REGULATION 2 —PHARMACISTS

02-00: GENERAL REQUIREMENTS FOR PHARMACISTS

02-00-0001 CHANGES IN EMPLOYMENT

Whenever any licensed pharmacist shall change his place of employment for any reason, it shall be the duty of the former and current employer and said licensed pharmacist to notify the Arkansas State Board of Pharmacy in writing of such change within five days after such change of employment. Notification must be made by letter, fax or email and must contain the new place of employment of the licensed pharmacist and his license number. (10/9/80, amended 10/14/81, and 11/13/2006).

02-00-0002—REPLACEMENT OF PHARMACIST'S CERTIFICATE

Any licensed pharmacist whose certificate has been lost or destroyed may procure a duplicate from the Arkansas State Board of Pharmacy by filing an affidavit that said certificate has been lost or destroyed and by paying a fee as defined in regulation 01-00-0007. (10/9/80 amended 8/23/96).

02-00-0003—PRACTICE AFTER INACTIVITY WHEN RECIPROCATING OR REINSTATING A LICENSE

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

(b) To be reciprocated and immediately practice without supervision, the pharmacist shall have practiced the profession of pharmacy, as defined by law, at least forty (40) hours per year in the previous two calendar years or be granted a waiver by the Board.

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

(1) Prior to resuming the unsupervised practice of pharmacy, practice 40 hours under direct pharmacist supervision of an Arkansas licensed pharmacist for each year or part of year out of practice. This time under supervision shall not exceed 240 hours.

(2) Cause the supervising pharmacist to document in writing to the Board, that the pharmacist has completed the designated number of hours of supervised practice.

(3) Meet with a Board representative in a practice situation so that the Board representative can, by observation, questioning, and other methods, ensure that the pharmacist is able to competently practice pharmacy. (10/12/93, Revised 11/30/2010)

02-00-0004—ARMED FORCES CERTIFICATES

Any person serving in the armed forces within the State of Arkansas, who is a licensed pharmacist in another state, may obtain a temporary permit to practice pharmacy in the State of Arkansas by furnishing certified proof of his registration from the Board of Pharmacy in his state of original registration, and the payment of a fee as defined in Regulation 01-00-0007. This permit shall entitle the holder thereof to practice in any store where an Arkansas licensed pharmacist is on duty a minimum of forty (40) hours per week. The permit must be renewed at each succeeding meeting of the Board. (10/09/80 amended 8/23/96).

02-01: INTERNSHIP/CLERKSHIP

02-01-0001—INTERNSHIP REQUIRED

Hereafter no extern, intern, or student of a pharmacy school shall be granted authority from this Board to practice pharmacy in Arkansas and serve any internship period in Arkansas unless he is licensed with the Arkansas State Board of Pharmacy and undergoes a criminal background check pursuant to Regulation 11 and conducted by the Arkansas State Police and the Federal Bureau of Investigation. Applications for an intern's license, and for criminal background checks, will be furnished by the Arkansas State Board of Pharmacy. The applicant will be responsible for the payment of applicable fees for state and federal criminal background check pursuant to written instructions provided by the Board, and for applicable fees for an intern's license to the Board. (Amended 6/23/96, 11/15/2003 and 03/01/2004).

02-01-0002—BOARD OF PHARMACY REGULATES INTERNSHIP PROGRAM

The Board of Pharmacy is charged with regulating the internship program in Arkansas Code §17-92-307. The Arkansas State Board of Pharmacy recognizes that in order to properly fulfill its obligation to the profession of pharmacy and general welfare and protection of the public health that it must implement and supervise an internship program in the State of Arkansas.

From time to time, as is required to establish a viable internship program, the Board will establish, publish, and disseminate criteria establishing requirements and standards necessary for qualifications for licensure under Arkansas Code §17-92-305, and §17-92-307.

Hereafter, every applicant for licensure by examination in Arkansas must have 2,000 hours of acceptable internship training obtained after beginning the professional college curriculum. Up to 1,500 hours of the required 2,000 may be obtained in a training program as part of school curriculum.

02-01-0003—DEFINITIONS

(a) "Licensed intern" means a person licensed by the Arkansas State Board of Pharmacy, as a licensed intern, and who is a student accepted by, and enrolled as a student in a College of Pharmacy approved by the Arkansas State Board of Pharmacy, or who is a graduate of a foreign college of pharmacy and has successfully completed a transcript verification program and who, due to circumstances beyond his/her control, has not been able to successfully complete a college of pharmacy equivalency exam program, equivalent to graduation from a Board of Pharmacy approved College of Pharmacy as set forth in regulation 02-02-0001 (A); provided, however, the graduate may qualify as a licensed intern, under this exception to the required college of pharmacy equivalency exam program set forth in regulation 02-02-0001 (A) only until the first offering of said equivalency.
    (1) "Extern" means an intern prior to graduation or a graduate who has taken and failed the Board exam.
    (2) "Graduate intern" means an intern who has graduated or completed requirements for examination as set forth in 02-02-0001 (a) and completed at least 500 hours of practical experience or training under Arkansas Board of Pharmacy approved conditions.

(b) "Graduation" means certification from a Board-approved College of Pharmacy that the student has fulfilled all requirements for graduation or has completed all foreign pharmacist requirements as set forth in regulation 02-02-0001 (a).

(c) "Supervision" means a licensed pharmacist and/or certified preceptor supervises the practical experience of a licensed intern with both personal and physical supervision, and actually gives instruction to the intern obtaining the experience during the entire period of such experience.
(d) "Class A pharmacy" means a pharmacy which has a pharmacy permit with a pharmacist on duty at least forty (40) hours per week, and no unsatisfactory deficiency and no more than three non-compliant deficiencies noted on its last Board inspection. (Amended 10/00, 11/13/2006, 7/5/2007, and 11/1/2007).

02-01-0004—REQUIREMENTS FOR INTERNSHIP TRAINING

(a) Any extern or intern receiving internship training practice or experience in the State of Arkansas must be licensed as an intern with the Arkansas State Board of Pharmacy. No credit for internship training will be allowed prior to licensure as an intern. The intern license application can be obtained from the office of the Board of Pharmacy. The intern license fee is specified in regulation 01-00-0007(a)10.
(b) An applicant for an intern license shall submit an application on a form provided by the Board and shall have the following qualifications:
    (1) Be of good moral character and temperate habits, and
    (2) Be enrolled as a student in a college of pharmacy approved by the Board, or
    (3) Be a graduate of a foreign college of pharmacy who has completed the transcript verification program, successfully completed the college of pharmacy equivalency exam program equivalent to graduation from a Board of Pharmacy approved College of Pharmacy (FPGEE), and either
        A. obtained minimum passing scores on both the Test of English as a Foreign Language (TOEFL) and the Test of Spoken English (TSE) within two years of the completion of the college of pharmacy equivalency exam or;
        B. obtained a minimum passing score for the Test of English as a Foreign Language Internet-based Test (TOEFL iBT) in each of the four sections as indicated and reported on one official score report as a result of one testing session within two years of the completion of the college of pharmacy equivalency exam.
(c) All students enrolled in any college of pharmacy shall be licensed as interns by the Board prior to any participation in the practice of Pharmacy as defined in §17-92-101, §17-92-301, and §17-92-307 in Arkansas.
(d) The intern license remains valid as long as the intern maintains active student status in a Board-approved College of Pharmacy, and for six (6) months after graduation from a College of Pharmacy, or completion of foreign pharmacist requirements as set forth in regulation 02-02-0001 (a). At this time, the intern license becomes void.
(e) An intern may not practice pharmacy as a graduate intern until approved and the intern has received a graduate intern registration from the Board.
(f) The licensed intern's certificate must be displayed in the drugstore or pharmacy in which the intern is being trained. Licensed interns shall not be left in sole charge of the prescription department at any time. Violation of this regulation may result in a cancellation of any and all internship hours toward licensure that may be accrued by the pharmacy intern, and the revocation of the preceptor's certificate.
(g) For the first 500 hours of pharmacy practice as a pharmacy intern, for each pharmacy setting where an intern practices pharmacy, the intern shall complete and file with the Board of Pharmacy office, prior to any practice, a "Training Plan" that is signed by the pharmacist in

charge for that particular work situation. Prior to completion of the first 500 hours of practical experience, the pharmacy intern may only work under the direct supervision of a certified preceptor. Hours of practical experience include only those hours worked under the direct supervision of a preceptor when regularly scheduled classes are not in session (summer break, spring break, Christmas break and months not scheduled for rotations) and may not exceed 40 hours per week. The pharmacist in charge must approve and verify, by signing the affidavit of experience, that the intern has earned their hours of practical experience under the direct supervision of a certified preceptor. Training plans shall expire on May 31 of each year. At no time may a preceptor supervise more than one licensed intern. Interns must file affidavits of experience prior to the expiration date of their training plan to get credit for these hours with the Board of Pharmacy.

(h) After the intern has completed 500 hours of intern training as specified in 02-01-0004 (g) and the hours have been approved by the Arkansas Board of Pharmacy, the intern may practice pharmacy in any Class A pharmacy under the supervision of a licensed pharmacist provided:
    1. The intern notifies the Board of Pharmacy in writing of his or her employment as a pharmacy intern within five days of starting to work in any pharmacy, and
    2. The intern notifies the Board of any change in his or her employment for any reason within five days of the change.
    3. Notification is made in writing by letter, fax, email or through the Board website and must contain the name of the intern, the name and address of the pharmacy, and the date of hire or date of change in employment. It is the intern's responsibility to verify that the notification has been received and processed by the Arkansas Board of Pharmacy.
    4. At no time may a supervising pharmacist or preceptor supervise more than one intern.

(i) Participation in a School or College of Pharmacy curriculum extern or clerkship program, approved by the Board of Pharmacy, will be credited week for week as training.

(j) The Arkansas State Board of Pharmacy examination will be offered upon graduation and proof of participation in an approved extern clerkship program in a school curriculum, or proof of completion of foreign pharmacist requirements as set forth in regulation 02-00-0001 (a).

(k) A graduate intern may practice pharmacy in the State of Arkansas under the supervision of a pharmacist in a Class A pharmacy and will not count in the pharmacist or preceptor to intern ratio. Failure to make a passing grade on the examination will reduce the applicant to extern status where they will count in the pharmacist to intern ratio. The candidate must sit for the exam within six (6) months of graduation.

(l) After presenting proof of 2,000 hours of practical experience or training under Arkansas Board of Pharmacy approved conditions, the intern may be designated as a candidate suitable for full licensure if other conditions have been met. Affidavits of 2000 hours of practical experience or internship training must be submitted to the Board of Pharmacy for full licensure, and can be obtained from the Board of Pharmacy office.
    (1) Before permitting a student to participate in any way in the practice of pharmacy, the pharmacist in charge must assure:
        (A) The preceptor or pharmacist is licensed.
        (B) The intern is currently licensed.
        (C) The intern has filed a current training plan, described in subdivision (g) of this section or has met all criteria described in subdivision (h) of this section.

(m) If the pharmacy intern is suspected to have, or evidence exists that a pharmacy intern may have violated any law or regulation regarding the practice of pharmacy, legend drugs or controlled

(n)

(1) The Board may revoke, suspend, or refuse to issue a license, or impose other appropriate penalties pursuant to Ark. Code Ann. § 17-92-315 against an intern for any of the acts or offenses set forth in Ark. Code Ann. § 17-92-311.
(2) The provisions of Board Regulation 02-04-0001 et seq. regarding unprofessional or dishonorable conduct shall be applicable to interns, and all references therein to "pharmacist" shall be construed as "intern" for purposes of this subsection.
(3) The procedures set for in Ark. Code Ann. § 19-92-313 and Board regulations applicable to disciplinary proceedings against pharmacists shall be applicable to any proceeding against an intern in this subsection.

(Revised 6/22/84, 4/07/89, 6/20/91, 4/10/92, 10/2004, 11/13/2006, 11/1/2007 and 7/10/2009)

02-01-0005—RULES APPLYING TO PRECEPTORS WHO TRAIN INTERNS

The Arkansas internship-training program requires that a pharmacist, who has been duly certified by the Arkansas State Board of Pharmacy, may serve as preceptor for an intern or extern. A pharmacist must meet the following requirements to be certified as a preceptor by the State Board of Pharmacy:

(a) Be an Arkansas pharmacist, licensed for more than one year and actively engaged in the practice of Pharmacy for the year immediately preceding the application for certification as a preceptor.
(b) Be a pharmacist employed in a pharmacy which currently holds a Class A rating indicated by the Inspection Sheet for pharmacies as outlined by the State Board of Pharmacy.
(c) For the initial application as preceptor, the applicant must satisfactorily complete a test on requirements and responsibilities of a preceptor as developed and administered by the Board of Pharmacy or its representatives.
(d) Have a pharmacy library (latest edition), which meets or exceeds the requirements of the "Inspection Sheet" for pharmacies.
(e) At least one preceptor from the internship site shall be a member of an appropriate national pharmaceutical organization. Preceptors shall be a member of at least one professional state organization.
(f) Must not have been convicted of any violation of Arkansas Code §17-92-311, unless the Board officially grants exception.
(g) Must have attended at least one professional meeting during each licensure biennium.
(h) Must agree to give immediate personal and direct physical supervision to the intern. A preceptor cannot supervise more than one intern at any specified time.
(i) Preceptors must renew their certification every two years by application and payment of fees specified in regulation 01-00-0007.

(Revised 11/13/2006 and 11/1/2007)

02-01-0006—PENALTY FOR VIOLATION

Violation of any of the rules and requirements set forth in this section may cause the preceptor to lose his or her certification, and may also cause the intern to lose internship training credit. (10/09/80, Revised 2/17/8 2/12/86, 2/10/87, 6/20/91, 8/23/96 and 11/1/2007).

02-01-0007—ACCREDITED PHARMACY DEGREE PROGRAM

An accredited pharmacy degree program shall be any program which meets at least the minimum standards established for a recognized Doctor of Pharmacy program by the American Council on Pharmaceutical Education.

At the October Board meeting each year, the Board of Pharmacy shall adopt a specific list (by name) of approved colleges. Until the list is revised, the existing list shall remain valid. (6/25/83, Revised 11/13/2006)

02-02: EXAMINATION

02-02-0001—REQUISITES FOR EXAMINATION

Before being admitted to the Arkansas State Board of Pharmacy Examination, each applicant must meet the following requirements:

(a) Satisfactory proof of graduation and receipt of the first professional undergraduate degree from a college of pharmacy approved by the Arkansas State Board of Pharmacy; or Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification from NABP.

(b) Applicants may request a blank application from the Board of Pharmacy, which must be completed and returned to the Board of Pharmacy office together with the fee as defined in regulation 01-00-0007, plus cost of the exam as determined by the Board. The application must be received no later than the date designated by the Board for receipt of applications.

(c) Each application must be accompanied by a recent 3" X 2" picture and a physical description stating age, height, weight, color of hair, eyes, and complexion of the applicant.

(d) Each applicant must undergo a state and federal criminal background check pursuant to Regulation 11, to be conducted by the Arkansas State Police and the Federal Bureau of Investigation. The Board will furnish the forms and instructions to applicants for the criminal background check. The applicant is responsible for the payment of fees for criminal background checks pursuant to written instructions provided by the Board.

(e)

(1) The examination will be held at a site and at a time or during a time period designated by the Board of Pharmacy, and each applicant will be notified in advance.

(2) Upon the receipt by the Board of Pharmacy of (1) certification of the requirements as defined in section (a) of this regulation, and (2) an application for licensure by examination; such applicant may practice pharmacy as a graduate intern, pursuant to regulation § 02-01-0002, in the State of Arkansas temporarily until the occurrence of the first of the following events:

(A) failure to take the exam at the designated time for the individual applicant; provided, however, the Board may grant a similar temporary privilege to practice pharmacy as a graduate intern subject to the same terms and conditions herein in the event the applicant is reasonably unable, due to circumstances beyond the applicant's control, to take the examination at the first designated time for the individual applicant;

(B) failure to receive a passing grade on the examination at the first designated time for the individual applicant;

(C)

i. the expiration of 6 calendar months following the applicant's graduation date from a college of pharmacy approved by the Arkansas State Board of Pharmacy; or
ii. reaching the intern license expiration date on December 31 of the second calendar year following issuance for foreign pharmacy graduates. Foreign pharmacy graduates may request an extension for the expiration of their intern permit while making progress towards the 2000 practice hours required for examination. Foreign pharmacy graduates must attain 500 initial practice hours in order to practice as a graduate intern.

(3) The granting of status as a graduate intern shall in no way entitle the recipient thereof to any rights of tenure of permanent license and is conferred gratuitously at the discretion the Board.

(f) The test or tests shall be graded and reported, and a reported score of 75 or above is considered passing.

(g) No person except members of the Board of Pharmacy or their authorized representatives will be permitted to enter the testing site during the course of examination.

(h) The applicant must make a score of 70% or more on the jurisprudence exam prior to making application for licensure as a pharmacist in the state of Arkansas. (10/09/80, Revised 1/14/81, 6/22/84, 6/13/85, 6/20/91, 2/11/97, 11/15/2003, 03/01/2004, 11/13/2006 and 11/1/2007)

02-02-0002—SCORE TRANSFER

The Arkansas State Board of Pharmacy participates in the National Association of Boards of Pharmacy Score Transfer Program. The Score Transfer Program requires the applicant, or test candidate, to submit a NAPLEX Score Transfer Form before the administration date of NAPLEX and fulfill other state requirements for licensure in the state to which the scores are transferred for licensure by examination in that state.

If a candidate takes NAPLEX in another participating state, properly transfers the score to Arkansas, and completes other requirements for licensure including but not limited to criminal background checks pursuant to Regulation 11, Arkansas will license the applicant by the examination process within twelve (12) months of receipt of the score transfer.

The Arkansas State Board of Pharmacy will provide information related to states participating, NAPLEX fees, and Arkansas fees. (6/20/91, Revised 11/15/2003 and 11/30/2010)

02-03: RECIPROCITY

02-03-0001—REQUIREMENTS FOR RECIPROCITY

No temporary license shall be granted to a reciprocity applicant until the preliminary application has been received and approved by the National Association of Boards of Pharmacy and the applicant has submitted the application to the Arkansas State Board of Pharmacy office, paid the reciprocity fee, undergone a criminal background check pursuant to Regulation 11, supplied a copy of the applicant's birth certificate, submitted proof of required continuing education, and supplied a current photograph of the applicant. The temporary license shall expire at the next meeting of the Board of Pharmacy after the issuance of the temporary license, or when the results of the criminal background check have been received, whichever is later. However, the temporary license will

automatically expire 180 days from the date of issue and the holder of the temporary license must cease practicing pharmacy in the State of Arkansas until reciprocity has been granted by the Arkansas State Board of Pharmacy.

Before issuing a temporary license, the Board Member must personally talk to the applicant and ascertain that he/she has passed the Arkansas Jurisprudence Exam.

A pharmacist is not eligible for an Arkansas license by reciprocity until he or she has been licensed six months in his/her state of original licensure by examination. Any practice in Arkansas within this six month period, must be as an intern and under the requirements set out in this criteria (unless consideration is made by the Board of Pharmacy and an exception is approved). The application for reciprocity will become null and void if it has not been completed within one year of the date of receipt in the Board of Pharmacy office. (10/09/80, Revised 4/07/89, 4/10/92, 2/10/97, and 11/15/2003)

02-04: DEFINING UNPROFESSIONAL OR DISHONORABLE CONDUCT:

02-04-0001—Preamble

In defining "unprofessional conduct," the definitions of professional conduct and a pharmacist's duty should be determined. Professional conduct may be defined as complying with all the laws and regulations that apply to a given professional activity.

A pharmacist's duty means the practicing pharmacist has a general duty to qualify himself by attaining and maintaining an acceptable level of professional competence and by using such skill and precaution in the preparation, compounding, dispensing, labeling and distribution of drugs and medical devices whether on prescription or not, so as to prevent injury or death to all who are exposed to his or her professional services; and if the pharmacist is an owner, operator, or director of a pharmacy, he has an additional duty to employ only qualified persons and such other duties as are incidental to the operation of a mercantile business establishment.

02-04-0002—Definition

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

(a) Violation of any provision of the pharmacy act.
(b) Violation of the Board of Pharmacy regulations.
(c) Violation of the Food, Drug and Cosmetic act.
(d) Violation of the Uniform Controlled Substances Act.
(e) Failure of a pharmacist to conduct himself or herself professionally in conformity with all applicable federal, state, and municipal laws and regulations in his or her relationship with the public, other health care professions, and fellow pharmacists.
(f) Failure to keep his or her pharmacy and/or area of professional practice clean, orderly, maintained and secured for the proper performance of his professional duties.
(g) Acquiring prescription stock from unlicensed sources or buying or selling legend drugs in violation of local, state, or federal law.
(h) Personal participation in the sale of alcoholic beverages while "on duty" as a pharmacist. (Exempts pharmacies selling alcoholic beverages before 6/85.)

(i) Failure to hold to the strictest confidences all knowledge concerning patrons, their prescriptions, and other confidence entrusted or acquired by him; divulging in the interest of the patron, only by proper release forms, or where required for proper compliance with legal authority.
(j) Participation in a plan or agreement, which compromises the quality or extent of professional services or facilities, at the expense of the public health and welfare.
(k) Participation in any plan, agreement, or arrangement which eliminates or detrimentally affects the traditional relationship of physician, patient, pharmacist, and the patient's freedom of choice of professional services.
(l) The distribution, promotion, or advertising of premiums, rebates, coupons, amounts off, etc., on prescription drugs unless the offer is given to all patients purchasing prescriptions in the same time period. Senior Citizen discounts shall not be considered a violation of this section.
(m) The solicitation of prescription business by providing prescribers with prescription blanks with the name of any licensed pharmacy or pharmacy printed thereon.
(n) Violation of regulations and procedures governing payment to pharmacies for pharmaceutical services for eligible public assistance recipients and/or other third party payment programs.
(o) The provision of medication carts, printing and maintenance of the data base to produce the doctor's order sheet or medication administration record, consultation and related services by provider pharmacists to long-term care facilities free of charge or obviously below cost.
(p) Falsifying contracts or agreements for legend drug purchases or violation of such contracts.
(q) Providing invalid or insufficient checks in payment for licenses or renewals.
(r) Receiving more than three (3) non-compliant deficiencies on two consecutive Board of Pharmacy inspections. The inspection is based on the Board of Pharmacy inspection form, which is available on request.
(s) Dishonorable conduct shall include, without limitation, conduct involving moral turpitude, fraud, dishonesty, or otherwise demonstrating lack of good moral character, whether or not said conduct involves the practice of pharmacy. (10/09/80, Revised 4/07/89, 6/07/90, 4/10/92 and 6/12/03)

02-05: BOARD ACTIONS

02-05-0001—EMERGENCY SUSPENSION

The Arkansas Administrative Procedures Act § 25-15-211 (c) states:

> "If the agency finds that public health, safety, or welfare imperatively requires emergency action and incorporates a finding to that effect in its order, summary suspension of a license may be ordered pending proceedings for revocation or other action, which proceedings shall be promptly instituted and determined."

Where the Executive Director of the Board of Pharmacy believes that the above condition exists, he shall call an emergency meeting with proper notifications of involved parties and media. Proper notifications shall be consistent with the Arkansas Administrative Procedures Act. This emergency meeting may be via a conference telephone call to a quorum of Board members.

The Executive Director of the Board of Pharmacy shall introduce evidence why he/she thinks an emergency exists and that a violation of the Pharmacy licensing law or regulation has occurred. The Board shall determine whether the license should be summarily suspended. A hearing shall be scheduled promptly for which notice shall be given pursuant to § 17-92-313. If

immediate action is requested, this hearing shall be within 14 days from the final Board decision. (10/12/88)

02-06: CONTINUING EDUCATION FOR PHARMACISTS

02-06-0001—ESTABLISHING AN ARKANSAS TRIPARTITE COMMITTEE ON CONTINUING PHARMACY EDUCATION

(a) The Arkansas Tripartite Committee on Continuing Pharmacy Education, hereinafter referred to as the Committee, is established to maintain professional competence through continuing education. The Committee shall consist of the Executive Director of the Arkansas State Board of Pharmacy, the Dean(s) of the colleges of pharmacy approved by the Arkansas State Board of Pharmacy that are located within the state of Arkansas, and the Executive Vice President of the Arkansas Pharmacists Association or the designated representatives of these individuals.

(b) The general areas of responsibility for the Committee shall be following:
  (1) Plan and coordinate continuing education opportunities.
  (2) Promote research in continuing pharmacy education.
  (3) Develop information and record systems, pertaining to the participation of pharmacists licensed in the state of Arkansas, in continuing education.
  (4) Make recommendations to the Arkansas State Board of Pharmacy concerning Continuing Education Regulations.

(c) The Committee will meet periodically to review and recommend changes in the criteria by which the continuing education will be approved and to accomplish the above responsibilities.

(d) The Executive Director of the Board of Pharmacy will carry out approval of continuing education according to the guidelines below.

(e) The Executive Director of the Board of Pharmacy will act as Chairman of the Committee. (Revised 7/5/2007)

02-06-0002—ACCREDITATION GUIDELINES

(a) Guidelines
  (1) The Continuing Education Unit (CEU) shall be the basis for accreditation of offerings within the state. One-tenth (0.1) CEU is defined as one (1) contact hour.
  (2) The Board of Pharmacy will accredit intrastate and interstate continuing education offerings that have been reviewed by an appropriate national agency.
  (3) Continuing education programs shall be accredited for the total length of the program.
  (4) Credit shall not be allowed for:
    (A) "Banquet" meetings with no educational program.
    (B) Unstructured demonstrations.
    (C) Unstructured question and answer sessions.
  (5) Credit (hour for hour) shall be allowed for:
    (A) Speakers.
    (B) Panels.
    (C) Structured discussions, workshops, and demonstrations.
    (D) Structured questions and answers sessions.
  (6) Keynote speakers and topics will be accredited on an individual basis.

(7) The Committee reserves the right for members or designees to review programs in operation.

(b) Accreditation Mechanism

(1) Members of the Committee shall be responsible for reviewing and recommending changes in the criteria for the accreditation of continuing education offerings.

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

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

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

(c) Requirements for Accreditation

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

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

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

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

(d) Program Criteria for Accreditation

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

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

(3) A description of the program content shall accompany the request for accreditation and must be evaluated prior to its presentation.

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

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

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

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

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

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

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

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

(8) The program administrator shall present accreditation certificates to pharmacists, who satisfy requirements of the program. The application for approval shall specifically state how the accreditation certificates will be presented to participants.

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

(10) Changes in speakers are acceptable if the quality of the program being presented is not diminished.
(11) The Executive Director of the Board of Pharmacy must receive any changes in topics to be presented at least seven (7) days before the program is to be presented.
(12) The organization presenting a continuing education program must provide reasonable notification to potential participants of any changes in date, time, or duration of the program; changes in speakers; or changes in topics to be presented.
(13) The program administrator shall require all participating pharmacists to sign in and out to show attendance during the entire CE session unit in order to be eligible for credit.
(14) The program administrator must keep a record of all attendees receiving credit for four (4) years for verification by the Board.

(e) Programs sponsored and conducted by local pharmacists' associations, will be accredited provided that the programs meet the criteria outlined in (c) and (d) of these guidelines in addition to the following procedures.
(1) The program shall be structured and shall be offered to all pharmacists who are members of the local association.
(2) Each program shall be a minimum of one hour in length.
(3) The local pharmacists' association shall provide a method of registration and verification of attendance as outlined in (d).

(f) Failure to follow the guidelines and requirements of Regulation 02-06-0002 will disqualify the program administrator or other entity requesting CE accreditation from being eligible for approval of future program requests.

(Revised 11/30/2010)

02-06-0003—IMPLEMENTATION OF PHARMACY CONTINUING EDUCATION

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

(b) Beginning with the 2002-2003 biennium—for licensure in the 2004-2005 biennium, and in all future two year periods through the 2008-2009 biennium, the requirements for continuing education will be as follows:
(1) 30 hours of continuing education each biennium, as approved by the Arkansas Tripartite Committee on Continuing Pharmacy Education.
(2) A minimum of twelve (12) continuing education hours of the thirty (30) required hours, must be live contact hours, as defined by the Committee. The live hours must be concerning drug therapy or patient care.

(c) Beginning with the 2010-2011 biennium – for licensure in the 2012-2013 biennium, and in all future two year periods, the requirements for continuing education will be as follows:
(1) 30 hours of continuing education each biennium, as approved by the Arkansas Tripartite Committee on Continuing Pharmacy Education.
(2) A minimum of twelve (12) continuing education hours of the thirty (30) required hours, must be live contact hours, as defined by the Committee.
(3) A minimum of twelve (12) continuing education hours of the thirty (30) required hours, must be accredited by the Accreditation Council for Pharmacy Education.

(d) The Arkansas State Board of Pharmacy will accept continuing education credits, approved by State Boards of Pharmacy in other states, toward licensure as a pharmacist in Arkansas provided that there is a reciprocal arrangement and that the requirements of this section are met.
(e) Pharmacists are required to retain certificates of participation in continuing education for a period of four years and to certify completion of the required continuing education on a form furnished by the Board of Pharmacy with the license renewal forms. The pharmacist must present certificates of participation to any representative of the Board of Pharmacy if requested to do so.
(f) Pharmacists who wish to retain their license, but do not want to meet the continuing education requirements, may go on inactive pharmacist status for an indefinite period. To reestablish active status and return to practice in Arkansas, a pharmacist must acquire half of the continuing education hours missed plus the continuing education hours for the current licensure period up to 60 hours. If the pharmacist has been on inactive status with regard to continuing education for two (2) calendar years or more and has not been actively practicing pharmacy in another state, said pharmacist shall also comply with all requirements in regulation 02-00-0003.
(g) Certifications awarded by the Board of Pharmaceutical Specialties during any biennium, will satisfy continuing education requirements for that biennium, subject to approval by the Arkansas Tripartite Committee on Continuing Pharmacy Education.
(h) Completion of post-graduate health professional course work may satisfy continuing education requirements subject to approval by the Arkansas Tripartite Committee on Continuing Pharmacy Education.

(4/07/89, Amended: 04/30/93, 6/98, 8/2001, 7/10/2009 and 11/30/2010)

REGULATION 4 —PHARMACY

04-00: GENERAL REGULATIONS REGARDING PHARMACIES

04-00-0001—EQUIPMENT SPECIFICATIONS

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

(a) Graduates capable of measuring from 0.1ml to at least 120ml
(b) Mortars and pestles--at least one (porcelain or glass)
(c) Hot and cold running water in the prescription department
(d) Spatulas
(e) Ointment slab or ointment papers
(f) Exempt narcotic record book
(g) Class III balance and weights or comparable electronic scale
(h) Equipment for labeling
(i) Refrigeration for the proper storage of biologicals and other medications. Medications shall be stored in a separate compartment or area from food.

Each pharmacy shall maintain a pharmacy library:

(1) available for use by the pharmacist and the patient, including either current drug information manuals, or computers capable of printing current drug information for the pharmacist and patient drug information and monographs for patients.
(2) other pharmacy reference books and periodicals necessary for effective pharmacy practice.

EXCEPTIONS: Pharmacies meeting the requirements of regulation 04-02-0100 or regulation 07-02-0001 shall be exempt from requirements of this regulation when not applicable. (10/09/80, Revised 6/25/83, 4/07/89, 6/07/90, 8/20/97, 11/1/2007 and 11/6/2008)

04-00-0002—TIME REQUIRMENTS FOR PHARMACIES AND FOR THE PHARMACIST IN CHARGE

(a) Unless expressly provided otherwise in Board regulations, all pharmacies in Arkansas shall be open a minimum of forty (40) hours per week and have on duty an Arkansas licensed pharmacist in charge. The pharmacist in charge shall be on duty in the pharmacy:
   (1) a minimum of fifty (50) percent of the pharmacy hours for pharmacies open 64 hours per week or less, or
   (2) at least thirty-two (32) hours per week for pharmacies open more than sixty-four (64) hours per week.
(b) Upon written application and appearance by the owner of a pharmacy before the Board, the Board may approve a minimum number of hours less than forty (40) per week for the pharmacy to be open to the public when the Board determines that the reduced number of hours would not be detrimental to the public health, safety, and welfare. For pharmacies approved to be open less than forty (40) hours per week, the pharmacist in charge shall be on duty in the pharmacy a minimum of fifty (50) percent of the pharmacy hours.
(c) In an emergency situation, the Executive Director of the Board of Pharmacy may determine that the health and welfare of the public might be in peril because of a community's limited access to pharmaceutical services if a pharmacy would be forced to close if it was required to remain

open forty (40) hours per week. The Executive Director may approve a retail pharmacy operation for less than forty (40) hours per week for a limited period of time but not beyond the date of the next meeting of the State Board of Pharmacy. Thereafter, the owner of the pharmacy may request an exemption as provided for in section (b) above. The Executive Director must take into consideration the ultimate health and welfare of the patients in the area in making the determination. (10/09/80, Revised 10/14/81, 6/20/91, and emergency 4/2001, 10/2004)

04-00-0003—VENDING MACHINES

The sale of any legend drugs or medicines by means of a coin-operated vending machine is expressly prohibited. (10/09/80)

04-00-0004—RE-USE OF DRUGS PROHIBITED

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

(a) to allow patients in nursing facilities to donate unused medications to charitable clinic pharmacies as provided by Ark. Code Ann. § 17-92-1101 *et seq.* and Board Regulations 04-03-0004 and 04-07-0006 or,

(b) to allow return of oral medications packaged in unit dose or blister packs, oral liquids in sealed unit dose packaging, and injectables in sealed unit dose vials or sealed multi-dose vials that have been sent to a long term care facility or correctional facility but have not been opened or partially used by that facility. The aforementioned medications may be returned to the dispensing pharmacy for reuse to another nursing home or correctional facility patient by relabeling the medication if the medication is returned to the pharmacy within 72 hours of delivery to the facility provided that:
   (1) The drugs were originally dispensed by that pharmacy to the facility,
   (2) Under the pharmacist's professional judgment the drugs are appropriate for return and reuse,
   (3) Any pharmacist or pharmacy accepting eligible drugs for return or reuse must adopt written policies and procedures governing such drugs to assure compliance with section (b) of this regulation,
   (4) Medications meet all federal and state standards for product integrity to the satisfaction of the dispensing pharmacist,
   (5) The pharmacist has the assurance from a healthcare professional responsible for the drugs at the facility that the drugs have been stored in accordance with the manufacturer's recommendations,
   (6) Medications requiring refrigeration can not be returned for re-use, and
   (7) Controlled substances can not be returned for re-use.
   (10/9/80, Revised 6/23/05, and 6/30/2007)

04-00-0005—PICK UP STATIONS

No person, firm, or business establishment shall offer to the public, in any manner, their services as a "pick-up-station" or intermediary for the purpose of having prescriptions filled or delivered, whether for profit or gratuitously. Nor may the owner of any pharmacy or drug store authorize any person, firm, or business establishment to act for them in this manner—provided however, intermediary delivery stations after approval by the Board may be operated in clinics in which a practitioner is in attendance at least one day per week and located in an area where pharmaceutical services are unavailable within ten miles of the clinic provided the filled

prescriptions are delivered to a designated representative of the pharmacist filling the prescription. (10/09/80, Amended 2/17/82, and 8/19/99)

04-00-0006—EMERGENCY PHARMACY SERVICES

Any pharmacy providing prescription drugs to one or more patients in a nursing home or other institution shall provide emergency prescription services for those patients and shall provide information to the nursing home or institution indicating how the pharmacists can be reached after pharmacy hours.

All pharmacies (other than hospital and institutional) who do not provide emergency drug services for non-institutionalized patients shall post a sign at least 8½ by 11" with letters of at least one (1) inch stating "This pharmacy will not provide emergency prescription drugs when the pharmacy is closed." (6/25/83)

04-00-0007—APPLICATIONS FOR PHARMACY PERMITS

Pharmacies shall apply for licensure and renewal on forms provided by the Board. The permit will be issued to qualified applicants in the name of the licensed pharmacist who shall be directly responsible to the Board of Pharmacy for the operation of the pharmacy. (Revised 11/15/2003 and 11/6/2008)

04-00-0008—REQUIREMENTS FOR A NEW PHARMACY PERMIT

Applications for pharmacy permits, other than biennial renewal of existing permits, will be reviewed by the Board of Pharmacy Staff. Applications for a pharmacy permit for a new pharmacy must have the name and license number of the pharmacist in charge at the time of submission and cannot be altered except by submission of an application for change of pharmacist in charge and the fee as defined in regulation 01-00-0007. If a post office box is used as the address for the pharmacy, the actual location including street address must also be included on the application as all pharmacy permits are for a specific physical location. The Executive Director may require that a representative of the owner(s) and the pharmacist in charge appear before the Board of Pharmacy to finalize the application. (Revised 11/6/2008)

04-00-0009—RESPONSIBILITY OF PHARMACIST, INTERN OR PHARMACY TECHNICIAN

(a) Any pharmacist, intern or pharmacy technician participating in the preparation of orders or dispensing of prescriptions and/or any pharmacist who is responsible for supervising pharmacy personnel participating in the preparation of orders or dispensing of prescriptions is responsible for the validity and legality of the order or prescription.
(b) Any pharmacist who is responsible to supervise pharmacy personnel is also responsible for any shortage of drugs classified as controlled drugs under state or federal law which occurs under their supervision.
(c) In a pharmacy’s electronic data processing system that can delineate the individual steps in the prescription filling process, the pharmacist overseeing each step would be specifically responsible for that part of the process.
(d) In a pharmacy’s electronic data processing system that is not capable of delineating the individual steps in the prescription filling process, the pharmacist(s) involved in the process will share a corresponding liability for each prescription filled. (Revised 11/6/2008)

04-00-0010—PHARMACIST IN CHARGE

(a) When a pharmacist ceases to be employed as a pharmacist in charge (PIC) at a pharmacy licensed by the Board, the pharmacist must immediately notify the Board in writing. The former PIC must provide an inventory of controlled drugs as defined in Regulation 04-00-0013 to the Board within five days of ceasing employment as the PIC.

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

(c) The pharmacist in charge is responsible for the security and accountability of all drugs stored in a pharmacy and is responsible for the validity and legality of all prescriptions and/or orders upon which drugs are dispensed in a pharmacy. The pharmacist in charge is responsible for ensuring that pharmacy staff has been appropriately trained to follow the pharmacy's policies and procedures.

(d) Any pharmacist, when making his or her initial application to be licensed as pharmacist in charge, must satisfactorily complete a test on the requirements and responsibilities of a pharmacist in charge. The test shall be developed and administered by the Board of Pharmacy or its representatives.

(e) The pharmacist in charge named on any licensed pharmacy permit or pharmacist on call as designated by the pharmacist in charge, shall have immediate access to the pharmacy at all times, and if requested by Board of Pharmacy inspectors he/she shall show satisfactory proof of access.

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

(1) Secure the services of an Arkansas-licensed pharmacist to serve as the pharmacist in charge; or

(2) Cease to operate as a pharmacy in the State of Arkansas. Operation of the pharmacy without a pharmacist in charge beyond the time limits set by the Board is a violation of law and each day so operated will be a separate offense. (Emergency--Amended 4/2001, Revised 3/14/2007, 11/6/2008 and 11/30/2010)

04-00-0011—PERMIT REQUIRED

The permit licenses the pharmacy to which it is issued and is not transferable. It is issued on the application of the owner and the licensed pharmacist in charge, on the sworn statement that it will be conducted in accordance with the provisions of law.

(a) Pharmacies opening for business must first secure a permit and be licensed with the Board of Pharmacy before they may lawfully conduct or operate a pharmacy. A fee defined in regulation 01-00-0007 is charged for issuing such original permit. All pharmacies must register with the Board and secure a biennial permit and pay a renewal fee as defined in regulation 01-00-0007.

(b) Permits must be posted in a conspicuous place. This requirement is not met when a permit is locked in a safe, placed in a desk drawer, or otherwise hidden away.

(c) No pharmacy may open for business, nor may it be inspected for the purpose of obtaining a permit, prior to the approval by the Board. (Revised 11/6/2008)

04-00-0012—CHANGE OF OWNERSHIP

(a) Upon a change of ownership of a pharmacy as set out herein, a new permit shall be secured by the new owner(s). The new owner(s) can continue operation of the pharmacy for fourteen (14) days after the effective date of the change of ownership; after the said fourteen (14) day period, the permit issued to the prior owner shall be void and same shall be surrendered to the Executive Director of the Board of Pharmacy.

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

(1) A change of ownership of a pharmacy, owned by a SOLE PROPRIETOR, is deemed to have occurred when:

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

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

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

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

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

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

(A) An individual or business acquires or disposes of twenty percent (20%) or more of the corporation's outstanding shares of voting stock. (This shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over the counter market); or

(B) The corporation merges with another business or corporation. (The corporation owning the pharmacy is required to notify the Arkansas State Board of Pharmacy if a change of ownership or merger occurs within the parent corporation of the corporation which owns the pharmacy); or

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

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

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

The responsibility to ensure compliance with this regulation rests both with the pharmacist and with the pharmacy permit holder if they are not the same. (10/09/80, Revised 2/17/82, 6/13/85, 2/10/87, 4/07/89, 6/20/91, 6/23/96, and 11/6/2008)

04-00-0013 —INVENTORY REQUIRED

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

charge shall be submitted with the application for change of ownership and the fee for change of ownership as defined in regulation 01-00-0007.

(b) When there is a change of pharmacy permit because of a change of pharmacist in charge only, an inventory of all drugs now or hereafter classified as Schedule II, III, IV or V drugs under either federal or state statutes will be made by the exiting pharmacist in charge and a copy of that inventory signed by said pharmacist shall be furnished to the Arkansas State Board of Pharmacy within seven days after the pharmacist's last day to work at the pharmacy and a copy left with the Controlled Substance Records of the Pharmacy. The new pharmacist in charge shall also immediately inventory all drugs now or hereafter classified as Schedule II, III, IV or V drugs under federal or state statutes and a copy of that inventory signed by the new pharmacist in charge shall be provided to the Arkansas State Board of Pharmacy with the application to change the pharmacy permit's pharmacist in charge.

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

(d) If a joint inventory is not provided, both copies of said inventory (exiting pharmacist in charge and new pharmacist in charge) must be received by the Board before a new permit will be issued. (10/09/83, Revised 6/25/80, 6/20/96 and 11/6/2008)

04-00-0014—OWNER'S RESPONSIBILITY – PHARMACIST IS LICENSED

No owner or owners of a drugstore, apothecary, pharmacy, etc., shall allow any of its employees to profess to the public in any manner that they are a licensed pharmacist when they are not licensed. (10/9/80, amended 6/20/91 and 11/6/2008)

04-00-0015---RESPONSIBILITY FOR SECURITY OF CONTROLLED DRUGS

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

(b) The permit holder shall provide diversion prevention and detection tools appropriate for the particular pharmacy setting and the pharmacist in charge shall implement and monitor the diversion control and detection tools provided by the permit holder. Appropriate tools may include perpetual inventory, automatic or limited-access online ordering, reports comparing drugs ordered v. drugs dispensed and drugs manually ordered or adjusted, and individual passwords for each employee to enter the pharmacy or access the computer.

(c) The pharmacist in charge and the permit holder shall also develop policies and procedures to prevent and detect diversion and the pharmacist in charge shall ensure that pharmacy staff is trained to follow the policies and procedures. Appropriate policies and procedures may include limiting access by non-pharmacists to controlled drug shipments, performing quarterly audits on high risk drugs, confirming pill count before opening a new bottle of high risk drugs, tracking pill count on stock bottles and requiring staff to use the tools provided by the permit holder.

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

(Adopted 11/30/2010)

04-01: PHARMACY PERMIT FEES

04-01-0001—PERMIT FEES

Any person, corporation or partnership operating a pharmacy in this state desiring to continue such operation must pay a renewal fee for the permit as established by law and/or regulation. If the fee is not paid on or before February 1st of any even-numbered year, a penalty as defined in regulation 01-00-0007 shall be levied for each month the pharmacy permit fee is delinquent. If the permit fee is unpaid by April 1st of any even-numbered year, the licensed pharmacy shall be expunged from the records of the State Board of Pharmacy, and the owner and/or pharmacist in charge thereof shall, within thirty days, remove all drug signs and legally dispose of all prescription legend drugs. (10/9/80, amended 6/13/85, amended 6/20/91 & 8/23/96)

04-02: REGULATIONS REGARDING RETAIL PHARMACIES

04-02-0001—APPLICATIONS FOR PHARMACY PERMITS

Retail pharmacies shall apply for licensure and renewal on forms provided by the Board. The permit will be issued to qualified applicants in the name of the licensed pharmacist who shall be directly responsible to the Board of Pharmacy for the operation of the prescription department. (Revised 11/15/2003)

04-02-0002—REQUIREMENTS FOR A NEW RETAIL PHARMACY PERMIT

No retail pharmacy may open for business within thirty (30) days of submission of the original application. Applications for a pharmacy permit for a new retail pharmacy must have the name and license number of the pharmacist in charge at the time of submission and cannot be altered except by submission of an application for change of pharmacist in charge and the fee as defined in regulation 01-00-0007. The pharmacist in charge of the new pharmacy application cannot be the pharmacist in charge of another pharmacy at the time of submission of the new pharmacy application. The Executive Director may require that a representative of the owner(s) and the pharmacist in charge appear before the Board of Pharmacy to finalize the application. After review by the Board of Pharmacy staff, an "Inspection Request Form" will be sent to the mailing address of the pharmacy making application. The inspection request form must be received in the Board of Pharmacy office at least one week before the facility will be ready for inspection.

Upon approval of the inspection of the physical facility by the Board of Pharmacy inspector, the Executive Director will complete the final approval of the application and the permit number will be issued.

04-02-0003—LEASED OPERATIONS—PHARMACY IS A DEPARTMENT OF ANOTHER BUSINESS

(a) In any building, firm, or place of business where the pharmacy is a leased operation, and/or in situations where the pharmacist in charge does not own a substantial part of the business and is not manager of the total operation, and/or where the pharmacy is a department in a larger business that is not a drugstore or pharmacy, the prescription department shall be completely separated from the remainder of the building by some type of partition and said department shall be arranged and constructed so that the public will not have access to any legend drugs or medicine.

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

(c) A copy of the signed lease must be submitted with the application of the original permit, and at such other times as the original lease is changed or renewed.

04-02-0004—NECESSARY EQUIPMENT REQUIRED

No pharmacy permit shall be issued or continued for the conduct of a pharmacy unless the premises are equipped with the necessary appliances for maintenance of proper sanitation and kept in a clean, sanitary and orderly manner.

04-02-0005—RETAIL VETERINARY PHARMACY

(a) A pharmacy that provides a prescription directly to a veterinary patient in Arkansas may accept payment for the prescription for a contracted price that is less than the price paid by the patient, only if:
   (i) The veterinarian collects payment from the patient and forwards the contracted price for the prescription to the pharmacy; or
   (ii) Payment from the patient is deposited into an account held jointly by the veterinarian and the pharmacy and payment for the contracted price is distributed to each party.

(b) Under no circumstances may a pharmacy provide any type of remuneration directly to a veterinarian in connection with a prescription or maintain a shared inventory with a veterinarian.

(c) A pharmacy may allow a veterinarian to place its icon or other logo on the veterinarian web site only if the site prominently displays a notice that patients may obtain prescriptions and refills from the pharmacy of their choice.
(Adopted 11/30/2010)

04-02-0010—REGULATING THE USE OF ELECTRONIC DATA PROCESSING IN LIEU OF PRESENT RECORD KEEPING SYSTEMS IN PHARMACIES HOLDING PHARMACY PERMITS

(a) These regulations shall be construed, if possible, so as not to be in violation of, or in conflict with, any federal regulation or requirement and if any part hereof is held invalid because of such conflict such invalidity shall not affect other provisions or applications of these regulations which can be given effect without the invalid provisions and to this end, the provisions of these regulations are declared severable. In any event DEA permission to use electronic data processing record keeping systems must be obtained.
(b) The Arkansas State Board of Pharmacy must approve the system prior to implementation.
(c) Input of drug information into the system may be performed only by a pharmacist, or by a pharmacy technician under the supervision of a pharmacist. The final verification of prescription information into the computer, shall be made by the supervising pharmacist who is then totally responsible for all aspects of the data and data entry. Any judgmental decision concerning patient utilization of drugs must be performed by a pharmacist.
(d) The original prescription order must be readily retrievable and filed according to all applicable regulations.

(e) An electronic data processing system must be readily retrievable electronically online or by hard copy, and shall be capable of printing a hard copy record. Said hard copy record, or electronic data base record, shall be available upon request by a Board of Pharmacy representative or other state or federal agencies with authority to obtain such records within 48 hours of the request. The system must be capable of furnishing the following information:

(1) Must provide online retrieval (electronic record or hard copy) of original prescription order information. This shall include, but not be limited to, the following:

(A) Original prescription order number, date filled; full name and address of patient; name, address and DEA number (if applicable) of practitioner.

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

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

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

(A) Initials or code designation of dispensing pharmacist for each refill.

(B) Date refilled.

(C) Number of authorized refills remaining.

(3) Daily Prescription Record

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

(i) Date of record.

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

(iii) If the pharmacy is using a hard copy printout, it may be replaced by monthly log containing same information. This information must be maintained at pharmacy for a period of two years.

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

(v) All required information must be entered on the records of all prescription orders filled at the pharmacy including non-refillable prescriptions and must be maintained for a period of no less than two (2) years.

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

(vii) A pharmacy shall make arrangements with supplier of data processing services or materials to assure continuing adequate and complete prescription orders and dispensing records. If for any reason the relationship with said supplier terminates, the pharmacy shall assure the continuity of records.

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

maintained, by the pharmacist in charge or his successor, in the pharmacy for a period of two years after the date of dispensing the appropriately authorized prescription.

(4) Must be capable of providing a refill-by-refill audit trail for any specific strength and dosage form of any drug in the system to contain but not limited to the following:
   (A) Practitioner's name.
   (B) Name and address of patient.
   (C) Name of drug (must include manufacturer's name if generic name used).
   (D) Quantity dispensed on original and each refill.
   (E) Prescription order number.
   (F) Initials or code designation of dispensing pharmacist on original and each refill.
   (G) Date of original and each refill.

(5) If the pharmacy closes, it shall be the responsibility of the pharmacist in charge to assure that all prescription records are readily retrievable and can be easily accessed. The pharmacist in charge, at the date of closing, shall store said records and within fourteen (14) days of closing shall notify the Board of Pharmacy where said records are located. That pharmacist in charge shall insure that a hard copy printout or a retrievable electronic record of any prescription records shall be produced and made available to a Board of Pharmacy representative on their request and to any other person authorized by law to examine or receive copies of prescription records. The records must be kept in a readily retrievable format for a period of two years from the official closing date of the pharmacy.

(6) In event of computer breakdown (down time), the pharmacy must have an approved auxiliary record keeping system. This system must contain all necessary information to insure prompt data entry into system as soon as computer is available.

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

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

(g) In a system that is not capable of delineating the individual steps in the prescription filling process, the pharmacist(s) involved in the process will share a corresponding liability for each prescription filled. (10/09/80, Revised 6/19/97, 10/00, 3/14/2007 and 11/30/2010).

04-02-0011—CENTRAL FILL PHARMACY

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

(a) Definitions

(1) “Central fill pharmacy” means a pharmacy which is licensed by the Arkansas State Board of Pharmacy (“the Board”) to prepare legend and controlled substances orders for dispensing pursuant to a valid prescription transmitted to it by a licensed retail pharmacy and to deliver the labeled and filled prescriptions in accordance to federal and state law; provided, however, the central fill pharmacy may deliver prescriptions for controlled substances only in accordance with DEA regulations. Such central fill pharmacy shall be deemed "authorized" to fill prescriptions on behalf of a retail pharmacy only if the retail pharmacy and central fill pharmacy have a contractual relationship providing for such activities or share a common owner. Both the retail pharmacy and the central fill

pharmacy involved in these activities share a corresponding responsibility regarding central fill prescriptions.

(b) Record keeping

(1) Every retail pharmacy that utilizes the services of a central fill pharmacy must keep a record of all central fill pharmacies, including name, address and DEA number that are authorized to fill prescriptions on its behalf. The retail pharmacy must also verify the registration for each central fill pharmacy authorized to fill prescriptions on its behalf at the beginning of each registration period for the central fill pharmacy. These records must be made available upon request for inspection.

(2) Every central fill pharmacy must keep a record of all retail pharmacies, including name, address and DEA number, for which it is authorized to fill prescriptions. The central fill pharmacy must also verify the registration for all retail pharmacies for which it is authorized to fill prescriptions at the beginning of each registration period for each retail pharmacy. These records must be made available upon request for inspection.

(c) Provision of prescription information of Schedule II controlled substances.

(1) Prescriptions for controlled substances listed in Schedule II may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile. The retail pharmacy transmitting the prescription information must:

(A) Write the word "CENTRAL FILL" on the face of the original prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

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

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

(D) Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier), the identity of carrier and the name of the retail pharmacy employee accepting delivery.

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

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

(B) Keep a record of the date of receipt of the transmitted prescription, the name of the pharmacist filling the prescription, and the date of filling of the prescription;

(C) Track the prescription drug order during each step in the filling process and identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any portion of the process including transmission, filling, dispensing, or delivery.

(D) Keep a record of the date the filled prescription was delivered to the retail pharmacy, the method of delivery (i.e. private, common or contract carrier) and the identity of the carrier.

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

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

(1) Prescriptions for legend or controlled substances listed in Schedule III, IV or V may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile. The retail pharmacy transmitting the prescription information must:

(A) Write the word "CENTRAL FILL" on the face of the original prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;

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

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

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

(E) Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier), the identity of the carrier and the name of the retail pharmacy employee accepting delivery.

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

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

(B) Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription;

(C) Track the prescription drug order during each step in the filling process and identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any portion of the process including, transmission, filling, dispensing, or delivery

(D) Keep a record of the date the filled prescription was delivered to the retail pharmacy, the method of delivery (i.e. private, common or contract carrier) and the identity of the carrier. Prescriptions for controlled substances that are prepared by the central fill pharmacy may only be delivered to the ultimate user in accordance with DEA regulations.

(e) Carriers to transport filled prescriptions

(1) Central fill pharmacies must comply with all federal and state requirements when using private, common or contract carriers to transport filled prescriptions to the ultimate user or to a retail pharmacy for delivery to the ultimate user. When central fill pharmacies contract with private, common or contract carriers to transport filled prescriptions to a retail pharmacy, the central fill pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a DEA Form 106.

(2) Retail pharmacies must comply with all federal and state laws when using private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy. When retail pharmacies contract with private, common or contract carriers to retrieve

filled prescriptions from a central fill pharmacy, the retail pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a DEA Form 106.

(f) Labeling

The central fill pharmacy shall:

(1) Affix to the package a label showing the retail pharmacy name and address and a unique identifier, which shall be the central fill pharmacy's DEA registration number or a Board assigned identifier, indicating that the prescription was filled at the central fill pharmacy

(2) Indicate in some manner which pharmacy filled the prescription (e.g., "Filled by ABC Pharmacy for XYZ Pharmacy").

(3) Comply with all other labeling requirements of federal and state statutes.

(g) Policies and Procedures

A policy and procedure manual as it relates to centralized filling shall be maintained at the filling, originating, and dispensing pharmacies and be available for inspection. Each pharmacy is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy's operations. The manual shall:

(1) Outline the responsibilities of each of the filling, originating, and dispensing pharmacies

(2) Include a list of the name, address, telephone numbers, and all license / registration numbers of the pharmacies involved in centralized prescription filling

(3) Include policies and procedures for:

(A) Notifying patients that their prescription may be outsourced to another pharmacy for centralized prescription filling and the name of that pharmacy

(B) Protecting the confidentiality and integrity of patient information

(C) Dispensing prescription drug orders when the filled order is not received or the patient comes in before the order is received

(D) Complying with federal and state laws and regulations

(E) Operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems

(F) Annually reviewing the written policies and procedures and documenting such review.

(11/15/2003, Revised 3/14/2006)

04-02-0012 – RETAIL PHARMACY OFF SITE ORDER ENTRY

The purpose of this section is to provide standards for remote or off-site order entry in retail pharmacies within Arkansas licensed by the Arkansas State Board of Pharmacy ("the Board").

(a) Definitions

(1) "Off-site order entry pharmacy" means a retail pharmacy which is licensed by the Board to process legend and controlled substance prescriptions that remotely accesses another pharmacy's electronic data base from outside the pharmacy in order to process prescription drug orders, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

(2) “Off-site order entry” does not include the dispensing of a prescription drug order but includes any of the following:

(A) receiving, interpreting, or clarifying prescription drug orders;

(B) data entering and transferring of prescription drug order information;

(C) performing drug regimen review;

(D) reconciling third party insurance claims;

(E) obtaining refill and substitution authorizations;

(F) interpreting clinical data for prior authorization for dispensing;

(G) performing therapeutic interventions; and

(H) providing drug information concerning a patient's prescription.

(3) “Drug regimen review” means an evaluation of prescription drug orders and patient profile records for:

(A) known allergies;

(B) rational therapy-contraindications;

(C) reasonable dose and route of administration;

(D) reasonable directions for use;

(E) duplication of therapy;

(F) drug-drug interactions;

(G) drug-food interactions;

(H) adverse drug reactions; and

(I) proper utilization, including over-utilization or under-utilization.

(b) The Arkansas State Board of Pharmacy may approve a request for off-site order entry where the retail pharmacy can demonstrate that the procedure will result in an improvement in patient care by increasing the amount time for pharmacist involvement in the process of medication review for safety and efficacy prior to the administration of the medication to the patient. Off-site order entry shall be prohibited out of state for prescriptions dispensed in the state of Arkansas.

(c) (1) The pharmacist-in-charge or the permit holder of the retail pharmacy shall submit a written request for off-site order entry a minimum of 30 days prior to the Board meeting at which the pharmacist seeks Board approval.

(2) The request shall be accompanied by a policy and procedure manual for off-site order entry which shall be maintained at all pharmacies involved in off-site order entry and be available for inspection. Each pharmacy is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy's operations. The manual shall:

(A) outline the responsibilities of each of the pharmacies;

(B) include a list of the name, address, and telephone numbers of the pharmacies involved in off-site prescription order entry; and

(C) include policies and procedures for:

(i) patient confidentiality and full compliance with HIPAA requirements;

(ii) maintenance of appropriate records to identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any processing and the store it was processed in;

(D) specify that only a pharmacist or pharmacy technician holding a current Arkansas license or registration in good standing shall enter orders at a remote or off-site entry location that is a duly licensed pharmacy.

(E) comply with federal and state laws and regulations; and

(F) include procedures for annually reviewing the written policies and procedures for needed modification with documentation of such review.

(d) General requirements.

(1) A Pharmacy may utilize the services of an off-site order entry pharmacy provided the pharmacies:

(A) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to process a non-dispensing function; and have;

(B) the same owner; or

(C) entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations.

(2) An off-site order entry pharmacy shall comply with the provisions contained in regulations 04-02-0010 REGULATING THE USE OF ELECTRONIC DATA PROCESSING IN LIEU OF PRESENT RECORD KEEPING SYSTEMS IN PHARMACIES HOLDING PHARMACY PERMITS and 07-00-0008 ELECTRONIC PRESCRIPTION PROCESSING AND PATIENT CONFIDENTIALITY to the extent applicable for the specific processing activity and this section including:

(A) duties which must be performed by a pharmacist; and

(B) supervision requirements for pharmacy technicians.

(3) Off-site order entry may only be performed by a retail pharmacy as appropriately licensed by the Arkansas State Board of Pharmacy

(e) Notifications to patients.

(1) A pharmacy that outsources off-site prescription order entry to another pharmacy shall prior to outsourcing their prescription:

(A) notify patients that prescription processing may be outsourced to another pharmacy; and

(B) give the name of that pharmacy; or if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may process the prescription, the patient shall be notified of this fact. Such notification may be provided through a one-time written notice to the patient or through use of a sign in the pharmacy.

(f) Records. All pharmacies shall maintain appropriate records which identify, by prescription drug order, the name(s), initials, or identification code(s) of each pharmacist or pharmacy technician who performs a processing function for a prescription drug order. Any record generated in this process whether in a hard copy or electronic format shall be maintained for a minimum period of two years from the last date of entry. Such records may be maintained:

(1) separately by each pharmacy and pharmacist; or

(2) in a common electronic file as long as the records are maintained in such a manner that the data processing system can produce a printout which lists the functions performed by each pharmacy and pharmacist.

(g) In the operation of the off-site order entry, patient confidentiality and full compliance with HIPAA requirements shall be observed at all times. (6/30/2007)

04-02-0100—NUCLEAR PHARMACY

The practice of nuclear pharmacy is hereby recognized as a specialty of pharmacy practice regulated by the Arkansas State Board of Pharmacy. As such, the following rules are

included to address those areas specific, or unique to, this specialty practice. These regulations are intended to supplement the regulations of other state and federal agencies.

(a) Definitions:

(1) Authentication of Product History—Identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

(2) "Nuclear pharmacy" means a pharmacy which provides radiopharmaceutical services, and shall be licensed by the Arkansas State Board of Pharmacy.

(3) "Practice of nuclear pharmacy" means a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs.

(4) "Qualified nuclear pharmacist" means a pharmacist who holds a current license issued by the Arkansas State Board of Pharmacy, and who is certified as a nuclear pharmacist by a certification board recognized by the Arkansas State Board of Pharmacy, or satisfies each of the following requirements:

(A) Meets minimal standards of training for status as an authorized user of radioactive material, as specified by the Arkansas Department of Health, Division of Radiation Control and Emergency Management of the Nuclear Regulatory Commission.

(B) Has successfully completed a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from a College of Pharmacy approved by the Arkansas State Board of Pharmacy, or other training program recognized by the Arkansas State Board of Pharmacy, with the minimum 200 hours apportioned as follows:

(i) Radiation physics and instrumentation
(ii) Radiation protection
(iii) Mathematics pertaining to the use and measurement of radioactivity
(iv) Radiation biology
(v) Radiopharmaceutical chemistry

(C) Has attained a minimum of 500 hours of clinical/practical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in, but not limited to, the following areas:

(i) Procuring radioactive materials
(ii) Compounding radiopharmaceuticals
(iii) Performing routine quality control procedures
(iv) Dispensing radiopharmaceuticals
(v) Distributing radiopharmaceuticals
(vi) Implementing basic radiation protection procedures
(vii) Consulting and educating the nuclear medicine community, pharmacists, other health professionals, and the general public.

(D) Has submitted an affidavit of experience and training to the Board of Pharmacy.

(5) "Quality assurance procedures" means all activities necessary to assure the quality of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by pertinent regulatory agencies.

(6) "Quality control testing" means the performance of chemical, biological and physical tests on compounded radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.

(7) "Radiopharmaceutical" means any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but which does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term also includes any biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

(8) "Radiopharmaceutical Services" means the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, distribution, transfer, record keeping, and disposal of radiochemicals, radiopharmaceuticals, and ancillary drugs, and also includes quality assurance procedures, radiological health activities, and consulting activities associated with the use of radiopharmaceuticals, health physics, and any other activities required for provision of pharmaceutical care.

(b) General requirements for pharmacies providing radiopharmaceutical services

(1) A permit to operate a nuclear pharmacy, providing radiopharmaceutical services, shall only be issued to a facility employing a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of a qualified nuclear pharmacist, who shall be in personal attendance when the nuclear pharmacy is open for business. The pharmacist-in-charge shall be responsible for all operations of the nuclear pharmacy.

(2) The permit to operate a nuclear pharmacy is effective only so long as the nuclear pharmacy also holds a current Arkansas Department of Health or Nuclear Regulatory Commission license.

(3) Nuclear pharmacies shall have adequate space and equipment commensurate with the scope of services required and provided. All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas: radiopharmaceutical preparation/dispensing area; radioactive material shipping/receiving area; radioactive material storage area; and radioactive waste decay area. The application for a permit to operate a nuclear pharmacy shall include detailed floor plans and no material change may be made without the permission of the Board.

(4) The nuclear pharmacy professional service area shall be secured from unauthorized personnel and must be totally enclosed and lockable.

(5) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radioactive materials in accordance with Board and Arkansas Department of Health or Nuclear Regulatory Commission statutes and regulations.

(6) Nuclear pharmacies shall compound and dispense radiopharmaceuticals in accordance with accepted standards of radiopharmaceutical quality assurance. The Board of Pharmacy recognizes that the preparation of radiopharmaceuticals involves the compounding skills of the nuclear pharmacist to assure that the final drug product meets accepted professional standards.

(7) A radiopharmaceutical shall be dispensed only to a licensed practitioner authorized by the Arkansas Department of Health or Nuclear Regulatory Commission to possess, use, and administer such drug. A radiopharmaceutical shall be dispensed only upon receipt of a prescription or medication order from such licensed practitioner. Otherwise, a radiopharmaceutical may be transferred to a person who is authorized to possess and use such drug for non-clinical applications.

(8) A nuclear pharmacy, upon receipt of an oral prescription order for a radiopharmaceutical, shall immediately have the prescription order reduced to writing, or recorded in a data processing system, which writing or record shall contain at least the following:
(A) the name of the institution and prescriber, or prescriber's agent;
(B) the date of dispensing and the calibration time of the radiopharmaceutical;
(C) the name of the procedure;
(D) the name of the radiopharmaceutical;
(E) the dose or quantity of the radiopharmaceutical;
(F) the serial number assigned to the order for the radiopharmaceutical;
(G) any specific instructions;
(H) the initials of the person who dispensed the order.

Orders for routine diagnostic radiopharmaceuticals, which have been previously established by the nuclear pharmacist with the physician, may be taken by a pharmacy technician and entered into the computer. The nuclear pharmacist shall verify the label with the written order. However, whenever an order is for a therapeutic or blood-product radiopharmaceutical, the prescription order must be received by a nuclear pharmacist and the patient's name must be obtained and recorded prior to dispensing.

(9) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:
(A) the name and address of the pharmacy;
(B) the name of the prescriber;
(C) the date of dispensing;
(D) the serial number assigned to the order for the radiopharmaceutical;
(E) the standard radiation symbol;
(F) the words "Caution Radioactive Material";
(G) the name of the procedure;
(H) the radionuclide and chemical form;
(I) the amount of radioactivity and the calibration date and time;
(J) if a liquid, the volume;
(K) if a solid, the number of items or weight;
(L) if a gas, the number of ampoules or vials;
(M) molybdenum 99 content to USP limits; and
(N) the name of the patient or the words "Per Physician's Order" in the absence of a patient name. The requirements of this subsection shall be met when the name of the patient is readily retrievable from the physician upon demand.

When the prescription is for a therapeutic or blood-product radiopharmaceutical, the patient name shall appear on the label prior to dispensing.

(10) The immediate inner container label of a radiopharmaceutical to be dispensed shall be labeled with:
(A) the standard radiation symbol;
(B) the words "Caution Radioactive Material";
(C) the identity of the radionuclide;
(D) the chemical form;
(E) the name of the procedure; and

(F) serial number of the radiopharmaceutical.

(11) When a radiopharmaceutical is dispensed under the authority of an Investigational New Drug Application (IND), the nuclear pharmacy records shall include an investigator's protocol for the preparation of the radiopharmaceutical, a copy of the Institutional Review Board approval form (or letter), and a letter from the manufacturer (sponsor) indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

(12) Each nuclear pharmacy shall have a current copy of state and applicable federal regulations governing the safe storage, handling, use, dispensing, transport, and disposal of radiopharmaceuticals.

(c) Minimum equipment

The professional area of the pharmacy shall have equipment appropriate for the pharmacy's specific scope of practice which may include but is not limited to the following:

(1) Radionuclide Dose Calibrator;
(2) Refrigerator;
(3) Single or multiple channel scintillation counter with well-type Nal(TI) or Ge(Li) detector;
(4) Radiochemical fume hood and filter system with suitable air sampling equipment;
(5) At least two GM survey meters (including one high-range meter);
(6) Microscope and hemacytometer;
(7) Supplies to perform quality assurance testing;
(8) Syringe and vial radiation shields;
(9) Lead-shielded drawing station;
(10) Decontamination supplies;
(11) Supplies to perform quality assurance testing;
(12) Lead transport shields for syringes and vials; and
(13) D.O.T. approved USA Type A, 7A approved transport containers and other labels and supplies for shipping radioactive materials. (10/14/98 and 11/1/2007)

04-03 REGULATIONS REGARDING RETAIL SPECIALTY PHARMACIES

04-03-0001—SPECIALTY PHARMACY PERMITS

The Board may issue a specialty pharmacy permit for a facility to provide unique aspects of pharmaceutical care to an identified patient population as provided in regulation 04-03-0001 *et seq*. Said specialty pharmacies and the pharmacists practicing therein shall comply with applicable federal and state laws and regulations, including Arkansas Pharmacy Law, A.C.A. § 17-92-101 *et seq.*, and Board Regulations, including without limitation regulations regarding retail pharmacies 04-02-0001 *et seq*., which are not expressly superseded by the regulation applicable to the specific type of specialty pharmacy.

04-03-0002 METHADONE CLINIC SPECIALTY PHARMACY PERMIT

(a) Definitions:

(1) "Methadone clinic pharmacy" means the place in which a licensed professional prepares methadone or buprenorphine to be administered and/or dispensed to a patient of the clinic.

(2) "Dispensing" means the preparation of one or more doses of methadone or buprenorphine in properly labeled, patient specific containers and delivery of said drugs to the patient to consume away from the clinic; only a licensed pharmacist or physician holding a dispensing permit issued by the Arkansas State Medical Board shall dispense methadone.

(3) "Administering" means giving a single dose of methadone or buprenorphine to a patient to consume on-site; a physician shall administer or supervise the administration of methadone and the clinic pharmacist shall retain appropriate methadone administration records.

(b) Permit
(1) Applications for methadone clinic permits shall be submitted pursuant to regulation 04-02-0001.
(2) Any pharmacist shall notify the Board of Pharmacy in writing and ascertain that a methadone clinic pharmacy permit has been issued to the clinic before beginning practice in that clinic.

(c) Pharmacy operations
(1) The pharmacist in charge shall provide written policies, procedures, and protocols for the operation of the pharmacy and shall obtain the approval of same by the Executive Director of the Pharmacy Board prior to operation of said pharmacy.
(2) A methadone clinic pharmacy shall stock and dispense methadone or buprenorphine only.

(d) Physical Facilities
(1) The pharmacy shall be a controlled area for the storage, safeguarding, preparation, and dispensing of methadone, a Schedule II narcotic, and buprenorphine, a Schedule III controlled substance, and shall have adequate facilities for pharmaceutical services including the procurement, storage, distribution, security and control of said drug consistent with all federal and state laws and regulations.
(2) The pharmacy shall have all equipment necessary to carry out the functions of the methadone clinic pharmacy and is otherwise exempt from regulation 04-02-0004; the equipment must be identified in the policies and procedures of each methadone clinic specialty pharmacy.

(e) Licensed pharmacist personnel requirements
(1) A methadone pharmacy shall be open to serve its patients, with a pharmacist or pharmacists on duty, a minimum of ten (10) hours per week or, if necessary, a greater period of time in order to perform pharmacy duties necessary to ensure patient safety.
(2) The pharmacy's operating hours must be approved by the Executive Director of the Arkansas State Board of Pharmacy. (Revised 11/15/2003)

04-03-0003 – STUDENT HEALTH CLINIC PHARMACY PERMIT

(a) Definitions:
(1) "Student Health Clinic Pharmacy" means a pharmacy located on a university or college campus for the purpose of filling prescriptions for students or employees or their spouses or dependents.
(2) "Board" means the Arkansas State Board of Pharmacy.

(b) Permit
(1) Applications for student health clinic pharmacy permits shall be submitted pursuant to regulation 04-02-0001.
(2) Any pharmacist shall notify the Board of Pharmacy in writing and ascertain that a student health clinic pharmacy permit has been issued to the clinic before beginning practice in that clinic.

(c) Pharmacy operations

(1) The pharmacist in charge shall provide written policies, procedures, and protocols for the operation of the pharmacy and shall obtain the approval of same by the Board prior to operation of said pharmacy.
(2) A student health clinic pharmacy may stock and dispense legend and controlled substances

(d) Physical Facilities
(1) The pharmacy shall be a controlled area for the storage, safeguarding, preparation, and dispensing of legend and controlled substances, and shall have adequate facilities for pharmaceutical services including the procurement, storage, distribution, security and control of said drugs consistent with all federal and state laws and regulations.
(2) The pharmacy shall have all equipment specified in regulation 04-00-0001.

(e) Licensed pharmacist personnel requirements
(1) The pharmacy's minimum operating hours must be approved by the Board prior to operation of said pharmacy.
(2) A pharmacist or pharmacists must be on duty during all hours of operation.
(3) The pharmacist in charge must work fifty-percent (50%) of the hours of operation. (07/15/2004)

04-03-0004 –PERMIT FOR PILOT PROGRAM FOR DONATED PRESCRIPTION MEDICATIONS PURSUANT TO ARK. CODE ANN. § 17-92-1101 ET SEQ.

(a) The definitions in Ark. Code Ann. § 17-92-1102 are applicable in the regulation unless the context otherwise requires.

(b) Permit
(1) (A) Application for a pilot program permit for the reuse of donated prescription medications authorized by Ark. Code Ann. § 17-92-1101 *et seq*. shall be on a form provided by the Board, signed by the pharmacist in charge, and shall be submitted pursuant to Board regulation, but the fee for the application will be waived. The application and documentation identified in the following subparagraph shall be delivered to the Board's office 30 days prior to the meeting at which the applicant desires to appear for consideration of its application.
(B) The application shall be accompanied by appropriate documentation including:
(i) that necessary to qualify the applicant as a charitable clinic as defined in Ark. Code Ann. § 17-92-1102(1),
(ii) written policies and procedures for the operation of the charitable clinic pharmacy,
(iii) protocols to include the procedure for screening and determining that the patient qualifies on the basis of income below two hundred percent (200%) of the federal poverty level,
(iv) a depiction of the physical facilities for the pharmacy and a description of provisions for security for and access to the pharmacy,
(v) a statement of any fees charged to patients,
(vi) a list stating the pharmacy's hours of operation, equipment and library materials, and
(vii) the proposed contract with nursing home(s) for donation of unused prescription mediations, and

(C) The pharmacist in charge and an appropriate officer or director of the organization shall appear before the Board for its consideration of the application.

(D) The contract with the nursing home for supplying donated prescription drugs must be renewed biennially.

(E) Either volunteer or paid health care professionals shall deliver pharmaceutical services for the pharmacy.

(2) Prior to opening the charitable clinic pharmacy, the pharmacist in charge shall notify the Board in writing identifying each pharmacist who will work at the pharmacy and, within ten days thereafter, provide similar notice of any changes in pharmacists working in the pharmacy.

(c) Pharmacy operations

(1) A pharmacy holding a permit under this regulation shall stock and dispense purchased legend drugs, donated prescription drugs, samples, and medications received from manufacturer-sponsored prescription drug assistance programs or any other sources; provided, however that the pharmacy shall not stock or dispense any controlled substance.

(2) Pharmacists shall dispense all medications to patients on individual prescriptions, shall properly label all drugs dispensed, and shall comply with requirements for storing, safeguarding, preparing and keeping records for prescription drugs as described in Board Regulation 04-07-0006.

(3) The pharmacist in charge shall cause the approved written policies, procedures, contracts with nursing homes, and protocols for the operation of the pharmacy to be maintained and available in the pharmacy for use by pharmacy staff and review by State Board of Pharmacy inspectors.

(d) Physical Facilities

The pharmacy shall be locked when a pharmacist is not present in the pharmacy and shall have adequate facilities for performing pharmaceutical services including the procurement, storage, distribution, security and control of said drugs consistent with all federal and state laws and regulations.

(e) Changes in pharmacy operations

The pharmacist in charge shall obtain approval by the Board's Executive Director prior to any change in any item identified in subparagraph (b) (1) (B) (i) - (vii) of this regulation.

(f) Limited Use Technician Permit

The Board of Pharmacy may issue a restricted charitable clinic pharmacy technician permit for the sole purpose of performing pharmacy technician duties as a volunteer in a prescription drug redispensing program permitted in accordance with Board Regulation 04-03-0004 (b). (6/23/05, Revised 6/30/07)

04-04: OUT OF STATE PHARMACIES

04-04-0001—OUT OF STATE PHARMACY REGULATION

Out of State pharmacies shall comply with the following qualifications to be, and remain, licensed in Arkansas by the Board.

(a)

(1) The pharmacy holds a current license in good standing in the state(s) in which it is located.

(2) Each pharmacist dispensing drugs into Arkansas shall be licensed as a pharmacist in Arkansas or in the state where he practices if that state has standards of licensure at least equivalent to those of Arkansas.

(b) A pharmacist currently licensed in Arkansas, shall be named in the application and shall serve as the pharmacy's pharmacist in charge for the Arkansas permit and as the contact person for communications by the Board. Said Arkansas Pharmacist shall be an employee of the out of state pharmacy who shall be present at the pharmacy's physical location at least fifty (50) percent of the number of hours per week the pharmacy is open up to a maximum of twenty (20) hours per week. The pharmacist in charge for the Arkansas Permit need not be the same person as the pharmacist in charge of the pharmacy pursuant to the law in the state in which the pharmacy is located.

(1) That pharmacist will be responsible for receiving and maintaining publications distributed by the Board.

(2) If at anytime the pharmacist so designated as the pharmacist in charge for the Arkansas permit shall leave that capacity or not be able to serve in that capacity, the pharmacy shall notify the Board within ten (10) calendar days and designate another Arkansas licensed pharmacist to perform this function by written notice to the Board within thirty (30) calendar days.

(c) The out of state pharmacy shall apply for licensure and renewal on forms provided by the Board. The Board may require such information as reasonably necessary to carry out the provisions of A.C.A. §17-92-401, including, without limitation, the name, address and position of each officer and director of a corporation or of the owners if the pharmacy is not a corporation.

Provided, however, the Board may grant an exemption from licensing under A.C.A. §17-92-401 upon application by any non-resident pharmacy which confines its dispensing activity to isolated transactions. In determining whether to grant an exemption, the Board shall consider:

(1) The number of prescriptions dispensed or reasonably expected to be dispensed into Arkansas.

(2) The number of patients served or reasonably expected to be served in Arkansas.

(3) Whether the pharmacy has promoted its services in Arkansas.

(4) Whether the pharmacy has a contract(s) with any employer(s) or organization(s) to provide pharmacy services to employees or other beneficiaries in Arkansas.

(5) Medical necessity.

(6) The effect on the health and welfare of persons in Arkansas.

(7) Any other relevant matters.

(d) The pharmacy shall pay a biennial license fee as defined in regulation 01-00-0007. When there is a change of Arkansas licensed pharmacist in charge, the fee for said change shall be paid as defined in regulation 01-00-0007. Final notification, to the Arkansas State Board of Pharmacy, of the new Arkansas licensed pharmacist in charge shall be on a form furnished by the Arkansas State Board of Pharmacy and accompanied by the fee for said change.

(e) The pharmacy shall maintain records of drugs dispensed to Arkansas addresses in such a manner so as to be readily retrievable upon request. These records shall be made available for inspection by the Board or by Arkansas law enforcement authorities.

(f) The pharmacy shall timely respond to any request for information from the Board or law enforcement authorities.

(g) The pharmacy shall maintain an incoming toll free telephone number for use by Arkansas customers to be answered by a pharmacist with access to patient records. This service shall be available a minimum of 40 hours a week, six days per week during normal business hours. This telephone number plus others available for use shall be printed on each container of drugs dispensed into Arkansas. The toll free number shall have sufficient extensions to provide reasonable access to incoming callers.

(h) Generic drugs shall be dispensed into Arkansas pursuant to the Arkansas Generic Substitution Act; provided, however, nothing herein shall be construed to mandate that an out of state pharmacy comply with the Arkansas Generic Substitution Act if such compliance would cause the out of state pharmacy to violate the Generic Substitution Act of the state wherein the facility of the dispensing out of state pharmacy is located.

(i) The facilities and records of the pharmacy shall be subject to inspection by the Board: provided, however, the Board may accept in lieu thereof satisfactory inspection reports by the licensing entity using similar standards of the state where the pharmacy is located.

(j) Each out of state pharmacy doing business in Arkansas by dispensing and delivering or causing to be delivered prescription drugs to Arkansas consumers shall designate a resident agent in Arkansas for service of process.

(k) Each out of state pharmacy doing business in Arkansas shall comply with Board of Pharmacy regulation 09-00-0001 (Patient Information, Drug Use Evaluation, and Patient Counseling).

Nothing herein shall be construed to mandate that an out of state pharmacy comply with Board regulation 09-00-0001 if such compliance would cause the out of state pharmacy to violate law or regulation of the state wherein the facility of the dispensing out of state pharmacy is located.

(l) Upon a change of ownership of a pharmacy as set out herein, a new permit shall be secured by the new owner(s). The new owner(s) can continue operation of the pharmacy for fourteen (14) days after the effective date of the change of ownership; after the said fourteen (14) day period, the permit issued to the prior owner shall be void and same shall be surrendered to the Executive Director of the Board of Pharmacy.

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

(1) A change of ownership of a pharmacy, owned by a SOLE PROPRIETOR, is deemed to have occurred when:

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

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

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

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

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

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

(A) An individual or business acquires or disposes of twenty percent (20%) or more of the corporation's outstanding shares of voting stock. (This shall not apply to any corporation

the voting stock of which is actively traded on any securities exchange or in any over the counter market); or

(B) The corporation merges with another business or corporation. (The corporation owning the pharmacy is required to notify the Arkansas State Board of Pharmacy if a change of ownership or merger occurs within the parent corporation of the corporation which owns the pharmacy); or

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

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

The responsibility to ensure compliance with this regulation rests both with the Arkansas pharmacist in charge and with the pharmacy owner if they are not the same.

(10/09/90, Revised 04/10/92, 6/23/96, 8/23/96, 10/12/99, 11/15/2003, 7/16/2006 and 11/6/2008).

04-05: REGULATIONS REGARDING HOSPITAL PHARMACIES

04-05-0001—HOSPITAL PHARMACEUTICAL SERVICES PERMIT

(a) Any pharmacist practicing in an Arkansas hospital must so notify the Board of Pharmacy and ascertain that a hospital pharmaceutical services permit has been issued. The hospital pharmaceutical services permit shall be issued in the name of the hospital showing a pharmacist in charge.

(b) Any hospital holding a retail pharmacy permit as of February 15, 1975, upon application for renewal must separate the facilities, stocks, records, etc., in compliance with A.C.A. 17-92-403--17-92-405.

All hospitals shall have adequate provisions for pharmaceutical services regarding the procurement, storage, distribution, and control of all medications. All federal and state regulations shall be complied with.

(1) Definitions

(A) "Hospital pharmacy" means the place or places in which drugs, chemicals, medicines, prescriptions, or poisons are prepared for distribution and administration for the use and/or benefit of patients in a hospital licensed by the Arkansas Department of Health.

"Hospital pharmacy" shall also mean the place or places in which drugs, chemicals, medicines, prescriptions or poisons are compounded for the dispensing to hospital employees, members of the immediate families of hospital employees, patients being discharged, and other persons in emergency situations.

"Hospital pharmacy" shall also mean the provision of pharmaceutical services as defined in the Pharmacy Practice Act by a pharmacist to a patient of the hospital.

(B) "Hospital employee" means any individual employed by the hospital whose compensation for services or labor actually performed for a hospital is reflected on the payroll records of a hospital.

(C) "Qualified hospital personnel" means persons other than licensed pharmacists who perform duties in conjunction with the overall hospital pharmaceutical services for inpatients.

(D) “Licensed pharmacist” means any person licensed to practice pharmacy by the Arkansas State Board of Pharmacy who provides pharmaceutical services as defined in the Pharmacy Practice Act to patients of the hospital.

(E) “Unit dose distribution system” means a pharmacy-coordinated method of dispensing and controlling medications in hospitals in which medications are dispensed in single unit packages for a specific patient on orders of a physician where not more than a 24-hour supply of said medications is dispensed, delivered, or available to the patient.

“Unit dose distribution system” also means a system that meets the requirement of a "Unit Dose Distribution System," provided that up to a 72-hour supply may be sent to the floor once a week if the system has been reviewed and approved administratively by the Board of Pharmacy.

(2) Compounding, dispensing and distributing

(A) Compounding is the act of selecting, mixing, combining, measuring, counting, or otherwise preparing a drug or medication.

(B) Dispensing is a function restricted to licensed pharmacists which involves the issuance of:

(i) one or more doses of a medication in containers other than the original, with such new containers being properly labeled by the dispenser as to content and/or directions for use as directed by the prescriber;

(ii) medication in its original container with a pharmacy prepared label that carries to the patient the directions of the prescriber as well as other vital information;

(iii) a package carrying a label prepared for nursing station use. The contents of the container may be for one patient (individual prescription) or for several patients (such as a nursing station medication container).

(C) Distributing, in the context of this regulation, refers to the movement of a medication from a central point to a nursing station medication center. The medication must be in the original labeled manufacturer's container or in a prepackaged container labeled according to federal and state statutes and regulations, by a pharmacist or under his direct and immediate supervision.

(3) Administering

An act, restricted to nursing personnel as defined in Nurses Practice Act 43 of 1971, in which a single dose of a prescribed drug or biological is given a patient. This activity includes the removal of the dose from a previously dispensed, properly labeled container, verifying it with the prescriber's orders, giving the individual dose to the proper patient and recording the time and dose given.

(4) Pharmacy and therapeutics committee

There is a committee of the medical staff to confer with the pharmacist in the formulation of policies, explained as follows:

(A) A pharmacy and therapeutics committee (P & T Committee), composed of a least one physician, the administrator or representative, the director of nursing service or representative, and the pharmacist is established in the hospital. It represents the organizational line of communication and the liaison between the medical staff and the pharmacist.

(B) The committee assists in the formation of broad professional policies regarding the evaluation, appraisal, selection, procurement, storage, distribution, use, and safety procedures, and all other matters relating to drugs in hospitals.

(C) The committee performs the following specific functions:

(i) Serves as an advisory group to the hospital medical staff and the pharmacist on matters pertaining to the choice drugs.

(ii) Develops and reviews periodically a formulary or drug list for use in the hospital;

(iii) Establishes standards concerning the use and control of investigational drugs and research in the use of recognized drugs;

(iv) Evaluates clinical data concerning new drugs or preparations requested for use in the hospital;

(v) Makes recommendations concerning drugs to be stocked on the nursing unit floors and emergency drug stocks;

(vi) Prevents unnecessary duplication in stocking drugs and drugs in combination having identical amounts of the same therapeutic ingredients.

(vii) The committee meets at least quarterly and reports to the medical staff by written report.

(viii) Develops and routinely evaluates a hospital-wide Medication Error Reduction Plan (MERP) to identify actual or potential medication-related errors and to perform a concurrent and retrospective review of clinical care. The MERP should address the areas of: prescribing, prescription, order communication, product labeling, product packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use.

(5) Pharmacy operations

The hospital has a pharmacy directed by a licensed pharmacist. The pharmacy is administered in accordance with accepted professional principles.

(A) Pharmacy supervision

There is a pharmacy directed by a licensed pharmacist, defined as follows:

(i) The director of pharmacy is trained in the specialized functions of hospital pharmacy.

(ii) The director of pharmacy is responsible to the administration of the hospital and the Board of Pharmacy for developing, supervising, and coordinating all the activities of the pharmacy department and all pharmacists providing professional services in the hospital.

(iii) All licensed pharmacists who provide pharmaceutical services as defined by the Pharmacy Practice Act shall practice under policies, procedures, and protocols approved by the director of pharmacy. These policies, procedures, and protocols shall be subject to review and approval by the Board of Pharmacy.

(6) Physical facilities

Facilities are provided for the storage, safeguarding, preparation, and dispensing of drugs, defined as follows:

(A) Drugs are issued to floor units in accordance with approved policies and procedures.

(B) Drug cabinets on the nursing units are routinely checked by the pharmacist. All floor stocks are properly controlled.

(C) A careful determination of the functions of a department will regulate the space to be allocated, the equipment necessary to carry out the functions, and the number of personnel required to utilize the equipment and to render a given volume of service, as these functions relate to the frequency or intensity of each function or activity. Adequate equipment should specifically relate to services rendered and functions

performed by the hospital pharmacy. Equipment lists will relate to the following services and functions:

(i) Medication preparation;
(ii) Library reference facilities;
(iii) Record and office procedures;
(iv) Sterile product manufacturing;
(v) Bulk compounding (manufacturing);
(vi) Product control (assay, sterility testing, etc.);
(vii) Product development and special formulations for medical staff.

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

(i) Graduates capable of measuring from 0.1 ml. up to at least 500 ml.
(ii) Mortars and pestles.
(iii) Hot and cold running water.
(iv) Spatulas (steel and non-metallic).
(v) Funnels.
(vi) Stirring rods.
(vii) Class A balance and appropriate weights.
(viii) Typewriter or other label printer.
(ix) Suitable apparatus for production of small-volume sterile products
(x) Suitable containers and labels.

(E) Each hospital pharmacy shall maintain a Pharmacy library:

(i.) available for use by the pharmacist and the patient, including either current drug information manuals, or computers capable of printing current drug information for the pharmacist and patient drug information and monographs for patients.
(ii.) other pharmacy reference books and periodicals necessary for effective pharmacy practice.

(F) Special locked storage space is provided to meet the legal requirements for storage of controlled drugs, alcohol, and other prescribed drugs.

(7) Personnel

Personnel competent in their respective duties are provided in keeping with size and activity of the department, explained as follows:

(A) The director of pharmacy is assisted by an adequate number of additional licensed pharmacists and such other personnel as the activities of the pharmacy may require to ensure quality pharmaceutical services.

(B) The pharmacy, depending upon the size and scope of its operations, is staffed by the following categories of personnel:

(i) Chief pharmacist (director of pharmacy)
(ii) One or more assistant chief pharmacists (assistant director of pharmacy).
(iii) Staff pharmacists.
(iv) Pharmacy residents (where program has been activated).
(v) Trained non-professional pharmacy helpers (qualified hospital personnel).
(vi) Clerical help.

(8) Emergency pharmaceutical services

Through the administrator of the hospital, the P & T Committee shall establish policies and procedures that include, but are not limited to the following:

(A) Upon admission to the emergency room on an outpatient basis and when examined by the physician where medications are prescribed to be administered, a record must be kept on file in the emergency room admission book or a copy of the Emergency Room medication order must be kept by the pharmacist to be readily accessible, for control and other purposes, as required by these regulations.

(B) If the physician wishes the patient to have medication to be taken with them from the Emergency Room supplies, the amounts to be taken shall be sufficient to last until medication may be obtained from local pharmacies, in any case not to exceed a 48-hour supply. All state and federal laws must be observed concerning all records, labeling, and outpatient dispensing requirement.

(C) Take home prescriptions for anti-infectives issued to patients at the time of discharge from the emergency room, filled by a pharmacist, shall be quantities consistent with the medical needs of the patient.

(9) Pharmacy records and labeling

Records are kept of the transactions of the pharmacy and correlated with other hospital records where indicated. All medication shall be properly labeled. Such record and labeling requirements are as follows:

(A) The pharmacy establishes and maintains, in cooperation with the accounting department, a satisfactory system of records and bookkeeping in accordance with the policies of the hospital for:

(i) Maintaining adequate control over the requisitioning and dispensing of all drugs and pharmaceutical supplies, and

(ii) Charging patients for drugs and pharmaceutical supplies.

(B) A record of procurement and dispersement of all controlled drugs is maintained in such a manner that the disposition of any particular item may be readily traced.

(C) The pharmacist shall receive and provide service pursuant to the perusal of the physician's original order or a direct copy thereof, except in emergency situations wherein the pharmacist may provide service pursuant to a verbal order or to an oral or written transcription of the physician's order provided that the pharmacist shall receive and review the original or direct copy within twenty-four (24) hours of the time the service is provided.

(D) A record shall be maintained by the pharmacy and stored separately from other hospital records for each patient (inpatient or outpatient) containing the name of the patient, the prescribing physician, the name and strength of drugs prescribed, the name and manufacturer (or trademark) of medication dispensed.

(E) The label of each medication container prepared for administration to inpatients, shall bear the name and strength of the medication, the expiration date, and the lot and control number. The label on the medication, or the container into which the labeled medication is placed, must bear the name of the patient.

(F) The label of each outpatient's individual prescription medication container bears the name of the patient, prescribing physician, directions for use, the name and strength of the medication dispensed (unless directed otherwise by the physician).

(10) Control of toxic or dangerous drugs

Policies are established to control the administration of toxic or dangerous drugs with specific reference to the duration of the order and the dosage, explained as follows:

(A) The medical staff has established a written policy that all toxic or dangerous medications not specifically prescribed as to time or number of doses, will be automatically stopped after a reasonable time limit set by the staff.

(B) The classifications ordinarily thought of as toxic or dangerous drugs are controlled substances, anticoagulants, antibiotics, oxytoxics, and cortisone products.

(C) Except for controlled drugs, all deteriorated non-sterile, non-labeled or damaged medication shall be destroyed by the pharmacist.

(D) All controlled drugs (Schedule II, III, IV, and V) should be listed and a copy sent, along with the drugs to the Arkansas Department of Health by registered mail or delivered in person for disposition.

(11) Drugs to be dispensed

Therapeutic ingredients of medications dispensed are included (or approved for inclusion) in the United States Pharmacopoeia, N.F. and U.S. Homeopathic Pharmacopoeia, or Accepted Dental Remedies (except for any drugs unfavorably evaluated therein) and drugs approved by provisions of the Arkansas Act 436 of 1975, or are approved for use by the P & T Committee of the hospital staff, explained as follows:

(A) The pharmacist, with the advice and guidance of the P & T Committee, is responsible for specifications as to quality, quantity, and source of supply of all drugs.

(B) There is available a formulary or list of drugs accepted for use in the hospital which is developed and amended at regular intervals by the P & T Committee with the cooperation of the pharmacist and the administration.

(12) Policy and procedure manual

(A) A policy and procedure manual pertaining to the operations of the hospital pharmacy with updated revisions adopted by the P & T Committee of each hospital shall be prepared and maintained at the hospital.

(B) The policy and procedure manual should include at a minimum the following:

(i) Provisions for procurement, storage, distribution and drug control for all aspects of pharmaceutical services in the hospital;

(ii) Specialized areas such as surgery, delivery, ICU and CCU units and emergency room stock and usage of medication shall be specifically outlined;

(iii) A system of requisitioning supplies and medications for nurses' stations stock shall be in written procedural form as to limits of medications to be stocked in each nursing unit;

(iv) Detailed job descriptions and duties of each employee by job title working in the pharmacy department must be developed and made a part of these policies and procedures.

(v) The pharmacy policy and procedure manual shall be subject to review and approval by the Board of Pharmacy on request from the Board.

(13) Employee prescription medication

(A) There will be a prescription on file for all prescription drugs dispensed to hospital employees and their immediate families. These records will be kept separate from all inpatient records.

(B) The only person(s) entitled to have employee prescriptions filled will be the employee listed on the hospital payroll and members of their immediate family.

(14) Patient discharge medication

Any take-home prescription dispensed to patients at time of discharge from the hospital shall be for drugs and quantities consistent with the immediate medical needs of the patient.

(15) Licensed pharmacist personnel requirements

The minimum requirements for licensed pharmacists in hospitals are:

(A) A general hospital, surgery and general medical care maternal and general medical care hospital, chronic disease hospitals, psychiatric hospitals, and rehabilitative facilities licensed for greater than fifty (50) beds, as determined by the institution's license issued by the Arkansas Department of Health, shall require the services of a pharmacist in charge, who shall be responsible for duties defined in Regulation 04-00-0010. Additional pharmacists shall be employed as are necessary to perform required pharmacy duties in keeping with the size and scope of the services of the hospital pharmacy's safe and efficient operation in the opinion of the Arkansas State Board of Pharmacy. Hospitals, providing specialized or unique patient care services, may request approval from the Arkansas State Board of Pharmacy to be exempt from the requirement of a pharmacist on duty forty (40) hours per week. The request for exemption must provide adequate written documentation to justify the services of a pharmacist for as many hours as are necessary to perform required pharmacy services, followed by an appearance before the Board for final approval of the request.

(B) The above classified hospitals, licensed for fifty (50) beds or less, as determined by the institution's license issued by the Arkansas Department of Health, shall require the services of pharmacist(s) including a pharmacist in charge, for as many hours as, in the opinion of the Arkansas State Board of Pharmacy and the Arkansas State Board of Health, are necessary to perform required pharmacy duties in keeping with the size and scope of the services of the hospital pharmacy's safe and efficient operation. The pharmacist(s) shall be on site at least five (5) days per week to perform and review pharmacy dispensing, drug utilization, and drug distribution activities. A pharmacist shall be available to provide emergency services to the staff when the pharmacy is closed.

(C) Recuperative centers, outpatient surgery centers, and infirmaries

(i) If the infirmary, recuperative center or outpatient surgery center has a pharmacy department, a licensed pharmacist must be employed to administer the pharmacy in accordance with all state and federal laws regarding drugs and drug control.

(ii) If the infirmary, recuperative center, or outpatient surgery center does not have a pharmacy department, it has provisions for promptly and conveniently obtaining prescribed drugs and biologicals from a community or institutional pharmacy.

(iii) If the infirmary, recuperative center, or outpatient surgery center does not have a pharmacy department, but does maintain a supply of drugs, a licensed pharmacist shall be responsible for the control of all bulk drugs and maintain records of their receipt and disposition. The pharmacist shall dispense drugs from the drug supply, properly labeled, and make them available to appropriate nursing personnel.

(iv) All medication for patients shall be on individual prescription basis.

(D) A pharmacist in charge, who is employed at any facility permitted by the Arkansas State Board of Pharmacy where a forty (40) hour work-week is required, may also be the pharmacist in charge at a hospital licensed for fifty (50) beds or less by the Arkansas Department of Health.

(16) Responsibility of a pharmacist in a hospital pharmacy

(A) The pharmacist in charge is responsible for the control of all medications distributed in the hospital where he practices, and for the proper provision of all pharmaceutical services.

(B) The following aspects of medication distribution and pharmaceutical service are functions involving professional evaluations of judgments and may not be performed by supportive personnel:

(i) Selection of the brand and supplier of medication.

(ii)Interpretation and certification of the medication order. This involves a number of professional responsibilities such as the determination of:

a. Accuracy and appropriateness of dose and dosage schedule.

b. Such items as possible drug interactions, medication sensitivities of the patient and chemical and therapeutic incompatibilities.

c. Accuracy of entry of medication order to patient's medication profile.

(C) Final certification of the prepared medication.

(17) Operation of pharmacy department without a pharmacist

At no time will the hospital pharmacy be open and in operation unless a licensed pharmacist is physically present except:

(A) Entrance may be obtained for emergency medication as set forth in the pharmacy policy and procedure manual when the pharmacy is closed outside its normal operation hours.

(B) When the pharmacist is summoned away from the pharmacy and there are other qualified personnel left in the pharmacy, the personnel left in the pharmacy could perform only those functions authorized within this regulation.

(18) The American Society of Health-System Pharmacists Guidelines

The American Society of Health-System Pharmacists' most recent statement on hospital drug control systems and Guidelines for Institutional Use of Controlled Substances shall be required reading by hospital pharmacists. (Revised 6/25/83, 4/7/89, 6/15/95, 8/2001, 11/1/2007, 11/6/2008 and 11/30/2010)

04-05-0002—MECHANICAL STORAGE AND DELIVERY

Hospitals using mechanical storage and delivery machines for legend drugs must secure a hospital pharmaceutical services permit, and these machines shall be stocked only by a licensed pharmacist under this permit. Drugs may be obtained from these machines only by a physician, or registered or licensed professional nurse or student nurse, or an intern or resident physician, or a licensed pharmacist acting under the prescribed rules of safety procedures as promulgated by the individual hospital or institution using the machine. Use of these machines shall not be to circumvent adequate pharmaceutical services. (Amended 8/23/96)

04-05-0003—REGULATING THE USE OF ELECTRONIC DATA PROCESSING IN LIEU OF PRESENT RECORD KEEPING SYSTEMS IN HOSPITAL PHARMACIES HOLDING HOSPITAL PHARMACY PERMITS

(a) These regulations shall be construed, if possible, so as not to be in violation of, or in conflict with, any federal regulation or requirement. If any part hereof is held invalid because of such conflict, such invalidity shall not affect other provisions or applications of these regulations, which can be given effect without the invalid provisions of these regulations, are declared severable.

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

(c) Input of drug information into the system shall be performed by a pharmacist or pharmacy technician. The final verification of prescription information, entered into the computer, shall be made by the supervising pharmacist who is then totally responsible for all aspects of the data and data entry. Any judgmental decision concerning patient utilization of drugs must be performed by a pharmacist.

(d) An electronic data processing system must be readily accessible electronically online or by hard copy, and shall be capable of printing a hard copy record. The hard copy record, or electronic data base record, shall be available upon request by a Board of Pharmacy representative or other state or federal agencies with authority to obtain such records within 48 hours of the request. The system must be capable of furnishing the following information:

(1) Patient Medication Profile (accessible electronically online or by hard copy.)
Definition. The Patient Medication Profile means the basic document used by the hospital pharmacist to monitor a patient's medication regimen, drug compliance, drug interactions, allergies and drug usage.

(A) The Patient Medication Profile must contain, at a minimum, the following:

(i) Patient name, patient identification number, practitioner's name, drug name, drug strength and dosage form, number of doses issued, initials, name or identification number of pharmacist approving original order into the system, and date original order was entered into the system.

(ii) The Final Patient Medication Profile must be maintained by the pharmacy

(2) Patient Daily Medication Record
The Patient Daily Medication Record is a document, whether electronic or hardcopy, which supports the Patient Medication Profile. The Patient Daily Medication Record provides a daily refill-by-refill audit trail on all drugs dispensed and supplements the base document, the Patient Medication profile. This record is produced on a daily basis. It may be used to fill patient medication orders, for transport to the patient care area. This record must show all medications dispensed on any given day.

(A) The Patient Daily Medication Record must contain, at a minimum, the following: date of record, patient name, patient identification number, drug name, drug strength and dosage form and number of doses issued on that day.

(B) The initials of the pharmacist who checked and verified the doses dispensed must appear on the Patient Daily Medication Record if not shown on the Patient Medication Profile described in this section. Since the Patient Medication Record supports the Patient Medication Profile, some information such as practitioner's name, initials, name or identification number of pharmacist entering the original order into the system, and the date of the original order may or may not be duplicated because the information is readily retrievable from the base document.

(C) The Patient Daily Medication Record must be kept and a bound log book must be signed by all pharmacists filling orders for that day. If a printed hard copy is used, the printout may be replaced by a monthly log containing the same information. This information must be maintained at the pharmacy for a period of two (2) years.

(D) The pharmacist in charge of the hospital pharmacy will maintain a bound log book in which each individual pharmacist and intern involved in the dispensing of medications will sign the log book each day, attesting to the fact that the prescription information entered into the computer that day has been reviewed by him and is correct as shown. The log shall identify the time of day at which the pharmacist started filling and stopped

filling prescriptions. The log book shall be maintained by the pharmacist in charge or his successor, in the hospital pharmacy employing such a system for a period of two (2) years after the date of dispensing the appropriately authorized prescription.

(3) Assure strict confidentiality of all patient records.

(4) If the hospital pharmacy closes, the pharmacist in charge, at the date of closing, shall store said records and within fourteen (14) days of closing shall notify the Board of Pharmacy where said records are located. A hard copy printout or electronic database of any daily log(s) shall be produced and made available to a Board of Pharmacy representative on their request and to any other person authorized by law to examine or receive copies of prescription records.

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

(e) Hospital pharmacies that make arrangements with outside suppliers of data processing services or materials must assure themselves of continuing, adequate and complete drug information data and issuing records. If for any reason the relationship with said supplier terminates, the pharmacy shall assure the continuity of records.

(f) In the event of computer breakdown (down time), the pharmacy must have an auxiliary record keeping system. The backup system must contain all necessary information to insure prompt data entry into the system as soon as computer is again available.

(g) Registrants holding a hospital pharmaceutical services permit, who fill outpatient prescriptions, and who wish to utilize electronic data processing equipment as a record keeping system must then comply with all the requirements of the Arkansas State Board of Pharmacy regulation 4-02-0010.

(h) The electronic data processing systems described in this regulation are acceptable as the disposition records for all drugs, except that the actual signed disposition (proof of use) records for Schedule II controlled substances must be retained separate from other records for a period of two (2) years. 10/09/80 (Revised 6/15/95, 6/19/97, & 10/11/2000)

04-05-0004 - OFF SITE ORDER ENTRY

The purpose of this section is to provide standards for remote or off-site order entry in hospital pharmacies within the state of Arkansas.

(a) The Arkansas State Board of Pharmacy may approve a request for off-site order entry where the hospital pharmacy can demonstrate that the procedure will result in an improvement in patient care by increasing the amount time of pharmacist involvement in the process of medication review for safety and efficacy prior to the administration of the medication to the patient.

(b) (1) The pharmacist-in-charge of the hospital pharmacy shall submit a written request for off-site order entry a minimum of 30 days prior to the Board meeting at which the pharmacist seeks Board approval.

(2) The request shall be accompanied by a policies and procedures for off-site order entry to include:

(A) Only a pharmacist holding a current license in good standing shall enter orders at a remote or off-site entry location.

(B) The pharmacist-in-charge at the hospital shall ascertain and maintain on-site documentation that all pharmacists that participate in the order entry process are:

(i) licensed with the Arkansas State Board of Pharmacy.

(ii) competent to enter faxed or scanned order for patients in that facility, including, but not limited to the ability to accurately:
(iii) receive, interpret, and accurately enter medication orders from any physician on staff at that facility;
(iv) access and interpret clinical data as it pertains to that patient's drug regimen;
(v) perform therapeutic interventions;
(vi) perform cross checks for known drug allergies, adverse drug reactions, and contraindications;
(vii) perform drug-drug interaction as well as drug-food interaction review;
(viii) identify any over-utilization or under-utilization.
(ix) available via telephone for any questions or issues from nursing staff as well as from staff physicians; this number shall be posted in a visible place at each nursing station, in all dictation rooms, and all other areas within the facility that physician might write order or nurse might fax or scan order.

(C) A clearly defined back-up system in the event of connection or communication failure and/or the need for on site pharmacist is deemed necessary.

The above competencies shall be in written policy and procedure and shall include training, testing and ongoing assessment of skills.

(D) Documentation that any remote or off-site order entry facility shall have compatible systems utilized at both the hospital as well as the facility itself, and shall include:
(i) software,
(ii) hardware, and
(iii) connectivity

(E) Documentation that the remote or off-site order procedures and other requirements of this regulation have been approved by Medical Staff and/or Pharmacy and Therapeutics Committee at that hospital as reflected in the minutes or comparable record.

(c) In the operation of the off-site order entry, patient confidentiality and full compliance with HIPAA requirements shall be observed at all times. (6/23/05)

04-06: INSTITUTIONAL PHARMACEUTICAL SERVICES PERMIT

04-06-0001—CLASS #1 INSTITUTIONAL PERMIT

(a) If a pharmacy is funded primarily by state or federal funds, and/or if prescription drugs are to be purchased, maintained or dispensed by a pharmacist in a facility that purchases drugs from Arkansas state contracts, and that facility does not meet the requirements set by the Board of Pharmacy to obtain a licensed pharmacy permit, a hospital pharmaceutical services permit, or a nursing home consultant's permit, then an exception may be made to issue an institutional pharmaceutical services permit. The institutional pharmaceutical services may be in facilities that provide extended health care to resident patients and are funded primarily by state or federal funds. The permit shall be issued in the name of the licensed pharmacist in charge.

(b) A licensed pharmacist employed or otherwise engaged to provide pharmaceutical service may have a flexible schedule of attendance in the institution, provided, however, the pharmacist must be physically present in the institution for a sufficient number of hours weekly to maintain adequate supply of medications at the service area from which medications are administered, to

maintain all records, to perform other pharmaceutical services authorized by law and provide adequate control and accountability of all drugs under his responsibility.

(c) Medication for patients shall be on an individual prescription basis by order from a licensed physician and the pharmacist shall dispense drugs, properly labeled, to be used for patients being treated at the facility.

(d) Facilities are to be provided for the storage, safe-guarding, preparation, and dispensing of drugs. Equipment and supplies necessary to the facilities' safe and economical operation shall be provided. Special locked storage space is to be provided to meet all requirements for storage of controlled drugs, and other prescription drugs.

(e) All policies and procedures related to the institutional pharmaceutical services must first be approved by the Board before a permit will be issued.

(f) Special floor stock or backup to meet emergency needs such as when the pharmacy is closed, will be permitted only when specifically outlined in the policies and procedures. The policies and procedures shall include:
   (1) lists establishing quantity limits of these emergency drugs;
   (2) the method of replacement;
   (3) maintenance of records accounting for drugs used;
   (4) proper preparation and labeling by the pharmacist.

(g) With recognition of DEA's statement of policy regarding emergency kits for long-term care facilities, and recognizing DEA's definition of long term care facilities, the following requirements must be met for facilities with institutional pharmaceutical services permits to store emergency kits, containing controlled substances and/or other legend drugs, in these facilities in Arkansas.
   (1) All contents of the emergency kit will be provided by one pharmacy designated by the facility.
   (2) The facility holding an institutional permit with the Board of Pharmacy must have resident patients to which the facility provides extended health care.
   (3) The controlled and legend drugs must remain the property of and under the responsibility of the pharmacy, which must have an Arkansas permit.
   (4) All medications must be administered only on the order of a practitioner and medications administered from the nurse's supply must be recorded as a prescription by the pharmacy prior to the pharmacy's replacement of the drug in the emergency supply.
   (5) All medication records must be maintained as required by law, and out of date drugs must be properly destroyed by the pharmacy.
   (6) Careful patient planning should be a cooperative effort between the pharmacy and the nursing department at the facility to make all medications available, and the emergency supply should only be used for emergency or unanticipated needs and shall not become a routine source or supply.
   (7) The pharmacy is responsible to assure compliance with this regulation, and any abuse or misuse of the intent of this regulation shall be immediately reported to the Board of Pharmacy.
   (8) Storage conditions for the emergency kit shall meet all state and federal requirements. The storage conditions shall be set out in the policy and procedures of the facility.

(h) Drug categories for emergency kits in facilities with institutional pharmaceutical services permits

The following is a list of categories of drugs which are acceptable in emergency kits in facilities with institutional pharmaceutical services permits in accordance with this regulation:

(1) Analgesics and controlled drugs
Schedule II injectable
Limit: one (1)
Maximum quantity: two (2)

(2) Schedule III, IV or V injectable
Limit: one (1)
Maximum quantity: ten (10)

(3) Schedule III, IV or V oral medications
Limit: two (2)
Maximum quantity: six (6)

(4) Anticonvulsants; injectable controlled drugs
Limit: one (1)
Maximum quantity: four (4)

(5) Anxiolytics; injectable controlled drugs
Limit: one (1)
Maximum quantity: four (4) (Amended 10/2001)

04-06-0002-CLASS #2 INSTITUTIONAL PHARMACEUTICAL SERVICES PERMIT

(a) When controlled drugs are needed for research or instruction by a licensed pharmacist, and these drugs are not to be sold or dispensed on prescriptions, an institutional pharmaceutical services permit for research or instruction (Class #2) may be issued.

(b) Total responsibility for such drugs is placed on the licensed pharmacist in whose name the permit is issued.

04-06-0003 – CLASS #3 INSTITUTIONAL PHARMACEUTICAL SERVICES PERMIT – CORRECTIONAL FACILITIES

(a) Definitions:
(1) "Correctional facility" means any place used for the confinement of persons charged with or convicted of an offense or otherwise confined under a court order.
(2) “Dispensary” means a correctional facility providing limited medical services by licensed personnel. This type of facility is not licensed by the Arkansas Department of Health as an infirmary and does not have patient beds.
(3) “Infirmary” means a correctional facility with an infirmary licensed by the Arkansas Department of Health having patient beds.

(b) If a correctional facility is funded primarily by city, county, state or federal funds, and/or if prescription drugs are to be purchased, maintained or dispensed in a facility that purchases drugs from Arkansas state contracts, and that facility does not meet the requirements set by the Board of Pharmacy to obtain a licensed pharmacy permit, a hospital pharmaceutical services permit, or

a nursing home consultant's permit, then the Board may issue an institutional pharmaceutical services permit. The institutional pharmaceutical services may be in facilities that provide extended health care to resident patients and are funded primarily by city, county, state or federal funds. The permit shall be issued in the name of the pharmacist providing consultant services to the facility. Any time there is a change in the pharmacist consultant for the facility, a new permit in the name of the new pharmacist shall be obtained.

(c) Medication for patients shall be on an individual prescription basis by order from a licensed prescriber, and the supervising nurse or other licensed nursing personnel shall administer properly labeled medications, to be used for patients being treated at the correctional facility.

(d) A licensed pharmacist, named on the permit, shall be employed or otherwise engaged to provide consultant pharmaceutical service at the correctional facility.

(e) Institutional pharmaceutical services permits may be issued to correctional infirmaries and dispensaries.

(1) Correctional infirmaries

(A.) All policies and procedures related to the institutional pharmaceutical services permit must first be approved by the Board staff before a permit will be issued to ensure compliance with all existing laws and regulations. Any changes to the policies and procedures related to the procurement, administration, distribution or storage of prescription medications shall be reported to the Board of Pharmacy within 30 days.

(B.) Policies and procedures for obtaining, dispensing, and administering drugs and biologicals shall be developed with the consultation of an Arkansas licensed pharmacist and the approval of medical staff.

(C.) Special floor stock or back up medications to meet the emergency needs of the patients in the correctional facility will be permitted only when specifically outlined in the policies and procedures manual. The policy and procedures manual shall at a minimum include:

i. lists of emergency medications which establish quantity limits for each medication; said list shall be subject to the approval of the Arkansas State Board of Pharmacy;
ii. the method of replacement;
iii. maintenance of records accounting for medications used;
iv. proper preparation and labeling by the pharmacy services provider.

(D.) The pharmacist consultant must conduct monthly site visits and will be responsible for the supervision of pharmacy services.

(2) Correctional Dispensaries

(A.) Pharmaceutical services shall be provided under supervision of licensed nursing personnel.

(B.) The dispensary shall maintain medical records on each patient.

(C.) All policies and procedures related to the institutional pharmaceutical services permit must first be approved by the Board staff before a permit will be issued to ensure compliance with all existing laws and regulations. Any changes to the policies and procedures related to the procurement, administration, distribution or storage of prescription medications shall be reported to the Board of Pharmacy within 30 days.

(D.) Policies and procedures for obtaining, dispensing, and administering drugs and biologicals shall be developed with the consultation of an Arkansas licensed pharmacist and the approval of medical staff.

(E.) Special floor stock or back up medications to meet the emergency needs of the patients in the correctional facility will be permitted only when specifically outlined in the policies and procedures manual. The policy and procedures manual shall at a minimum include:

i. lists of emergency medications which establish quantity limits for each medication, said list shall be subject to the approval of the Arkansas State Board of Pharmacy;
ii. the method of replacement;
iii. maintenance of records accounting for medications used;
iv. proper preparation and labeling by the pharmacy services provider.

(F.) The pharmacist consultant shall conduct quarterly site visits and will be responsible for the supervision of pharmacy services.

(f) Pharmacist Consultant Responsibilities: Pharmacist consultants in correctional facilities are involved in the following areas of pharmaceutical care which include drug storage, distribution and utilization in that correctional facility:

(1) Supervision of Services. The pharmacist consultant shall:

(A.) develop, coordinate, and supervise all pharmaceutical services. The pharmacist consultant for the correctional facility must ensure that pharmacist consultation is available on a 24-hours-per-day, 7-days-per-week basis. Pharmacist consultant(s) shall devote a sufficient number of hours based upon the needs of the facility, during regularly scheduled visits to carry out these responsibilities.

(B.) assist the correctional facility in developing procedures to ensure the provision of emergency drugs, and shall report to the Board of Pharmacy any pharmacy refusing to provide medication for the pharmacy's regular patients in the facility on a 24-hours-per-day, 7-days-per-week basis.

(C.) provide written consultation on compliance with federal and state laws governing legend drugs (including controlled substances).

(D.) be knowledgeable of all laws and regulations pertaining to correctional facilities and shall communicate with the state agencies involved with enforcement and regulation of these facilities.

(E.) spend sufficient time to evaluate discontinued or other unused medication for return or destruction, destroy unused medication, check entries in a bound and numbered controlled drugs book, and make general observations at the dispensing stations. Medications may only be returned from a correctional facility in accordance with Regulation 04-00-0004.

(F.) indicate the day the pharmacist consultant(s) visited the correctional facility, a brief statement of purpose, finding, and actions for each resident record reviewed.

(2) Control and accountability of all legend drugs (including controlled substance)

(A) The pharmacist consultant shall check to see that only approved drugs and biologicals are used in the facility and shall be administered in compliance with federal and state laws. Records of receipt and disposition of all controlled drugs shall be maintained in sufficient detail to enable an accurate reconciliation. The pharmacist consultant shall

determine that drug records are in order and that an account of all controlled drugs is maintained and reconciled.

(3) Patient Drug Regimen Review

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

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

(C.) Additionally, the pharmacist consultant shall routinely review patient charts in accordance with state and federal regulations and:

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

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

(iii) Review patient compliance with drug regimen.

(iv) Review drug allergies or sensitivities.

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

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

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

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

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

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

(xi) A pharmacist consultant(s) shall quarterly in dispensaries and monthly in licensed correctional infirmaries, review patient medication records in accordance with state and federal regulations, consult with and provide a written report of findings to the director of nursing or the patient's physician.

(4) Labeling of drugs and biologicals and proper storage

(A.) It is the duty of the pharmacist consultant(s) to ascertain during each visit to the correctional facility, 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. (11/1/2007)

04-07: CHARITABLE CLINIC PERMIT

04-07-0001—ISSUANCE OF CHARITABLE CLINIC PERMIT

The Arkansas State Board of Pharmacy may provide for the issuance of a charitable clinic pharmacy permit to clinics and facilities furnishing medical care and dental care to poor and underprivileged persons, in which drugs are dispensed without charge to such persons on orders or

prescriptions of practitioners authorized by law to prescribe or administer said drugs and to which the requirements of a licensed pharmacist on duty for a minimum of forty (40) hours shall not apply.

04-07-0002—PRESCRIPTIONS

All medication for patients shall be on individual prescription basis, and the pharmacist shall dispense drugs, properly labeled, and adhere to the requirements for proper storage, safeguarding, preparation and record keeping for prescription drugs.

04-07-0003—POLICIES AND PROCEDURES FOR CLINICS

All policies and procedures related to the charitable clinic pharmacy permit must first be approved by the Board staff before a permit will be issued to ensure compliance with all existing laws and regulations.

04-07-0004—CATEGORIES FOR PERMITS

The staff of the Board of Pharmacy is authorized to approve and issue charitable clinic permits for:

(a) Clinics of the Arkansas Department of Health
   (1) recognizing that medications are provided to patients in the absence of a pharmacist and that the medications dispensed in these clinics are limited to birth control medications, drugs to treat tuberculosis, and drugs to treat sexually transmitted disease treatment program.
   (2) Packaged and labeled prescription drugs shall be initialed by the pharmacist to assure accuracy and appropriateness. The prescribing practitioner or a licensed nurse may issue these pre-dispensed prescription drugs, by placing the patients name, date of issue and prescription number on the label at the time of issue to patients on order of the prescriber.
   (3) The prescription number, as placed on the label of the dispensed prescription drug, is to be placed with the prescribing practitioner's order in the patients medical record. The pharmacist shall monitor patients' medical records to assure that medication profiles and prescription orders are maintained and utilized.
   (4) Since the pharmacist is not present when the patient receives the medication, the pharmacist shall develop protocol to assure that the patient is monitored and counseled by the prescribing practitioner or nurse consistent with the requirements of Board of Pharmacy regulation 09-00-0001.

(b) Other facilities meeting the requirements of this regulation -- provided that, if a pharmacist is not present, there shall be a limited formulary negotiated by the Executive Director and approved by the Board of Pharmacy at its next meeting. The dispensing medication distribution provisions of this section shall apply.

04-07-0005—PHARMACIST PRESENT WHEN MEDICATION PROVIDED

Other facilities meeting the requirements of this regulation and where a pharmacist is present when medications are provided to the patient shall not be restricted to a medication formulary. (Revised 04/30/93)

04-07-0006 REGULATION REGARDING CHARITABLE CLINIC PHARMACIES PROCURING AND DISPENSING DONATED PRESCRIPTION MEDICATION

(a) Purpose

(1) This regulation is to implement a state pilot program whereby Arkansas nursing facilities donate unused prescription medications to charitable clinic pharmacies to be dispensed to medically indigent Arkansas residents as authorized under ACA § 17-92-1101 *et seq.*

(2) No controlled substance shall be donated or transferred by a nursing facility to or accepted by a charitable clinic pharmacy under this regulation or Regulation 04-03-0004.

(b) Definitions

(1) The words defined in Ark. Code Ann. § 17-92-1102 shall have the same meanings in this regulation unless the context otherwise requires.

(2) "Charitable clinic pharmacy" means a pharmacy holding a permit issued under Regulation 04-03-0004.

(3) "Manifest" means a list of drugs being transferred or destroyed.

(c) Donation of prescription drugs

(1) A charitable clinic pharmacy shall accept donations of unused prescription medications only from Arkansas nursing facilities licensed with the Arkansas Department of Human Services, Office of Long Term Care.

(2) A charitable clinic pharmacy shall accept from such a nursing facility only those unused prescription medications identified in a contract with the nursing facility that has been approved by the Board in cooperation with the Arkansas Department of Human Services Office of Long Term Care and the Arkansas Department of Health.

(3) The charitable clinic pharmacy shall accept only those prescription drugs that the nursing facility has maintained in compliance with the applicable Arkansas Department of Health rules and regulations.

(d) The consultant pharmacist for the nursing facility shall be responsible for verifying or causing the following to be performed regarding delivery of unused prescription medication to a charitable clinic pharmacy:

(1) Determine quality and suitability of the unused prescription drugs for reuse by verifying the following:

(A) Health care professionals have maintained the drugs in compliance with applicable Arkansas Department of Health regulations

(B) The drugs can be identified.

(C) The drugs are not adulterated or mutilated.

(D) The expiration dates are more than 30 days after the date the drugs are to be delivered to the charitable clinic pharmacy.

(2) A manifest has been properly completed to include the following;

(A) Names of Consultant Pharmacist and Director of Nursing or designee, the nursing home and the name of the receiving pharmacy;

(B) Name, strength, expiration date and quantity of each prescription drug to be donated;

(3) A copy of the manifest is delivered to the charitable clinic pharmacist and pharmacy.

(4) Deliver the unused drugs only to a pharmacist designated by the charitable clinic pharmacy.

(5) The name of the patient and any identifying information has been redacted or otherwise removed from the drug packaging before the drug are delivered to the charitable clinic pharmacy.

(6) Sign and date each manifest before delivery of the unused prescription medications to the charitable clinic pharmacy certifying that he has complied with the provisions of this paragraph.

(7) Maintain a copy of the manifest signed and dated by the charitable clinic pharmacist in the nursing facility for a minimum of 2 years; said document shall be made available upon request by Board inspectors.

(e) Eligible prescription drugs.
(1) A charitable clinic pharmacy shall accept from a nursing facility only those unused prescription medications identified in the contract identified in paragraph c(2) of this regulation; the charitable clinic pharmacy shall not accept any unused prescription medication identified in said contract for which the charitable clinic pharmacy does not have or reasonably anticipate a patient need.
(2) Eligible prescription drugs are those packaged in single-unit doses or blister packs provided that the outside packaging can be opened if the single-unit dose packaging remains intact, or the manufacturer's original sealed or tamper evident packaging.
(3) The expiration date placed on the medication by the original pharmacy dispensing to the nursing home patient, consistent with USP standards, shall become the actual expiration date for the eligible medication;
(4) No lost identity or unknown drugs shall be accepted by a charitable clinic pharmacy;
(5) No adulterated or misbranded drugs shall be accepted by a charitable clinic pharmacy; and
(6) Only those drugs that have physically been in the nursing facility at all times since being dispensed by the originating pharmacy shall be accepted by a charitable clinic pharmacy.
(7) Compounded drugs shall not be accepted by a charitable clinic pharmacy.

(f) Patients eligible for donated prescription drugs
The charitable clinic pharmacy shall dispense donated prescriptions medications only to indigent patients as defined in Ark. Code Ann. § 17-92-1102 (4)

(g) Pharmacies eligible to accept and dispense unused prescription medications from nursing homes.
(1) A pharmacy shall hold a permit in good standing under Board regulation 04-03-0004.
(2) Prescription medications donated under this Section shall not be sold, resold, offered for sale, traded or transferred to another charitable clinic pharmacy.

(h) Procedures for charitable clinic pharmacies to dispense donated prescription drugs.
(1) (A) A pharmacist on staff at the charitable clinic pharmacy shall verify, utilizing an appropriate reference resource, that the drug name and strength noted on the label of each unit of the packaged donated medication is correct.
(B) The pharmacist verifying the drug shall place his/her initials on the medication label.
(C) If the identity of the drug cannot be verified, the pharmacist shall segregate the unidentified drug for destruction and shall not dispense the medication.
(D) Medications shall not be removed from the donor's original packaging until after verification by the charitable clinic pharmacist; a pharmacist shall then re-label the medication with the name and strength of the medication and the expiration date from the donor's original drug package.
(2) Pharmacists shall dispense unused prescription drugs only upon the valid prescription of an Arkansas licensed health care practitioner.
(3) (A) Pharmacists shall label each medication to be dispensed according to Ark. Code Ann. § 17-92-505.

(B) Pharmacists shall redact or otherwise remove any labeling on an unused prescription drug identifying the original patient or pharmacy, not removed at the nursing home, prior to delivering the medication to a patient.

(C) Pharmacists shall label all donated drugs dispensed with the name of the charitable clinic pharmacy and shall deliver the current drug information to the patient or caregiver.

(D) Pharmacists shall label all donated drugs dispensed with an expiration date. If multiple packages of unused prescription drugs with varied expiration dates are used to fill a single prescription, the earliest expiration date shall be used for the dispensed prescription.

(E) Pharmacists dispensing donated medications shall comply with all aspects of Board regulation 09-00-0001 regarding Patient Counseling.

(4) Storage.

(A) The room in which the medications are stored shall be locked at all times except during clinic hours or other times when a licensed pharmacist is physically present in the pharmacy. A pharmacist shall be on duty during all hours of pharmacy operation.

(B) The room in which the medications are stored shall have proper environmental controls to assure the integrity of the medication in accordance with the drug manufacturer's recommendations

(i) Responsibilities of pharmacist in charge of charitable clinic pharmacy.

(1) Accept delivery of the donated unused prescription drugs from the nursing home in person or cause another pharmacist at the charitable clinic to do so.

(2) Verify that the unused prescription drugs offered by the nursing facility are those identified in the contract described in paragraph c(2) of this regulation and are accurately identified in the manifest provided by the nursing home and resolve any discrepancy before accepting and signing for the medication.

(3) Retain a copy of the nursing facility's manifest in the pharmacy records for a minimum of 2 years and make said documents available to Board inspectors.

(4) Cause the unused prescription drugs to be taken directly from the nursing home to the clinic pharmacy to be properly stored. At no time are the medications to be out of the direct control of a licensed pharmacist.

(5) Cause expired, adulterated, and lost-identity drugs to be segregated from other medications in the pharmacy and then to be destroyed; pharmacists shall not dispense such drugs.

(6) Upon receipt of notice of the recall of a drug, cause a uniform destruction on all of said drugs in the inventory of the charitable clinic, irrespective of lot numbers.

(7) Destruction of drugs.

(A) Create a manifest to be made of expired, adulterated, recalled and/or or other unused prescription drugs, and then cause said drugs to be destroyed.

(B) Observe the destruction of said drugs in the company of a witness, thereafter both of whom sign the manifest verifying the destruction of said drugs.

(C) Maintain a copy of each drug destruction manifest in the files of the pharmacy for a minimum two (2) years and make said records available for review by Board inspectors. (6/23/05)

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.

(f) 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.

(g) 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".

(Adopted 2/2001, Revised emergency 6/2003 & 10/26/2003, Revised 11/30/2010)

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—SCHEDULE V--EXEMPT NARCOTICS

A pharmacist may sell a Schedule V exempt product only after a personal consultation with the patient wanting to purchase the product. A determination must be made confirming that the person has a medical need for the product.

If the pharmacist has reason to believe that the patient has self-medicated with a Schedule V exempt product, for more than ten (10) days, the sale should not be repeated without a valid explanation. If the pharmacist does not accept the explanation, the patient should be referred to a physician.

The pharmacist or pharmacy should seriously question situations where records suggest that the patient is self-medicating by buying these products more than twice in thirty (30) days, when sales in two (2) consecutive months total more than four (4) or when it appears the patient makes purchases every month.

If a sale is made, the pharmacist must:

(a) Make the determination to sell;
(b) Assure the exempt book is kept properly and signed by the pharmacist;
(c) Be able to identify the patient by personal knowledge, photo ID, or other identification. (6/07/90)

07-04-0006—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 & 6/26/03)