitioner and transmitted from the practitioner's office or a long-term care facility in compliance with all sections of this part.

(B) Any faxed new prescription order that is not signed must be:

(i) Treated as a verbal order; and

(ii) Verified to the pharmacist's satisfaction that it is legitimate.

(5) The original fax shall be:

(A) Assigned the number of the prescription dispensed; and

(B) Maintained in pharmacy records for at least two (2) years.

(6) The receiving fax machine must be in the prescription department of the pharmacy to protect patient-authorized or pharmacist-authorized prescribing practitioner confidentiality and security.

(7)(A) Refill authorizations for prescriptions, other than Schedule II, may be transmitted using a facsimile device.

(B) Any faxed authorization to renew or refill a prescription that is not signed must be:

(i) Treated as a verbal order; and

(ii) Verified to the pharmacist's satisfaction that it is legitimate.

(e) **Patient/prescriber consideration.**

(1) No pharmacist shall enter into any agreement with a practitioner or healthcare facility concerning the provision of facsimile machine services or equipment that adversely affects any person's freedom to choose the pharmacy at which a prescription will be filled.

(2) A pharmacy/pharmacist shall not provide a fax machine to a prescriber, a long-term care facility, or any healthcare facility free of charge or for less than the pharmacy's/pharmacist's cost.

(3) No agreement between a prescriber and a pharmacy shall require that prescription orders be transmitted by facsimile machine from the prescriber to only that pharmacy.

(4) A pharmacy/pharmacist shall not enter into any agreement whereby the pharmacy/pharmacist pays to obtain the prescription order by fax or any electronic data transfer.

17 CAR § 160-2003. Prescription transfers.

(a)(1) The transfer of original prescription information for a legend drug or a controlled substance for the purpose of dispensing is permissible between pharmacies on a one-time basis only.

(2) However, pharmacies electronically sharing a real-time online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(b) Transfers are subject to the following requirements:

(1) The transfer is communicated directly between two (2) licensed or registered individuals where one (1) of the two (2) must be a pharmacist, and the transferring individual records the following information:

(A) Void the transferred prescription;

(B) Record the:

(i) Name, address, and Drug Enforcement Administration registration number of the pharmacy to which it was transferred; and

(ii) Name of the individual receiving the prescription information; and

(C) Record the:

(i) Date of the transfer; and

(ii) Name of the individual transferring the information;

(2) The individual receiving the transferred prescription information shall electronically record or reduce to writing the following:

(A) Record that the prescription is a transferred prescription; and

(B) Provide all information required to be on a prescription pursuant to 21 C.F.R. § 1306.05 and include:

(i) Date of issuance of original prescription;

(ii) Original number of refills authorized on original prescription;

(iii) Date of original dispensing;

(iv) Number of valid refills remaining and date or dates and locations of previous refill or refills;

(v) Pharmacy's name, address, Drug Enforcement Administration registration number, and prescription number from which the prescription information was transferred; and

(vi) Name of individual who transferred the prescription;

(3) The original and transferred prescription or prescriptions must be maintained for a period of two (2) years from the date of last refill;

(4) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transfer;

(5) Pharmacies transferring prescriptions may utilize facsimile or other electronic means to communicate information for transfers; and

(6) Transfers of controlled substances must follow federal laws and regulations.

17 CAR § 160-2004. Signing prescriptions.

(a) Every licensed pharmacist or intern who shall fill or refill a prescription shall attest that he or she has personally filled said prescription by placing upon said prescription his or her signature with date thereof unless the pharmacy is electronically processing prescriptions.

(b) If the pharmacy uses an electronic prescription processing system, they must fill prescriptions in accordance with 17 CAR § 160-2009.

17 CAR § 160-2005. Secret codes prohibited.

The treatment of disease, injury, or deformity by secret means or secret drugs being contrary to both the spirit and the letter of the Arkansas Medical Practices Act, Arkansas Code § 17-95-201 et seq., § 17-95-301 et seq., and § 17-95-401 et seq., and dispensing of secret medicines or drugs being contrary to both the spirit and the letter of the Pharmacy Practice Act and the Food, Drug, and Cosmetic Act, Arkansas Code § 20-56-201 et seq., hereafter no licensed pharmacist or intern shall enter into any agreement or arrangement with a physician or other practitioner authorized by law to prescribe medicine or drugs for the compounding and/or dispensing of a secret formula or coded prescription.

17 CAR § 160-2006. Maintenance and retention of drug records.

(a) All drug records, including but not limited to purchase invoices, official dispensing records, and prescription and inventory records:

(1) Must be kept in such a manner that all data is readily retrievable; and

(2) Shall be retained as a matter of record by the pharmacist for at least two (2) years.

(b) At least every twelve (12) months, all prescriptions for legend drugs that are not controlled substances when refilled must:

(1) Be verified by the prescribing practitioner;

(2) Have a new prescription written; and

(3) Have a new prescription number assigned to the prescription.

(c) The prescription number of the updated prescription shall be recorded on the new prescription.

(d) Provided, however, this rule recognizes and in no way affects the six-month and five-refill limits on controlled drug prescriptions pursuant to Arkansas Code § 5-64-308(b).

17 CAR § 160-2007. Generic substitution.

(a) The Arkansas State Board of Pharmacy recognizes the Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (The Orange Book or The Green Book) as the basis for the determination of generic equivalency within the limitations stipulated in that publication.

(b) If the Food and Drug Administration approves a drug product as bioequivalent and publishes that product with an "A" (AA, AB, AN, AO, AP, and AT) rating in the Approved Drug Products with Therapeutic Equivalence Evaluations (The Orange Book or The Green Book), an Arkansas pharmacist or any pharmacist dispensing drugs to patients in Arkansas may substitute that product consistent with law.

(c) Conversely, if the drug product is "B" rated, is changed from an "A" rating to a "B" rating, or is not rated, the pharmacist may not substitute without the consent of the prescribing practitioner.

(d) When a pharmacist substitutes a bioequivalent drug product for the drug prescribed, the patient shall be notified of the substitution by a pharmacist involved in the dispensing process.

17 CAR § 160-2008. Dispensing generically equivalent drug product.

A pharmacist shall not dispense a generically equivalent drug product under Arkansas Code § 17-92-503(a) and (b) if:

(1) In the case of a written prescription, on the prescription the prescriber:

(A) Writes in his or her own handwriting words that specify that no substitution shall be made; and

(B) Then also signs the prescription;

(2) The prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly states at the time the prescription is given that it is to be dispensed as communicated, and same is either entered into the pharmacy's electronic prescription system or reduced to writing on the prescription by the pharmacist; or

(3) The person for whom the drug product is prescribed indicates the prescription is to be dispensed as written or communicated.

17 CAR § 160-2009. Electronic prescription processing and patient confidentiality.

(a) **Definitions.** As used in this part:

(1) "Confidential information" means information that is personally identifiable and, therefore, can be traced back to the patient or prescribing practitioner, that is accessed or maintained by the pharmacist in the patient's records or that is communicated to the patient as part of patient counseling, which is privileged and may be released only to the patient or prescriber or as the patient or prescriber directs, to those practitioners, other authorized healthcare professionals, and other pharmacists where, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and wellbeing, and to such other persons or governmental agencies authorized by law to receive such confidential information, regardless of whether such information is:

(A) In the form of paper;

(B) Preserved on microfilm; or

(C) Stored on electronic media;

(2) "Electronic transmission" means transmission of information in electronic form such as:

(A) Computer-to-computer;

(B) Electronic device to computer;

(C) Email; or

(D) The transmission of the exact visual image of a document by way of electronic equipment; and

(3) "Prescription drug order" means a lawful order of a practitioner for a drug or device for a specific patient that is communicated to a pharmacist.

(b) **Patient confidentiality requirements.**

(1) Prescription information and other patient healthcare information shall be maintained in a manner that protects the integrity and confidentiality of such information as provided by rules of the Arkansas State Board of Pharmacy.

(2) The pharmacy shall provide a mechanism for patients to prevent the disclosure of any information, confidential or otherwise, about them that was obtained or collected by the pharmacist or pharmacy incidental to the delivery of pharmaceutical care other than as authorized by law or rules of the board.

(3) The pharmacist-in-charge shall:

(A)(i) Establish written policies and procedures for maintaining the integrity and confidentiality of prescription information and patient healthcare information.

(ii) All employees of the pharmacy with access to any such information shall be required to read, sign, and comply with the established policies and procedures; and

(B) Ensure that the requirements of this rule are established and implemented.

(c) **Manner of issuance of a prescription drug order.**

(1)(A) A prescription drug order may be transmitted to a pharmacy by electronic transmission.

(B) If transmitted by way of electronic transmission, the prescription drug order shall be immediately reduced to a form by the pharmacist that may be maintained for the time required by law or rules.

(C) Persons other than those bound by a confidentiality agreement, pursuant to a consent agreement, shall not have access to pharmacy records containing personally identifiable confidential information concerning the pharmacy's patients or prescribers.

(2) All prescription drug orders communicated by way of electronic transmission shall:

(A) Be sent only to the pharmacy of the patient's choice with no intervening person having access to the prescription drug order;

(B) Identify the transmitter's phone number for verbal confirmation, the time and date of transmission, and the pharmacy intended to receive the transmission, as well as any other information required by federal or state law;

(C) Be transmitted by the authorized practitioner or the designated agent of the practitioner; and

(D) Be deemed the original prescription drug order provided it meets the requirement of this rule and other law or regulation.

(3)(A) All electronic equipment for receipt of prescription drug orders communicated by way of electronic transmission shall be maintained so as to ensure against unauthorized access.

(B) The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the prescription drug order consistent with existing federal or state laws, rules, or regulations.

(4) The prescribing practitioner may authorize his or her agent to transmit a prescription drug order by electronic transmission to the pharmacy provided that the identity of the transmitting agent is included in the order.

(d) **Patient records.**

(1) Personally identifiable confidential information in the patient medication record may be released to:

(A) The patient;

(B) The prescriber;

(C) Other licensed practitioners then caring for the patient;

(D) Another licensed pharmacist;

(E) The board or its representatives; or

(F) Any other person duly authorized by law to receive such information.

(2) Personally identifiable confidential information in the patient medication record may be released to others only on written release of the patient.

(3) Personally identifiable confidential information in the patient medication record related to identity of the prescriber may be released only on written release of the prescriber.

(e) **Discipline.** The board may refuse to issue or renew, or may suspend, revoke, restrict the licenses or the registration of, or fine any person for divulging or revealing confidential information to a person other than as authorized by rules of the board.

(f) **Security.**

(1) To maintain the confidentiality of patient and prescriber records, the computer system shall have adequate security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records.

(2) Once the drug has been dispensed, any alterations in prescription drug order data shall be documented, including the identification of the pharmacist responsible for the alteration.

(g) **Providing electronic equipment by pharmacists or pharmacies to practitioners or healthcare facilities prohibited.**

(1) A pharmacist or pharmacy shall not provide a computer modem or other similar electronic device to a prescriber or healthcare facility for the purpose of

providing an incentive to the practitioner or healthcare facility to refer patients to a particular pharmacy or department.

(2) This shall not prohibit a hospital from providing in-house equipment for the use of practitioners and the hospital pharmacy to communicate within the facility.

17 CAR § 160-2010. Proper practitioner-patient relationship.

In accordance with Arkansas Code § 17-92-1004(c) and § 17-92-1003(15), an in-person physical exam of the patient performed by a practitioner, physician, doctor or other prescribing health professional ("a practitioner") prior to the issuance of any prescription is required in order to establish a valid prior patient-practitioner relationship for purposes of Arkansas Code § 17-92-1004(c) and a "proper practitioner-patient relationship" for purposes of Arkansas Code § 17-92-1003(15), unless the prescribing practitioner:

(1) Is consulting at the specific request of another practitioner who:

(A) Maintains an ongoing relationship with the patient;

(B) Has performed an in-person physical exam of the patient; and

(C) Has agreed to supervise the patient's ongoing care and use of prescribed medications; or

(2) Interacts with the patient through an on-call or cross-coverage situation.

17 CAR § 160-2011. Therapeutic substitution.

(a) A pharmacist whose practice is located within this state may substitute medications for therapeutically equivalent medications.

(b) However, a pharmacist shall not substitute a medication for a therapeutically equivalent medication if:

(1) A prescription is in writing and the prescriber indicates in his or her own handwriting by name or initial that no substitution is to be made;

(2) A prescription is not in writing and the prescriber expressly indicates that the prescription is to be dispensed as communicated; or

(3)(A) The Arkansas State Board of Pharmacy has:

(i) Determined that a therapeutically equivalent medication should not be substituted; and

(ii) Notified all pharmacists of that determination.

(B) Examples include but are not limited to any:

(i) Antipsychotics;

(ii) Antidepressants;

(iii) Controlled substances; and

(iv) Oncolytic agents.

(c) Therapeutic equivalence may be established with clinical publications comparing dosages of drugs in a therapeutic class.

(d)(1) Before dispensing, the pharmacist shall:

(A) Discuss verbally any suggested substitution with the patient; and

(B) Inform the patient that the patient has a right to refuse the substitution.

(2) This discussion shall include without limitation:

(A) Notification to the patient that the therapeutically equivalent drug does not contain the identical active ingredient present in the prescribed drug; and

(B) All differences in dosage and frequency between the prescribed drug and the therapeutically equivalent drug.

(e) The pharmacist shall send notice of the substitution to the prescriber in writing or by electronic communication within twenty-four (24) hours after the drug is dispensed to the patient.

(f) This section does not apply to specific acts of drug therapy management or disease state management delegated to a pharmacist based upon a written protocol or patient care plan approved by a physician under Arkansas Code § 17-92-101(18)(A)(ix);

Subpart 21. Drug Products/Prescriptions — Food and Drug Administration Approval of Drugs

17 CAR § 160-2101. Controlled substances approved by the Food and Drug Administration.

(a) Any wholesale drug company or drug manufacturer doing business in Arkansas pursuant to Acts 1969, No. 173, as amended by Acts 1979, No. 75, and Acts 1981, No. 257 shall not distribute any controlled substance or legend drug or both in the State of Arkansas if:

(1) That product requires approval by the Food and Drug Administration for marketing and distribution; and

(2) The product in fact has not been approved for marketing and distribution by the Food and Drug Administration.

(b) Violation of this rule shall be grounds for suspension or revocation of the license of the wholesale drug or drug manufacturer's license to do business in the State of Arkansas.

17 CAR § 160-2102. Drug products must have a new drug application or an abbreviated new drug application.

(a)(1) In order to provide for the protection of the public health and safety, drug products that are offered for sale by or stored at the premises of any manufacturer, distributor, wholesaler, or pharmacy located in Arkansas must have an approved new drug application (NDA) or abbreviated new drug application (ANDA) designation by the Food and Drug Administration pursuant to 21 U.S.C. § 355 unless they are exempt from the requirements for such a designation.

(2) In order to protect the public health and safety, drug products offered for sale by or stored at the premises of a manufacturer, wholesaler, distributor, or pharmacy location in Arkansas, which do not have the required NDA or ANDA designation or exemption therefrom referenced in the above paragraph, are hereby

declared to be contraband and subject to surrender to and destruction by the Department of Health.

(b)(1) Whenever it is made to appear to the Arkansas State Board of Pharmacy that any licensee of the board is in possession of a stock of drugs that are contraband as defined above, a representative of the board shall confirm with the Food and Drug Administration by telephone that the particular drug or drugs involved do not have the requirement.

(2) Upon receipt of this confirmation, the board shall inform the owner or person in charge of the contraband status of the drugs in question.

(c)(1) Retention, dispensing, promotion, or advertisement of drug products by a licensee of the board, either at its business premises or at any separate storage facility after notification of their contraband status:

(A) Shall constitute a direct and immediate danger to the public health and safety; and

(B) Will be good and sufficient cause for the suspension or revocation of any license issued by the board for knowingly retaining, dispensing, promoting, or advertising any drug products that are contraband under this rule.

(2) This suspension or revocation would occur only after proper hearings are held by the board.

Subpart 22. Drug Products/Prescriptions — Compounding

17 CAR § 160-2201. Standards for compounding and dispensing sterile products.

(a) The purpose of this rule is to provide standards in the conduct, practices, and operations of a pharmacy preparing and dispensing products requiring sterility, such as:

(1) Injectables;

(2) Ophthalmics; and

(3) Inhalants.

(b)(1) Compounding a drug product that is commercially available in the marketplace or that is essentially a copy of a commercially available Food and Drug Administration-approved drug product is generally prohibited.

(2) However, in special circumstances a pharmacist may compound an appropriate quantity of a drug that is only slightly different than a Food and Drug Administration-approved drug that is commercially available:

(A) Based on documentation provided by the prescribing physician of a patient-specific medical need (e.g., the physician requests an alternate product due to hypersensitivity to excipients or preservative in the Food and Drug Administration-approved product, or the physician requests an effective alternate dosage form); or

(B) If the drug product is not commercially available.

(3)(A) The unavailability of such drug product must be documented prior to compounding.

(B) The recommended methodology for documenting unavailability is to print the screen of wholesalers showing back-ordered, discontinued, or out-of-stock items.

(C) This or similar documentation must be available when requested by the Arkansas State Board of Pharmacy.

(c) Except for those products where stability prohibits advanced compounding, all products dispensed by the pharmacy shall be in a form ready for administration, except in healthcare facilities where medications may be provided as demanded by policies and procedures.

(d) Pharmacies and pharmacists dispensing sterile products shall comply with all applicable federal, state, and local regulations, laws, and rules concerning pharmacy and also these additional rules:

(1)(A) Guidelines for preparation of sterile products will be based on the distinction of sterile products as either low-risk, medium-risk, or high-risk products.

(B) Sterile products compounded under all of the following conditions are considered low-risk sterile products:

(i) The finished products are compounded with aseptic manipulations entirely within a Class 100 environment or better air quality using only sterile:

(a) Ingredients;

(b) Products;

(c) Components; and

(d) Devices;

(ii) The compounding involves only transfer, measuring, and mixing manipulations with closed or sealed packaging systems that are performed promptly and attentively;

(iii) Manipulations are limited to:

(a) Aseptically opening ampules;

(b) Penetrating sterile stoppers on vials with sterile needles and syringes; and

(c) Transferring sterile liquids in sterile syringes to sterile administration devices and packages of other sterile products; and

(iv)*(a)* For a low-risk preparation, in the absence of passing a sterility test, the storage periods shall not exceed the following time periods.

(b) Before administration, the sterile products are exposed for no more than forty-eight (48) hours at controlled room temperature, fourteen (14) days at two degrees to eight degrees Centigrade (2°C – 8°C), and forty-five (45) days in solid frozen state at negative twenty degrees Centigrade (-20°C) or colder, while properly stored.

(C) When sterile products compounded aseptically under low-risk conditions and one (1) or more of the following conditions exists, such products are considered medium-risk sterile products:

(i) Multiple individual or small doses of sterile products are combined or pooled to prepare a sterile product that will be administered either to multiple patients or to one (1) patient on multiple occasions;

(ii) The compounding process includes complex aseptic manipulations other than the single-volume transfer;

(iii) The compounding process requires unusually long duration, such as that required to complete dissolution or homogeneous mixing;

(iv) The sterile products:

(a) Do not contain broad-spectrum bacteriostatic substances; and

(b) Are administered over several days; and

(v)*(a)* For a medium-risk preparation, in the absence of passing a sterility test, the storage periods shall not exceed the following time periods.

(b) Before administration, the sterile products are exposed for no more than thirty (30) hours at controlled room temperature, seven (7) days at two degrees to eight degrees Centigrade (2°C – 8°C), and forty-five (45) days in solid frozen state at negative twenty degrees Centigrade (-20°C) or colder, while properly stored.

(D) Sterile products compounded under any of the following conditions are considered high-risk sterile products:

(i) Nonsterile ingredients are incorporated or a nonsterile device is employed before terminal sterilization;

(ii)*(a)* Sterile ingredients, components, devices, and mixtures are exposed to air quality inferior to a Class 100 environment.

(b) This includes storage in environments inferior to a Class 100 environment of opened or partially used packages of manufactured sterile products that lack antimicrobial preservatives;

(iii) Nonsterile preparations are exposed no more than six (6) hours before being sterilized;

(iv) It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients; or

(v)*(a)* For a high-risk preparation, in the absence of passing a sterility test, the storage periods shall not exceed the following time periods.

(b) Before administration, the sterile products are exposed for no more than twenty-four (24) hours at controlled room temperature, three (3) days at two degrees to eight degrees Centigrade (2°C – 8°C), and forty-five (45) days in solid frozen state at negative twenty degrees Centigrade (-20°C) or colder, while properly stored;

(2) **Pharmacist requirements.** Any pharmacist-in-charge who performs or supervises the preparation or sterilization of sterile medications shall:

(A)(i) Have available written policies and procedures for all steps in the compounding of sterile preparations.

(ii) In addition, said policies and procedures shall address personnel education and training and evaluation, storage and handling, clothing, personal hygiene, hand washing, aseptic technique, quality assurance, expiration dating, and other procedures as needed;

(B)(i) Certify that all participating pharmacists and pharmacy technicians have completed a board-approved training and testing program in sterile product preparation.

(ii) Documentation of training and testing shall be available for review by February 30, 2002; and

(C) Develop policies and procedures to annually test and review the techniques of participating pharmacists and pharmacy technicians to ensure adherence to aseptic procedures;

(3) **Pharmacy technician requirements.**

(A) Pharmacy technicians participating in the preparation of sterile products shall have completed a board-approved pharmacist-supervised training and testing program in sterile product preparation as described in 17 CAR § 160-906(b).

(B) Documentation of training and testing shall be available;

(4) **Work area and equipment.** Any pharmacy dispensing sterile parenteral solutions shall meet or exceed the following requirements:

(A)(i) A separate controlled limited access area, also called a buffer area or buffer room, for compounding sterile solutions, which shall be of adequate space for compounding, labeling, dispensing, and sterile preparation of the medication.

(ii) This area shall have controlled temperature and humidity.

(iii) Cleanliness of the area is of critical importance.

(iv) Drugs and other materials taken into the limited access area shall be removed from cardboard and other particle-generating materials before being taken into the area;

(B)(i) The controlled limited access area shall have a certified and inspected Class 100 environment.

(ii) Such an environment exists inside a certified laminar airflow hood (clean room, biological safety cabinet, or other barrier isolator meeting Class 100 requirements) used for the preparation of all sterile products.

(iii) The Class 100 environment device or area is to be inspected and certified yearly.

(iv) Barrier isolator workstations are closed systems and are not as sensitive to their external environment as laminar airflow equipment.

(v) It is recommended to place them in a limited access area with cleaning and sanitizing in the surrounding area on a routine basis;

(C)(i) Hazardous drugs shall be prepared within a certified Class 11, Type A (exhaust may be discharged to the outdoors) or Class 11, Type B (exhaust may be discharged to the outdoors) laminar flow biological safety cabinet.

(ii) The Class 11, Type B can be obtained with a "bag-in-bag-out" filter to protect the personnel servicing the cabinet and facilitate disposal.

(iii) When preparing cytotoxic agents, gowns and gloves shall be worn.

(iv) All new construction, and those undergoing renovation requiring the moving of existing hoods used in the preparation of cytotoxic drugs, shall exhaust the hood to the outdoors unless the board grants an exception.

(v) The cabinet of choice is a Class 11, Type B.

(vi) For the purpose of this rule, hazardous drugs shall be defined as agents that exhibit characteristics of genotoxicity, carcinogenicity, teratogenicity, or evidence of serious organ or other toxicity at low doses;

(D) The area shall be designed to avoid excessive traffic and airflow disturbances;

(E) The area shall be ventilated in a manner not interfering with laminar flow hood conditions; and

(F) Daily procedures must be established for cleaning the compounding area;

(5) **Storage.** All pharmacies preparing and dispensing sterile products must provide:

(A) Adequate controlled room temperature storage space for all raw materials;

(B)(i) Adequate storage space for all equipment.

(ii) All drugs and supplies shall be stocked on shelving above the floor;

(C)(i) Adequate refrigerator storage space for compounded solutions, with routinely documented temperatures.

(ii) Temperature ranges required are thirty-six degrees to forty-six degrees Fahrenheit (36°F – 46°F) or two to eight degrees Centigrade (2°C – 8°C); and

(D)(i) Adequate freezer storage space if finished products are to be frozen, e.g., reconstituted antibiotics.

(ii) There shall be a procedure to routinely document temperatures;

(6) **Labeling.** In addition to regular labeling requirements, the label shall include:

(A) Parenteral products shall have the rate of infusion when applicable;

(B)(i) Expiration date.

(ii) Policies and procedures shall address label change procedures as required by physician orders;

(C) Storage requirements or special conditions;

(D) Name of ingredients and amounts contained in each dispensing unit; and

(E) All products dispensed to outpatients and removed from the site of preparation for administration different than the site of preparation shall have label information as required by state law;

(7) **Shipping.**

(A) Policies and procedures shall ensure product stability during delivery.

(B) Pharmacy must ensure ability to deliver products within an appropriate time frame;

(8) **Home patient care services.** The pharmacist-in-charge of the pharmacy dispensing sterile parenteral solutions shall provide the following or ensure that they are provided prior to providing medications:

(A) The pharmacist must ensure that the patient is properly trained if self-administering;

(B) In situations where a pharmacy or pharmacist employs a nurse to administer medications, the pharmacist-in-charge must:

(i) Employ a registered nurse;

(ii) Ensure that proper records are maintained in compliance with laws, rules, and regulations; and

(iii) Make these records available to inspectors from appropriate agencies;

(C) Twenty-four-hour service shall be ensured by the pharmacy;

(D) Pharmacists shall recommend and monitor clinical laboratory data as requested;

(E) Side effects and potential drug interactions should be documented and reported to the physician; and

(F) Patient histories and therapy plans should be maintained;

(9) **Destruction of cytotoxic drugs.**

(A) Any pharmacy providing cytotoxic drugs shall establish procedures ensuring the return and proper destruction of any unused radioactive or cytotoxic drugs or other hazardous material (destruction containers for needles).

(B) In every instance, the pharmacist-in-charge shall monitor the delivery, storage, and administration records of medications dispensed from his or her pharmacy; and

(10) When preparing high-risk sterile products, the pharmacist-in-charge is responsible for making sure the above procedures, in addition to the following, shall be met:

(A) Compound all medications in one (1) of the following environments:

(i) A separate controlled limited access area with a positive air flow room inspected and certified as meeting Class 10,000 requirements (Class 10,000 as defined by Federal Standard 209E);

(ii) An enclosed room providing a Class 100 environment for compounding; or

(iii)*(a)* A barrier isolator that provides a Class 100 environment for compounding.

(b) It is recommended that all pharmacies have an anteroom designed to be separate from the buffer room.

(c) The anteroom should be available for the:

(1) Decontamination of supplies and equipment; and

(2) Donning of protective apparel.

(d) A sink should be available in the anteroom area so that personnel can scrub prior to entering the buffer room;

(B)(i) Use total aseptic techniques, including gowning, mask, and hair net.

(ii) Scrubs may be worn, instead of gowning, if not worn or covered outside of the controlled limited access area;

(C) Provide a system for tracking each compounded product including:

(i) Personnel involved in each stage of compounding;

(ii) Raw materials used, including:

(a) Quantities;

(b) Manufacturer;

(c) Lot number; and

(d) Expiration date;

(iii) Labeling; and

(iv) Compounding records shall be kept for two (2) years;

(D) Establishment of procedures for sterilization of all products prepared with any nonsterile ingredients by filtration with twenty-two hundredths (0.22) micron or other means appropriate for the product components;

(E)(i) All high-risk-level compounded sterile products for administration by injection into the vascular and central nervous systems that are prepared in groups of more than twenty-five (25) identical individual single-dose packages, such as ampules, bags, syringes, and vials, in multiple-dose vials for administration to multiple patients, or are exposed longer than twelve (12) hours at two degrees to eight degrees Centigrade (2°C – 8°C) and longer than six (6) hours at warmer than eight degrees Centigrade (8°C) before they are sterilized shall be tested to ensure they are sterile, do not contain excessive bacterial endotoxins, and are of labeled potency before they are dispensed or administered as provided below.

(ii) **Sterility testing — Bacterial and fungal.**

(a) The United States Pharmacopeia (USP) Membrane Filtration method is the method of choice where feasible, e.g., components are compatible with the membrane.

(b) The USP Direct Transfer method is preferred when the Membrane Filtration method is not feasible.

(c) An alternative method may be used if verification results demonstrate that the alternative is at least as effective and reliable as the:

(1) USP Membrane Filtration method; or

(2) USP Direct Transfer method.

(d) The pharmacist-in-charge shall establish written procedures requiring daily observation of the media and requiring an immediate recall if there is any evidence of microbial growth, and said procedures must be available to board inspectors.

(iii) **Bacterial Endotoxin (Pyrogen) testing.** The USP Bacterial Endotoxin Test or verified equivalent shall be used to ensure compounded sterile products do not contain excessive endotoxins.

(iv) **Potency testing.**

(a) The potency of all compounded products meeting the criteria described in 17 CAR § 160-2201(d)(10)(E) above must be tested to verify the potency stated on the label.

(b) Products for which there is no known or commercially available potency test standard require board approval prior to compounding.

(v)*(a)* The USP Membrane Filtration method and the USP Direct Transfer method are the Membrane Filtration and Direct Transfer methods described in Chapter 71, United States Pharmacopeia (USP), 2001 Edition.

(b) The USP Bacterial Endotoxin Test is the bacterial filtration test described in Chapter 85, USP, 2001 Edition.

(c) Should there be any amendment or change in any of the above methods or test by USP subsequent to the effective date of this paragraph, said change or amendment to USP shall be effective under this rule after the expiration of thirty (30) days from the effective date of said change or amendment,

unless within said time period the Executive Director of the Arkansas State Board of Pharmacy objects to said change or amendment.

(d)(1) In that case, the executive director shall publish the reasons for objection and afford all interested parties an opportunity to present commentary.

(2) Said notice and commentary shall be pursuant to Arkansas Code § 25-15-204, as amended, and the resulting decision by the board shall be reflected by an amendment to this rule;

(F) Establishment of procedures for yearly testing the techniques of pharmacists using simulated aseptic procedures and documentation thereof; and

(G) Any construction requirements as required by this rule, i.e., separate controlled limited access area and certification of Class 10,000, must be complied with by January 2004.

17 CAR § 160-2202. Good compounding practices.

(a)(1) This rule describes the requirements of minimum current good compounding practice for the preparation of drug products by pharmacies or other facilities with permits issued by the Arkansas State Board of Pharmacy.

(2)(A) Compounding a drug product that is commercially available in the marketplace or that is essentially a copy of a commercially available Food and Drug Administration-approved drug product is generally prohibited.

(B) However, in special circumstances a pharmacist may compound an appropriate quantity of a drug that is only slightly different than a Food and Drug Administration-approved drug that is commercially available:

(i) Based on documentation provided by the prescribing physician of a patient-specific medical need, e.g., the physician requests an alternate product due to hypersensitivity to excipients or preservative in the Food and Drug Administration-approved product, or the physician requests an effective alternate dosage form; or

(ii) If the drug product is not commercially available.

(3) The unavailability of such drug product must be documented prior to compounding.

(4) The recommended methodology for documenting unavailability is to print the screen of wholesalers showing back-ordered, discontinued, or out-of-stock items.

(5) This or similar documentation must be available when requested by the board.

(b) **Definitions.** The following words or terms, when used in this part, shall have the following meaning unless the context clearly indicates otherwise:

(1) "Component" means any ingredient used in the compounding of a drug product, including those that may not appear in such product;

(2) "Compounding" means preparation, mixing, assembling, packaging, and labeling of a drug or device as the result of a duly authorized practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice.

(A) Compounding may also be for the purpose of, or as an incident to:

(i) Research;

(ii) Teaching; or

(iii) Chemical analysis.

(B) Compounding includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(C) Reconstitution of commercial products is not considered compounding for the purposes of this part;

(3)(A) "Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device either directly or indirectly by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes:

(i) Any packaging or repackaging of the substance or substances or labeling or relabeling of its container; and

(ii) The promotion and marketing of such drugs or devices.

(B) Manufacturing also includes any preparation of a drug or device that is given or sold for resale by:

(i) Pharmacies;

(ii) Practitioners; or

(iii) Other persons.

(C) The distribution of inordinate amounts of compounded products without a practitioner/patient/pharmacist relationship is considered manufacturing; and

(4) "Pharmacy-generated products" means a medical product that is prepared, packaged, and labeled in a pharmacy that can be sold by the pharmacy without a prescription.

(c) **Pharmacist responsibilities.**

(1) All pharmacists who engage in drug compounding shall:

(A) Be proficient in compounding; and

(B) Continually expand their compounding knowledge by participating in seminars and/or studying appropriate literature.

(2) The pharmacist has the responsibility to:

(A) Ensure the validity of all prescriptions;

(B) Approve or reject all components, drug product containers, closures, in-process materials, and labeling;

(C) Prepare and review all compounding records and procedures to ensure that no errors have occurred in the compounding process;

(D) Ensure the proper maintenance, cleanliness, and use of all equipment used in a prescription compounding practice; and

(E) Ensure only personnel authorized by the pharmacist-in-charge shall be in the immediate vicinity of the drug compounding operation.

(d) **Drug compounding facilities.**

(1) Pharmacies engaging in compounding shall have a specifically designated and adequate area (space) for the orderly compounding of prescriptions, including the placement of equipment and materials.

(2) The aseptic processing for sterile products shall be in an area separate and distinct from the area used for the compounding of nonsterile drug products.

(3) The area or areas used for the compounding of drugs shall be maintained in a good state of repair.

(4) Bulk drugs and other chemicals or materials used in the compounding of drugs must be stored in adequately labeled containers:

(A) In a clean, dry area; or

(B) If required, under proper refrigeration.

(5) Adequate lighting and ventilation shall be provided in all compounding areas.

(6) Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product.

(7) These areas used for compounding shall be maintained in a clean and sanitary condition.

(8) If parenteral products are being compounded, standards set out in 17 CAR § 160-2201 must be met.

(e) **Compounding equipment.**

(1) Equipment used in the compounding of drug products shall be of appropriate design and capacity as well as suitably located to facilitate operations for its:

(A) Intended use;

(B) Cleaning; and

(C) Maintenance.

(2) Compounding equipment shall be of suitable composition so the surfaces that contact components shall not be reactive, additive, or absorptive so as to alter the purity of the product compounded.

(3) Equipment and utensils used for compounding shall be cleaned and sanitized immediately prior to use to prevent contamination.

(4) Equipment and utensils must be stored in a manner to protect from contamination.

(5)(A) Automated, mechanical, electronic, limited commercial scale manufacturing or testing equipment, and other types of equipment may be used in the compounding of drug products.

(B) If such equipment is used, it shall be routinely inspected, calibrated if necessary, or checked to ensure proper performance.

(6) Immediately prior to the initiation of compounding operations, the equipment and utensils must be:

(A) Inspected by the pharmacist; and

(B) Determined to be suitable for use.

(7)(A) When drug products with special precautions (antibiotics, hazardous materials, and cytotoxins) are involved:

(i) Appropriate measures must be utilized in order to prevent cross-contamination; and

(ii) Proper disposal procedures must be followed.

(B) These measures include either the dedication of equipment for such operations or the meticulous cleaning of equipment prior to its use for the preparation of other drugs.

(f) **Component selection requirements.**

(1) Pharmacists shall first attempt to use United States Pharmacopoeia — The National Formulary (USP-NF) drug substances for compounding that have been made in a Food and Drug Administration-registered facility.

(2) If components are not obtainable from a Food and Drug Administration-registered facility or if the Food and Drug Administration and/or the company cannot document Food and Drug Administration registration, pharmacists compounding prescriptions shall use their professional judgment in first receiving,

storing, or using drug components that meet official compendia requirements or another high-quality source.

(g) **Control of drug products.**

(1) Drug product containers and closures shall be handled and stored in a manner to:

(A) Prevent contamination; and

(B) Permit inspection and cleaning of the work area.

(2) Containers and closures shall be suitable material so as to not alter the compounded drug as to:

(A) Quality;

(B) Strength; or

(C) Purity.

(h) **Drug compounding controls.**

(1) There shall be written procedures for the compounding of drug products to ensure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess.

(2) Procedures shall include a listing of:

(A) The components;

(B) Their amounts in weight or volume;

(C) The order of component mixing; and

(D) A description of the compounding process.

(3) All equipment and utensils and the container/closure system relevant to the sterility and stability of the intended use of the drug shall be listed.

(4) All written procedures shall be followed in the execution of the compounding procedure.

(5)(A) Components shall be accurately weighed, measured, or subdivided as appropriate.

(B) These operations should be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight and measure is correct as stated in the written compounding procedures.

(6)(A) Written procedures shall be established and followed that describe the tests or examination to be conducted on the product compounded (e.g., degree of weight variation among capsules) to ensure reasonable uniformity and integrity of compounded drug products.

(B) Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product.

(C) Such control procedures shall include, but are not limited to, the following, where appropriate:

(i) Capsule weight variation;

(ii) Adequacy of mixing to ensure uniformity and homogeneity; and

(iii) Clarity, completeness, or pH of solutions.

(7)(A) Appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile shall be established and followed.

(B) Such procedures shall:

(i) Follow accepted standards of practice; and/or

(ii) Include validation of any sterilization process.

(8)(A) Beyond-use dates and storage requirements (e.g., refrigeration) should be established.

(B) The USP-NF guidelines should be used.

(i) **Labeling.**

(1) If a component is transferred from the original container to another (e.g., a powder is taken from the original container, weighed, placed in a container) and stored in another container, the new container shall be identified with the:

(A) Component name;

(B) Lot and expiration date if available;

(C) Strength and concentration;

(D) Weight or measure; and

(E) Route of administration.

(2)(A) Products prepared in anticipation of a prescription prior to receiving a valid prescription should not be an inordinate amount.

(B) A regularly used amount should be prepared based on a history of prescriptions filled by the pharmacy.

(C) These products shall be labeled or documentation referenced with the:

(i) Complete list of ingredients or preparation name and reference;

(ii) Federal expiration date, up to one (1) year;

(iii) Assigned beyond-use date:

(a) Based on published data;

(b) Appropriate testing; or

(c) USP-NF standards;

(iv) Storage under conditions dictated by their composition and stability, e.g., in a clean, dry place or in the refrigerator; and

(v) Batch or lot number.

(3) Upon the completion of the drug preparation operation, the pharmacist shall examine the product for correct labeling.

(4) The prescription label shall contain the following:

(A) Patient name;

(B) Prescriber's name;

(C) Name and address of pharmacy;

(D) Directions for use;

(E) Date filled;

(F) Beyond-use date and storage (may be auxiliary labels); and

(G) An appropriate designation that this is a compounded prescription, with reference to active ingredients.

(j) **Records and reports.**

(1) Any procedures or other records required to comply with good compounding practices shall be retained for the same period of time as required for retention of prescription records.

(2) All records required to be retained under good compounding practices, or copies of such records, shall be readily available for authorized inspection.

(3) Computer information and the hard copy of the prescription should indicate that the prescription is to be compounded.

(4) Adequate records must be kept of controlled substances (scheduled drugs) used in compounding.

(k) **Pharmacy-generated product requirements.**

(1) A pharmacy-generated product (PGP) may be prepared from legend drugs, not to exceed recommended strengths and doses.

(2) PGP will be labeled properly and will be sold with the public's health and welfare in mind.

(3)(A) PGP cannot be bulk compounded to sell to a second entity for resale.

(B) This would require a manufacturer's permit.

(l) **Compounding for a prescriber's office use.**

(1) Pharmacies may prepare compounded drug products for a duly authorized prescriber's office use.

(2) An order by the duly authorized prescriber, indicating the formula and quantity ordered, will be filed in the pharmacy.

(3)(A) The product is to be administered in the office and not dispensed to the patient.

(B) The product shall be labeled "For Office Use Only—Not for Resale".

(4) A record of the compounded drug product may be kept as a prescription record in the pharmacy computer.

(5) A label may be generated and a number assigned by the pharmacy computer for the compounded drug product.

(6) Patient-specific prescriptions for controlled substances cannot be filled "for office or medical bag use".

(7)(A) A retail pharmacy is not precluded from making more than five percent (5%) of its annual sales to licensed practitioners.

(B) The pharmacy must, however, obtain a State Wholesale Legend Drug and/or Controlled Substance Distributor Permit.

(m) **Compounding veterinary products.**

(1) Prescriptions for animals may be compounded based on an order or prescription from a duly authorized prescriber.

(2) These prescriptions are to be handled and filled the same as the human prescriptions.

(3) Patient-specific prescriptions for controlled substances cannot be filled "for office or medical bag use".

(4) **Veterinary office use.**

(A) Compounded preparations distributed for veterinary office use in accordance with the labeling requirements do not require a patient-specific prescription but do require that the compounded preparation be administered to a patient in the course of the veterinary practitioner's professional practice.

(B) Compounded preparations distributed for office use pursuant to this rule shall not be further distributed to other practitioners or dispensed to a patient for self-administration except as provided below.

(5)(A) Veterinary compounded preparations may be sold to a veterinary practitioner for office use if the preparations are compounded by an Arkansas-licensed Class A pharmacy or Food and Drug Administration-registered and Arkansas-permitted 503B outsourcing facility and sold directly to the veterinary practitioner by the pharmacy or outsourcing facility in compliance with Food and Drug Administration guidance and regulations.

(B) Veterinary compounded preparations sold to a veterinary practitioner for veterinary office use may be dispensed to the owner of a veterinary patient to treat an immediate emergency medical need when:

(i) Timely access to a patient-specific supply of compounded medication is not available;

(ii) No commercially available product can meet the need of the patient;

(iii) Lack of treatment will likely result in patient harm; and

(iv) The supply does not exceed seven (7) days.

Subpart 23. Drug Products/Prescriptions — Samples

17 CAR § 160-2301. Drug samples.

(a) **Definitions.** As used in this part:

(1) "Coupon" means a form that may be redeemed as part of, or all of, the cost of a prescription for a legend drug after it has been dispensed;

(2)(A) "Drug sample" means a unit of a legend drug that:

(i) Is distributed to a practitioner by a manufacturer or a manufacturer's representative at no charge;

(ii) Is not intended to be sold; and

(iii) Is intended to promote the sale of the drug.

(B) "Drug sample" shall not mean a drug under clinical investigations approved by the Food and Drug Administration; and

(3)(A) "Legend drug" means a drug limited by Section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act to being dispensed by or upon a medical practitioner's prescription because the:

(i) Drug is habit-forming;

(ii) Drug is toxic or has potential for harm; or

(iii) New drug application for the drug limits its use to use under a practitioner's supervision.

(B) The product label of a legend drug is required to contain the statement "CAUTION, FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION".

(C) Provided, however, a legend drug includes prescription drugs subject to the requirement of Section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act that shall be exempt from Section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act if certain specified conditions are met.

(b) Unprofessional conduct pursuant to 17 CAR § 160-601 shall include the following:

(1) It shall be unprofessional conduct for a licensed pharmacy, pharmacist, or pharmacy intern licensed in the State of Arkansas to sell, purchase, or trade or offer to sell, purchase, or trade any drug sample;

(2) It shall be considered unprofessional conduct for any licensed pharmacy, pharmacist, or pharmacy intern licensed in the State of Arkansas to sell, purchase, trade, or counterfeit, or offer to sell, purchase, trade, or counterfeit any coupon; and

(3)(A) The possession of a drug sample by a pharmacy, pharmacist, or licensed intern shall be considered unprofessional conduct unless:

(i) Prior approval has been obtained from the Arkansas State Board of Pharmacy; or

(ii) The sample was provided for personal use by the:

(a) Pharmacist;

(b) Intern; or

(c) His or her family.

(B)(i) If a licensed pharmacy, pharmacist, or pharmacy intern believes that he or she has a valid reason to possess and/or distribute a drug sample free of charge, the involved pharmacist shall make a written request to the board so that the board may review the request to ensure that there is not a violation of federal or state law, rule, or regulation.

(ii) Upon written request stating the purpose or use of the drug sample and quantity to be possessed, the board shall approve possession of sample drugs when reasonably necessary to serve a public purpose when consistent with federal and state law.

(iii) The board may impose any conditions upon possession as determined appropriate.

(c)(1) The pharmacist-in-charge of the pharmacy where the drug samples will be located shall maintain same:

(A) Separated from other stock; and

(B) In original sample packages.

(2) No compensation shall be charged for sample drugs.

Subpart 24. Drug Products/Prescriptions — Controlled Substances

17 CAR § 160-2401. Schedule II prescription drugs.

(a)(1) **Emergency prescriptions.** In the case of an emergency situation, as defined by this rule, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner provided that the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period, never more than seventy-two (72) hours.

(2) Dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner.

(3) For the purposes of authorizing an oral prescription for a controlled substance listed in Schedule II of the List of Controlled Substances, 5 CAR pt. 22, the term "emergency situation" means those situations in which the prescribing practitioner determines that:

(A) Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user;

(B) No appropriate alternative treatment is available, which includes the administration of a drug that is not a Schedule II; and

(C)(i) It is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the pharmacist dispensing the drug prior to the dispensing.

(ii) The prescription shall be immediately reduced to writing by the pharmacist.

(iii) Within seven (7) days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist.

(iv) The statement "Authorization for Emergency Dispensing" and the date of the oral order must be on the face of the prescription.

(v) Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing.

(vi)*(a)* The pharmacist shall notify the nearest office of the Drug Enforcement Administration if the prescribing practitioner fails to deliver a written prescription.

(b) Failure of the pharmacist to do so shall void the authority conferred by this part to dispense without a written prescription of a prescribing practitioner.

(b) Licensees of the Arkansas State Board of Pharmacy may not dispense a quantity of a Schedule II narcotic that exceeds the prescriber's authority to prescribe.

17 CAR § 160-2402. Partial filling of a Schedule II prescription.

(a)(1) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible.

(2)(A) If the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and makes a notation of the quantity supplied on the face of the written prescription or written record of the emergency oral prescription, the remaining portion of the prescription may be filled within seventy-two (72) hours of the first partial filling.

(B) However, if the remaining portion is not or cannot be filled within the seventy-two-hour period, the pharmacist shall so notify the prescribing practitioner.

(3) No further quantity may be supplied beyond seventy-two (72) hours without a new prescription.

(b)(1) A prescription for a Schedule II controlled substance written for a patient in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units.

(2) If there is any question whether a patient may be classified as having a terminal illness, the pharmacist may contact the practitioner prior to partially filling the prescription.

(3) Both the pharmacist and the prescribing practitioner have a corresponding responsibility to ensure that the controlled substance is for a terminally ill patient.

(4) The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient".

(c) For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained and readily retrievable) the:

(1) Date of the partial filling;

(2) Quantity dispensed;

(3) Remaining quantity authorized to be dispensed; and

(4) Identification of the dispensing pharmacist.

(d)(1) Prior to any subsequent partial filling, the pharmacist is to determine that the additional partial filling is necessary.

(2) The total quantity of Schedule II controlled substances dispensed in all partial filling must not exceed the total quantity prescribed.

(3) A Schedule II prescription for a patient in an LTCF or a patient with a medical diagnosis documenting a terminal illness, if partially filled, shall be totally dispensed within sixty (60) days and dispensing cannot occur after:

(A) Sixty (60) days; or

(B) The medication has been discontinued by the prescriber.

17 CAR § 160-2403. Computer records for partial filling.

(a) Information pertaining to current Schedule II prescriptions for patients in an LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if the system has the capability to permit:

(1) Output (display or print) of the:

(A) Original prescription number;

(B) Date of issue;

(C) Identification of prescribing individual practitioner;

(D) Identification of patient;

(E) Address of the LTCF or address of the hospital or residence of the patient;

(F) Identification of medication authorized to include:

(i) Dosage;

(ii) Form;

(iii) Strength; and

(iv) Quantity; and

(G) Listing of the partial fillings that have been dispensed under each prescription;

(2) Immediate, real-time updating of the prescription record each time a partial filling of the prescription is conducted; and

(3) Retrieval of partially filled Schedule II prescription information is the same as required for Schedule III and IV prescription refill information.

(b) The authority to dispense Schedule II prescriptions for partial quantities does not apply to other classes of patients, such as a patient with severe intractable pain who is not diagnosed as terminal.

17 CAR § 160-2404. Time limit on a new Schedule II prescription.

(a) Prescriptions written for Schedule II controlled substances may be dispensed up to six (6) months from the date written if the pharmacist is certain of the validity of the prescription.

(b) An exception to this would be prescriptions written for a patient classified as terminally ill or a long-term care facility patient, and these prescriptions:

(1) Are valid for sixty (60) days from date of issue; and

(2) May be partially filled.

17 CAR § 160-2405. Theft or loss of controlled drugs.

(a) In the event a holder of a pharmacy permit issued by the Arkansas State Board of Pharmacy under Arkansas Code § 17-92-405 and 17 CAR § 160-1501 has suffered a theft or loss of controlled substances, said permit holder shall:

(1) Notify the Division of Pharmacy Services and Drug Control of the Department of Health, the nearest Drug Enforcement Administration Diversion Field Office, and the board immediately upon discovery by phone or fax; and

(2) Deliver a completed Drug Enforcement Administration Form 106 to each of the agencies listed in subdivision (b)(1) of this section within seven (7) days of the occurrence of said loss or the discovery of said loss.

17 CAR § 160-2406. Schedule V — Exempt products and pharmacist-authorized drugs.

(a) A pharmacist-authorized drug is a nonprescription drug that is subject to the same restrictions as are imposed for ephedrine, pseudoephedrine, or phenylpropanolamine under:

(1) Arkansas Code §§ 5-64-1103(c) and (d)(4); and

(2) Arkansas Code § 5-64-1104.

(b)(1) A pharmacist may dispense a Schedule V exempt product or a pharmacist-authorized drug only after making a professional determination that there is a legitimate medical and pharmaceutical need for the product.

(2) A pharmacist must base the decision to dispense on factors relevant to the patient's medical need and the appropriateness of the requested product, including without limitation:

(A) The patient's medication filling history as maintained in the pharmacy's system;

(B) The pharmacist's personal knowledge of the patient; and/or

(C)(i) The pharmacist's screening of the patient's existing medical conditions and physical symptoms as appropriate for the treatment being considered.

(ii) The screening may include a review of the patient's:

(a) Medical history;

(b) Disease history;

(c) Prescription history;

(d) Physical symptoms; and

(e) Relevant vital signs such as blood pressure.

(iii) All screening performed by the pharmacist must be documented and maintained in the patient's pharmacy record.

(c)(1) A pharmacist should not dispense a Schedule V exempt product or pharmacist-authorized drug if the pharmacist is aware of information indicating that the patient is inappropriately self-medicating.

(2)(A) If the patient does not provide a satisfactory explanation regarding inappropriate self-medicating, the pharmacist must:

(i) Decline to dispense the product; and

(ii) Refer the patient to a physician.

(B) For ephedrine, pseudoephedrine, or phenylpropanolamine products, a pharmacist should question a patient regarding inappropriate self-medicating when records indicate that the patient may be exceeding the maximum recommended daily dose.

(C) For Schedule V exempt narcotics, a pharmacist should question a patient regarding inappropriate self-medicating when records indicate that the patient has been dispensed a Schedule V exempt product:

(i) More than ten (10) days;

(ii) More than twice in a thirty-day period;

(iii) More than four (4) times in two (2) consecutive months; or

(iv) Every month.

(d) The Arkansas State Board of Pharmacy may revoke or suspend a certificate of licensure, license, registration, or permit or may refuse to issue a certificate of licensure, license, registration, or permit to any person or entity that dispenses or sells a Schedule V exempt product or pharmacist-authorized drug in violation of a state or federal pharmacy:

(1) Law;

(2) Rule; or

(3) Regulation.

(e) A pharmacist is immune from civil liability for refusing to dispense, sell, transfer, or otherwise furnish a Schedule V exempt product or pharmacist-authorized drug based on a professional determination or a determination of age or identity.

(f)(1) Nothing in this rule shall be interpreted to require that a Schedule V exempt product or pharmacist-authorized drug must be sold upon request.

(2) There shall be no penalty or other disciplinary action taken against a pharmacist who chooses not to sell these products to a patient or individual.

17 CAR § 160-2407. Schedule V — Exempt narcotics.

A controlled substance listed in Schedule V that is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

(1) Such dispensing is made only by a pharmacist and not by a nonpharmacist employee even if under the supervision of a pharmacist, although after the pharmacist has fulfilled his or her professional and legal responsibilities set forth in this section, the actual cash or credit transaction, or delivery may be completed by a nonpharmacist;

(2) Not more than two hundred forty cubic centimeters (240 cc) (eight ounces (8 oz.)) of any such controlled substance containing opium, nor more than one hundred twenty cubic centimeters (120 cc) (four ounces (4 oz.)) of any other such controlled substance nor more than forty-eight (48) dosage units of any such controlled substance containing opium, nor more than twenty-four (24) dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given forty-eight-hour period;

(3) The purchaser is at least eighteen (18) years of age;

(4) The pharmacist requires every purchaser of a controlled substance under this section not known to him or her to furnish suitable identification, including proof of age where appropriate;

(5)(A) A bound record book for dispensing of controlled substances under this section is maintained by the pharmacist, which book shall contain the:

(i) Name and address of the purchaser;

(ii) Name and quantity of controlled substance purchased;

(iii) Date of each purchase; and

(iv) Name or initials of the pharmacist who dispensed the substance to the purchaser.

(B) The book shall be maintained in accordance with the recordkeeping requirement of 21 C.F.R. § 1304.04; and

(6) A prescription is not required for distribution or dispensing of the substance pursuant to any other federal, state, or local law.

17 CAR § 160-2408. Schedule V — Ephedrine, pseudoephedrine, or phenylpropanolamine.

(a) As provided in Arkansas Code § 5-64-1101 et seq., unless dispensed under a valid prescription, all sales or transfers of ephedrine, pseudoephedrine, or phenylpropanolamine are subject to the following quantity limits and restrictions:

(1) In a single transaction, no more than three (3) packages of one (1) or more products that contain:

(A) Ephedrine, pseudoephedrine, or phenylpropanolamine; or

(B) Their salts, isomers, or salts of isomers;

(2) In a single transaction, no more than a single package of any product that contains ephedrine, pseudoephedrine, or phenylpropanolamine that contains more than ninety-six (96) pills, tablets, gelcaps, capsules, or other individual units or more than three grams (3g) of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, or a combination of any of these substances, whichever is smaller;

(3) In a single transaction, any product containing ephedrine, pseudoephedrine, or phenylpropanolamine, unless:

(A) The product is:

(i) Sold in a package size of not more than three grams (3g) of ephedrine, pseudoephedrine, or phenylpropanolamine base; and

(ii) Packaged in a blister pack, each blister containing not more than two (2) dosage units;

(B) When the use of a blister pack is technically infeasible, that is packaged in a unit dose packet or pouch; or

(C) In the case of a liquid, the drug is sold in a package size of not more than three grams (3g) of ephedrine, pseudoephedrine, or phenylpropanolamine base;

(4) No product containing ephedrine, pseudoephedrine, or phenylpropanolamine may be sold or transferred to any person under eighteen (18) years of age unless the person is purchasing an exempt product under Arkansas Code § 5-64-1103(b); or

(5) No more than five grams (5g) of any product containing ephedrine or nine (9) grams of any product containing pseudoephedrine or phenylpropanolamine to a single patient in any thirty-day period.

(b) A pharmacist may not dispense and a pharmacy technician or intern may not sell or transfer ephedrine, pseudoephedrine, or phenylpropanolamine unless the patient has provided either:

(1) A driver's license or nondriver's identification card issued by the Department of Finance and Administration that contains:

(A) A photograph of the person;

(B) The person's date of birth; and

(C) A functioning magnetic stripe or bar code; or

(2) An identification card issued by the Department of Defense to active duty military personnel and their dependents that contains:

(A) A photograph of the person; and

(B) The person's date of birth.

(c) In addition to documenting the professional determination required by 17 CAR § 160-2406(a), a sale of ephedrine, pseudoephedrine, or phenylpropanolamine must also be approved by scanning the license or identification card into the real-time electronic logbook using the magnetic stripe or bar code except and unless using a military ID as described in 17 CAR § 160-2408(b)(2), in which case the identification may be manually entered into the real-time electronic logbook.

(d) A pharmacist, pharmacy, or pharmacy employee must also comply with federal law prohibiting the sale of more than three and six-tenths grams (3.6g) of ephedrine, pseudoephedrine, or phenylpropanolamine to a patient in any twenty-four-hour period.

Subpart 25. Drug Products/Prescriptions — Prescription Delivery Standards

17 CAR § 160-2501. Prescription Delivery Standards.

(a) Pharmacies providing home delivery services in Arkansas shall:

(1) Contact the patient or caregiver for approval prior to any billing or delivery of medications;

(2) Notify the patient of the delivery plan and expected arrival;

(3) Ensure that the medications will be maintained within appropriate temperature guidelines;

(4) Arrange for any controlled substances to require proof of delivery; and

(5) Have a plan in place for local medication supply availability when delivery cannot be accomplished in a timely manner to maintain the patient's ongoing therapy.

(b) If a pharmacy or pharmacist owns or controls, is owned or controlled by, or is under ownership or control with an insurance company, pharmacy benefits manager, pharmaceutical manufacturer, pharmaceutical wholesaler, or pharmacy benefits manager affiliate, then the pharmacy, including any common ownership or controlling entities, or pharmacist, shall not require that a patient receive his or her prescriptions through home delivery services.

Subpart 26. Wholesale Distribution — Wholesale Drug Distributors of Legend/Controlled Substances

17 CAR § 160-2601. Definitions.

As used in this part, unless the context otherwise requires:

(1) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing;

(2) "Blood component" means that part of blood separated by physical or mechanical means;

(3) "Board" means the Arkansas State Board of Pharmacy;

(4) "Controlled substance" means those substances, drugs, or immediate precursors listed in Schedules I through VI of the Uniform Controlled Substances Act, Arkansas Code § 5-64-101 et seq., and revised by the coordinator pursuant to his or her authority under Arkansas Code §§ 5-64-214 – 5-64-216;

(5) "Drug sample" means a unit of a prescription drug that:

(A) Is not intended to be sold; and

(B) Is intended to promote the sale of the drug;

(6) "Legend drug" means a drug limited by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., to being dispensed by or upon a medical practitioner's prescription because the drug is:

(A) Habit-forming;

(B) Toxic or having potential for harm; or

(C)(i) Limited in its use to use under a practitioner's supervision by the new drug application for the drug.

(ii) The product label of a legend drug is required to contain the statement "CAUTION; FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION".

(iii) A legend drug includes prescription drugs subject to the requirement of the Federal Food, Drug, and Cosmetic Act that shall be exempt if certain specified conditions are met;

(7) "Manufacturers" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug;

(8) "Outsourcing facility" means a facility at one (1) geographic location or address that:

(A) Is engaged in the compounding of sterile drugs for human use;

(B) Is registered as an outsourcing facility with the Food and Drug Administration;

(C) Complies with all of the requirements of Section 503B of the Federal Food, Drug, and Cosmetic Act;

(D) Shall be licensed under the wholesale distribution rules as a 503B Outsourcer;

(E) Shall have an Arkansas-licensed pharmacist-in-charge on staff a minimum of thirty-two (32) hours per week;

(F) All compounding shall be done under the supervision of a licensed pharmacist and comply with federal requirements applicable to outsourcing facilities; and

(G) Does not provide:

(i) Patient-specific prescription products unless also licensed as a pharmacy; and

(ii) Any products that are prohibited under the Food and Drug Administration guidelines of a 503B Outsourcer;

(9) "Person" includes:

(A) Individual;

(B) Partnership;

(C) Corporation;

(D) Business firm; and

(E) Association;

(10) "Prescription drug" means controlled substances, legend drugs, and veterinary legend drugs as defined herein;

(11) "Reverse distribution" means the receipt of prescription drugs including controlled substances, whether received from Arkansas locations or shipped to Arkansas locations, for the purpose of:

(A) Destroying the drugs; or

(B) Returning the drugs to their original manufacturers or distributors;

(12) "Veterinary legend drugs" means drugs defined in 21 C.F.R. § 201.105 and bearing a label required to bear the cautionary statement, "CAUTION: FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN";

(13) "Wholesale distribution" means the distribution of prescription drugs to persons other than consumers or patients and reverse distribution of such drugs, but does not include:

(A) Intra-company sales;

(B) The purchase or other acquisition:

(i) By a hospital or other healthcare entity that is a member of a group purchasing organization; or

(ii) From other hospitals or healthcare entities that are members of such organizations;

(C) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in Section 501(c)(3) of the Internal Revenue Code to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(D)(i) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other healthcare entities that are under common control.

(ii) For the purposes of this part, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization whether by ownership or stock or voting rights, by contract or otherwise;

(E) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

(F) The distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(G) The sale, purchase, or trade of blood components intended for transfusion; and

(14)(A) "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs, including but not limited to:

(i) Manufacturers;

(ii) Repackers' own-label distributors;

(iii) Private label distributors;

(iv) Jobbers;

(v) Brokers;

(vi) Warehouses, including:

(a) Manufacturers' and distributors' warehouses;

(b) Chain drug warehouses; and

(c) Wholesale drug warehouses;

(vii) Independent wholesale drug traders;

(viii) Prescription drug repackagers;

(ix) Physicians;

(x) Dentists;

(xi) Veterinarians;

(xii) Birth control and other clinics;

(xiii) Individuals;

(xiv) Hospitals;

(xv) Nursing homes and their providers;

(xvi) Health maintenance organizations and other healthcare providers; and

(xvii) Retail and hospital pharmacies that conduct wholesale distributions.

(B) A wholesale drug distributor shall not include any for-hire carrier or person or entity hired solely to transport prescription drugs.

17 CAR § 160-2602. Sales permit required.

It shall be unlawful for any person to sell or offer for sale by advertisement, circular, letter, sign, or oral solicitation or any other means any prescription drug unless the person holds and possesses a permit authorizing such sale as provided by this part.

17 CAR § 160-2603. Wholesale distributors, third-party logistics providers, manufacturers, and outsourcing facilities — Permit required.

(a)(1) Every wholesale distributor, third-party logistics provider, manufacturer, and outsourcing facility that shall engage in the distribution of prescription drugs, to include without limitation manufacturing in this state, shipping into this state, or selling or offering to sell in this state, shall register with the Arkansas State Board of Pharmacy by application for a permit on a form:

(A) Furnished by the board; and

(B) Accompanied by a fee as defined in 17 CAR § 160-107.

(2) The board may require a separate license for each facility directly or indirectly owned or operated by the same business entity within this state, or for a

parent entity with divisions, subdivisions, subsidiaries, and/or affiliate companies within this state when:

(A) Operations are conducted at more than one (1) location; and

(B) There exists joint ownership and control among all the entities.

(b)(1) The permit may be renewed biennially at a renewal permit fee as defined in 17 CAR § 160-107.

(2)(A) All permits issued under this section shall expire on December 31 of each year.

(B) A penalty as defined in 17 CAR § 160-107 will be charged, provided that if the renewal is unpaid by April 1 of any year, the license shall be null and void.

(c)(1) Upon a change of ownership of a wholesale distributor, as set out herein, a new permit shall be secured by the new owner or owners.

(2)(A) The new owner or owners can continue operation of the wholesale distributor for fourteen (14) days after the effective date of the change of ownership.

(B) After said fourteen-day period, the:

(i) Permit issued to the prior owner shall be void; and

(ii) Operation of the wholesale distributor in Arkansas shall cease.

(3) A change of ownership of a wholesale distributor occurs under, but is not limited to, the following circumstances:

(A) A change of ownership of a wholesale distributor owned by a sole proprietor is deemed to have occurred when the:

(i) Business is sold and the sale becomes final or the new owner assumes control of the wholesale distributor, whichever occurs first; or

(ii) Proprietor enters into a partnership with another individual or business entity;

(B) A change of ownership of a wholesale distributor owned by a partnership is deemed to have occurred when:

(i) There is an addition or deletion of one (1) or more partners in a partnership to which a wholesale distributor's license has been issued; or

(ii) The business is sold and the sale becomes final or the new owner assumes control of the wholesale distributor, whichever occurs first;

(C) A change of ownership of a wholesale distributor owned by a corporation is deemed to have occurred when:

(i)*(a)* An individual or business acquires or disposes of twenty percent (20%) of the corporation's outstanding shares of voting stock.

(b) This shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market;

(ii)*(a)* The corporation merges with another business or corporation.

(b) The corporation owning the wholesale distributor is required to notify the board if a change of ownership or merger occurs within the parent corporation of the corporation that owns the wholesale distributor;

(iii) The corporation's charter expires or is forfeited; or

(iv) The business is sold and the sale becomes final or the new owner assumes control of the wholesale distributor, whichever occurs first;

(D) The board may:

(i) Issue a limited-use wholesale distributor license to entities that do not engage in the wholesale distribution of prescription drugs except medical gases; and

(ii) Waive certain requirements of regulation based on the limited nature of such distribution; or

(E) Each permit issued hereunder shall be displayed by the holder thereof in a conspicuous place.

17 CAR § 160-2604. Shipment to certain licensed professionals.

(a) All wholesale distributors must, before shipping to a recipient in this state any prescription drug as defined in this part, ascertain that the person to whom shipment is made is either a licensed physician licensed by the Arkansas State Medical Board, a licensed Doctor of Dentistry, a licensed Doctor of Veterinary Medicine, a licensed Doctor of Podiatric Medicine, a hospital licensed by the State Board of Health, a licensed wholesale distributor as defined in this part, a licensed pharmacy licensed by the Arkansas State Board of Pharmacy, or other entity authorized by law to purchase or possess prescription drugs.

(b) No wholesale distributor shall ship any prescription drug to any person after receiving written notice from the Arkansas State Board of Pharmacy or other state or federal agency that the person:

(1) No longer holds a registered pharmacy permit; or

(2) Is not a licensed:

(A) Physician;

(B) Dentist;

(C) Veterinarian; or

(D) Hospital.

17 CAR § 160-2605. Minimum required information for licensure.

(a) The Arkansas State Board of Pharmacy requires the following from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license:

(1) The name, full business address, and telephone number of the licensee;

(2) All trade or business names used by the licensee;

(3) Addresses, telephone numbers, and the names of contact persons for the facility used by the licensee for the storage, handling, and distribution of prescription drugs;

(4) The type of ownership or operation, i.e., partnership, corporation, or sole proprietorship; and

(5) The names of the owner and/or operator of the licensee, including:

(A) If a person, the name of the person;

(B) If a partnership, the name of each partner and the name of the partnership;

(C) If a corporation, the:

(i) Name and title of each corporate officer and director;

(ii) Corporate names;

(iii) Name of the state of incorporation; and

(iv) Name of the parent company, if any; or

(D) If a sole proprietorship, the:

(i) Full name of the sole proprietor; and

(ii) Name of the business entity.

(b) Where operations are conducted at more than one (1) location by a single wholesale distributor, each such location shall be licensed by the board.

(c) Changes in any information on the application for licensure shall be submitted to the board within thirty (30) days after such change.

17 CAR § 160-2606. Minimum qualifications.

(a) The Arkansas State Board of Pharmacy will consider the following factors in determining eligibility for licensure of persons who engage in the wholesale distribution of prescription drugs:

(1) Any convictions of the applicant under any federal, state, or local laws related to:

(i) Drug samples;

(ii) Wholesale or retail drug distribution; or

(iii) Distribution of controlled substances;

(2) Any felony convictions of the applicant under federal, state, or local laws;

(3) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(5) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(6) Compliance with licensing requirements under previously granted licenses, if any;

(7) Compliance with the requirements to maintain and/or make available to the state licensing authority or to federal, state, or local law enforcement officials those records required to be maintained by wholesale drug distributors; and

(8) Any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

(b) The board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

17 CAR § 160-2607. Personnel.

The licensed wholesale distributor shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs.

17 CAR § 160-2608. Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(a) The following are required for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their:

(1) Officers;

(2) Agents;

(3) Representatives; and

(4) Employees.

(b) **Facilities.** All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate:

(A) Cleaning;

(B) Maintenance; and

(C) Proper operation;

(2) Have storage areas designed to provide adequate:

(A) Lighting;

(B) Ventilation;

(C) Temperature;

(D) Sanitation;

(E) Humidity;

(F) Space;

(G) Equipment; and

(H) Security conditions;

(3) Have a designated and clearly identified area for storage of prescription drugs that are:

(A) Outdated, damaged, deteriorated, misbranded, or adulterated; or

(B) In immediate or sealed secondary containers that have been opened;

(4) Be maintained in a clean and orderly condition; and

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(c) **Security.**

(1)(A) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(B) Access from outside the premises shall be kept to a minimum and well-controlled.

(C) The outside perimeter of the premises shall be well-lighted.

(D) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(2)(A) All facilities shall be equipped with an alarm system to detect entry after hours.

(B) This requirement shall not apply to those wholesale drug distributors of legend/controlled substances that carry only medical gas.

(3)(A) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion.

(B) When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(d) **Storage.**

(1) All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs with requirements in the current edition of an official compendium.

(2) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(3) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.

(4) The recordkeeping requirements in subsection (g) of this section shall be followed for all stored drugs.

(5) The requirements of this subsection do not apply to reverse distributors.

(e) **Examination of materials.**

(1)(A) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution.

(B) This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected:

(A) For identity of the prescription drug products; and

(B) To ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(3) The recordkeeping requirements in subsection (g) of this section shall be followed for all incoming and outgoing prescription drugs.

(f) **Returned, damaged, and outdated prescription drugs.**

(1) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

(2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be:

(A) Identified as such; and

(B) Quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3)(A) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed or returned to the supplier unless examination, testing, or other investigation proves that the drug meets appropriate standards of:

(i) Safety;

(ii) Identity;

(iii) Strength;

(iv) Quality; and

(v) Purity.

(B) In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the:

(i) Conditions under which the drug has been held, stored, or shipped before or during its return; and

(ii) Condition of the drug and its container, carton, or labeling as a result of storage or shipping.

(4) The recordkeeping requirements in subsection (g) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(g) **Recordkeeping.**

(1)(A) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs.

(B) These records shall include the following information:

(i) The source of the drugs, including the:

(a) Name and principal address of the seller or transferor; and

(b) Address of the location from which the drugs were shipped;

(ii) The identity and quantity of the drugs received and distributed or disposed of; and

(iii) The dates of receipt and distribution or other disposition of the drugs.

(2) Inventories and records shall be made available for inspection and photocopying by any official authorized by the Arkansas State Board of Pharmacy for a period of two (2) years following disposition of the drugs.

(3)(A) Records described in this part that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period.

(B) Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by any official authorized by the board.

17 CAR § 160-2609. Written policies and procedures.

(a) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures that shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for:

(1) Identifying, recording, and reporting losses or thefts; and

(2) Correcting all errors and inaccuracies in inventories.

(b) Wholesale drug distributors shall include in their written policies and procedures the following:

(1)(A) A procedure whereby the oldest approved stock of a prescription drug product is distributed first.

(B) The procedure may permit deviation from this requirement if such deviation is temporary and appropriate;

(2)(A) A procedure to be followed for handling recalls and withdrawals of prescription drugs.

(B) Such procedure shall be adequate to deal with recalls and withdrawals due to any:

(i) Action initiated at the request of:

(a) The Food and Drug Administration; or

(b) Other federal, state, or local law enforcement or other government agency, including the Arkansas State Board of Pharmacy;

(ii) Voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(iii) Action undertaken to promote public health and safety by replacement of existing merchandise with an improved product or new package design;

(3) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of:

(A) Strike, fire, flood, or other natural disaster or

(B) Other situations of local, state, or national emergency; and

(4)(A) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed.

(B) This procedure shall provide for written documentation of the disposition of outdated prescription drugs.

(C) This documentation shall be maintained for two (2) years after disposition of the outdated drug.

17 CAR § 160-2610. Responsible persons.

Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

17 CAR § 160-2611. Compliance with federal, state, and local laws.

(a) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and rules.

(b) Wholesale drug distributors that deal in controlled substances shall:

(1) Register with the:

(A) Appropriate state-controlled substance authority; and

(B) Drug Enforcement Administration; and

(2) Comply with all applicable state, local, and Drug Enforcement Administration rules.

(c) In the event a holder of a wholesaler permit issued by the Arkansas State Board of Pharmacy under Arkansas Code § 17-92-108, § 20-64-505 et seq., and 17 CAR § 160-2601 and 17 CAR § 160-2603 has suffered a theft or loss of controlled substances, said permit holder shall:

(1) Notify the board, the Division of Pharmacy Services and Drug Control of the Department of Health, and the Drug Enforcement Administration immediately upon discovery by telephone or fax; and

(2) Deliver a completed Drug Enforcement Administration Form 106 to each of the agencies listed in subdivision (c)(1) of this section within seven (7) days of the occurrence of the loss or the discovery of the loss.

17 CAR § 160-2612. Salvaging and reprocessing.

Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or rules that relate to prescription drug product salvaging or reprocessing, including 21 C.F.R. pt. 207, 21 C.F.R. pt. 210d, and 21 C.F.R. pt. 211.

17 CAR § 160-2613. Applicability.

Nothing in this part shall apply to the sale of chemicals or poisons for use for nonmedical purposes or for uses as insecticides or biologics or medicine used for the cure, mitigation, or prevention of disease of animals or fowl or for agricultural uses that comply with the requirements of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., and all amendments thereto unless those products are prescription drugs under this part.

17 CAR § 160-2614. Inspection of premises and records.

(a) The Arkansas State Board of Pharmacy may conduct inspections upon all premises, including delivery vehicles, purporting or appearing to be used by a person licensed under this part.

(b) The board, in its discretion, may accept a satisfactory inspection by the Food and Drug Administration or a state agency of another state that the board determines to be comparable to that made by the Food and Drug Administration or the board.

Subpart 27. Wholesale Distribution — Medical Equipment, Legend Devices, and/or Medical Gas

17 CAR § 160-2701. Definitions.

As used in this part:

(1) "Home medical equipment, legend device, and medical gas supplier" means a person, business, corporation, agency, company, etc., licensed to supply home medical equipment, medical gases, and/or legend devices to patients on an order from medical practitioners licensed to order, use, or administer these products and to other persons, businesses, corporations, agencies, companies, etc., licensed to supply:

(A) Home medical equipment;

(B) Medical gases; and/or

(C) Legend devices;

(2) "Home medical equipment services" means the delivery, installation, maintenance, replacement, and/or instruction in the use of medical equipment used by a sick or disabled individual, to allow the individual to be maintained in a noninstitutional environment;

(3)(A) "Legend device" means a device that because of any potential for harmful effect or the method of its use is not safe except under the supervision of a practitioner.

(B) These devices, as approved by the Food and Drug Administration, may be labeled "Caution: Federal (USA) law restricts this device to sale by or on the order of a physician";

(4)(A) "Medical equipment" means technologically sophisticated medical devices including but not limited to:

(i) Oxygen and oxygen delivery systems;

(ii) Ventilators;

(iii) Respiratory disease management devices;

(iv) Electronic and computer driven wheelchairs and seating systems;

(v) Apnea monitors;

(vi) Transcutaneous electrical nerve stimulator units;

(vii) Low air loss cutaneous pressure management devices;

(viii) Sequential compression devices;

(ix) Neonatal home phototherapy devices;

(x) Feeding pumps;

(xi) Electrically powered hospital beds;

(xii) Infusion pumps; and

(xiii) Patient lifts.

(B) The term "medical equipment" does not include:

(i) Medical equipment used or dispensed in the normal course of treating patients by:

(a) Hospitals;

(b) Hospices;

(c) Nursing facilities; or

(d) Home health agencies;

(ii) Medical equipment used or dispensed by healthcare professionals licensed in Arkansas, provided the professional is practicing within the scope of that professional's practice act; or

(iii) Upper and lower extremity prosthetics and related orthotics or:

(a) Canes;

(b) Crutches;

(c) Walkers;

(d) Bathtub grab bars;

(e) Standard wheelchairs;

(f) Commode chairs; and

(g) Bath benches;

(5) "Medical gas" means those gases and liquid oxygen intended for human consumption; and

(6) "Order" means an order issued by a licensed medical practitioner legally authorized to order medical gases and/or legend devices.

17 CAR § 160-2702. Licensure required.

(a)(1) No person or entity subject to licensure shall sell or rent or offer to sell or rent directly to patients in this state any home medical equipment, legend devices, and/or medical gases unless the person or entity is licensed as required by Acts 1995, No. 1101.

(2) The licensure requirements of this act will apply to all companies, agencies, and other business entities that are in the business of supplying medical equipment to patients in their homes and that bill the patient or the patient's insurance, Medicare, Medicaid, or other third-party payer for the rent or sale of that equipment.

(3) The application for a license shall be:

(A) On a form furnished by the Arkansas State Board of Pharmacy; and

(B) Accompanied by payment of fee as defined in 17 CAR § 160-107.

(4) The board shall require a separate license for each facility directly or indirectly owned or operated within this state by the same person or business entity within this state, or for a parent entity with divisions, subdivisions, subsidiaries, and/or affiliate companies when:

(A) Operations are conducted at more than one (1) location; and

(B) There exists joint ownership and control among all the entities.

(b) **Minimum required information for licensure.**

(1)(A) Applicants may apply for an Arkansas Supplier of Medical Equipment, Legend Devices, and/or Medical Gas Permit using forms provided by the board.

(B) Entities that complete the application process and otherwise meet the qualifications for a permit will be granted a license.

(C) Licenses will not be granted to those that are exempt from licensure requirements and board rules as provided in Arkansas Code § 17-92-903.

(D) The board requires the following from each applicant for a Supplier of Medical Equipment, Legend Devices, and/or Medical Gas Permit as part of the initial licensing procedure and as part of any renewal of such license:

(i) The name, full business address, and telephone number of the licensee;

(ii) All trade or business names used by the licensee;

(iii) Addresses, telephone numbers, and the names of responsible on-site managers for the facility used by the licensee for the storage, handling, and distribution of:

(a) Medical equipment;

(b) Legend devices; and/or

(c) Medical gases;

(iv) Full disclosure of the type of ownership or operation, i.e. partnership, corporation, LLC, LLP, or sole proprietorship; and

(v) The name or names of the owner and/or operator of the entity, including:

(a) If a person, the name of the person;

(b) If a partnership, the name of each partner and the name of the partnership;

(c) If a corporation, the:

(1) Name and title of each corporate officer and director;

(2) Corporate names;

(3) Name of the state of incorporation;

(4) Employer identification number; and

(5) Name of the parent company, if any; or

(d) If a sole proprietorship, the:

(1) Full name of the sole proprietor; and

(2) Name of the business entity.

(2) Where operations are conducted at more than one (1) location by a supplier of medical equipment, legend devices, and/or medical gases, each such location shall be licensed by the board.

(3) If the entity is located outside of Arkansas, the name and address of the Arkansas resident agent.

(4) Copies of other licenses and permits issued to the entity.

(5) Changes in any information on the application for licensure shall be submitted to the board within thirty (30) days after such change.

(6) Copy of liability insurance for products and services provided in the amount of five hundred thousand dollars ($500,000) or more.

(7) A written description of the proposed operation.

(c) **Minimum qualifications for licensure.** The board will consider the following factors in determining eligibility for licensure of entities that engage in supplying home medical equipment, medical gases, or legend devices, or any combination thereof, to patients on an order from medical practitioners licensed to order, use, or administer these products and to other licensed suppliers of home medical equipment, medical gases, or legend devices or any combination thereof:

(1) Any convictions of the applicant under any federal, state, or local laws related to the distribution of:

(A) Medical equipment;

(B) Legend devices; and/or

(C) Medical gases;

(2) Any felony convictions of the applicant under federal, state, or local laws;

(3) The furnishing by the applicant of false or fraudulent material in the application;

(4) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant;

(5) Compliance with licensing requirements under previously granted licenses, if any;

(6) Compliance with the requirements to maintain and/or make available to the board or to federal, state, or local law enforcement officials those records required to be maintained by suppliers of:

(A) Medical equipment;

(B) Legend devices; and/or

(C) Medical gases; and

(7) Any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

(d)(1) The biennial license renewal fee is defined in 17 CAR § 160-107.

(2) All licenses issued under this act shall expire on December 31 of each calendar year.

(3)(A) Each application for renewal of the license must be made on or before December 31 of each year.

(B)(i) Penalties for late payment are defined in 17 CAR § 160-107.

(ii) The license shall be considered null and void if the fee is not paid by April 1 of each year.

(e)(1) Each license issued hereunder shall be displayed by the holder thereof in a conspicuous place.

(2) The board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

17 CAR § 160-2703. Standards of practice.

(a)(1) Written policies and procedures must be:

(A) Available for review; and

(B) Designed to meet all the following standards.

(2) Documentation of all staff training must be kept in each employee's personnel file.

(3) All local, state, and federal regulatory agency policies concerning home medical equipment and oxygen must be followed.

(b) **Order intake.**

(1) A home medical equipment provider shall recognize the importance of order intake.

(2) The provider is responsible for ensuring that order intake personnel are appropriately trained in the following:

(A) Identifying equipment;

(B) Determining patient/caregiver needs;

(C) Determining referral sources needs;

(D) Knowing equipment coverage criteria based on diagnosis;

(E) Responding appropriately during a medical equipment emergency;

(F) Explaining service procedures;

(G) Billing third parties; and

(H) Verifying insurance.

(3) The provider must ensure that only trained order intake personnel receive referrals.

(c) **Selection of appropriate equipment.**

(1) When providing equipment services for a patient, a provider shall consider:

(A) Physician orders;

(B) Equipment needs of the patient;

(C) Economic situation of the patient and caregiver; and

(D) Requirement of any third-party payer source.

(2)(A) A provider shall recognize those items that require special fitting and evaluation.

(B) Fitting of custom items shall be performed within a reasonable time frame by specially trained personnel.

(d) **Delivery and set up — Patient and caregiver education.**

(1)(A) A provider shall maintain trained personnel to:

(i) Coordinate order fulfillment; and

(ii) Schedule equipment services with timely delivery.

(B) Documentation of training will be maintained.

(2) A provider shall ensure delivery personnel are appropriately trained to:

(A) Conduct an environment/equipment compatibility assessment;

(B) Appropriately and safely set up the equipment;

(C) Instruct patient and caregivers in the safe operation and client maintenance of the equipment; and

(D) Recognize when additional education and/or follow-up patient compliance monitoring is appropriate.

(3) Written instructions must be provided to the patient/caregiver upon delivery, and documentation of receipt of written instruction must be maintained in the patient record.

(e) **Services during use.**

(1)(A) A provider shall document that patients are advised of service hours and emergency service procedures.

(B) If equipment malfunction may threaten the customer's health, access to twenty-four-hours-per-day, three-hundred-sixty-five-days-per-year emergency service must be available for equipment maintenance or replacement.

(2) A provider shall establish a schedule at the time of the initial delivery for any appropriate follow-up home medical equipment services such as:

(A) Periodic maintenance;

(B) Supply delivery; and

(C) Other related activities.

(f) **Retrieval, disinfection, and maintenance of home medical equipment.**

(1) A provider shall ensure that state/federal requirements for equipment disinfection are followed, including:

(A) Red-tagging for biohazards;

(B) Maintaining dirty equipment isolation;

(C) Equipment cleaning and disinfection areas and procedures; and

(D) Appropriate staff training on hazard prevention.

(2) Cleaning and disinfection solutions must be:

(A) Bactericidal;

(B) Tuberculocidal; and

(C) Viricidal.

(3) Centers for Disease Control and Prevention universal precautions and Occupational Safety and Health Administration regulations concerning equipment handling must be followed.

(4)(A) Create and implement a preventative maintenance program based on manufacturers' guidelines, which includes appropriate recordkeeping.

(B) Trained staff must be utilized.

(g) **Patient record.**

(1) A supplier must maintain a record for each customer when:

(A) Required by state or federal law; or

(B) A physician's order is required.

(2) The patient record must include an intake form and applicable physician's orders.

(3) Records should be safeguarded from loss and kept confidential.

(4) Documentation of proper patient/caregiver instruction must be maintained in the patient record.

(h) **Patient rights.**

(1) The patient has the right to considerate and respectful service.

(2) The patient has the right to obtain service without regard to:

(A) Race;

(B) Creed;

(C) National origin;

(D) Sex;

(E) Age;

(F) Disability;

(G) Diagnosis; or

(H) Religious affiliation.

(3)(A) Subject to applicable law, the patient has the right to confidentiality of all information pertaining to his or her medical equipment and service.

(B) Individuals or organizations not involved in the patient's care may not have access to the information without the patient's written consent.

(4) The patient has the right to a timely response to his or her request for home medical equipment services.

(5) The patient has the right to select the home medical equipment supplier of his or her choice.

(6) The patient has the right to voice grievances without fear of termination of service or other reprisals.

(7) The patient has the right to expect reasonable continuity of service.

(8) The patient has the right to an explanation of charges for equipment and supplies.

(i) **Quality assurance.**

(1) There is an ongoing continuous quality improvement program designed to monitor and evaluate the:

(A) Quality of patient care;

(B) Improvement of patient services, if applicable; and

(C) Resolution of identified problems.

(2) Continuous quality improvement activities are defined in a written plan.

(3) Issues monitored should be determined by evaluating all complaints or incidents and items that are:

(A) High-volume;

(B) High-risk; or

(C) Problem-prone.

(j) Liability insurance coverage for products provided and operations of each licensed entity is required in the amount of at least five hundred thousand dollars ($500,000).

(k) **Prohibited practices.** The following practices are prohibited:

(1)(A) Patient freedom of choice.

(B) Participation in any plan, agreement, or arrangement that eliminates the patient's right to select a provider, licensed under this act, of his or her choice shall be considered a violation of this part;

(2)(A) Bribes, kickbacks, and rebates.

(B) It shall be considered a violation of this part for anyone to knowingly and willfully offer, pay, solicit, or receive any payment in return for referring an individual to another person for the furnishing, or arranging for the furnishing, of any item or service covered by this part;

(3) The solicitation of DME business by providing prescribers with prescription blanks, patient order forms, or patient order invoices with the name of any home medical equipment, legend device, and/or medical gas provider printed thereon; and

(4)(A) A provider of home medical equipment and/or medical gas may provide more than five percent (5%) of its annual sales to licensed practitioners or facilities.

(B) The provider must, however, obtain a State Wholesale Legend Drug and/or Controlled Substance Distributor Permit.

Subpart 28. Wholesale Distribution — Wholesale Distributor of List I Chemicals

17 CAR § 160-2801. Definitions.

As used in this part unless the context otherwise requires:

(1) "Board" means the Arkansas State Board of Pharmacy;

(2) "Person" includes:

(A) An individual;

(B) A general or limited partnership;

(C) A corporation;

(D) A business firm;

(E) A limited liability company; and

(F) An association;

(3) "List I chemical" means ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, optical isomers, and salts of optical isomers, alone or in a mixture;

(4) "Manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a List I chemical;

(5) "Wholesale distribution" means the distribution of List I chemicals to persons other than consumers or patients, but does not include entities exempt by Arkansas Code § 5-64-1006 as amended by Acts 2001, No. 1209; and

(6)(A) "Wholesale distributor" means any person engaged in wholesale distribution of List I chemicals, including but not limited to:

(i) Manufacturers;

(ii) Repackers;

(iii) Own-label distributors;

(iv) Private label distributors;

(v) Jobbers;

(vi) Brokers;

(vii) Warehouses, including:

(a) Manufacturers' and distributors' warehouses;

(b) Chain drug warehouses; and

(c) Wholesale drug warehouses;

(viii) Independent wholesale drug traders;

(ix) List I chemical repackagers;

(x) Physicians;

(xi) Dentists;

(xii) Veterinarians;

(xiii) Clinics;

(xiv) Individuals;

(xv) Hospitals;

(xvi) Nursing homes and their providers; and

(xvii) Retail and hospital pharmacies that conduct wholesale distributions.

(B) A wholesale distributor shall not include any for-hire carrier or person or entity hired solely to transport List I chemicals.

17 CAR § 160-2802. Wholesale distributor of List I chemicals.

(a)(1) Every wholesale distributor that shall engage in the wholesale distribution of List I chemicals, to include without limitation manufacturing in this state, shipping in or into this state, or selling or offering to sell in this state, if not exempted by Acts 2001, No. 1209, shall register with the Arkansas State Board of Pharmacy by application for a permit on a form:

(A) Furnished by the board; and

(B) Accompanied by a fee as defined in 17 CAR § 160-107.

(2) The board may require a separate permit for each facility directly or indirectly owned or operated by the same business entity or for a parent entity with divisions, subdivisions, subsidiaries, and/or affiliate companies when:

(A) Operations are conducted at more than one (1) location; and

(B) There exists joint ownership and control among all the entities.

(b) The permit shall be renewed as defined in 17 CAR § 160-107.

(c) All permits issued under this section shall expire as defined in 17 CAR § 160-107.

(d) A change of ownership of a wholesale distributor of List I chemicals occurs under, but is not limited to, the following circumstances:

(1) A change of ownership of a wholesale distributor of List I chemicals owned by a sole proprietor is deemed to have occurred when:

(A) The business is sold and the sale becomes final or the new owner assumes control of the wholesale distributor, whichever occurs first; or

(B) The proprietor enters into a partnership with another individual or business entity;

(2) A change of ownership of a wholesale distributor of List I chemicals owned by a partnership is deemed to have occurred when:

(A) There is an addition or deletion of one (1) or more partners in a partnership to which a List I chemical wholesale distributor's permit has been issued; or

(B) The business is sold and the sale becomes final or the new owner assumes control of the wholesale distributor of List I chemicals, whichever occurs first;

(3) A change of ownership of a wholesale distributor owned by a corporation is deemed to have occurred when:

(A)(i) An individual or business acquires or disposes of twenty percent (20%) of the corporation's outstanding shares of voting stock.

(ii) This shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; or

(B)(i) The corporation merges with another business or corporation.

(ii) The corporation owning the wholesale distributor is required to notify the board if a change of ownership or merger occurs within the parent corporation of the corporation that owns the wholesale distributor;

(C) The corporation's charter expires or is forfeited; or

(D) The business is sold and the sale becomes final or the new owner assumes control of the wholesale distributor, whichever occurs first; or

(4) A change of ownership of a wholesale distributor of List I chemicals owned by a limited liability company is deemed to have occurred when:

(A) There is an addition or deletion of one (1) or more members of the limited liability company to which a List I chemical wholesale distributor's permit has been issued;

(B) The assets of the limited liability company devoted to or utilized in the wholesale distribution of List I chemicals are sold and the sale becomes final or the new owner assumes control of the wholesale distribution of List I chemicals; or

(C) There is dissolution of the limited liability company.

(e)(1) The board may, after notice and hearing, suspend or revoke the registration of a List I wholesale distributor or impose other disciplinary action pursuant to Arkansas Code § 17-92-315 upon a finding of any of the following:

(A) Violation of or failure to maintain qualification under 17 CAR § 160-2801;

(B) Violation of any federal, state, or local law or rule regarding List I chemicals; or

(C) Revocation, suspension, or surrender of a license or other authority issued by the Drug Enforcement Administration as a List I wholesale distributor or to otherwise possess, distribute, or sell or offer to distribute or sell List I chemicals.

(2) The board shall follow the same procedures for hearings for a List I chemical wholesale distributor as applicable to hearings for pharmacists as set forth in Arkansas Code § 17-92-101 et seq. and this part.

17 CAR § 160-2803. Minimum required information for obtaining a permit.

(a) The Arkansas State Board of Pharmacy requires the following from each wholesale drug distributor of List I chemicals as part of the initial registration procedure and as part of any renewal of such permit:

(1) The name, full business address, and telephone number of the permit holder;

(2) All trade or business names used by the permit holder;

(3) Addresses, telephone numbers, and the names of contact persons for the facility used by the permit for the storage, handling, and distribution of List I chemicals;

(4) The type of ownership or operation, i.e.:

(A) Partnership;

(B) Corporation; or

(C) Sole proprietorship; and

(5) The name or names of the owner and/or operator of the permit holder, including:

(A) If a person, the name of the person;

(B) If a partnership, the name of each partner and the name of the partnership;

(C) If a corporation, the:

(i) Name and title of each corporate officer and director;

(ii) Corporate names;

(iii) Name of the state of incorporation; and

(iv) Name of the parent company, if any;

(D) If a sole proprietorship, the:

(i) Full name of the sole proprietor; and

(ii) Name of the business entity; or

(E) If a limited liability company, the:

(i) Name and state of organization of the limited liability company; and

(ii) Name of each member and manager of the limited liability company.

(b) Where operations are conducted at more than one (1) location by a single wholesale distributor of List I chemicals, each such location shall obtain a permit issued by the board.

(c) Changes in any information on the application for licensure shall be submitted to the board within thirty (30) days after such a change.

17 CAR § 160-2804. Minimum qualifications.

(a) The Arkansas State Board of Pharmacy will consider the following factors in determining eligibility for obtaining a permit as a wholesale distributor of List I chemicals:

(1) Any convictions of the applicant under any federal, state, or local laws or rules pertaining to wholesale or retail drug distribution of:

(A) List I chemicals;

(B) Controlled substances; or

(C) Prescription drugs;

(2) Any felony convictions of the applicant under federal, state, or local laws;

(3) The applicant's past experience in the manufacture or distribution of:

(A) List I chemicals;

(B) Prescription drugs; or

(C) Controlled substances;

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with manufacturing or distribution of:

(A) List I chemicals;

(B) Prescription drugs; or

(C) Controlled substances;

(5) Suspension or revocation by federal, state, or local government of any permit currently or previously held by the applicant for the manufacture or distribution of any:

(A) Drugs;

(B) List I chemicals;

(C) Prescription drugs; or

(D) Controlled substances;

(6) Compliance with registration requirements under previously granted permits, if any;

(7) Compliance with the requirements to maintain and/or make available to the board or to federal, state, or local law enforcement officials those records required to be maintained by wholesale drug distributors of List I chemicals; and

(8) Any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

(b) The applicant shall be registered with the Drug Enforcement Administration as a retail distributor of List I chemicals and said registration shall be in good standing.

(c) The board reserves the right to deny a permit to an applicant if it determines that the granting of such a permit would not be in the public interest.

17 CAR § 160-2805. Personnel.

A wholesale distributor of List I chemicals that is issued a permit by the Arkansas State Board of Pharmacy shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of List I chemicals.

17 CAR § 160-2806. Minimum requirements for the storage and handling of List I chemicals.

The following are required for the storage and handling of List I chemicals by wholesale drug distributors and their officers, agents, representatives, and employees:

(1) **Facilities.** All facilities at which List I chemicals are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(A) Be of suitable size and construction to facilitate:

(i) Cleaning;

(ii) Maintenance; and

(iii) Proper operation;

(B) Have storage areas designed to provide adequate:

(i) Lighting;

(ii) Ventilation;

(iii) Temperature;

(iv) Sanitation;

(v) Humidity;

(vi) Space;

(vii) Equipment; and

(viii) Security conditions;

(C) Have a designated and clearly identified area for storage of List I chemicals that are:

(i) Outdated, damaged, deteriorated, misbranded, or adulterated; or

(ii) In immediate or sealed secondary containers that have been opened;

(D) Be maintained in a clean and orderly condition; and

(E) Be free from infestation by insects, rodents, birds, or vermin of any kind;

(2) **Security.**

(A)(i) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(ii) Access from outside the premises shall be kept to a minimum and well-controlled.

(iii) The outside perimeter of the premises shall be well-lighted.

(iv) Entry into areas where List I chemicals are held shall be limited to authorized personnel.

(B) All facilities shall be equipped with an alarm system to detect entry after hours.

(C)(i) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion.

(ii) When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records;

(3) **Storage.**

(A) All List I chemicals shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such List I chemicals in the current edition of an official compendium.

(B) If no storage requirements are established for the List I chemical, the chemical may be held at "controlled" temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(C) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of List I chemicals;

(4) **Examination of materials.**

(A)(i) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated List I chemicals that are otherwise unfit for distribution.

(ii) This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(B) Each outgoing shipment shall be carefully inspected for identity of the List I chemical products and to ensure that there is no delivery of List I chemicals that have been damaged in storage or held under improper conditions; and

(5) **Returned, damaged, and outdated List I chemicals.**

(A) List I chemicals that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other List I chemicals until they are destroyed or returned to their supplier.

(B) Any List I chemicals whose immediate or sealed outer or sealed secondary containers have been opened or used shall be:

(i) Identified as such; and

(ii) Quarantined and physically separated from other List I chemicals until they are either destroyed or returned to the supplier.

(C)(i) If the conditions under which a List I chemical has been returned cast doubt on the product's safety, identity, strength, quality, or purity, then the product shall be destroyed or returned to the supplier unless examination, testing, or other investigation proves that the product meets appropriate standards of:

(a) Safety;

(b) Identity;

(c) Strength;

(d) Quality; and

(e) Purity.

(ii) In determining whether the conditions under which a List I chemical has been returned cast doubt on the product's safety, identity, strength, quality, or purity, the wholesale distributor of List I chemicals shall consider, among other things, the:

(a) Conditions under which the List I chemical has been held, stored, or shipped before or during its return; and

(b) Condition of the product and its container, carton, or labeling as a result of storage or shipping.

17 CAR § 160-2807. Inspection of premises and records.

(a) The Arkansas State Board of Pharmacy may conduct inspections upon all premises, including delivery vehicles, purporting or appearing to be used by a person maintaining a permit under this part.

(b) The board, in its discretion, may accept a satisfactory inspection by a state agency of another state that the board determines to be comparable to that made by the board.

17 CAR § 160-2808. Suspicious orders for List I chemicals.

(a) Wholesale distributors of List I chemicals should use their best judgment in identifying suspicious orders.

(b) The wholesalers should use the following criteria in order to identify suspicious orders:

(1) **All levels/all chemicals.**

(A) New customer or unfamiliar representative or established customer who begins ordering List I chemicals.

(B) Customers who:

(i) Do not seem to know industry practice; or

(ii) Fail to provide reasons for an order at variance with accepted legitimate industry practice.

(C) Customer whose communications are not prepared or conducted in a professional business manner.

(D) Customer who:

(i) Provides evasive responses to any questions; or

(ii) Is unable to supply information as to whether chemicals are for domestic use or for export.

(E) Customer who has difficulty pronouncing chemical names.

(F) New customer who does not seem to know federal or state government rules.

(G) Customer whose stated use of List I chemicals is incompatible with the:

(i) Destination country's commercial activities; or

(ii) Consignee's line of business.

(H) Customer who wants predominantly or only regulated chemicals.

(I) Customer who wants multiple regulated or surveillance list products, particularly if in contrast to customary use and practice.

(J) Customer who is vague or resists providing information about the firm's:

(i) Address;

(ii) Telephone number; and

(iii) Reason for seeking that chemical.

(K) Customer who provides false or suspicious:

(i) Addresses;

(ii) Telephone numbers; or

(iii) References.

(L) Customer who is vague or will not furnish references for credit purposes.

(M) Customer who refuses or is reluctant to establish a credit account or provide purchase order information.

(N) Customer who prefers to pay by cashier's check, postal money order, etc.

(O) Customer who desires to pay cash.

(P) Customer who wants to pick up the chemicals outside of normal practice in the supplier's experience.

(Q) Customer with little or no business background available.

(R) An established customer who deviates from previous orders or ordering methods.

(S) Customer who wants air freight or express delivery.

(T) Customer who wants chemicals shipped to post office boxes or an address other than their usual business address, i.e., residence address.

(U) Customer using a freight forwarder as ultimate consignee.

(V) Customer who requests unusual methods of delivery or routes of shipment.

(W) Customer who provides unusual shipping, labeling, or packaging instructions.

(X) Customer who requests the use of intermediate consignees whose location or business is incompatible with the purported end user's nature of business or location.

(Y) Above-threshold hydrochloride gas or iodine sales to a noncommercial customer;

(2) **Distributor (nonretail) of regulated over-the-counter products.**

(A) Customer who does not want to tell you what area they will resell into.

(B) Customer who does not want to tell you in what volumes they will resell.

(C) Customer who refuses to tell you who their customers are.

(D) Customer who does not have limits on resales.

(E) Customer who pushes to buy more than your sales limit.

(F) Customer who repeatedly buys your sales limit at the shortest interval you set.

(G) Customer who does not know what their customers' limits are on individual resales.

(H) Customer who resells to nontraditional outlets for regulated over-the-counter products, i.e.:

(i) Hair salons;

(ii) Head shops;

(iii) Drug paraphernalia stores;

(iv) Liquor stores;

(v) Record stores; and

(vi) Video shops.

(I) Customer who resells large volumes into the independent convenience store market.

(J) Any customer who asks for large bottle sizes, sixty (60) count or higher.

(K) Customer who buys only the largest size available.

(L) Customer who:

(i) Does not sell other pharmaceutical products; or

(ii) Appears to sell those other products in token amounts.

(M) Any customer that resells multiple cases that flow through to individual retail outlets.

(N) New customer who wants to sell regulated over-the-counter products into:

(i) California;

(ii) Arizona;

(iii) Nevada;

(iv) Oregon;

(v) Utah;

(vi) Washington;

(vii) New Mexico;

(viii) Texas;

(ix) Kansas;

(x) Missouri; or

(xi) Arkansas.

(O) Any customer who wants to sell to an outlet relocated from California, Missouri, or Kansas to any of the states identified in subdivision (b)(2)(N) of this section.

(P) Any customer who wants to export, particularly to:

(i) Mexico;

(ii) Canada; or

(iii) Southeast Asia.

(Q) Customer who:

(i) Will not provide you with evidence of registration with the Drug Enforcement Administration; or

(ii) Has applied by November 13, 1995, for single-entity ephedrine, pseudoephedrine, and phenylpropanolamine products.

(R) Customer who will not provide you with evidence of applicable state registrations/licenses.

(S)(i) Customer who sells mail order and who does not report sales to the Drug Enforcement Administration monthly.

(ii) Note they must also be registered.

(T) Nominal retail customer who sells above the federal retail twenty-four-gram individual sale limits; and

(3) **Wholesale drug distribution indicators.**

(A) Individual pharmacies that intend to export.

(B) Individual pharmacies or chains that won't set a voluntary limit for individual sales at some fraction of the federal limit to qualify as a retail outlet.

(C) Pharmacies that stock large shelf volumes in stores that have repeated thefts or other sales problems.

Subpart 29. Pharmaceutical Care/Patient Counseling

17 CAR § 160-2901. Patient information, drug use evaluation, and patient counseling.

(a)(1) The intent of this subpart is to improve pharmaceutical care by defining basic standards of care.

(2) Pharmacy care/pharmaceutical care is defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.

(3) These outcomes are:

(A) Cure of disease;

(B) Elimination or reduction of a patient's symptomatology;

(C) Arresting or slowing a disease process; or

(D) Preventing a disease or symptomatology.

(4) Pharmaceutical care (clinical pharmacy) involves four (4) major functions on behalf of the patient:

(A) Identifying potential and actual drug-related problems;

(B) Resolving actual drug-related problems;

(C) Preventing potential drug-related problems; and

(D)(i) Optimizing patient therapy outcomes.

(ii) It is recognized that the patient might be best served if medication is not provided.

(b) **Patient information (profile).**

(1) In order to effectively counsel patients, the pharmacist must, through communication with the patient or caregiver, make a reasonable effort to obtain, record, and maintain the following information for each patient.

(2) It is recognized that most of this can be obtained using pharmacy technicians and designed forms, etc.:

(A) Name, address, and telephone number;

(B) Date of birth (age);

(C) Gender;

(D) Medical history:

(i) Significant patient health problems known to the pharmacist;

(ii) Prescription drug reactions/prescription drug allergies; and

(iii) List of prescription medications and legend drug administration devices known to the pharmacist;

(E)(i) Transitory patients or situations where the pharmacy will only provide medication one (1) time.

(ii) In obtaining patient information, if the pharmacist knows or is informed by the patient that this is a one-time situation, the pharmacist may forego the above requirement to record and maintain the information; and

(F) Pharmacist comments.

(c) **Drug use evaluation for new and refill prescriptions.** Drug use evaluation or drug utilization review includes the following activities:

(1) The pharmacist shall evaluate the prescription or medication order for reasonable:

(A) Dose and route of administration; and

(B) Directions for use;

(2) The pharmacist shall evaluate medication orders and patient information for:

(A) **Duplication of therapy.** Is the patient taking the same or similar medication or medications;

(B) Prescription drug-prescription drug interactions;

(C) Proper utilization (overutilization or underutilization); and

(D) Known drug allergies;

(3) **Drug-drug contraindications as defined by the Arkansas State Board of Pharmacy.** Is this medication contraindicated with another medication the patient is taking;

(4)(A) It is recognized that the ultimate decision to use the medication or not use the medication rests with the physician who has more complete patient information.

(B) It is the pharmacist's responsibility to:

(i) Monitor the patient's medication therapy in the areas addressed in this rule; and

(ii) Inform the physician of the suspected problem; and

(5) If a problem is suspected and the physician is informed, the pharmacist shall document the process.

(d) **Patient counseling.**

(1)(A) A pharmacist shall counsel the patient or caregiver face-to-face if the patient or caregiver is in the pharmacy.

(B) If not, a pharmacist shall make a reasonable effort to counsel the patient or caregiver.

(2) Alternative forms of patient information may be used to supplement, but not replace, face-to-face patient counseling.

(3) Patient counseling as described herein shall also be required for outpatients of hospitals and institutions when medications are dispensed on discharge from the hospital or institution.

(4)(A) Patient counseling as described in this section shall not be required for inpatients of a hospital or institution where a nurse or other licensed healthcare professional is authorized to administer the medication.

(B) However, the pharmacist shall provide drug therapy counseling when:

(i) It is professionally deemed to be appropriate;

(ii) Medications are provided by the pharmacy; and

(iii) A pharmacist is on duty and a patient is discharged from the hospital or institution.

(5) The pharmacist shall maintain and make available to all patients appropriate patient-oriented reference materials:

(A) USP-DI;

(B) Facts and Comparisons Patient Drug Facts; or

(C) An equivalent or better publication as determined by the board.

(6)(A) It is recognized that the ultimate decision to not provide patient counseling rests with the physician.

(B) If the physician in specific instances (blanket requests not accepted) requests that information not be provided to the patient and gives reason, the pharmacist should honor that request in almost all instances.

(e)(1) "Patient counseling" means the effective communication by the pharmacist of information, as defined in this act, to the patient or caregiver in order to improve therapeutic outcome by encouraging proper use of prescription medications and drug delivery devices.

(2) For original prescription medication orders (excluding renewed or updated prescriptions the patient has been recently taking) and orders for legend devices, specific areas of counseling shall include:

(A) Name and general description of the medication dispensed, i.e., antibiotic, antihistamine, blood pressure medicine, etc.;

(B) Name, general description, and directions for use of drug delivery devices, i.e., insulin syringes, morphine pump, etc.;

(C) Explanation of:

(i) Route of administration;

(ii) Dosage;

(iii) Times of administration; and

(iv) Continuity of therapy;

(D) Special directions for storage as deemed necessary by the pharmacist;

(E) If the drug has been determined to have a significant side effect by the board, the patient shall be properly counseled to the extent deemed necessary by the pharmacist;

(F)(i) When the prescription drug dispensed has a significant side effect if taken with over-the-counter drugs, the pharmacist should counsel the patient about that interaction.

(ii) **Example.** Coumadin with aspirin;

(G)(i) If the prescription medication is significantly affected by food or diet, the pharmacist should so advise the patient.

(ii) **Example.** Tetracycline with milk or food; and

(H) The pharmacist shall inform the patient or caregiver that he or she is available to answer questions about medications or general health information.

(3)(A) **Refills.** — On refills, the pharmacist shall present the opportunity for the patient or caregiver to ask questions.

(B) However, counseling on refills is not required except when needed in the professional judgment of the pharmacist.

(f) **Drug interactions — Significant side effects.**

(1) Recognizing that a pharmacist cannot be expected to recognize all possible drug interactions and also recognizing that the pharmacist and the patient do not have time to explain the numerous side effects of drugs, the pharmacy shall maintain a computer program that will identify significant drug interactions.

(2) These are drugs with side effects that may be managed most effectively if the patient is aware of:

(A) The specific side effect; and

(B) What to do if it occurs.

(3) The pharmacist-in-charge will be responsible for ensuring that the computer system adequately flags and warns the pharmacist of any occurrence of significant drug interactions or significant side effects.

(4) If a pharmacy was in business before September 1, 1997, and at that time did not have a computer system, said pharmacy may substitute Patient Drug Facts or other drug interaction manuals to reference drug interactions and side effects for effective patient counseling.

(5) This method should only be used until such time as the pharmacy acquires an adequate computer program as described in this section.

(6) The pharmacist will be responsible for counseling the patient on these interactions with verbal and, where appropriate, written information.

17 CAR § 160-2902. Prescription orders to administer medication and/or immunizations.

Except as limited by this part or Arkansas Code § 17-92-101, an Arkansas-licensed pharmacist, intern, or pharmacy technician has the ability to administer medications they have been trained to administer.

17 CAR § 160-2903. Point-of-care treatment.

(a) A pharmacist who tests for conditions under Arkansas Code § 17-92-101(18)(A)(x) shall:

(1) Hold a license to practice pharmacy in this state;

(2) Report a diagnosis or suspected existence of reportable diseases as required by the Department of Health;

(3) Furnish patient records to a healthcare practitioner designated by the patient upon the request of the patient; and

(4) Maintain records of all patients receiving services under this section for two (2) years.

(b) A pharmacist may treat the following conditions within the framework of a statewide written protocol:

(1) Influenza;

(2) Pharyngitis caused by Streptococcus A;

(3) SARS coronavirus; or

(4) Other health conditions adopted by rule according to the Pharmacy Practice Act.

(c)(1) The Arkansas State Board of Pharmacy shall publish the statewide written protocol as developed and adopted with consultation and approval of the Arkansas State Medical Board.

(2) The statewide written protocol:

(A) Shall include the age of people that can be treated under the protocol;

(B) Shall include medicinal drugs approved by the Food and Drug Administration that are indicated for treatment of these conditions, including without limitation any over-the-counter medication; and

(C) Shall not include any controlled substances in Schedules I – IV.

(d) A pharmacist shall only treat conditions:

(1) For which the pharmacist has tested; and

(2) That are approved under Arkansas Code § 17-92-101(18)(A)(x)*(c)* or Arkansas State Board of Pharmacy rules as described in statute.

(e) This section does not apply to specific acts of drug therapy management or disease state management delegated to a pharmacist based upon a written protocol or patient care plan approved by a physician, Arkansas Code § 17-92-101.

Subpart 30. Arkansas Pharmacy Support Group

Codification Notes. This subpart as promulgated prior to codification into the Code of Arkansas Rules provided as follows: "(6/20/91, Revised 7/10/2009)"

17 CAR § 160-3001. Definitions.

As used in this part:

(1) "Board" means the Arkansas State Board of Pharmacy;

(2) "Board-approved interveners" means persons trained in intervention and designated by the Arkansas State Board of Pharmacy to implement the intervention process when necessary;

(3) "Committee" means a committee appointed by the Arkansas State Board of Pharmacy to formulate and administer the impaired pharmacists program, to be known as the Arkansas Pharmacy Support Group (ARPSG);

(4) "Impaired pharmacist" or "impaired pharmacy technician" means a pharmacist or pharmacy technician who is unable to practice pharmacy with reasonable skill, competency, or safety to the public because of substance abuse;

(5)(A) "Impaired pharmacist program" means a plan approved by the Arkansas State Board of Pharmacy for intervention, treatment, and rehabilitation of an impaired pharmacist or pharmacy technician.

(B) The program for each impaired pharmacist/pharmacy technician will be embodied by a contract with the ARPSG and the impaired pharmacist/pharmacy technician will be required to comply with the contractual terms;

(6) "Intervention" means a process whereby an alleged impaired pharmacist/pharmacy technician is confronted by the Arkansas State Board of Pharmacy or Arkansas State Board of Pharmacy-approved interveners who:

(A) Provide documentation that a problem exists; and

(B) Attempt to convince the pharmacist to seek evaluation and treatment;

(7) "Rehabilitation" means the process whereby an impaired pharmacist/pharmacy technician advances in an impaired pharmacist program with progressive advocacy from the ARPSG to an optimal level of competence to practice pharmacy without endangering the public; and

(8) "Verification" means a process whereby alleged professional impairment is identified or established.

17 CAR § 160-3002. Administration.

(a)(1) The impaired pharmacist program authorized by Arkansas Code § 17-92-701 et seq., shall be administered by the ARPSG in accordance with guidelines set by the Arkansas State Board of Pharmacy.

(2) The ARPSG shall serve as a diversion program to which the board may refer licensees where appropriate in lieu of or in addition to other disciplinary action, and also be a source of treatment, referral, and monitoring for pharmacists who desire to avail themselves of its services on a strictly voluntary basis.

(b)(1) The board shall appoint an executive committee of five (5) persons who are recovering pharmacists and members of the ARPSG.

(2) The executive committee members shall serve three-year terms.

(3) The executive committee is authorized to appoint subcommittees to assist in operations as needed, but all subcommittee actions are subject to review and approval of the executive committee.

(c)(1) The board shall also appoint an executive secretary who shall be a nonvoting member of the executive committee and who shall serve at the pleasure of the board.

(2) The executive secretary shall be responsible for:

(A) Administrative duties of the ARPSG; and

(B) Supervision of ARPSG contracts and monitoring functions.

(3) The executive secretary shall be compensated as may be determined by the board.

(d) **ARPSG Executive Committee responsibilities.** Subject to guidance and direction by the board, the ARPSG Executive Committee shall be responsible for:

(1) Formulating and administering a program to monitor compliance by impaired pharmacists/pharmacy technicians with the recovery guidelines established by the ARPSG contract with the impaired pharmacist/pharmacy technician and approved by the board;

(2) Appointing a member of the ARPSG as a monitor for impaired pharmacists/pharmacy technicians who are under contract with the ARPSG to supervise

compliance with the recovery guidelines established in the contract and approved by the board;

(3) Recommending to the board that an impaired pharmacist/pharmacy technician has progressed in recovery and can return to the practice of pharmacy on terms determined by the board without posing a threat to himself or herself or to the public;

(4) Approving addiction professionals, addiction centers, and medical providers to perform evaluations of pharmacists/pharmacy technicians who:

(A) Are ordered to participate in the ARPSG; or

(B) Voluntarily request participation in the program;

(5) Develop and administer requirements for personal drug testing of participants in the ARPSG;

(6) Reviewing and monitoring information relating to the compliance of pharmacists/pharmacy technicians in the ARPSG;

(7) Assisting the pharmacists' professional association in publicizing the program; and

(8) Preparing of reports for the board as requested.

17 CAR § 160-3003. Arkansas State Board of Pharmacy referral.

(a) The Arkansas State Board of Pharmacy shall inform each pharmacist/pharmacy technician referred to the program by board action of the:

(1) Procedures followed in the program;

(2) Rights and responsibilities of the pharmacist/pharmacy technician in the program; and

(3) Possible consequences of noncompliance with the program.

(b) The Executive Director of the Arkansas State Board of Pharmacy shall be immediately informed:

(1) When a pharmacist/pharmacy technician has failed to comply with any contractual term of the treatment program; or

(2) If the ARPSG Executive Committee determines that the pharmacist/pharmacy technician poses a threat to the health and safety of the public.

(c)(1) Participation in a program under this subpart shall not be a defense to any disciplinary action that may be taken by the board.

(2) Further, no provision of this section shall preclude the board from commencing disciplinary action against a licensee who is terminated from a program pursuant to this section.

(d) The board shall be informed when, in the opinion of the ARPSG Executive Committee, a pharmacist/pharmacy technician who enters the program is eligible to resume professional practice without posing a threat to himself or herself or the public.

17 CAR § 160-3004. Review activities.

(a) The Arkansas State Board of Pharmacy shall review the activities of the Executive Committee.

(b) As part of this evaluation, the board may review files of all participants in the ARPSG program.

(c) The board shall also resolve complaints received regarding the impaired pharmacists program.

17 CAR § 160-3005. Civil liability.

(a) All persons acting on behalf of the Arkansas State Board of Pharmacy in the impaired pharmacists program under this section shall be considered:

(1) To be acting on behalf of the board; and

(2) Officers or employees of the state.

(b)(1) All patient records:

(A) Shall be confidential; and

(B) Shall not be subject to public inspection except pursuant to an order of a court of competent jurisdiction.

(2) However, the records:

(A) May be introduced as evidence in any relevant proceedings before the board; and

(B) Shall be produced upon board request.

17 CAR § 160-3006. Funding.

(a) The Arkansas State Board of Pharmacy is authorized to provide up to fifty thousand dollars ($50,000) per year to the ARPSG Executive Committee for expenses incurred in management and operation of the program.

(b) The Executive Committee shall prepare a budget for a July 1 to June 31 fiscal year outlining planned expenses of the ARPSG and submit the budget for review and approval prior to the board's June meeting.

Subpart 31. Criminal Background Checks

17 CAR § 160-3101. Definitions.

As used in this part:

(1) "Board" means the Arkansas State Board of Pharmacy;

(2) "Criminal background check" means both a state criminal records check conducted by the Division of Arkansas State Police (state background check) and a nationwide criminal records check conducted by the Federal Bureau of Investigation (federal background check), including the taking of fingerprints; and

(3) "Provisional license or registration" means a nonrenewable provisional license or registration that shall expire when the results of the nationwide criminal background check are received by the Arkansas State Board of Pharmacy or one hundred eighty (180) days after issue, whichever comes first.

17 CAR § 160-3102. Background check required.

(a) The Arkansas State Board of Pharmacy shall not issue an initial license/registration or reinstate a license/registration until the state and federal criminal background checks have been completed.

(b) The board may issue a provisional license or registration to applicants for a new pharmacist or intern license or for a new or reinstated pharmacy technician registration as provided in this subpart.

17 CAR § 160-3103. Application procedure.

(a)(1) Effective March 1, 2004, prior to or contemporaneously with filing an application form for the applicable license or registration, each applicant for a new intern or pharmacist license or a new or reinstated registration as a pharmacy technician shall apply for state and federal criminal background checks using forms furnished by and pursuant to instructions provided by the Arkansas State Board of Pharmacy.

(2) Before performing any practice of pharmacy while physically present within the State of Arkansas, a pharmacist shall:

(A) Apply for state and federal criminal background checks described herein; and

(B) Obtain documentation from the board of its approval of the pharmacist's practice of pharmacy while physically present in Arkansas.

(b) Each applicant shall authorize the release of criminal background check reports to the board and shall pay any applicable fees associated with the state and federal criminal background checks pursuant to written instructions provided by the board.

(c) The state and federal criminal background checks may be used for an initial license/registration issued by the board for twelve (12) months after each check is completed.

17 CAR § 160-3104. Eligibility for license/registration.

(a) Notwithstanding the provisions of Arkansas Code § 17-1-103, a person is not eligible to receive or hold an intern or pharmacist license or pharmacy technician registration issued by the Arkansas State Board of Pharmacy if that person has pleaded guilty or nolo contendere to, or has been found guilty of, any of the following offenses,

regardless of whether an adjudication of guilt or sentencing or imposition of sentence is withheld, by any court in the State of Arkansas or of any similar offense by a court in another state or of any similar offense by a federal court:

(1) Any felony listed under Arkansas Code § 17-3-102;

(2) Any act:

(A) Involving gross immorality or dishonesty; or

(B) That is related to the qualifications, functions, and duties of a person holding the license or registration; or

(3) Any violation of Arkansas pharmacy or drug law or rules, including but not limited to:

(A) This chapter;

(B) The Uniform Controlled Substances Act, Arkansas Code § 5-64-101 et seq.; and

(C) The Food, Drug, and Cosmetic Act, Arkansas Code § 20-56-201 et seq.

(b) If an applicant who has such a conviction wishes to request a waiver of the conviction from the board, he or she must submit a request for waiver form along with the following documentation:

(1) Copies of court documents pertinent to each conviction, including complete copy of the court file, certified by the court clerk;

(2) Documents from probation/parole officers, court clerk, or other officials proving that any probation, parole, restitution, rehabilitation, community service, or other court-ordered sentence has been successfully completed or, if still ongoing, with information regarding the history of compliance and current status;

(3) A notarized statement by the applicant explaining:

(A) The circumstances of each conviction; and

(B) Why he or she should be granted a waiver; and

(4) An applicant may submit any additional evidence of rehabilitation, including:

(A) Letters of reference from past and/or current employers;

(B) Letters of reference from pharmacy instructors concerning attendance, participation, and performance in pharmacy programs;

(C) Letters from treatment/recovery program attesting to current sobriety and length of time of sobriety, if appropriate;

(D) Letters of reference from other knowledgeable professionals such as probation or parole officers;

(E) Fitness-to-practice release letter from appropriate healthcare professional; or

(F) Any other pertinent information may be considered.

(c) The application and request for waiver shall not be considered until the application, all fees, all the documentation identified in subsection (b) of this section, and both federal and state criminal background check reports are received by the board.

(d)(1) The board's Informal Review Committee or its designee shall determine whether the:

(A) Applicant is rehabilitated;

(B) Conviction has served the intended disciplinary purpose; and

(C) Applicant can practice or work in the capacity that is the subject of the application without undue risk to the public health, safety, or welfare because of the subject conviction.

(2) The Informal Review Committee or its designee shall consider all relevant data, including without limitation:

(A) The age at which the offense was committed;

(B) The circumstances surrounding the offense;

(C) The length of time since the offense was committed;

(D) Subsequent work history;

(E) Employment references;

(F) Character references; and

(G) Other evidence demonstrating that the applicant does not pose a threat to the public health, safety, or welfare.

(e) Each applicant with a disqualifying conviction who requests a waiver may appear before the Informal Review Committee or its designee or may choose to allow the Informal Review Committee to make a determination on the request upon the file documentation obtained by the board and that submitted by the applicant.

(f) No application with a disqualifying conviction will be processed until:

(1) All required documentation has been received; and

(2) The applicant's request has been submitted to the Informal Review Committee or its designee.

17 CAR § 160-3105. Arkansas State Board of Pharmacy waiver of conviction.

(a) In the event that the Informal Review Committee or its designee determines not to waive a conviction, an applicant can request a full Arkansas State Board of Pharmacy hearing on the request for a waiver of the conviction.

(b)(1) The applicant's written request for a full board hearing on the waiver must be received by the board office no later than thirty (30) days after the Informal Review Committee's denial of the initial waiver request.

(2) The applicant will be scheduled to appear before the board as soon as is practicable.

(3) The applicant may, if desired, submit additional documentation described in 17 CAR § 160-3104(b) for the board's consideration.

(c) The board shall consider the matters as identified in 17 CAR § 160-3104 in determining whether to waive a conviction.

17 CAR § 160-3106. Professional license and registration.

(a)(1) The Arkansas State Board of Pharmacy may issue a provisional license or registration limited to six (6) months' duration only to applicants who:

(A) Certify on their board applications that they have no criminal convictions;

(B) Meet all other qualifications for licensure or registration established by the board; and

(C) Certify that they have submitted Division of Arkansas State Police and Federal Bureau of Investigation Criminal Background Check forms and associated fees pursuant to written instructions provided by the board, or, at the board's discretion, when state criminal background check reports are available within a reasonable time after application and the board has received a state criminal background check report on the applicant acceptable to the board and pursuant to this rule, and the applicant certifies that he or she has submitted division and Federal Bureau of Investigation Criminal Background Check forms and associated fees for the Federal Bureau of Investigation check pursuant to written instructions provided by the board.

(2) The provisional license or registration shall permit the subject thereof to temporarily perform, pending the board's receipt of the criminal background check report or reports, the activities authorized by the license, permit, or registration that is the subject of the application.

(3) An applicant who discloses any conviction identified in 17 CAR § 160-3104 on the application form:

(A) Shall not be eligible to receive a provisional license or registration; and

(B) Will be considered for the applicable license or registration upon the board's receipt of the criminal background check reports.

(b)(1) Upon receipt of both the federal and state criminal background check reports containing no conviction of any offense identified in 17 CAR § 160-3104, and upon the applicant meeting all other qualifications for the subject license/registration, the board shall issue the appropriate license/registration to the applicant.

(2)(A) Upon receipt of either criminal background check report that contains a conviction of an offense identified in 17 CAR § 160-3104, the Executive Director of the Arkansas State Board of Pharmacy shall cause to be served upon the applicant notice of:

(i) The reported conviction;

(ii) The applicant's failure to disclose the conviction in the application;

(iii) Any other relevant facts or law;

(iv) The immediate revocation of the provisional license/registration pursuant to Arkansas Code § 17-92-317; and

(v) The opportunity for a hearing.

(B)(i) In order to obtain a hearing on the subject issues, an applicant shall serve a written request for a hearing upon the executive director within ten (10) days of service upon the applicant of the notice described in the preceding paragraph.

(ii) The hearing shall be conducted in accordance with the Arkansas Administrative Procedure Act, Arkansas Code § 25-15-201 et seq.

(c) Failure of an applicant to disclose any conviction of an offense identified in 17 CAR § 160-3104 shall constitute grounds for the suspension, revocation, or denial of a license or registration.

(d) **Fees and applications.**

(1) The license/registration fee shall be submitted with the application.

(2) The fee is not refundable.

17 CAR § 160-3107. Applicant confidentiality.

(a)(1) All reports obtained under this part are confidential and are restricted to the exclusive use of the Arkansas State Board of Pharmacy.

(2) The information contained in reports:

(A) Shall not be released or otherwise disclosed to any other person or agency except by court order; and

(B) Are specifically exempt from disclosure under the Freedom of Information Act of 1967, Arkansas Code § 25-19-101 et seq.

(b) Criminal conviction reports may be reviewed by or provided to the subject, the subject's attorney, or other designee at the request of the subject as follows:

(1)(A) To the subject, in person, upon his or her producing positive verification acceptable to the board of his or her identity, or by mail upon receipt of an acknowledged authorization in a form acceptable to the board.

(B) The board will mail a copy of the report by certified mail, return receipt requested, delivery restricted to the subject or his or her authorized agent at the address stated in the request; or

(2) To the subject's attorney or other designated individual, in person, upon presentation of an acknowledged authorization by the subject and presentation of positive verification of the attorney's or designated individual's identity, both of which are acceptable to the board.

17 CAR § 160-3108. Challenges to the accuracy of the report.

(a) The Arkansas State Board of Pharmacy shall make determinations based on the information obtained from the Bureau and shall not be responsible for allegations regarding the disposition, expungement, or accuracy of the information.

(b) A person may challenge the completeness or accuracy of a report of criminal conviction information issued by the State Police Identification Bureau or the Federal Bureau of Investigation as provided in Arkansas Code § 12-12-1013, as amended.

(c) Upon receipt of a corrected criminal conviction report, the board shall conduct a new evaluation of the report and the applicant's qualifications for the applicable license or registration.

17 CAR § 160-3109. Prelicensure criminal background check.

(a) An individual may petition for a prelicensure determination of whether:

(1) The individual's criminal record will disqualify the individual from licensure; and

(2) A waiver may be obtained.

(b) The individual must obtain the prelicensure criminal background check petition form from the Arkansas State Board of Pharmacy.

(c) The board will respond with a decision in writing to a completed petition within a reasonable time.

(d) The board's response will state the reason or reasons for the decision.

(e) All decisions of the board in response to the petition will be determined by the information provided by the individual.

(f)(1) Any decision made by the board in response to a prelicensure criminal background check petition is not subject to appeal.

(2) The board will retain a copy of the petition and response, and it will be reviewed during the formal application process.

Subpart 32. Automation — Automated and Robotic Pharmacy Systems

Codification Notes. This subpart as promulgated prior to codification into the Code of Arkansas Rules provided as follows: "(10/2001)"

17 CAR § 160-3201. Purpose and scope.

The purpose of this subpart is to recognize the use of automated pharmacy systems and or robotic pharmacy systems in community or institutional pharmacy settings.

17 CAR § 160-3202. Definitions.

As used in this part:

(1) "Automated pharmacy systems" include, but are not limited to, mechanical systems that:

(A) Perform operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of medications; and

(B) That collect, control, and maintain all transaction information; and

(2) "Robotic pharmacy system" means a mechanical system controlled by a computer that:

(A) Performs operations or activities relative to the storage, packaging, labeling, and dispensing of medications; and

(B) Collects, controls, and maintains all transaction information.

17 CAR § 160-3203. General requirements.

(a) Duties and responsibilities of the permit holder:

(1) Providing the Arkansas State Board of Pharmacy prior written notice of the installation, removal, or substantive change of the automated or robotic pharmacy system;

(2) Such notice must include, but is not limited to the:

(A) Name, address, and permit number of the pharmacy;

(B) Identification of the responsible pharmacist;

(C) Manufacturer's name and model of the system; and

(D) Policies and procedures for the system operation, for initial installations;

(3) Obtaining written approval and authorization from the board prior to implementation;

(4) Developing and implementing an ongoing quality assurance program that monitors performance of the system, which is evidenced by written policies and procedures developed by the pharmacy and includes the following:

(A) Method of ensuring accurate packaging and loading of the system;

(B) Procedures for conducting quality control checks of final dispensing for accuracy;

(C) Manufacturer's schedules and recommendations for maintenance of the device; and

(D) Plan for maintenance of all related documentation for a minimum of two (2) years; and

(5) Ensuring that the system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate recordkeeping and security safeguards.

(b) **Pharmacy practice.** The automated/robotic pharmacy system:

(1) Can be utilized in licensed pharmacies and licensed healthcare facilities where legally permissible; and

(2) Shall comply with the following provisions:

(A) Documentation as to type of equipment, serial numbers, content, policies and procedures, and location shall be maintained onsite in the pharmacy for review by an agent of the board; and

(B) The system shall be used only in settings where there is an established program of pharmaceutical care that ensures medication orders or prescriptions are reviewed by a pharmacist in accordance with established policies and procedures and good pharmacy practice.

(c) The system shall have adequate security systems and procedures, evidenced by written policies and procedures, to:

(1) Prevent unauthorized access;

(2) Comply with federal and state rules; and

(3) Maintain patient confidentiality.

(d)(1) The filling/stocking of all medications in the system shall be accomplished by qualified personnel under the supervision of a licensed pharmacist.

(2) An electronic or hard copy record of medications filled into the system shall be maintained and include identification of the person filling the device.

(e)(1) Access to and limits on access to the automated pharmacy system must be defined by policy and procedures and must comply with state and federal rules.

(2) Proper identification and access control, including electronic passwords, biometric identification, or other coded identification, must be limited and authorized by the pharmacist-in-charge.

(3) The pharmacist-in-charge must:

(A)Be able to stop or change access at any time; and

(B) Maintain a current and retrievable list of:

(i) All persons who have access; and

(ii) The limits of that access.

(f) The pharmacist-in-charge shall have the sole responsibility to:

(1) Assign, discontinue, or change access system;

(2) Ensure that access to the medications comply with state and federal rules; and

(3) Ensure that the system is filled/stocked accurately and in accordance with established, written policies and procedures.