ARKANSAS STATE BOARD OF PHARMACY REGULATIONS

REGULATION 1 —GENERAL OPERATIONS

01-00-0001—DESCRIPTION OF THE BOARD

The Arkansas State Board of Pharmacy shall consist of six pharmacist members as provided by Arkansas Code 17-92-201 (a)(1) and (2), AND 17-92-201(d) plus a consumer member and a senior citizen consumer member as provided by Arkansas Code 17-92-201 (a)(3). The qualifications, powers, and duties of the Board shall be those enumerated by the provisions of A.C.A. 17-92-201 through 17-92-208. (10/9/80, amended 6/20/91)

01-00-0002—LOCATION OF BOARD OFFICES

The office of the Arkansas State Board of Pharmacy shall be located at 101 East Capitol, Suite 218, Little Rock, Arkansas. All communications thereto may be addressed to Arkansas State Board of Pharmacy, 101 East Capitol, Suite 218, Little Rock, AR 72201. (10/9/89)

01-00-0003—REQUESTS FOR INFORMATION

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, signed by the writer and containing a return address. Communications need not be typed but should be legible. (10/9/80)

01-00-0004—LICENSEES GOVERNED BY PHARMACY PRACTICE ACT

Except wherein items of practice and procedure are specifically set out in these regulations, the practice and procedure before the Arkansas State Board of Pharmacy shall be governed by the provisions of the Pharmacy Practice Act. (10/9/80)

01-00-0005—CERTIFICATES OF LICENSURE--EXPIRATION

(a) All retail pharmacy permits, out-of-state pharmacy permits, specialty pharmacy permits, nursing home consultant pharmacist 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) Non-renewable provisional licenses and provisional registrations shall expire six 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 permit, license, registration, or certificate.

(f) Charitable clinic permits shall expire on December 31 of the first even-numbered year following the date of the issuance of the permit, license, registration, or certificate.

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

(1) Every licensed pharmacist engaged in the active practice of pharmacy shall pay to the Board of Pharmacy a renewal fee as defined in regulation 01-00-0007. If the renewal fee for any pharmacist license is unpaid by the first day of February following the date of expiration, the holder thereof must pay a penalty as defined in regulation 01-00-0007 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 the holder must be reinstated as a licensed pharmacist by satisfying the State Board of Pharmacy that he or she is of the same moral character and temperate habits as was required at the time of the original registration, and satisfy the Board of Pharmacy that he or she is competent and qualified to compound and fill prescriptions, and must pay a reinstatement fee as defined in regulation 01-00-0007 for each delinquent year up to a maximum as defined in regulation 01-00-0007 plus the current year's renewal fee.

(2) Every registered pharmacy technician shall pay to the Board of Pharmacy a renewal fee as defined in regulation 01-00-0007. 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 regulation 01-00-0007 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. The pharmacy technician may be reinstated as a pharmacy technician upon payment of a reinstatement fee as defined in regulation 01-00-0007 plus the renewal fee.

(3) Every nursing home consultant shall pay to the Board of Pharmacy a renewal fee as defined in regulation 01-00-0007. If the renewal fee for the nursing home consultant is unpaid by the first day of February following the date of expiration, the holder thereof must pay a penalty as defined in regulation 01-00-0007 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.

(4) Every preceptor shall pay to the Board of Pharmacy a renewal fee as defined in regulation 01-00-0007. 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 regulation 01-00-0007 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) 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 of Pharmacy a renewal fee as defined in regulation 01-00-0007. 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 regulation 01-00-0007 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.

(10/09/80, Revised 10/14/81, Act of 1985, 6/20/91, 8/23/96, 11/13/2006, and 7/27/2011)

01-00-0006—BOARD OF PHARMACY MEETING REQUIREMENTS

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 of Pharmacy. Examination of candidates for licensure to practice pharmacy shall be on dates, and at times and places as determined by the Board of Pharmacy. (10/09/80 Revised 6/20/91, and 11/13/2006)

01-00-0007—FEES CHARGED BY THE 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 new permit must be obtained, and 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 ($150) per year;

(iii) When there is a change in ownership in a specialty pharmacy, a new permit must be obtained and 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 new permit must be obtained, and 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, a new permit must be obtained and 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 new permit must be obtained and 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)

(A) The fee for issuance of, and the reinstatement of a nursing home pharmacy consultant permit shall be thirty-five dollars ($35.00);

(B) The fee for the renewal of a nursing home consultant pharmacist permit shall be thirty-five dollars ($35.00) per year;

(10) The fee for intern registration shall be forty-five ($45.00) dollars.

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

(12) 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);

(13) The fee for the Arkansas State Board of Pharmacy law book shall be twenty-five dollars ($25.00) except to interns on initial licensure, and applicants for reciprocity, on a one-time basis. A copy of each edition as revised shall be provided free to each pharmacy permit holder;

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

(15) The penalty for late payment of renewal of any permit, license, registration or certificate, unless specifically stated in this regulation, 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;

(16)

(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, a new permit must be obtained and the fee shall be one hundred

fifty dollars ($150);

(17)
(A) The fee for the original issuance of a pharmacy technician's permit shall not exceed thirty-five ($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 Board Regulation 04-03-0004 (f).

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

(19)
(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).

(20) The fee for issuance of a temporary permit for a pharmacist on active duty in a branch of the armed forces shall not exceed twenty-five dollars ($25.00) and shall be administered as defined in regulation 02-00-0004.

(21) The fee for registration as a preceptor shall be twenty dollars ($20.00) every two years.

(22)
(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, a new permit must be obtained and the fee shall not exceed one hundred fifty dollars ($150).

(b) All fees for examination for license shall be payable with the application and shall not be subject to refund. All other fees are only refundable if it is determined that there has been an overpayment.

(c) 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. However, the following are not subject to reinstatement if not renewed within ninety (90) days after expiration:
(1) pharmacy permits,
(2) out of state pharmacy permits,
(3) specialty pharmacy permits,
(4) hospital permits,
(5) ambulatory care center pharmacy permits,
(6) wholesale distributors of legend drugs and/or controlled substance permits, or both; and
(7) suppliers of medical equipment, legend devices, and/or medical gas licenses,
(8) institutional pharmacy permits
(9) List I chemical permits

(10) 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, nursing home consultant pharmacists 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 license, permit, certificate, or registration. 8/23/96 (Revised 6/19/97 8/19/99, 6/2001, 11/13/2006, and 7/5/2007)

01-00-0008—DECLARATORY ORDER

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

(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 petitioner is licensed by the Board under A.C.A. §17-92-101 *et seq*.;

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

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

(5) The declaratory ruling that the petitioner seeks;

(6) The regulation, statute or order which is the subject of the petition;

(7) The facts relevant to the order which petitioner seeks; 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 known to the petitioner who may have a specific personal interest in the application of the regulation, statute or order or who may be adversely affected by the declaratory order sought by the petitioner;

(10) The signature of petitioner or petitioner's attorney, if any; and
(11) All documents pertinent to the petition shall be attached thereto.

(c) Filing of the Petition.
(1) The original and three copies of each petition shall be in writing and shall be delivered in person or by mail to the Executive Director of the Board during regular business hours at the Board's offices. The Executive Director shall mark said petition as having been received by the Board and return a file-marked copy to 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 substantially conforms to section (b) above or 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 petitioner of any regulation, statute or order by the Board;
(F) whether the petition involves any subject, question or issue which the subject of a formal or informal matter or investigation currently pending before the Board, a court or other agency of this state or the federal government;
(G) whether the petition seeks a ruling on a moot or hypothetical question, speculative facts or 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 regulation, statute or order applicable to an entire class of persons;
(J) whether the promulgation of a regulation or an adjudication would be more appropriate to resolve the question; and
(K) any other pertinent matter.

(e) Parties
(1) Petitioner, persons identified in section b (9) 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 petition to intervene shall be filed in the manner as set forth the same matters as required by section b herein. 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.

(f) Disposition of Petition. The Board may:
(1) Decide the issue solely upon the facts presented in the petition; in such case the decision will apply only to the extent of the facts presented in the petition and amended to the petition;
(2) Require that additional information be submitted before the petition will be considered; 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) 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; notice of the hearing and purpose therefore 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;
(6) Consider the petition and any attachments without oral presentation; and/or

(g) Order
(1) The Board shall state its decision in writing signed by the President or other person designated by the Board.
(2) The Board's decision deciding the issue presented by the petition shall include findings of fact and conclusions of law supporting the declaratory order; 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. (Adopted 8/19/99)

01-00-0009—INSPECTOR'S WARNING NOTICE

(a) Purpose. An inspector's warning notice protects public health by allowing registrants to expeditiously correct violations of laws and rules, and report these corrections to the Board 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 Arkansas State Board of Pharmacy that is found to be violating any Arkansas Code pertaining to the practice of pharmacy or any regulation of the Arkansas State Board of Pharmacy 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 Board for review and hearing.
(f) Board review of two warning notices. Any registrant receiving two or more warning notices within a twelve-month period may be referred to the Board for review and hearing. (Adopted 2/2001)

REGULATION 5 - LONG-TERM-CARE FACILITIES

05-00—NURSING HOME CONSULTANTS

05-00-0001—DEFINITIONS

(a) Consultant pharmacist in charge
A nursing home consultant pharmacist in charge, means a pharmacist who assumes the ultimate responsibility to ensure adherence to all laws and regulations concerning pharmacy services in a nursing home.
The consultant pharmacist in charge is required to perform a majority of the consultative services provided in the nursing home and must abide by, pharmacy law and regulations, and the policy and procedures of the nursing home.

(b) Consultant pharmacist at large
A nursing home consultant pharmacist at large is a pharmacist who practices as a consultant in one or more homes to assist the consultant pharmacist in charge.

(c) Consultant pharmacist shall mean consultant pharmacist in charge and consultant pharmacist at large collectively. (Reg. Revised 02/11/2003 and 7/10/2009)

05-00-0002— GENERAL REQUIREMENTS

(a) Any pharmacist desiring to serve as a consultant pharmacist for a nursing home shall submit an application on a form provided by the Board of Pharmacy and secure a nursing home consultant permit which shall be posted in the home(s) for which he or she is consulting.

(b) Before a pharmacist can be licensed as a consultant pharmacist, he or she must satisfactorily complete a test on requirements developed by the Board to measure the knowledge of pharmaceutical duties and responsibilities in a nursing home and certify that he or she has read and understands these regulations and will abide by them.

(c) For renewal of a nursing home consultant pharmacist permit, it is required that, in addition to the continuing education required for all pharmacists, consultant pharmacists shall annually obtain three (3) hours of continuing education specifically related to his/her role as a consultant in a nursing home. Each consultant pharmacist shall report this continuing education on the renewal form approved by the Board. (Reg. Revised 02/11/2003, 11/1/2007 and 7/10/2009)

05-00-0003—RESPONSIBILITIES

Consultant pharmacists in a nursing home are involved in the following areas of pharmaceutical care which include drug storage, distribution and utilization in that nursing home:

(a) Supervision of Services
  (1) The consultant pharmacist(s) shall develop, coordinate, and supervise all pharmaceutical services. The consultant pharmacist for the nursing home must ensure that pharmacist consultation is available on a 24-hours-per-day, 7-days-per-week basis. 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.
  (2) Consultant pharmacists shall assist the nursing home in developing procedures to ensure the provision of emergency drugs, and shall report to the Board of Pharmacy any pharmacy refusing to provide medication for the pharmacy's regular patients in the nursing home on a 24-hours-per-day, 7-days-per-week basis.

(3) The consultant pharmacist(s) shall provide written consultation on compliance with federal and state laws governing legend drugs (including controlled substances).
(4) The consultant pharmacist(s) shall be knowledgeable of all laws and regulations pertaining to nursing homes and shall communicate with the state agencies involved with enforcement and regulation of nursing homes.
(5) The consultant pharmacist(s) shall spend sufficient time to evaluate discontinued or other unused medication for destruction or donation, destroy unused medication not intended for donation, check entries in a bound, numbered controlled drugs book, process unused medication for donation as provided in ACA § 17-92-1101 et seq. and Board Regulation 04-07-0006, and make general observations at the nursing stations.
(6) An individualized resident record shall indicate the day the consultant pharmacist(s) visited the home, a brief statement of purpose, finding, and actions.

(b) Control and accountability of all legend drugs (including controlled substance)
(1) The consultant pharmacist develops written procedures for control and accountability of all drugs and biologicals throughout the facility and supervises the implementation of these procedures.
(2) Only approved drugs and biologicals are used in the facility and shall be dispensed in compliance with federal and state laws. Records of receipt and disposition of all controlled drugs shall be maintained in sufficient detail to enable an accurate reconciliation. The consultant pharmacist shall determine that drug records are in order and that an account of all controlled drugs is maintained and reconciled.
(3) The consultant pharmacist(s) shall establish procedures to ensure that:
(A) All legend drugs and controlled substances must be stored in a secured location and appropriately locked.
(B) Proper records of receipt and administration of controlled drugs must be maintained for review by the consultant pharmacist.
(C) Non-controlled legend drugs.
(i) Drugs to be destroyed. The consultant pharmacist shall cause a designated nurse to record all discontinued and outdated non-controlled legend drugs in a bound and numbered drug destruction book when the drug is discontinued or becomes outdated. The consultant pharmacist(s) and a designated nurse shall jointly inventory and destroy the drugs and each shall sign the drug destruction book to document the destruction of these drugs.
(ii) Drugs to be donated. The consultant pharmacist shall cause all drugs that are designated for donation to charitable clinics licensed by the Board under Regulation 04-03-0004 and ACA § 17-92-1101 et seq., to be processed in accordance with Board Regulation 04-07-0006.
(D) Controlled drugs. All discontinued and outdated controlled drugs shall be signed out of narcotic inventory at the time of discontinuation or at the point of becoming outdated and shall be entered on the Arkansas Department of Health's *Report of Drugs Surrendered* form by a designated nurse and the director of nurses. Said outdated or discontinued drugs shall be secured in the office of the director of nurses pursuant to paragraph 3(A) of this section until sent to the Department of Health. The consultant pharmacist shall confirm the quantity of drugs segregated for shipment to the Arkansas Department of Health is accurately entered on the inventory of controlled substances recorded on the *Report of Drugs Surrendered* form.

(E) The controlled drugs shall be sent to the Arkansas Department of Health by licensed facility personnel, to be designated by the administrator, at least quarterly. The Arkansas Department of Health's receipt of drugs destroyed shall be reconciled with the nurse/pharmacist inventory. The consultant pharmacist shall make recommendations ensuring that the facility conforms to the polices and procedures established by the Division of Pharmacy Services and Drug Control, Arkansas Department of Health.

(c) Patient Drug Regimen Review

(1) The primary duty of the consultant pharmacist(s) to the patients' concerns is to apply his or her expertise on drugs to the patient's specific situation.

(2) State and federal regulations shall be the minimum standards for an adequate drug regimen review.

(3) Additionally, the consultant pharmacist shall routinely review each patient's chart and:

(A) Ascertain that patient history and drug utilization is being properly recorded.

(B) Review drug usage (including O.T.C. and prescriptions).

(C) Review patient compliance with drug regimen.

(D) Review drug allergies or sensitivities.

(E) Determine whether the patient is predisposed to side effects due to disease, illness, or age.

(F) Determine whether potential exists for significant drug interaction.

(G) Develop procedures to monitor patients' records for signs that indicate abuse or misuse of drugs by the patient or individuals.

(H) Make recommendations regarding drug therapy to the physician, nurse or other persons involved in the patient's care.

(I) Communicate to the facility, procedures that ensure adequate pharmacy services are available for emergencies that might develop in the nursing home for a specific patient.

(J) Promote pharmacists' ability and knowledge to all persons involved in patient care and to offer assistance in solving specific problems relating to patient drug regimen.

(4) A consultant pharmacist(s) shall quarterly in ICF/MR and assisted living (level II) facilities and monthly in nursing homes, review each patient's medication record, consult with and provide a written report of findings to the director of nursing or the patient's physician

(d) Labeling of drugs and biologicals and proper storage

(1) All legend drugs (including controlled substances) on the premises of a nursing home except for the emergency kit maintained pursuant to Board regulations 05-00-0004 and 05-00-0005, shall be stored under lock pursuant to Arkansas Department of Health regulations, and always be in a properly labeled container as dispensed upon a prescription by the pharmacy of the patient's choice.

(2) It is the duty of the consultant pharmacist(s) to ascertain that medications are properly labeled, properly stored, refrigerated when needed, expiration dates routinely checked, and that appropriate accessory and cautionary instructions are on all medications when required.

(e) Quality assurance and patient assessment committee

(1) A consultant pharmacist(s) 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.

(2) The consultant pharmacist shall ensure that there are written policies and procedures for safe and effective drug therapy, distribution, control, and use.

(3) The policies and procedures shall include and are not limited to:

(A) Stop order policies or other methods to ensure appropriateness of continued drug therapy.
(B) Maintaining the contents of the emergency kit in compliance with Board regulation 05-00-0005.
(C) Policies for the safe procurement, storage, distribution, and use of drugs and biologicals. (10/9/80, Reg. Revised 2/17/82, 6/25/83, 10/12/93, 02/11/2003, 6/23/05 and 7/10/2009)

05-00-0004—EMERGENCY KITS FOR LONG-TERM-CARE FACILITIES

(a) With recognition of D.E.A.'s statement of policy regarding emergency kits for long- term-care facilities and other law applicable to non-controlled legend drugs, the following regulation is adopted to permit controlled substances and non-controlled legend drugs to be stored in emergency kits in long-term-care facilities in Arkansas.

Requirements

(1) All contents of the emergency kit will be provided by one pharmacy designated by the long-term-care facility. This pharmacy must be properly registered with D.E.A.
(2) The emergency kit shall be properly sealed, stored, and 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 CFR 1306.11 and 21 CFR 1306.21.
(4) The categories of drugs that may be contained in an emergency kit are identified in Board regulation 05-00-0005. The contents of the kit shall be determined by the medical director, director of nurses and consultant pharmacist at the long-term-care facility. Any exceptions to the established standard categories must be approved by the Board of Pharmacy. 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 Board regulation 05-00-0005 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 72 hours by the designated provider pharmacy based on a prescription for the patient to whom the drugs were administered.
(7) Violation of this regulation 05-00-0001 through 05-00-0005 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) 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. 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. (10/14/1981 and 7/27/2011)

(b) Recognizing the emergency and or unanticipated need for certain legend (non-controlled) 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 exist between the Arkansas licensed home health agency and the Arkansas licensed pharmacy, and this must be available for review by the Board of Pharmacy 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 shall only be used for emergency or unanticipated needs and shall not become a routine source or supply.
(7) Only the following medications can be supplied for emergency use by licensed home health agencies under this paragraph by the pharmacy in sufficient but limited quantities:
(A) Heparin flush: pediatric (one strength)
(B) Heparin flush: adult (one strength)
(C) Sterile water for injection: small volume
(D) Sodium chloride for injection: small volume
(E) Adrenalin (epinephrine) injection: single dose only
(F) Benadryl (diphenhydramine) injection : single dose only
Note: For heparin, adrenaline and benadryl, all patients shall have a precalculated dose.
(G) If a container is opened and partially used, the unused portion shall be immediately discarded.
(8) The pharmacy is responsible to ensure compliance with this regulation, and any abuse or misuse of the intent of this regulation shall be immediately reported to the Board of Pharmacy.
(9) The pharmacy and the agency shall develop policy and procedures to address storage conditions for medications. (Revised 10/12/93, 10/14/97, 02/11/2003, 6/23/05, and 7/10/2009)

05-00-0005—DRUG CATEGORIES FOR EMERGENCY KITS IN LONG-TERM CARE FACILITIES

The following is a list of categories of drugs which are acceptable in emergency kits in long-term-care facilities in accordance with this regulation of the Arkansas State Board of Pharmacy. In every instance where injectables are indicated, only single-dose injectables are acceptable**.**

(a) Analgesics, controlled drugs
(1) Schedule 2:
Limit: one (1)
Maximum quantity: two (2)
(2) Schedule 3, 4 or 5
Limit: three (3)
Maximum quantity: if oral: six (6);
if injectable: two (2)
(b) Antibiotics
(1) Oral doses:

Limit: five (5)
Maximum quantity: five (5)

(2) Parenteral doses:
Limit: three (3)
Maximum quantity: one (1)

(c) Anticoagulant
Limit: one (1)
Maximum quantity: three (3)

(d) Antidiarrheals
Limit: one (1)
Maximum quantity: ten (10)

(e) Antihistamine Injectables
Limit: two (2)
Maximum quantity: four (4)

(f) Antinauseants
Limit: three (3)
Maximum quantity: four (4)

(g) Antipsychotic injectables
Limit: two (2)
Maximum quantity: four (4)

(h) Anxiolytics
Limit: one (1)
Maximum quantity: four (4)

(i) Cardiac life support medications

(1) Injectables:
The content and quantity of injectable cardiac life support medications is to be recommended by the quality assurance and patient assessment committee at the long-term-care facility and approved by the Executive Director of the Arkansas State Board of Pharmacy.

(2) Hypertensive crisis medications:
Limit: three (3)
Maximum quantity: eight (8)*
*When nitroglycerine sublingual is used: quantity –1 bottle of 25

(j) Coagulants
Limit: one (1)
Maximum quantity: one (1)

(k) Hypoglycemics
Limit: three (3)
Maximum quantity: two (2)

(l) Injectable seizure control medications
Limit: two (2)
Maximum quantity: four (4)

(m) Large volume parenterals
Limit: three (3)
Maximum quantity: two (2)

(n) Poison control

Limit: two (2)
Maximum quantity: two (2)

(o) Breathing Medication
Limit (1)
Maximum quantity: two (2)

(p) Corticosteroid
Limit (1)
Maximum quantity: two (2)

(Revised 02/11/2003, 11/1/2007 and 7/10/2009)

REGULATION 7—DRUG PRODUCTS/PRESCRIPTIONS

07-00: GENERAL REGULATIONS REGARDING DRUGS/PRESCRIPTIONS

07-00-0001—Facsimile (Fax) Prescription Drug Order

A prescription drug order which is transmitted by an electronic device which sends an exact copy image to the receiver (pharmacy) over telephone lines.

(a) Faxing Schedule II prescriptions
   (1) 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. The facsimile serves as the original written prescription. This exception does not apply to oral dose medications. (Also see Regulation #07-04-0001)
   (2) 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. The facsimile serves as the original written prescription. (See also regulation 07-04-0001)
   (3) 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. It must be noted on the prescription that this is a hospice patient. The facsimile serves as the original written prescription. (see regulation 07-04-0001)

(b) Faxing from a long-term-care facility to a pharmacy – a pharmacist may accept a fax prescription from a long-term-care facility provided:
   (1) For Schedule II drugs, all requirements of a written prescription are met, including the prescriber's signature on the faxed order and it is faxed by the nurse/person the physician and the long-term-care facility has designated as his/her "agent" to transmit the order, and must contain the nurse/person's signature.
   (2) For drugs other than Schedule II, the order is faxed by the nurse/person the physician and the long-term-care facility has designated as his/her "agent" to transmit the order, and must contain the nurse/person's signature.
   (3) The pharmacist verifies the fax is from the machine in the long-term-care facility.

(c) Faxed prescriptions
   (1) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V which 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 promptly reduced to writing by the pharmacist.
   (2) All law and regulation 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 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 document. Any faxed new prescription order that is not signed must be treated as a verbal order and verified to the pharmacist's satisfaction that it is legitimate.
(5) The original fax shall be assigned the number of the prescription dispensed, and maintained in pharmacy records for at least two years.
(6) The receiving fax machine must be in the prescription department of the pharmacy to protect patient/pharmacist authorized prescribing practitioner confidentiality and security.
(7) Refill authorizations for prescriptions, other than Schedule II, may be transmitted using a facsimile device. Any faxed authorization to renew or refill a prescription that is not signed must be treated as a verbal order and verified to the pharmacist's satisfaction that it is legitimate.

(d) Patient/prescriber consideration
(1) No pharmacist shall enter into any agreement with a practitioner or health care facility concerning the provision of facsimile machine services or equipment which 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/pharmacist 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. (10/12/93 Amended 2/15/95, 10/14/1997 and 7/10/2009)

07-00-0002—PRESCRIPTION TRANSFERS

(a) The transfer of original prescription information for a legend drug or a controlled substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization. Transfers are subject to the following requirements:
(1) The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:
(A) Write the word "Void" on the face of the invalidated prescription.
(B) Record on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.
(C) Record the date of the transfer and the name of the pharmacist transferring the information.

(b) The pharmacist receiving the transferred prescription information shall reduce to writing the following:
(1) Write the word "transfer" on the face of the transferred prescription.

(2) Provide all information required to be on a prescription pursuant to 21 CFR 1306.05 and include:
    (A) date of issuance of original prescription;
    (B) original number of refills authorized on original prescription;
    (C) date of original dispensing;
    (D) number of valid refills remaining and date(s) and locations of previous refill(s);
    (E) pharmacy's name, address, DEA registration number and prescription number from which the prescription information was transferred;
    (F) name of pharmacist who transferred the prescription.

(c) The original and transferred prescription(s) must be maintained for a period of two years from the date of last refill.

(d) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transfer.

07-00-0003—SIGNING PRESCRIPTIONS

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. If the pharmacy uses an electronic prescription processing system, they must fill prescriptions in accordance with regulation 07-00-0008. (10/09/80, Revised 10/14/81, 6/20/91, and 8/19/99)

07-00-0004—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, and dispensing of secret medicines or drugs being contrary to both the spirit and the letter of the Arkansas Pharmacy Act and the Arkansas Food, Drug, and Cosmetic Act, 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 secret formula or coded prescription. (10/09/80)

07-00-0005—MAINTENANCE AND RETENTION OF DRUG RECORDS

All drug records, including but not limited to purchase invoices, official dispensing records, prescription, and inventory records, must be kept in such a manner that all data is readily retrievable, and shall be retained as a matter of record by the pharmacist for at least two years.

At least every 12 months all prescriptions for legend drugs which are not controlled substances when refilled must be verified by the prescribing practitioner, a new prescription written, and a new prescription number assigned to the prescription. The prescription number of the updated prescription shall be recorded on the new prescription.

Provided, however, this regulation recognizes, and in no way affects, the six-month and five-refill limit on controlled drug prescriptions pursuant to A.C.A. 5-64 308(c). (10/09/80, Revised 12/12/86)

07-00-0006—GENERIC SUBSTITUTION

The Arkansas State Board of Pharmacy recognizes the Federal Food and Drug Administration’s Approved Drug Products with Therapeutic Equivalence Evaluations (The Orange

Book) as the basis for the determination of generic equivalency within the limitations stipulated in that publication. If the Federal 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), an Arkansas pharmacist, or any pharmacist dispensing drugs to patients in Arkansas, may substitute that product consistent with law. 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. 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. (6/21/2001)

07-00-0007—A PHARMACIST SHALL NOT DISPENSE A GENERICALLY EQUIVALENT DRUG PRODUCT UNDER ACA § 17-92-503 (a) AND (b) OF THE GENERIC SUBSTITUTION ACT IF:

(a) In the case of a written prescription, on the prescription the prescriber writes in his or her own handwriting words that specify that no substitution shall be made and then also signs the prescription.
(b) 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 reduced to writing on the prescription by the pharmacist, or
(c) The person for whom the drug product is prescribed indicates the prescription is to be dispensed as written or communicated. (4/07/89)

07-00-0008—ELECTRONIC PRESCRIPTION PROCESSING AND PATIENT CONFIDENTIALITY

(a) Definitions
  (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 which 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 health care professionals, and other pharmacists where, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well being; and to such other persons or governmental agencies authorized by law to receive such confidential information, regardless of whether such information is in the form of paper, preserved on microfilm, or is stored on electronic media.
  (2) “Electronic transmission” means transmission of information in electronic form such as computer-to-computer, electronic device to computer, e-mail, or the transmission of the exact visual image of a document by way of electronic equipment.
  (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 health care information shall be maintained in a manner that protects the integrity and confidentiality of such information as provided by rules of the Board.
  (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) Establish written policies and procedures for maintaining the integrity and confidentiality of prescription information and patient health care information. 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.

(B) Assure that the requirements of this regulation are established and implemented.

(c) Manner of issuance of a prescription drug order

(1) A prescription drug order may be transmitted to a pharmacy by electronic transmission. 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. 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.

(D) Be deemed the original prescription drug order provided it meets the requirement of this regulation and other law or regulation.

(3) 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. The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the prescription drug order consistent with existing federal or state laws 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 the patient, the prescriber, other licensed practitioners then caring for the patient, another licensed pharmacist, the Board or it's representatives, or any other person duly authorized by law to receive such information. Personally identifiable confidential information, in the patient medication record, may be released to others only on written release of the patient. 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 of Pharmacy 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.

(e) Security:
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. 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.

(f) Providing electronic equipment by pharmacists or pharmacies to practitioners or health care facilities prohibited
A pharmacist or pharmacy shall not provide a computer modem or other similar electronic device to a prescriber or health care facility for the purpose of providing an incentive to the practitioner or health care facility to refer patients to a particular pharmacy or department. 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. (Amended 10/2000, 3/2001)

07-00-0009—PROPER PRACTITIONER-PATIENT RELATIONSHIP

In accordance with Ark. Code Ann. § 17-92-1004(c) and Ark. Code Ann. § 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 Ark. Code Ann. § 17-92-1004(c) and a "Proper Physician-Patient Relationship" for purposes of Ark. Code Ann. § 17-92-1003(15), unless:

(a) the prescribing practitioner is consulting at the specific request of another practitioner who:
  (1) maintains an ongoing relationship with the patient;
  (2) has performed an in-person physical exam of the patient; and
  (3) has agreed to supervise the patient's ongoing care and use of prescribed medications; or

(b) the prescribing practitioner interacts with the patient through an on-call or cross-coverage situation.(Emergency 10/31/2007, 2/25/2008)

07-01: F.D.A. APPROVAL OF DRUGS

07-01-0001—CONTROLLED SUBSTANCES APPROVED BY F.D.A.

(a) Any wholesale drug company or drug manufacturer, doing business in Arkansas pursuant to Act 173 of 1969, as amended by Act 75 of 1979 and Act 257 of 1981, shall not distribute any controlled substance or legend drug or both in the State of Arkansas, if that product requires approval by the Food and Drug Administration for marketing and distribution, and the product, in fact has not been approved for marketing and distribution by the Food and Drug Administration.

(b) Violation of this regulation 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. 10/14/81

07-01-0002—DRUG PRODUCTS MUST HAVE A NEW DRUG APPLICATION OR AN ABBREVIATED NEW DRUG APPLICATION

(a) In order to provide for the protection of the public health and safety, drug products which 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 Federal Food and Drug Administration pursuant to 21 USC 355 unless they are exempt from the requirements for such a designation.

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, or exemption there from referenced in the above paragraph, are hereby declared to be contraband and subject to surrender to and destruction by the Arkansas State Health Department.

(b) Whenever it is made to appear to the Board that any licensee of the Arkansas State Board of Pharmacy is in possession of a stock of drugs which are contraband as defined above, a representative of the Board shall confirm with the Federal Food Drug Administration, by telephone, that the particular drug or drugs involved do not have the requirement. 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) Retention, dispensing, promotion, or advertisement of drug products by a licensee of the Board of Pharmacy, either at their business premises or at any separate storage facility after notification of their contraband status, shall constitute a direct and immediate danger to the public health and safety and will be good and sufficient cause for the suspension or revocation of any license issued by the Board of Pharmacy for knowingly retaining, dispensing, promoting, or advertising any drug products which are contraband under this regulation.

This suspension or revocation would occur only after proper hearings are held by the Board of Pharmacy. (10/14/81, Revised 6/20/91)

07-02: COMPOUNDING

07-02-0001—STANDARDS FOR COMPOUNDING AND DISPENSING STERILE PRODUCTS

The purpose of this regulation is to provide standards in the conduct, practices, and operations of a pharmacy preparing and dispensing products requiring sterility, such as injectables, ophthalmics, and inhalants.

Compounding a drug product that is commercially available in the marketplace or that is essentially a copy of a commercially available FDA-approved drug product is generally prohibited. However, in special circumstances a pharmacist may compound an appropriate quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available 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 FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available. The unavailability of such drug product must be documented prior to compounding. The recommended methodology for documenting

unavailability is to print the screen of wholesalers showing back-ordered, discontinued, or out-of-stock items. This or similar documentation must be available when requested by the Board.

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 health care facilities where medications may be provided as demanded by policies and procedures.

Pharmacies and pharmacists dispensing sterile products shall comply with all applicable federal, state, and local law and regulation concerning pharmacy and also these additional rules:

(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.

(1) Sterile products compounded under all of the following conditions are considered low-risk sterile products:

(A) The finished products are compounded with aseptic manipulations entirely within a Class 100 environment or better air quality using only sterile ingredients, products, components, and devices.

(B) The compounding involves only transfer, measuring, and mixing manipulations with closed or sealed packaging systems that are performed promptly and attentively.

(C) Manipulations are limited to aseptically opening ampules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices and packages of other sterile products.

(D) For a low-risk preparation, in the absence of passing a sterility test, the storage periods shall not exceed the following time periods: before administration, the sterile products are exposed for no more than forty-eight (48) hours at controlled room temperature, fourteen (14) days at two (2) to eight (8) degrees centigrade, and forty-five (45) days in solid frozen state at negative twenty (–20) degrees centigrade or colder, while properly stored.

(2) When sterile products compounded aseptically under low-risk conditions, and one or more of the following conditions exists, such products are considered medium-risk sterile products:

(A) 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 patient on multiple occasions.

(B) The compounding process includes complex aseptic manipulations other than the single-volume transfer

(C) The compounding process requires unusually long duration, such as that required to complete the dissolution or homogeneous mixing.

(D) The sterile products do not contain broad-spectrum bacteriostatic substances, and they are administered over several days.

(E) For a medium-risk preparation, in the absence of passing a sterility test, the storage periods shall not exceed the following time periods: before administration, the sterile products are exposed for no more than thirty (30) hours at controlled room temperature, seven (7) days at two (2) to eight (8) degrees centigrade, and forty-five (45) days in solid frozen state at negative twenty (–20) degrees centigrade or colder, while properly stored.

(3) Sterile products compounded under any of the following conditions are considered high-risk sterile products:

(A) Nonsterile ingredients are incorporated, or a nonsterile device is employed before terminal sterilization

(B) Sterile ingredients, components, devices, and mixtures are exposed to air quality inferior to a Class 100 environment. 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.

(C) Nonsterile preparations are exposed no more than 6 hours before being sterilized.

(D) 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.

(E) For a high-risk preparation, in the absence of passing a sterility test, the storage periods shall not exceed the following time periods: before administration, the sterile products are exposed for no more than twenty-four (24) hours at controlled room temperature, three (3) days at two (2) to eight (8) degrees centigrade, and forty-five (45) days in solid frozen state at negative twenty (–20) degrees centigrade or colder, while properly stored.

(b) Pharmacist requirements:

Any pharmacist in charge who performs or supervises the preparation or sterilization of sterile medications shall:

(1) Have available written policies and procedures for all steps in the compounding of sterile preparations. 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.

(2) Certify that all participating pharmacists and pharmacy technicians have completed a Board approved training and testing program in sterile product preparation. Documentation of training and testing shall be available for review, by February 30, 2002.

(3) Develop policies and procedures to annually test and review the techniques of participating pharmacists and pharmacy technicians to assure adherence to aseptic procedures.

(c) Pharmacy technician requirements:

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 Board regulation 03-00-0006 (b). Documentation of training and testing shall be available.

(d) Work area and equipment:

Any pharmacy dispensing sterile parenteral solutions shall meet or exceed the following requirements:

(1) 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. This area shall have controlled temperature and humidity. Cleanliness of the area is of critical importance. 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.

(2) The controlled limited access area shall have a certified and inspected Class100 environment. 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. The Class 100 environment device or area is to be inspected and certified yearly. Barrier isolator workstations are closed systems and are not as sensitive to their external environment as laminar airflow equipment. It is

recommended to place them in a limited access area with cleaning and sanitizing in the surrounding area on a routine basis.

(3) 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. 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. When preparing cytotoxic agents, gowns and gloves shall be worn. 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 of Pharmacy grants an exception. The cabinet of choice is a Class 11, Type B. For the purpose of this regulation, 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.

(4) The area shall be designed to avoid excessive traffic and airflow disturbances.

(5) The area shall be ventilated in a manner not interfering with laminar flow hood conditions.

(6) Daily procedures must be established for cleaning the compounding area.

(e) Storage:

All pharmacies preparing and dispensing sterile products must provide:

(4) Adequate controlled room temperature storage space for all raw materials.

(5) Adequate storage space for all equipment. All drugs and supplies shall be stocked on shelving above the floor.

(6) Adequate refrigerator storage space for compounded solutions, with routinely documented temperatures. Temperature ranges required are 36-46° F or 2-8° C.

(7) Adequate freezer storage space if finished products are to be frozen (e.g. reconstituted antibiotics.) There shall be a procedure to routinely document temperatures.

(f) Labeling:

In addition to regular labeling requirements, the label shall include:

(1) Parenteral products shall have the rate of infusion when applicable.

(2) Expiration date (Policies and procedures shall address label change procedures as required by physician orders.)

(3) Storage requirements or special conditions.

(4) Name of ingredients and amounts contained in each dispensing unit.

(5) 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.

(g) Shipping:

(1) Policies and procedures shall assure product stability during delivery.

(2) Pharmacy must assure ability to deliver products within an appropriate time frame.

(h) Home patient care services:

The pharmacist in charge of the pharmacy dispensing sterile parenteral solutions shall provide the following or assure that they are provided prior to providing medications.

(1) The pharmacist must assure that the patient is properly trained if self-administering.

(2) In situations where a pharmacy or pharmacist employs a nurse to administer medications, the pharmacist in charge must:

(A) Employ a registered nurse.

(B) Assure that proper records are maintained in compliance with laws and regulations.

(C) Make these records available to inspectors from appropriate agencies.

(3) 24-hour service shall be assured by the pharmacy.
(4) Pharmacists shall recommend and monitor clinical laboratory data as requested.
(5) Side effects and potential drug interactions should be documented and reported to the physician.
(6) Patient histories and therapy plans should be maintained.

(i) Destruction of cytotoxic drugs:

Any pharmacy providing cytotoxic drugs shall establish procedures assuring the return and proper destruction of any unused radioactive or cytotoxic drugs or other hazardous material (destruction containers for needles).

In every instance, the pharmacist in charge shall monitor the delivery, storage, and administration records of medications dispensed from his/her pharmacy.

(j) 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:
(1) Compound all medications in one of the following environments:
(A) 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).
(B) An enclosed room providing a Class 100 environment for compounding.
(C) A barrier isolator that provides a Class 100 environment for compounding.

It is recommended that all pharmacies have an anteroom designed to be separate from the buffer room. The anteroom should be available for the decontamination of supplies and equipment, and donning of protective apparel. A sink should be available in the anteroom area so that personnel can scrub prior to entering the buffer room.

(2) Use total aseptic techniques, including gowning, mask, and hair net. Scrubs may be worn, instead of gowning, if not worn or covered outside of the controlled limited access area.
(3) Provide a system for tracking each compounded product including:
(A) Personnel involved in each stage of compounding;
(B) Raw materials used including quantities, manufacturer, lot number, and expiration date;
(C) Labeling;
(D) Compounding records shall be kept for 2 years.
(4) Establishment of procedures for sterilization of all products prepared with any non-sterile ingredients by filtration with 0.22 micron or other means appropriate for the product components.
(5)
(A) 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), or in multiple dose vials for administration to multiple patients, or are exposed longer than twelve (12) hours at a two (2) to eight (8) degrees centigrade and longer than six (6) hours at warmer than eight (8) degrees centigrade 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.
(B) Sterility Testing (Bacterial and Fungal) – The USP Membrane Filtration Method is the method of choice where feasible (e.g. components are compatible with the membrane). The USP Direct Transfer Method is preferred when the membrane

filtration is not feasible. An alternative method may be used if verification results demonstrate that the alternative is at least as effective and reliable as the USP Membrane Filtration Method or the USP Direct Transfer Method. 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.

(C) 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.

(D) Potency Testing – The potency of all compounded products meeting the criteria described in Board regulation 07-02-0001 (j) (5) above must be tested to verify the potency stated on the label. Products for which there is no known or commercially available potency test standard require Board approval prior to compounding.

(E) 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. The USP Bacterial Endotoxin Test is the bacterial filtration test described in Chapter 85, USP, 2001 Edition. 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 regulation after the expiration of thirty (30) days from the effective date of said change or amendment, unless within said time period, the Executive Director objects to said change or amendment. In that case, the Executive Director shall publish the reasons for objection and afford all interested parties an opportunity to present commentary; said notice and commentary shall be pursuant to A.C.A. § 25-15-204, as amended, and the resulting decision by the Board shall be reflected by an amendment to this regulation.

(6) Establishment of procedures for yearly testing the techniques of pharmacists using simulated aseptic procedures and documentation thereof.

(7) Any construction requirements as required by this regulation (i.e. separate controlled limited access area and certification of Class 10,000) must be complied with by January 2004. Adopted: 6/85 (Amended 8/2001, 2/2003 & emergency 6/2003 & 10/26/2003).

07-02-0002—GOOD COMPOUNDING PRACTICES

(a) This regulation 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.

Compounding a drug product that is commercially available in the marketplace or that is essentially a copy of a commercially available FDA-approved drug product is generally prohibited. However, in special circumstances a pharmacist may compound an appropriate quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available 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 FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available. The unavailability of such drug product must be documented prior to compounding. The recommended methodology for documenting unavailability is to print the screen of wholesalers

showing back-ordered, discontinued, or out-of-stock items. This or similar documentation must be available when requested by the Board.

(b) Definitions:

The following words or terms, when used in this regulation, shall have the following meaning, unless the context clearly indicates otherwise:

(1) "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, research, teaching, or 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 regulation.

(2) "Component" means any ingredient used in the compounding of a drug product, including those that may not appear in such product.

(3) "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 any packaging or repackaging of the substance(s) or labeling or re-labeling of its container, and the promotion and marketing of such drugs or devices. Manufacturing also includes any preparation of a drug or device that is given or sold for resale by pharmacies, practitioners, or other persons. The distribution of inordinate amounts of compounded products, without a practitioner/patient/pharmacist relationship is considered manufacturing.

(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 be proficient in compounding and shall continually expand their compounding knowledge by participating in seminars and/or studying appropriate literature.

(2) The pharmacist has the responsibility to:

(A) Assure 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;

(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 non-sterile drug products.

(3) The area(s) 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 in a clean, dry area or, 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 area(s) used for compounding shall be maintained in a clean and sanitary condition.

(8) If parenteral products are being compounded, standards set out in Board Regulation 07-02-0001 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 intended use, cleaning, and 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) Automated, mechanical, electronic, limited commercial scale manufacturing or testing equipment, and other types of equipment may be used in the compounding of drug products. 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 inspected by the pharmacist and determined to be suitable for use.

(7) When drug products with special precautions (antibiotics, hazardous materials and cytotoxins) are involved, appropriate measures must be utilized in order to prevent cross-contamination and proper disposal procedures must be followed. 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 ~~an~~ a Food and Drug Administration registered facility.

(2) If components are not obtainable from an FDA 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 prevent contamination and to permit inspection and cleaning of the work area.

(2) Containers and closures shall be suitable material as to not alter the compounded drug as to quality, strength, or purity.

(h) Drug compounding controls:
  (1) There shall be written procedures for the compounding of drug products to assure 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 the components, their amounts (in weight or volume), the order of component mixing, and 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) Components shall be accurately weighed, measured, or subdivided as appropriate. 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) 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.
    (A) 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.
    (B) Such control procedures shall include, but are not limited to, the following (where appropriate):
      (i) capsule weight variation;
      (ii) adequacy of mixing to assure uniformity and homogeneity; and
      (iii) clarity, completeness or pH of solutions.
  (7) Appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile shall be established and followed. Such procedures shall follow accepted standards of practice and/or include validation of any sterilization process.
  (8) Beyond use dates and storage requirements (e.g. refrigeration) should be established. 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) Products prepared in anticipation of a prescription prior to receiving a valid prescription should not be an inordinate amount.
    (A) A regularly used amount should be prepared based on a history of prescriptions filled by the pharmacy.
    (B) 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, or;
(b) appropriate testing, or;
(c) USP-NF standards.
(iv) storage under conditions dictated by its 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) PGP cannot be bulk compounded to sell to a second entity for resale. 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) The product is to be administered in the office and not dispensed to the patient. 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 retail pharmacy is not precluded from making more that five percent (5%) of its annual sales to licensed practitioners. The pharmacy must, however, obtain a State Wholesale Legend Drug and/or Controlled Substance Distributor Permit.

(m) Compounding veterinarian 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) Compounding for office stock for veterinarians is prohibited, except for compounds to be used in life-threatening situations where lack of immediate availability of the product could result in patient harm and no FDA-approved product is commercially available. (Adopted 2/2001, Revised emergency 6/2003 & 10/26/2003)

07-03: SAMPLES

07-03-0001—DRUG SAMPLES

(a) Definitions

(1) "Drug sample" means a unit of a legend drug which is distributed to a practitioner by a manufacturer or a manufacturer's representative at no charge, is not intended to be sold, and is intended to promote the sale of the drug. "Drug sample" shall not mean a drug under clinical investigations approved by the federal Food and Drug Administration.

(2) "Coupon" means a form which may be redeemed as part of, or all of, the cost of a prescription for a legend drug after it has been dispensed.

(3) "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 drug is (a) habit forming, (b) toxic or having potential for harm, or (c) the new drug application for the drug limits its use to use under a practitioner's supervision. The product label of which is required to contain the statement "CAUTION, FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION."

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 which shall be exempt from Section 502 (f)(1) if certain specified conditions are met.

(b) Unprofessional conduct pursuant to regulation 02-04-0001 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."

(3)

(A) The possession of a drug sample by a pharmacy, pharmacist or licensed intern shall be considered unprofessional conduct unless prior approval has been obtained from the Board of Pharmacy or unless the sample was provided for personal use by the pharmacist, intern, or his or her family.

(B) 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 of Pharmacy so that the Board may review the request to assure that there is not a violation of federal or state law or Board of Pharmacy regulation.

Upon written request stating the purpose or use of 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. The Board may impose any conditions upon possession as determined appropriate.

The pharmacist in charge of the pharmacy where the drug samples will be located shall maintain same separated from other stock and in original sample packages.

No compensation shall be charged for sample drugs. (10/12/86)

07-04: CONTROLLED SUBSTANCES

07-04-0001—SCHEDULE II PRESCRIPTION DRUGS

(a) Emergency Prescriptions -- In the case of an emergency situation, as defined by this regulation, 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 72 hours). Dispensing, beyond the emergency period, must be pursuant to a written prescription signed by the prescribing individual practitioner. For the purposes of authorizing an oral prescription for a controlled substance listed in Schedule II of the Arkansas Controlled Substance List, the term "emergency situation" means those situations in which the prescribing practitioner determines that:

(1) Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user;
(2) No appropriate alternative treatment is available (which includes the administration of a drug which is not a Schedule II), and
(3) 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.

The prescription shall be immediately reduced to writing by the pharmacist. 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. The statement "Authorization for Emergency Dispensing," and the date of the oral order, must be on the face of the prescription. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription, which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the DEA if the prescribing practitioner fails to deliver a written prescription--failure of the pharmacist to do so shall void the authority conferred by this regulation to dispense without a written prescription of a prescribing practitioner.

07-04-0002—PARTIAL FILLING OF A SCHEDULE II PRESCRIPTION

The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he 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 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

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. 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. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record, on the prescription, whether the patient is "terminally ill" or an "LTCF patient".

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 date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.

Prior to any subsequent partial filling, the pharmacist is to determine that the additional partial filling is necessary. The total quantity of Schedule II controlled substances dispensed, in all partial filling, must not exceed the total quantity prescribed. A Schedule II prescription for a patient in a 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 sixty (60) days or after the medication has been discontinued by the prescriber.

07-04-0003—COMPUTER RECORDS FOR PARTIAL FILLING

Information, pertaining to current Schedule II prescriptions for patients in a 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:

(a) Output (display or print) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of the LTCF or address of the hospital or residence of the patient, identification of medication authorized (to include dosage, form, strength and quantity) and listing of the partial fillings that have been dispensed under each prescription.
(b) Immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted.
(c) Retrieval of partially filled Schedule II prescription information is the same as required for Schedule III and IV prescription refill information.

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.

07-04-0004--TIME LIMIT ON A NEW SCHEDULE II PRESCRIPTION

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. 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 are valid for 60 days from date of issue and may be partially filled. (2/15/95, Amended 10/14/97)

07-04-0005—THEFT OR LOSS OF CONTROLLED DRUGS

In the event a holder of a pharmacy permit issued by the Arkansas State Board of Pharmacy under ACA §17-92-405 and Board Regulation 04-05-0001 has suffered a theft or loss of controlled substances. Said permit holder shall:

(a) Notify Arkansas Department of Health Division of Pharmacy Services and Drug Control, the nearest Drug Enforcement Administration Diversion Field Office, and the Arkansas State Board of Pharmacy immediately upon discovery by phone or fax, and

(b) Deliver a completed DEA Form-106 to each of the agencies listed in (a) within 7 days of the occurrence of said loss or the discovery of said loss.

(10/09/83 Revised 6/26/03 and 7/27/2011)

07-04-0006—SCHEDULE V--EXEMPT PRODUCTS & 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 Ark. Code Ann. § 5-64-1103(c) and (d)(4) and § 5-64-1104.

(b) 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. 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:

1. the patient's medication filling history as maintained in the pharmacy's system;
2. the pharmacist's personal knowledge of the patient; and/or
3. the pharmacist's screening of the patient's existing medical conditions and physical symptoms as appropriate for the treatment being considered. The screening may include a review of the patient's medical history, disease history, prescription history, physical symptoms, and relevant vital signs, such as blood pressure. All screening performed by the pharmacist must be documented and maintained in the patient's pharmacy record.

(c) 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. If the patient does not provide a satisfactory explanation regarding inappropriate self-medicating, the pharmacist must decline to dispense the product and refer the patient to a physician.

1. 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.
2. 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:
   A. more than ten (10) days;
   B. more than twice in a thirty (30) day period;
   C. more than four (4) times in two (2) consecutive months; or
   D. 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 law or 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) Nothing in this regulation shall be interpreted to require that a Schedule V exempt product or Pharmacist Authorized Drug must be sold upon request. 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. (Adopted 7/27/2011)

07-04-0007—SCHEDULE V--EXEMPT NARCOTICS

A controlled substance listed in Schedule V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

(a) 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 professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a nonpharmacist);

(b) Not more than 240 cc. (8 ounces) of any such controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other such controlled substance nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given 48-hour period;

(c) The purchaser is at least eighteen (18) years of age;

(d) The pharmacist requires every purchaser of a controlled substance under this section not known to him to furnish suitable identification (including proof of age where appropriate);

(e) A bound record book for dispensing of controlled substances under this section is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the

purchaser (the book shall be maintained in accordance with the recordkeeping requirement of §21 CFR 1304.04); and

(f) A prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State or local law. (6/07/90 Revised 7/27/2011)

07-04-0008—SCHEDULE V—EPHEDRINE, PSEUDOEPHEDRINE OR PHENYLPROPRANOLAMINE

(a) As provided in Ark. Code Ann. § 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 ephedrine, pseudoephedrine, or phenylpropanolamine, or 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 sold in a package size of not more than three grams (3g) of ephedrine, pseudoephedrine, or phenylpropanolamine base and is 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 (3 g) of ephedrine, pseudoephedrine, or phenylpropanolamine base; or

(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 Ark. Code Ann. § 5-64-1103 (b).

(5) No more than 5 grams of any product containing ephedrine or 9 grams of any product containing pseudoephedrine or phenylpropanolamine to a single patient in any 30 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 a driver's license or non-driver’s identification card issued by the Arkansas Department of Finance and Administration or an identification card issued by the United States Department of Defense to active duty military personnel that contains a photograph of the person, the person's date of birth, and a functioning magnetic stripe or bar code. In addition to documenting the professional determination required by Regulation 07-04-0006(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.

(c) A pharmacist, pharmacy or pharmacy employee must also comply with Federal law prohibiting the sale of more than 3.6 grams of ephedrine, pseudoephedrine, or phenylpropanolamine to a patient in any 24 hour period. (Adopted 7/27/2011)

REGULATION 9 —PHARMACEUTICAL CARE/PATIENT COUNSELING

09-00: PATIENT COUNSELING

09-00-0001--PATIENT INFORMATION, DRUG USE EVALUATION, AND PATIENT COUNSELING

The intent of this regulation is to improve pharmaceutical care by defining basic standards of care. 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. These outcomes are: (1) cure of disease, (2) elimination or reduction of a patient's symptomatology, (3) arresting or slowing a disease process, or (4) preventing a disease or symptomatology.

Pharmaceutical care (clinical pharmacy) involves four major functions on behalf of the patient: (1) identifying potential and actual drug-related problems, (2) resolving actual drug related problems, (3) preventing potential drug-related problems, and (4) optimizing patient therapy outcomes. It is recognized that the patient might be best served if medication is not provided.

(a) Patient information (profile)
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. It is recognized that most of this can be obtained using pharmacy technicians and designed forms, etc.
(1) Name, address, telephone number;
(2) Date of birth (age);
(3) Gender;
(4) Medical history
(A) Significant patient health problems known to the pharmacist;
(B) Prescription drug reactions/prescription drug allergies;
(C) List of prescription medications and legend drug administration devices known to the pharmacist.
(5) Transitory patients or situations where the pharmacy will only provide medication one time
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.
(6) Pharmacist comments

(b) 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:
(A) Reasonable dose and route of administration;
(B) Reasonable 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(s)?;

(B) Prescription drug-prescription drug interactions;
(C) Proper utilization (over or under utilization);
(D) Known drug allergies.

(3) Drug-drug contraindications as defined by the Board. (Is this medication contraindicated with another medication the patient is taking?)
(4) 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. It is the pharmacist's responsibility to monitor the patient's medication therapy in the areas addressed in this regulation and inform the physician of the suspected problem.
(5) If a problem is suspected and the physician is informed, the pharmacist shall document the process.

(c) Patient counseling.
(1) A pharmacist shall counsel the patient or caregiver "face to face" if the patient or caregiver is in the pharmacy. 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) Patient counseling as described in this regulation shall not be required for inpatients of a hospital or institution where a nurse or other licensed health care professional is authorized to administer the medication. However, the pharmacist shall provide drug therapy counseling it is when professionally deemed to be appropriate and when medications are provided by the pharmacy, and when 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 USP-DI or *Facts and Comparisons Patient Drug Facts* or an equivalent or better publication as determined by the Board.
(6) It is recognized that the ultimate decision to not provide patient counseling rests with the physician. 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.

(d) "Patient counseling" shall mean 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.
(1) 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 route of administration, dosage, times of administration, and 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 of Pharmacy, the patient shall be properly counseled to the extent deemed necessary by the pharmacist.
(F) 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. (Example: coumadin with aspirin)
(G) If the prescription medication is significantly affected by food or diet, the pharmacist should so advise the patient. (Example: tetracycline with milk or food)
(H) The pharmacist shall inform the patient or caregiver that he/she is available to answer questions about medications or general health information.

(2) Refills--On refills the pharmacist shall present the opportunity for the patient or caregiver to ask questions. However, counseling on refills is not required except when needed in the professional judgment of the pharmacist.

(d) Drug interactions – significant side effects
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 which will identify significant drug interactions. (These are drugs with side effects which may be managed most effectively if the patient is aware of the specific side effect and what to do if it occurs.) The pharmacist in charge will be responsible for assuring that the computer system adequately flags and warns the pharmacist of any occurrence of significant drug interactions or significant side effects. (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. This method should only be used until such time as the pharmacy acquires an adequate computer program as described in this section.)
The pharmacist will be responsible for counseling the patient on these interactions with verbal and, where appropriate, written information. (2/12/91, 2/10/98, 07/15/2004)

09-00-0002—PRESCRIPTION ORDERS TO ADMINISTER MEDICATION AND/OR IMMUNIZATIONS

(a) Medications Administration Advisory Committee:
(1) The purpose of the Medication Administration Advisory Committee shall include functioning in an advisory capacity to assist the Board with implementation and oversight of the provisions regarding medication administration authority.
(2) The Medication Administration Advisory Committee shall be composed of five members, to be approved by the Governor, who have the following qualifications:
(A) Two members shall be licensed physicians selected from a list of three names per position submitted jointly by the State Medical Board and the Arkansas Medical Society.

(B) Two members shall be licensed pharmacists-- one pharmacist shall be recommended by the Arkansas Pharmacists Association and one pharmacist shall be a member of the Arkansas State Board of Pharmacy.

(C) One member shall be an advanced practice nurse holding a certificate of prescriptive authority selected from a list of three names submitted jointly by the State Nursing Board and the Arkansas Nurses Association.

(D) The Board may remove any advisory committee member, after notice and hearing for incapacity, incompetence, neglect of duty, or malfeasance in office.

(E) The members shall serve without compensation, but may be reimbursed to the extent special moneys are appropriated therefore for actual and necessary expenses incurred in the performance of their duties.

(3) The five initial members appointed to the committee shall draw lots to determine staggered lengths of their initial terms. Successive members shall serve three (3) year terms.

(b) Authority to administer medications/immunizations:

(1) An Authority to Administer is a written protocol, as defined in ACA § 17-92-101, from a practitioner for administration by a pharmacist of an approved medication or immunization.

(2) Pharmacists may provide pharmaceutical care to patients seven (7) years of age and older by administering medications or immunizations to an eligible patient upon receiving an Authority to Administer or a valid prescription order by a practitioner so authorized to prescribe such medications or immunizations as provided in ACA § 17-92-101(16)(A)(i). After completing the course of study described in (b)(5)(B) – (E) of this section, licensed interns, as defined by Regulation 02-01-0003 (a), may provide pharmaceutical care to patients seven (7) years of age and older by administering medications or immunizations to an eligible patient, under the supervision of an appropriately licensed pharmacist with an Authority to Administer and in accordance with Regulations 02-01-004 and 02-01-0005(h).

(3) An Authority to Administer, once granted, is valid for a time period not to exceed one (1) year--unless such an order is invalidated by the practitioner granting the authority.

(4) An Authority to Administer is valid only for the pharmacist meeting the requirements set forth by the Arkansas State Board of Pharmacy and is not transferable.

(5) Unless otherwise specifically authorized by the Board, a person must possess a Certification for the Authority to Administer Medications/Immunizations issued by the Board to be qualified to accept an Authority to Administer. Certification for the credential (Authority to Administer Medications/Immunizations) will be issued to pharmacists who:

(A) obtain and maintain a license to practice pharmacy issued by the Arkansas State Board of Pharmacy;

(B) successfully complete a Board approved course of study, examination, and certification consisting of a training program that includes the current guidelines and recommendations of the Centers of Disease Control and Prevention. The course of study should include, at a minimum:

(i) basic immunology, including the human immune response;

(ii) the mechanism of immunity, adverse effects, dose, and administration schedule of available vaccines and approved medication/immunization;

(iii) how to handle an emergency situation in the event one should arise as a result of the administration of the medication /immunization;
(iv) how to persuade patients to be immunized and options for record keeping for patients that do get immunized;
(v) how to administer subcutaneous, intradermal, and intramuscular injection; and
(vi) record keeping requirements for these medications as required by law or regulation.

(C) obtain supervised instructions on the physical administration of vaccines during such course of study and certification;

(D) obtain and maintain current certification in Cardiopulmonary Resuscitation (CPR) or Basic Cardiac Life Support (BCLS), these certification courses must be accredited by the American Heart Association and must contain a live component where proficiency is tested; and

(E) successful completion of the above described course of study may be accomplished by:
(i) successfully completing the Board-approved course of study in a College of Pharmacy curriculum; or
(ii) successfully completing an American Council of Pharmaceutical Education (ACPE) Certificate Program of not less than twelve (12) hours on the course of study described in paragraph (b)(5)(B) above.

(F) The College of Pharmacy or the provider of said course of study shall provide participants a certificate of completion. A copy of said certificate shall be mailed to the Board of Pharmacy offices and placed in the pharmacist's permanent file.

(6) Pharmacists who complete items (A) through (E) of section (5) above may apply to the Board for a Certification for the Authority to Administer Medications/Immunizations. The certificate is valid until the pharmacist's license expires. The certificate shall be displayed in the pharmacy at which the pharmacist is working, and may be renewed when the pharmacist renews his or her license biennially after demonstrating continuing competency for certification.

(7) Continuing competency for certification for Authority to Administer must be maintained. A minimum of two (2) of the thirty (30) hour requirement for continuing education, each biennium, must be dedicated to this area of practice. In addition, the pharmacist must maintain a current certificate in cardiopulmonary resuscitation (CPR) or basic cardiac life support (BCLS).

(8) An Authority to Administer order shall meet the following requirements:
(A) must properly identify the practitioner issuing the order;
(B) must identify the medication or vaccine covered in any such order;
(C) must identify the medication or vaccine administered, site of the administration, dose administered, identity of pharmacist administering the dose; and
(D) must bear the date of the original order.

(c) Seven classifications of approved medications for administration
(1) Immunizations
(2) Vaccines
(3) Allergy medications
(4) Vitamins
(5) Minerals

(6) Antihyperglycemics
(7) Anti-nausea medications

(d) Record keeping: Pharmacists shall maintain the following information for a minimum of two years:
(1) Authority to Administer
(2) Signed Patient Consent Form containing at least the following information
(a) Name of Patient
(b) Description of the medication or vaccine
(c) Description of the risks and possible side effects of the medication or vaccine
(d) Lot number of the medication or vaccine
(e) Expiration date of the medication or vaccine
(f) Date of administration
(Revised 07/15/2004, 03/14/2006, 7/5/2007 and 7/27/2011)

09-01: DISEASE STATE MANAGEMENT

09-01-0001 DISEASE STATE MANAGEMENT

The purpose of this regulation is to provide standards for the maintenance of records of a pharmacist engaged in the provision of disease state management as authorized in §17-92-101 (16) and §17-92-205 (a).

(a) Definitions. The following words and terms, when used in this regulation, shall have the following meanings, unless the context clearly indicates otherwise:
(1) "Act" means the Arkansas Pharmacy Practice Act
(2) "Board" means the Arkansas State Board of Pharmacy
(3) "Confidential record" means any health-related record maintained by a pharmacy or pharmacist--such as a patient medication record, prescription drug order, or medication order.
(4) "Disease state management" means the performance of specific acts of disease state management delegated to a pharmacist for an individual patient by an authorized practitioner through written protocol. (Disease state management shall not include the selection of drug products not prescribed by the practitioner, unless the drug product is named in the practitioner initiated protocol.)
(5) "Written protocol" means a practitioner's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Arkansas State Medical Board under the Medical Practice Act.
(A) A written protocol must contain at a minimum the following:
(i) A statement identifying the individual practitioner authorized to prescribe drugs and responsible for the delegation of disease state management;
(ii) A statement identifying the individual pharmacist authorized to dispense drugs and to engage in disease state management delegated by the practitioner;
(iii) A statement identifying the types of disease state management decisions that the pharmacist is authorized to make which shall include:
(a) A statement of the ailments or diseases involved, drugs, and types of drug therapy management authorized; and

(b) A specific statement of the procedures, decision criteria, or plan the pharmacist shall follow when exercising disease state management authority

(iv) A statement of the activities the pharmacist shall follow in the course of exercising disease state management authority, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made. Documentation shall be recorded within a reasonable time of each intervention and may be performed on the patient medication record, patient medical chart, or in a separate log book; and

(v) A statement that describes appropriate mechanisms and time schedule for the pharmacist to report to the physician monitoring the pharmacist's exercise of delegated disease state management and the results of the disease state management.

(B) A standard protocol may be used, or the attending practitioner may develop a disease state management protocol for the individual patient. If a standard protocol is used, the practitioner shall record, what deviations if any, from the standard protocol are ordered for that patient;

(C) Maintenance of records:

(i) Every patient record required to be kept under this regulation shall be kept by the pharmacist and be available, for at least two (2) years from the date of such record, for inspecting and copying by the Board or its representative and to other authorized local, state, or federal law enforcement or regulatory agencies.

(ii) Patient records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

(a) The records maintained in the alternative system contain all of the information required on a manual record; and

(b) The data processing system is capable of producing a hard copy of the record upon the request of the Board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(D) Written protocol:

(i) A copy of the written protocol and any patient-specific deviations from the protocol shall be maintained by the pharmacist and available for inspection by a Board Inspector upon request.

(ii) Written protocols, including standard protocols, any patient specific deviations from a standard protocol, and any individual patient protocol, shall be reviewed by the practitioner and pharmacist at least annually and revised, if necessary. Such review shall be documented in the pharmacist's records. Documentation of all services provided to the patient, by the pharmacist, shall be reviewed by the physician on the schedule established in the protocol.

(iii) Any protocol from a practitioner shall be maintained in the pharmacy and available for inspection by a Board Inspector upon request.

(E) Confidentiality:

(i) A pharmacist shall provide adequate security to prevent indiscriminate or unauthorized access to confidential records. If confidential health information

is not transmitted directly between a pharmacy and a practitioner, but is transmitted through a data communication device, the confidential health information may not be accessed or maintained by the operator of the data communication device unless specifically authorized to obtain the confidential information by this regulation.

(ii) Confidential records are privileged and may be released only to:
   (a) the patient or the patient's agent;
   (b) practitioners and other pharmacists when, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well-being;
   (c) other persons, the Board, or other state or federal agencies authorized by law to receive such information;
   (d) a law enforcement agency engaged in investigation of suspected violations of the Controlled Substances Act; or
   (e) a person employed by any state agency which licenses a practitioner as defined in the Act if such person is engaged in the performance of the person's official duties.

(iii) This regulation shall not affect or alter the provisions relating to the confidentiality of the physician-patient communication as specified in the Medical Practice Act.

(Adopted 8/19/99)

09-01-0003 —QUALIFICATIONS, RESOURCES, AND RECORD KEEPING REQUIRED FOR PRACTICING DISEASE STATE MANAGEMENT IN ARKANSAS.

(a) To practice disease state management a pharmacist must:
   (1) be a licensed pharmacist in the State of Arkansas
   (2) complete requirements for a credential as established by a Board of Pharmacy approved organization.

(b) Resource requirements for the provision of disease state management services shall include—but are not limited to the following:
   (1) Maintain a distinct area that provides privacy for the provision of disease state management services;
   (2) Maintain references that include a current copy/edition of applicable national practice guidelines and such other resources as may be necessary for the provision of optimal care;
   (3) Maintain devices, supplies, furniture, and equipment as may be needed for the provision of optimal care.

(c) Record keeping requirements for disease state management.
   The pharmacist shall record, maintain, and transfer data essential to the continuity of care and consistent with all applicable state and federal laws and regulations; and these records and all related files shall be available to the Arkansas State Board of Pharmacy inspectors and professional staff upon request. Additionally, a transferable pharmaceutical care record is to be maintained and is to include:
   (1) The written request for consultation from the patient or physician;

(2) The physician approved protocol and/or patient care plan, which is to recognize all concomitant diseases and the patient's complete medication history/profile;
(3) Pharmacy progress notes; and,
(4) Laboratory data.
(Adopted 8/19/99, Revised 11/12/2009)

09-01-0004 —MINIMUM COMPETENCIES AND STANDARDS

(a) Minimum competencies for pharmaceutical care in all disease state management areas:
(1) The pharmacist shall be capable of identifying and accessing the patient's current health status, health-related needs and problems, and desired therapeutic outcomes.
(2) The pharmacist shall be capable of implementing, and evaluating a pharmaceutical care plan that assures the appropriateness of the patient's medication(s), dosing regimens, dosage forms, routes of administration, and delivery systems.
(3) The pharmacist shall be capable of communicating appropriate information to the patient and/or caregiver and other health care professionals regarding prescription or non-prescription medications and/or medical devices, disease states, or medical conditions, and the maintenance of health and wellness.
(4) The pharmacist shall be capable of monitoring and documenting the patient's progress toward identified endpoints and outcomes of the pharmaceutical care plan and shall intervene when appropriate.
(Adopted 8/19/99, Revised 11/12/2009)

09-01-0005 —NOTIFICATION OF CREDENTIAL IN DISEASE STATE MANAGEMENT REQUIRED:

Every pharmacist who receives a credential in disease state management from a Board approved organization must provide a copy of the credential to the Board of Pharmacy office. The Board of Pharmacy will notify any party requesting notification that the pharmacist is so qualified.

(Adopted 8/19/99, Revised 8/2001, 07/2004, 11/12/2009)