REGULATION 7—DRUG PRODUCTS/PRESCRIPTIONS

07-00: GENERAL REGULATIONS REGARDING DRUGS/PRESCRIPTIONS

Definitions:

"Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

"Biosimilar" or "biosimilarity", in reference to a biological product means:
(a) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and
(b) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

"Biosimilar product" is a biological product (drug) that is FDA approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product or originator product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.

"Drug" is defined as:

(a) A substance recognized by an official pharmacopoeia or formulary,
(b) A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease,
(c) A substance (other than food) intended to affect the structure or any function of the body,
(d) A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device,

Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)

"Generic Drug" A generic drug or "generic" is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, FDA requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug. The FDA bases evaluations of substitutability, or "therapeutic equivalence," of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand name product.

"Interchangeable biological product" is biosimilar to an FDA-approved reference product and meets additional standards for interchangeability. An interchangeable biological product may be

substituted for the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product.

"Prescription" means an order for medicine or medicines usually written as a formula by a physician, optometrist, dentist, veterinarian, or other licensed medicinal practitioner. It contains the names and quantities of the desired substance, with instructions to the pharmacist for its preparation and to the patient for the use of the medicine at a particular time.

"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.

"Written prescription" means a prescription that is presented to an apothecary, pharmacy or pharmacist in compliance with federal law and regulations, including a written, oral, faxed, or electronic prescription. (5/31/2014)

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 either entered into the pharmacy's electronic prescription system or promptly reduced to writing by the pharmacist.

(2) All laws and regulations applicable to oral prescription drug orders shall also apply to all facsimile orders including, but not limited to, generic substitution, maintenance of records, information required, etc.

(3) A prescription order transmitted by facsimile device shall contain all prescription information required by federal and state law.

(4) A 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, 7/10/2009, and 5/31/2014)

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 electronically record or 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. (Amended 5/31/2014)

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 AND BIOLOGICAL 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 ~~or The Green Book~~), Approved Animal Drug Products (The Green Book), Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (The Purple Book) and their list of authorized generics 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 or The Green Book), lists the drug (biological product) as being interchangeable (The Purple Book), or lists the drug as an authorized generic, 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 not listed in this manner, ~~"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, Amended 5/31/2014)

07-00-0007—A PHARMACIST SHALL NOT DISPENSE A GENERICALLY EQUIVALENT OR INTERCHANGEABLE BIOLOGICAL 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 either entered into the pharmacy's electronic prescription system or 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, Amended 5/31/2014)

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

(a) Definitions

(1) “Confidential information” means information that is personally identifiable and, therefore, can be traced back to the patient or prescribing practitioner that is accessed or maintained by the pharmacist in the patient's records or which is communicated to the patient, as part of patient counseling, which is privileged and may be released only to the patient or prescriber or, as the patient or prescriber directs; to those practitioners, other authorized health care professionals, and other pharmacists where, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well-being; and to such other persons or governmental agencies authorized by law to receive such confidential information, regardless of whether such information is in the form of paper, preserved on microfilm, or is stored on electronic media.

(2) “Electronic transmission” means transmission of information in electronic form such as computer-to-computer, electronic device to computer, e-mail, or the transmission of the exact visual image of a document by way of electronic equipment.

(3) “Prescription drug order” means a lawful order of a practitioner for a drug or device for a specific patient that is communicated to a pharmacist.

(b) Patient confidentiality requirements:

(1) Prescription information and other patient health care information shall be maintained in a manner that protects the integrity and confidentiality of such information as provided by rules of the Board.

(2) The pharmacy shall provide a mechanism for patients to prevent the disclosure of any information (confidential or otherwise) about them that was obtained or collected by the pharmacist or pharmacy incidental to the delivery of pharmaceutical care other than as authorized by law or rules of the Board.

(3) The pharmacist in charge shall:

(A) Establish written policies and procedures for maintaining the integrity and confidentiality of prescription information and patient health care information. All employees of the pharmacy, with access to any such information, shall be required to read, sign, and comply with the established policies and procedures.

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

(c) Manner of issuance of a prescription drug order

(1) A prescription drug order may be transmitted to a pharmacy by electronic transmission. If transmitted by way of electronic transmission, the prescription drug order shall be immediately reduced to a form, by the pharmacist, that may be maintained for the time required by law or rules. Persons other than those bound by a confidentiality agreement, pursuant to a consent agreement, shall not have access to pharmacy records containing personally identifiable confidential information concerning the pharmacy's patients or prescribers.

(2) All prescription drug orders, communicated by way of electronic transmission shall:

(A) Be sent only to the pharmacy of the patient's choice with no intervening person having access to the prescription drug order.

(B) Identify the transmitter's phone number for verbal confirmation, the time and date of transmission, and the pharmacy intended to receive the transmission -- as well as any other information required by federal or state law.

(C) Be transmitted by the authorized practitioner or the designated agent of the practitioner.

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

(3) All electronic equipment, for receipt of prescription drug orders communicated by way of electronic transmission, shall be maintained so as to ensure against unauthorized access. The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the prescription drug order consistent with existing federal or state laws or regulations.

(4) The prescribing practitioner may authorize his or her agent to transmit a prescription drug order, by electronic transmission, to the pharmacy -- provided that the identity of the transmitting agent is included in the order.

(d) Patient records:

(1) Personally identifiable confidential information in the patient medication record, may be released to the patient, the prescriber, other licensed practitioners then caring for the patient, another licensed pharmacist, the Board or it's representatives, or any other person duly authorized by law to receive such information. Personally identifiable confidential information, in the patient medication record, may be released to others only on written release of the patient. Personally identifiable confidential information, in the patient medication record related to identity of the prescriber, may be released only on written release of the prescriber.

(e) Discipline:

The Board of Pharmacy may refuse to issue or renew, or may suspend, revoke, restrict the licenses or the registration of, or fine any person for divulging or revealing confidential information to a person other than as authorized by rules of the Board.

(e) Security:

To maintain the confidentiality of patient and prescriber records, the computer system shall have adequate security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. Once the drug has been dispensed, any alterations in prescription drug order data shall be documented -- including the identification of the pharmacist responsible for the alteration.

(f) Providing electronic equipment by pharmacists or pharmacies to practitioners or health care facilities prohibited

A pharmacist or pharmacy shall not provide a computer modem or other similar electronic device to a prescriber or health care facility for the purpose of providing an incentive to the practitioner or health care facility to refer patients to a particular pharmacy or department. This shall not prohibit a hospital from providing in-house equipment for the use of practitioners and the hospital pharmacy to communicate within the facility. (Amended 10/2000, 3/2001)

07-00-0009—PROPER PRACTITIONER-PATIENT RELATIONSHIP

In accordance with Ark. Code Ann. § 17-92-1004(c) and Ark. Code Ann. § 17-92-1003(15), an in-person physical exam of the patient performed by a practitioner, physician, doctor or other prescribing health professional ("a practitioner") prior to the issuance of any prescription is required in order to establish a valid prior patient-practitioner relationship for purposes of Ark. Code Ann. § 17-92-1004(c) and a "Proper Physician-Patient Relationship" for purposes of Ark. Code Ann. § 17-92-1003(15), unless:

(a) the prescribing practitioner is consulting at the specific request of another practitioner who:
    (1) maintains an ongoing relationship with the patient;
    (2) has performed an in-person physical exam of the patient; and
    (3) has agreed to supervise the patient's ongoing care and use of prescribed medications; or
(b) the prescribing practitioner interacts with the patient through an on-call or cross-coverage situation.(Emergency 10/31/2007, 2/25/2008)

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

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

(a) Any wholesale drug company or drug manufacturer, doing business in Arkansas pursuant to Act 173 of 1969, as amended by Act 75 of 1979 and Act 257 of 1981, shall not distribute any controlled substance or legend drug or both in the State of Arkansas, if that product requires approval by the Food and Drug Administration for marketing and distribution, and the product, in fact has not been approved for marketing and distribution by the Food and Drug Administration.
(b) Violation of this regulation shall be grounds for suspension or revocation of the license of the wholesale drug or drug manufacturer's license to do business in the State of Arkansas. (10/14/81)

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

(a) In order to provide for the protection of the public health and safety, drug products which are offered for sale by, or stored at the premises of any manufacturer, distributor, wholesaler, or pharmacy located in Arkansas must have an approved new drug application (NDA) or abbreviated new drug application (ANDA) designation by the Federal Food and Drug Administration pursuant to 21 USC 355 unless they are exempt from the requirements for such a designation.

    In order to protect the public health and safety, drug products offered for sale by, or stored at the premises of, a manufacturer, wholesaler, distributor, or pharmacy location in Arkansas, which do not have the required NDA or ANDA, or exemption there from referenced in the above paragraph, are hereby declared to be contraband and subject to surrender to and destruction by the Arkansas State Health Department.
(b) Whenever it is made to appear to the Board that any licensee of the Arkansas State Board of Pharmacy is in possession of a stock of drugs which are contraband as defined above, a representative of the Board shall confirm with the Federal Food Drug Administration, by telephone, that the particular drug or drugs involved do not have the requirement. Upon receipt of this confirmation, the Board shall inform the owner, or person in charge, of the contraband status of the drugs in question.
(c) Retention, dispensing, promotion, or advertisement of drug products by a licensee of the Board of Pharmacy, either at their business premises or at any separate storage facility after notification of their contraband status, shall constitute a direct and immediate danger to the public health and safety and will be good and sufficient cause for the suspension or revocation of any license issued by the Board of Pharmacy for knowingly retaining, dispensing, promoting, or advertising any drug products which are contraband under this regulation.

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

07-02: COMPOUNDING

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

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

Compounding a drug product that is commercially available in the marketplace or that is essentially a copy of a commercially available FDA-approved drug product is generally prohibited. However, in special circumstances a pharmacist may compound an appropriate quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available based on documentation provided by the prescribing physician of a patient specific medical need (e.g. the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available. The unavailability of such drug product must be documented prior to compounding. The recommended methodology for documenting unavailability is to print the screen of wholesalers showing back-ordered, discontinued, or out-of-stock items. This or similar documentation must be available when requested by the Board.

Except for those products where stability prohibits advanced compounding, all products dispensed by the pharmacy shall be in a form ready for administration, except in health care facilities where medications may be provided as demanded by policies and procedures.

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

(a) Guidelines for preparation of sterile products will be based on the distinction of sterile products as either low-risk, medium-risk or high-risk products.
  (1) Sterile products compounded under all of the following conditions are considered low-risk sterile products:
    (A) The finished products are compounded with aseptic manipulations entirely within a Class 100 environment or better air quality using only sterile ingredients, products, components, and devices.
    (B) The compounding involves only transfer, measuring, and mixing manipulations with closed or sealed packaging systems that are performed promptly and attentively.
    (C) Manipulations are limited to aseptically opening ampules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices and packages of other sterile products.
    (D) For a low-risk preparation, in the absence of passing a sterility test, the storage periods shall not exceed the following time periods: before administration, the sterile products are exposed for no more than forty-eight (48) hours at controlled room temperature, fourteen (14) days at two (2) to eight (8) degrees centigrade, and forty-five (45) days in solid frozen state at negative twenty (–20) degrees centigrade or colder, while properly stored.

(2) When sterile products compounded aseptically under low-risk conditions, and one or more of the following conditions exists, such products are considered medium-risk sterile products:
   (A) Multiple individual or small doses of sterile products are combined or pooled to prepare a sterile product that will be administered either to multiple patients or to one patient on multiple occasions.
   (B) The compounding process includes complex aseptic manipulations other than the single-volume transfer
   (C) The compounding process requires unusually long duration, such as that required to complete the dissolution or homogeneous mixing.
   (D) The sterile products do not contain broad-spectrum bacteriostatic substances, and they are administered over several days.
   (E) For a medium-risk preparation, in the absence of passing a sterility test, the storage periods shall not exceed the following time periods: before administration, the sterile products are exposed for no more than thirty (30) hours at controlled room temperature, seven (7) days at two (2) to eight (8) degrees centigrade, and forty-five (45) days in solid frozen state at negative twenty (–20) degrees centigrade or colder, while properly stored.

(3) Sterile products compounded under any of the following conditions are considered high-risk sterile products:
   (A) Nonsterile ingredients are incorporated, or a nonsterile device is employed before terminal sterilization
   (B) Sterile ingredients, components, devices, and mixtures are exposed to air quality inferior to a Class 100 environment. This includes storage in environments inferior to a Class 100 environment of opened or partially used packages of manufactured sterile products that lack antimicrobial preservatives.
   (C) Nonsterile preparations are exposed no more than 6 hours before being sterilized.
   (D) It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients.
   (E) For a high-risk preparation, in the absence of passing a sterility test, the storage periods shall not exceed the following time periods: before administration, the sterile products are exposed for no more than twenty-four (24) hours at controlled room temperature, three (3) days at two (2) to eight (8) degrees centigrade, and forty-five (45) days in solid frozen state at negative twenty (–20) degrees centigrade or colder, while properly stored.

(b) Pharmacist requirements:
Any pharmacist in charge who performs or supervises the preparation or sterilization of sterile medications shall:
(1) Have available written policies and procedures for all steps in the compounding of sterile preparations. In addition, said policies and procedures shall address personnel education and training and evaluation, storage and handling, clothing, personal hygiene, hand washing, aseptic technique, quality assurance, expiration dating, and other procedures as needed.
(2) Certify that all participating pharmacists and pharmacy technicians have completed a Board approved training and testing program in sterile product preparation. Documentation of training and testing shall be available for review, by February 30, 2002.

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

(c) Pharmacy technician requirements:
Pharmacy technicians participating in the preparation of sterile products shall have completed a Board approved pharmacist supervised training and testing program in sterile product preparation as described in Board regulation 03-00-0006 (b). Documentation of training and testing shall be available.

(d) Work area and equipment:
Any pharmacy dispensing sterile parenteral solutions shall meet or exceed the following requirements:

(1) A separate controlled limited access area (also called a buffer area or buffer room) for compounding sterile solutions, which shall be of adequate space for compounding, labeling, dispensing, and sterile preparation of the medication. This area shall have controlled temperature and humidity. Cleanliness of the area is of critical importance. Drugs and other materials, taken into the limited access area, shall be removed from cardboard and other particle generating materials before being taken into the area.

(2) The controlled limited access area shall have a certified and inspected Class100 environment. Such an environment exists inside a certified laminar airflow hood (clean room, biological safety cabinet or other barrier isolator meeting Class 100 requirements) used for the preparation of all sterile products. The Class 100 environment device or area is to be inspected and certified yearly. Barrier isolator workstations are closed systems and are not as sensitive to their external environment as laminar airflow equipment. It is recommended to place them in a limited access area with cleaning and sanitizing in the surrounding area on a routine basis.

(3) Hazardous drugs shall be prepared within a certified Class 11, Type A (exhaust may be discharged to the outdoors) or Class 11, Type B (exhaust may be discharged to the outdoors) laminar flow biological safety cabinet. The Class 11, Type B can be obtained with a “bag in-bag out” filter to protect the personnel servicing the cabinet and facilitate disposal. When preparing cytotoxic agents, gowns and gloves shall be worn. All new construction, and those undergoing renovation requiring the moving of existing hoods used in the preparation of cytotoxic drugs, shall exhaust the hood to the outdoors, unless the Board of Pharmacy grants an exception. The cabinet of choice is a Class 11, Type B. For the purpose of this regulation, hazardous drugs shall be defined as agents that exhibit characteristics of genotoxicity, carcinogenicity, teratogenicity, or evidence of serious organ or other toxicity at low doses.

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

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

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

(e) Storage:
All pharmacies preparing and dispensing sterile products must provide:

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

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

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

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

(f) Labeling:
In addition to regular labeling requirements, the label shall include:
(1) Parenteral products shall have the rate of infusion when applicable.
(2) Expiration date (Policies and procedures shall address label change procedures as required by physician orders.)
(3) Storage requirements or special conditions.
(4) Name of ingredients and amounts contained in each dispensing unit.
(5) All products dispensed to outpatients, and removed from the site of preparation for administration different than the site of preparation, shall have label information as required by state law.

(g) Shipping:
(1) Policies and procedures shall assure product stability during delivery.
(2) Pharmacy must assure ability to deliver products within an appropriate time frame.

(h) Home patient care services:
The pharmacist in charge of the pharmacy dispensing sterile parenteral solutions shall provide the following or assure that they are provided prior to providing medications.
(1) The pharmacist must assure that the patient is properly trained if self-administering.
(2) In situations where a pharmacy or pharmacist employs a nurse to administer medications, the pharmacist in charge must:
(A) Employ a registered nurse.
(B) Assure that proper records are maintained in compliance with laws and regulations.
(C) Make these records available to inspectors from appropriate agencies.
(3) 24-hour service shall be assured by the pharmacy.
(4) Pharmacists shall recommend and monitor clinical laboratory data as requested.
(5) Side effects and potential drug interactions should be documented and reported to the physician.
(6) Patient histories and therapy plans should be maintained.

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

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

(j) When preparing high-risk sterile products, the pharmacist in charge is responsible for making sure the above procedures, in addition to the following, shall be met:
(1) Compound all medications in one of the following environments:
(A) A separate controlled limited access area with a positive air flow room inspected and certified as meeting Class 10,000 requirements (Class 10,000 as defined by Federal Standard 209E).
(B) An enclosed room providing a Class 100 environment for compounding.
(C) A barrier isolator that provides a Class 100 environment for compounding.

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

(2) Use total aseptic techniques, including gowning, mask, and hair net. Scrubs may be worn, instead of gowning, if not worn or covered outside of the controlled limited access area.
(3) Provide a system for tracking each compounded product including:
(A) Personnel involved in each stage of compounding;
(B) Raw materials used including quantities, manufacturer, lot number, and expiration date;
(C) Labeling;
(D) Compounding records shall be kept for 2 years.
(4) Establishment of procedures for sterilization of all products prepared with any non-sterile ingredients by filtration with 0.22 micron or other means appropriate for the product components.
(5)
(A) All high-risk level compounded sterile products for administration by injection into the vascular and central nervous systems that are prepared in groups of more than twenty-five (25) identical individual single-dose packages (such as ampules, bags, syringes, and vials), or in multiple dose vials for administration to multiple patients, or are exposed longer than twelve (12) hours at a two (2) to eight (8) degrees centigrade and longer than six (6) hours at warmer than eight (8) degrees centigrade before they are sterilized shall be tested to ensure they are sterile, do not contain excessive bacterial endotoxins, and are of labeled potency before they are dispensed or administered as provided below.
(B) Sterility Testing (Bacterial and Fungal) – The USP Membrane Filtration Method is the method of choice where feasible (e.g. components are compatible with the membrane). The USP Direct Transfer Method is preferred when the membrane filtration is not feasible. An alternative method may be used if verification results demonstrate that the alternative is at least as effective and reliable as the USP Membrane Filtration Method or the USP Direct Transfer Method. The pharmacist in charge shall establish written procedures requiring daily observation of the media and requiring an immediate recall if there is any evidence of microbial growth and said procedures must be available to Board inspectors.
(C) Bacterial Endotoxin (Pyrogen) Testing – The USP Bacterial Endotoxin Test, or verified equivalent, shall be used to ensure compounded sterile products do not contain excessive endotoxins.
(D) Potency Testing – The potency of all compounded products meeting the criteria described in Board regulation 07-02-0001 (j) (5) above must be tested to verify the potency stated on the label. Products for which there is no known or commercially available potency test standard require Board approval prior to compounding.
(E) The USP Membrane Filtration Method and the USP Direct Transfer Method are the membrane filtration and direct transfer methods described in Chapter 71,United States Pharmacopeia (“USP”), 2001 Edition. The USP Bacterial Endotoxin Test is the bacterial filtration test described in Chapter 85, USP, 2001 Edition. Should there be any amendment or change in any of the above methods or test by USP subsequent to the effective date of this paragraph, said change or amendment to USP shall be effective under this regulation after the expiration of thirty (30) days from the effective date of said change or amendment, unless within said time period, the Executive Director objects to said change or amendment. In that case, the Executive Director shall publish the reasons for objection and afford all interested parties an

opportunity to present commentary; said notice and commentary shall be pursuant to A.C.A. § 25-15-204, as amended, and the resulting decision by the Board shall be reflected by an amendment to this regulation.

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

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

07-02-0002—GOOD COMPOUNDING PRACTICES

(a) This regulation describes the requirements of minimum current good compounding practice for the preparation of drug products by pharmacies or other facilities with permits issued by the Arkansas State Board of Pharmacy.

Compounding a drug product that is commercially available in the marketplace or that is essentially a copy of a commercially available FDA-approved drug product is generally prohibited. However, in special circumstances a pharmacist may compound an appropriate quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available based on documentation provided by the prescribing physician of a patient specific medical need (e.g. the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available. The unavailability of such drug product must be documented prior to compounding. The recommended methodology for documenting unavailability is to print the screen of wholesalers showing back-ordered, discontinued, or out-of-stock items. This or similar documentation must be available when requested by the Board.

(b) Definitions:

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

(1) "Compounding" means preparation, mixing, assembling, packaging, and labeling of a drug or device as the result of a duly authorized practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice.

(A) Compounding may also be for the purpose of, or as an incident to, research, teaching, or chemical analysis.

(B) Compounding includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(C) Reconstitution of commercial products is not considered compounding for the purposes of this regulation.

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

(3) "Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substance(s) or labeling or re-labeling of its container, and the promotion and marketing of such drugs or devices. Manufacturing also includes any preparation of a drug or device that is given or sold for resale by pharmacies, practitioners,

or other persons. The distribution of inordinate amounts of compounded products, without a practitioner/patient/pharmacist relationship is considered manufacturing.

(4) "Pharmacy generated products" means a medical product that is prepared, packaged, and labeled in a pharmacy that can be sold by the pharmacy without a prescription.

(c) Pharmacist responsibilities:

(1) All pharmacists, who engage in drug compounding, shall be proficient in compounding and shall continually expand their compounding knowledge by participating in seminars and/or studying appropriate literature.

(2) The pharmacist has the responsibility to:

(A) Assure the validity of all prescriptions;

(B) Approve or reject all components, drug product containers, closures, in-process materials, and labeling;

(C) Prepare and review all compounding records and procedures to ensure that no errors have occurred in the compounding process;

(D) Ensure the proper maintenance, cleanliness, and use of all equipment used in a prescription compounding practice;

(E) Ensure only personnel authorized by the pharmacist in charge shall be in the immediate vicinity of the drug compounding operation.

(d) Drug compounding facilities:

(1) Pharmacies engaging in compounding shall have a specifically designated and adequate area (space) for the orderly compounding of prescriptions, including the placement of equipment and materials.

(2) The aseptic processing for sterile products shall be in an area separate and distinct from the area used for the compounding of non-sterile drug products.

(3) The area(s) used for the compounding of drugs shall be maintained in a good state of repair.

(4) Bulk drugs and other chemicals or materials used in the compounding of drugs must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.

(5) Adequate lighting and ventilation shall be provided in all compounding areas.

(6) Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product.

(7) These area(s) used for compounding shall be maintained in a clean and sanitary condition.

(8) If parenteral products are being compounded, standards set out in Board Regulation 07-02-0001 must be met.

(e) Compounding equipment

(1) Equipment used in the compounding of drug products shall be of appropriate design and capacity as well as suitably located to facilitate operations for its intended use, cleaning, and maintenance.

(2) Compounding equipment shall be of suitable composition so the surfaces that contact components shall not be reactive, additive, or absorptive so as to alter the purity of the product compounded.

(3) Equipment and utensils used for compounding shall be cleaned and sanitized immediately prior to use to prevent contamination.

(4) Equipment and utensils must be stored in a manner to protect from contamination.

(5) Automated, mechanical, electronic, limited commercial scale manufacturing or testing equipment, and other types of equipment may be used in the compounding of drug products.

If such equipment is used, it shall be routinely inspected, calibrated (if necessary), or checked to ensure proper performance.

(6) Immediately prior to the initiation of compounding operations, the equipment and utensils must be inspected by the pharmacist and determined to be suitable for use.

(7) When drug products with special precautions (antibiotics, hazardous materials and cytotoxins) are involved, appropriate measures must be utilized in order to prevent cross-contamination and proper disposal procedures must be followed. These measures include either the dedication of equipment for such operations or the meticulous cleaning of equipment prior to its use for the preparation of other drugs.

(f) Component selection requirements:

(1) Pharmacists shall first attempt to use United States Pharmacopoeia / The National Formulary (USP-NF) drug substances for compounding that have been made in ~~an~~ a Food and Drug Administration registered facility.

(2) If components are not obtainable from an FDA registered facility or if the Food and Drug Administration and/or the company cannot document Food and Drug Administration registration, pharmacists compounding prescriptions shall use their professional judgment in first receiving, storing, or using drug components that meet official compendia requirements or another high quality source.

(g) Control of drug products:

(1) Drug product containers and closures shall be handled and stored in a manner to prevent contamination and to permit inspection and cleaning of the work area.

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

(h) Drug compounding controls:

(1) There shall be written procedures for the compounding of drug products to assure that the finished products have the identity, strength, quality and purity they purport or are represented to possess.

(2) Procedures shall include a listing of the components, their amounts (in weight or volume), the order of component mixing, and a description of the compounding process.

(3) All equipment and utensils and the container/closure system relevant to the sterility and stability of the intended use of the drug shall be listed.

(4) All written procedures shall be followed in the execution of the compounding procedure.

(5) Components shall be accurately weighed, measured, or subdivided as appropriate. These operations should be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight and measure is correct as stated in the written compounding procedures.

(6) Written procedures shall be established and followed that describe the tests or examination to be conducted on the product compounded (e.g. degree of weight variation among capsules) to ensure reasonable uniformity and integrity of compounded drug products.

(A) Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product.

(B) Such control procedures shall include, but are not limited to, the following (where appropriate):

(i) capsule weight variation;

(ii) adequacy of mixing to assure uniformity and homogeneity; and

(iii) clarity, completeness or pH of solutions.

(7) Appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile shall be established and followed. Such procedures shall follow accepted standards of practice and/or include validation of any sterilization process.

(8) Beyond use dates and storage requirements (e.g. refrigeration) should be established. The USP-NF guidelines should be used.

(i) Labeling:

(1) If a component is transferred from the original container to another (e.g. a powder is taken from the original container, weighed, placed in a container) and stored in another container, the new container shall be identified with the:
(A) component name;
(B) lot and expiration date if available;
(C) strength and concentration;
(D) weight or measure; and
(E) route of administration

(2) Products prepared in anticipation of a prescription prior to receiving a valid prescription should not be an inordinate amount.
(A) A regularly used amount should be prepared based on a history of prescriptions filled by the pharmacy.
(B) These products shall be labeled or documentation referenced with the:
(i) complete list of ingredients or preparation name and reference;
(ii) federal expiration date—up to one (1) year;
(iii) assigned beyond –use date:
(a) based on published data, or;
(b) appropriate testing, or;
(c) USP-NF standards.
(iv) storage under conditions dictated by its composition and stability (e.g., in a clean, dry place or in the refrigerator); and
(v) batch or lot number.

(3) Upon the completion of the drug preparation operation, the pharmacist shall examine the product for correct labeling.

(4) The prescription label shall contain the following:
(A) patient name;
(B) prescriber's name;
(C) name and address of pharmacy;
(D) directions for use;
(E) date filled;
(F) beyond use date and storage (may be auxiliary labels); and
(G) an appropriate designation that this is a compounded prescription, with reference to active ingredients.

(j) Records and Reports:

(1) Any procedures or other records required to comply with good compounding practices shall be retained for the same period of time as required for retention of prescription records.

(2) All records required to be retained under good compounding practices, or copies of such records, shall be readily available for authorized inspection.

(3) Computer information and the hard copy of the prescription should indicate that the prescription is to be compounded.
(4) Adequate records must be kept of controlled substances (Scheduled drugs) used in compounding.

(k) Pharmacy generated product requirements:
(1) A pharmacy generated product (PGP) may be prepared from legend drugs, not to exceed recommended strengths and doses.
(2) PGP will be labeled properly and will be sold with the public's health and welfare in mind.
(3) PGP cannot be bulk compounded to sell to a second entity for resale. This would require a manufacturer's permit.

(l) Compounding for a prescriber's office use:
(1) Pharmacies may prepare compounded drug products for a duly authorized prescriber's office use.
(2) An order by the duly authorized prescriber, indicating the formula and quantity ordered, will be filed in the pharmacy.
(3) The product is to be administered in the office and not dispensed to the patient. The product shall be labeled "For Office Use Only—Not for Resale".
(4) A record of the compounded drug product may be kept as a prescription record in the pharmacy computer.
(5) A label may be generated and a number assigned by the pharmacy computer for the compounded drug product.
(6) Patient specific prescriptions for controlled substances cannot be filled "for office or medical bag use".
(7) A retail pharmacy is not precluded from making more that five percent (5%) of its annual sales to licensed practitioners. The pharmacy must, however, obtain a State Wholesale Legend Drug and/or Controlled Substance Distributor Permit.

(m) Compounding veterinarian products:
(1) Prescriptions for animals may be compounded based on an order or prescription from a duly authorized prescriber.
(2) These prescriptions are to be handled and filled the same as the human prescriptions.
(3) Patient specific prescriptions for controlled substances cannot be filled "for office or medical bag use".

(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.

(b) Licensees of the Arkansas State Board of Pharmacy may not dispense a quantity of a Schedule II Narcotic that exceeds the prescriber's authority to prescribe. (Amended 11/1/2017)

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

The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription).

The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

A prescription, for a Schedule II controlled substance written for a patient in a long-term-care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness, may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist may contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record, on the prescription, whether the patient is "terminally ill" or an "LTCF patient".

For each partial filling, the dispensing pharmacist shall record, on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable), the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.

Prior to any subsequent partial filling, the pharmacist is to determine that the additional partial filling is necessary. The total quantity of Schedule II controlled substances dispensed, in all partial filling, must not exceed the total quantity prescribed. A Schedule II prescription for a patient in a LTCF or a patient with a medical diagnosis documenting a terminal illness, if partially filled, shall be totally dispensed within sixty (60) days and dispensing cannot occur after sixty (60) days or after the medication has been discontinued by the prescriber.

07-04-0003—COMPUTER RECORDS FOR PARTIAL FILLING

Information, pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness, may be maintained in a computerized system -- if the system has the capability to permit:

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

The authority to dispense Schedule II prescriptions for partial quantities does not apply to other classes of patients -- such as a patient with severe intractable pain who is not diagnosed as terminal.

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

Prescriptions written for Schedule II controlled substances may be dispensed up to six (6) months from the date written if the pharmacist is certain of the validity of the prescription. An exception to this would be prescriptions written for a patient classified as terminally ill or a long-term-care facility patient and these prescriptions are valid for 60 days from date of issue and may be partially filled. (2/15/95, Amended 10/14/97)

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

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

(a) Notify Arkansas Department of Health Division of Pharmacy Services and Drug Control, the nearest Drug Enforcement Administration Diversion Field Office, and the Arkansas State Board of Pharmacy immediately upon discovery by phone or fax, and
(b) Deliver a completed DEA Form-106 to each of the agencies listed in (a) within 7 days of the occurrence of said loss or the discovery of said loss.

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

07-04-0006—SCHEDULE V--EXEMPT PRODUCTS & PHARMACIST-AUTHORIZED DRUGS

(a) A Pharmacist-Authorized Drug is a nonprescription drug that is subject to the same restrictions as are imposed for ephedrine, pseudoephedrine, or phenylpropanolamine under Ark. Code Ann. § 5-64-1103(c) and (d)(4) and § 5-64-1104.

(b) A pharmacist may dispense a Schedule V exempt product or a Pharmacist Authorized Drug only after making a professional determination that there is a legitimate medical and pharmaceutical need for the product. A pharmacist must base the decision to dispense on factors relevant to the patient's medical need and the appropriateness of the requested product, including, without limitation:
    1. the patient's medication filling history as maintained in the pharmacy's system;
    2. the pharmacist's personal knowledge of the patient; and/or
    3. the pharmacist's screening of the patient's existing medical conditions and physical symptoms as appropriate for the treatment being considered. The screening may include a review of the patient's medical history, disease history, prescription history, physical symptoms, and relevant vital signs, such as blood pressure. All screening performed by the pharmacist must be documented and maintained in the patient's pharmacy record.

(c) A pharmacist should not dispense a Schedule V exempt product or Pharmacist Authorized Drug if the pharmacist is aware of information indicating that the patient is inappropriately self-medicating. If the patient does not provide a satisfactory explanation regarding inappropriate self-medicating, the pharmacist must decline to dispense the product and refer the patient to a physician.
    1. For ephedrine, pseudoephedrine, or phenylpropanolamine products, a pharmacist should question a patient regarding inappropriate self-medicating when records indicate that the patient may be exceeding the maximum recommended daily dose.
    2. For Schedule V exempt narcotics, a pharmacist should question a patient regarding inappropriate self-medicating when records indicate that the patient has been dispensed a Schedule V exempt product:
        A. more than ten (10) days;
        B. more than twice in a thirty (30) day period;
        C. more than four (4) times in two (2) consecutive months; or
        D. every month.

(d) The Arkansas State Board of Pharmacy may revoke or suspend a certificate of licensure, license, registration or permit or may refuse to issue a certificate of licensure, license, registration or permit to any person or entity that dispenses or sells a Schedule V exempt product or Pharmacist Authorized Drug in violation of a state or federal pharmacy law or regulation.

(e) A pharmacist is immune from civil liability for refusing to dispense, sell, transfer or otherwise furnish a Schedule V exempt product or Pharmacist Authorized Drug based on a professional determination or a determination of age or identity.

(f) Nothing in this regulation shall be interpreted to require that a Schedule V exempt product or Pharmacist Authorized Drug must be sold upon request. There shall be no penalty or other disciplinary action taken against a pharmacist who chooses not to sell these products to a patient or individual. (Adopted 7/27/2011)

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

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

(a) Such dispensing is made only by a pharmacist and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a nonpharmacist);
(b) Not more than 240 cc. (8 ounces) of any such controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other such controlled substance nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given 48-hour period;
(c) The purchaser is at least eighteen (18) years of age;
(d) The pharmacist requires every purchaser of a controlled substance under this section not known to him to furnish suitable identification (including proof of age where appropriate);
(e) A bound record book for dispensing of controlled substances under this section is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of §21 CFR 1304.04); and
(f) A prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State or local law. (6/07/90 Revised 7/27/2011)

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

(a) As provided in Ark. Code Ann. § 5-64-1101, et seq., unless dispensed under a valid prescription, all sales or transfers of ephedrine, pseudoephedrine or phenylpropanolamine are subject to the following quantity limits and restrictions:

(1) In a single transaction, no more than three (3) packages of one (1) or more products that contain ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers;
(2) In a single transaction, no more than a single package of any product that contains ephedrine, pseudoephedrine, or phenylpropanolamine, that contains more than ninety-six (96) pills, tablets, gelcaps, capsules, or other individual units or more than three grams (3g) of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, or a combination of any of these substances, whichever is smaller;
(3) In a single transaction, any product containing ephedrine, pseudoephedrine, or phenylpropanolamine, unless:
(A) The product is sold in a package size of not more than three grams (3g) of ephedrine, pseudoephedrine, or phenylpropanolamine base and is packaged in a blister pack, each blister containing not more than two (2) dosage units;

(B) When the use of a blister pack is technically infeasible, that is packaged in a unit dose packet or pouch; or

(C) In the case of a liquid, the drug is sold in a package size of not more than three grams (3 g) of ephedrine, pseudoephedrine, or phenylpropanolamine base; or

(4) No product containing ephedrine, pseudoephedrine, or phenylpropanolamine may be sold or transferred to any person under eighteen (18) years of age, unless the person is purchasing an exempt product under Ark. Code Ann. § 5-64-1103 (b).

(5) No more than 5 grams of any product containing ephedrine or 9 grams of any product containing pseudoephedrine or phenylpropanolamine to a single patient in any 30 day period.

(b) A pharmacist may not dispense and a pharmacy technician or intern may not sell or transfer ephedrine, pseudoephedrine, or phenylpropanolamine unless the patient has provided either:

(1) a driver's license or non-driver's identification card issued by the Arkansas Department of Finance and Administration that contains a photograph of the person, the person's date of birth, and a functioning magnetic stripe or bar code; or

(2) An identification card issued by the United States Department of Defense to active duty military personnel and their dependents that contains a photograph of the person and the person's date of birth.

(c) In addition to documenting the professional determination required by Regulation 07-04-0006(a), a sale of ephedrine, pseudoephedrine, or phenylpropanolamine must also be approved by scanning the license or identification card into the real-time electronic logbook using the magnetic stripe or bar code except and unless using a military ID as described in regulation 07-04-0008 (b)(2) in which case the identification may be manually entered into the real-time electronic logbook.

(d) A pharmacist, pharmacy or pharmacy employee must also comply with Federal law prohibiting the sale of more than 3.6 grams of ephedrine, pseudoephedrine, or phenylpropanolamine to a patient in any 24 hour period. (Adopted 7/27/2011, Amended 5/31/2014)