

# Pharmacy Practice Act

## 17-92-101. Definitions

As used in this chapter:

- (1) "Biological product" means a biological product as defined by 42 U.S.C. 262(i)(1), as existing on January 1, 2019; and;
- (2) "Credentialing" means the issuance of or approval by the Arkansas State Board of Pharmacy of a credential issued to a pharmacist by an agency approved by the board certifying that the pharmacist has met the standards of competency established by the Arkansas State Board of Pharmacy for disease state management or other pharmacy services necessitating a credential;
- (3) "Dentist" means a practitioner of dentistry duly licensed under the laws of this or some other state;
- (4)
  - (A) "Disease state management" means a strategy that utilizes a team-oriented, multidisciplinary approach to improve health care outcomes and quality of care, and when possible, to control health care cost through management of targeted chronic disease states.
  - (B) Disease state management focuses on improving health care from prevention to diagnosis and treatment to ongoing follow-up.
  - (C) Disease state management will involve, but not be limited to, patient education, self-care techniques, and outpatient drug therapy management pursuant to a patient care plan;
- (5) "Drug" shall include all medicines and preparations recognized in the United States Pharmacopoeia or the National Formulary as substances intended to be used for the care, mitigation, or prevention of disease of either man or other animals;
- (6) "Generically equivalent" means a drug that is pharmaceutically and therapeutically equivalent to the drug prescribed;
- (7) "Interchangeable biological product" means a biological product that is interchangeable as defined by 42 U.S.C. 262(i)(3), as existing on January 1, 2019.
- (8)
  - (A) "Licensed pharmacist" means a person holding a license under the provisions of this chapter.
  - (B) A "licensed pharmacist" shall be considered an individual healthcare provider;
- (9) "Medicine" means a drug or preparation of drugs in suitable form for use as a curative or remedial substance;
- (10) "Optometrist" means a practitioner of optometry duly licensed under the laws of this state;
- (11) "Patient care plan" means a written course of action that is patient- or physician- or pharmacist-specific and disease-specific for helping a patient to achieve outcomes that improve a patient's quality of life;
- (12) "Pharmaceutically equivalent" means drug products that have identical amounts of the same active chemical ingredients in the same dosage form and that meet the identical, compendious, or other applicable standards of strength, quality, and purity according to the United States Pharmacopoeia or another nationally recognized

compendium;

- (13) “Pharmacy” means the place licensed by the Arkansas State Board of Pharmacy in which drugs, chemicals, medicines, prescriptions, and poisons are compounded, dispensed, or sold at retail;
- (14) “Pharmacy care” means the process by which a pharmacist in consultation with the prescribing practitioner identifies, resolves, and prevents potential and actual drug-related problems and optimizes patient therapy outcomes through the responsible provision of drug therapy or disease state management for the purpose of achieving any of the following definite outcomes that improve a patient's quality of life:
  - (A) Cure of disease;
  - (B) Elimination or reduction of a patient's symptomology;
  - (C) Arresting or slowing a disease process; or
  - (D) Preventing a disease or symptomology;
- (15) “Physician” means a practitioner of medicine duly licensed under the laws of this or some other state;
- (16) “Poisons” means any drug, chemical, medicine, or preparation liable to be destructive to adult human life in quantities of sixty (60) grains or less;
- (17)
  - (A) “Practice of pharmacy” means the healthcare provider profession of:
    - (i)
      - (a) Dispensing, selling, distributing, transferring possession of, vending, bartering, or, in accordance with rules adopted by the Arkansas State Board of Pharmacy, administering drugs, medicines, poisons, or chemicals that under the laws of the United States or the State of Arkansas may be sold or dispensed only on the prescription and order of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.
      - (b) Except as limited by rules adopted by the Arkansas State Board of Pharmacy, a pharmacist has the ability to administer medications.
      - (c) Influenza vaccines and influenza immunizations may be administered to a person seven (7) years of age and older under a general written protocol.
      - (d) Vaccines and immunizations other than influenza vaccines and influenza immunizations may be administered to a person from seven (7) years of age to eighteen (18) years of age general written protocol required under § 20-15-1203 if written consent of the parent or legal guardian of the minor is obtained before the administration of the vaccine or immunization.
      - (e) Vaccines and immunizations other than influenza vaccines and influenza immunizations may be administered to a person eighteen (18) years of age or older under a general written protocol.
      - (f) Medications other than vaccines and immunizations may be administered to a person seven (7) years of age or older under a patient-specific order or prescription and subject to reporting of the administration to the prescribing physician.
      - (g) A general written protocol under subdivisions (16)(A)(i)(c) and (e) of this section and patient-specific orders or prescriptions under subdivisions (16)(A)(i)(d) and (f) shall be from a

physician licensed by the Arkansas State Medical Board and practicing in Arkansas or within fifty (50) miles of the Arkansas border;

- (h) Under a statewide protocol, a pharmacist may initiate therapy and administer or dispense, or both, drugs that include Naloxone and nicotine replacement therapy products;
  - (ii) Placing, packing, pouring, or putting into a container for dispensing, sale, distribution, transfer of, possession of, vending, or bartering any drug, medicine, poison, or chemical that under the laws of the United States or the State of Arkansas may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals;
  - (iii) Placing in or affixing upon any container described in subdivision (16)(A)(ii) of this section a label required to be placed upon drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals;
  - (iv) Preparing, typing, or writing labels to be placed in or affixed on any container described in subdivision (16)(A)(ii) of this section, which label is required to be placed upon drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals;
  - (v) Interpreting prescriptions for drugs, medicines, poisons, or chemicals issued by practitioners authorized by law to prescribe drugs, medicines, poisons, or chemicals that may be sold or dispensed only on prescription;
  - (vi) Selecting, taking from, and replacing upon shelves in the prescription department of a pharmacy or apothecary drugs, medicines, chemicals, or poisons that are required by the laws of the United States or the State of Arkansas to be sold or dispensed only on prescription of a practitioner authorized by law to prescribe them;
  - (vii) Compounding, mixing, preparing, or combining drugs, medicines, chemicals, or poisons that under the laws of the United States or the State of Arkansas may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe them;
  - (viii) Advising and providing information concerning utilization of drugs and devices and participation in drug utilization reviews;
  - (ix)
    - (a) Performing a specific act of drug therapy management or disease state management delegated to a pharmacist for an individual patient based upon a written protocol or a patient care plan approved by a physician, who shall be licensed in this state under the Arkansas Medical Practices Act, § 17-95-201 et seq., § 17-95-301 et seq., and § 17-95-401 et seq.
    - (b) Drug therapy management shall not include the selection of drug products not prescribed by the physician unless the drug products are either named in the physician-initiated protocol or the physician-approved patient care plan;
  - (x) Providing pharmacy care; and
  - (xi) Providing pharmacokinetic services.
- (B) The provisions of subdivisions (16)(A) and (16)(C) of this section shall not apply to employees of wholesale drug companies or other drug distributors who do not fill prescriptions or sell or dispense drugs to the consumer.

- (C)
- (i) The Arkansas State Board of Pharmacy may permit pharmacy technicians other than pharmacists or interns to perform some or all of those functions described in board regulations under the direct, personal supervision of a licensed pharmacist pursuant to regulations defining the minimum qualifications of such employees, the ratio of pharmacy technicians to supervising pharmacists, and the scope of the duties, practices, and procedures that the Arkansas State Board of Pharmacy determines will promote the delivery of competent, professional pharmaceutical services and promote the public health and welfare. Nothing in this chapter shall be construed as allowing pharmacy technicians to administer medications.
  - (ii) The conduct of a pharmacy technician is the responsibility of the pharmacist-in-charge and supervising pharmacist of the pharmacy who shall not permit the employee to perform any act, task, or function that involves the exercise of independent judgment by the employee.
  - (iii) Pharmacy products prepared by pharmacy technicians shall be verified for accuracy by the supervising pharmacist prior to release for patient use, and the verification shall be documented.
  - (iv) The use of pharmacy technicians in a manner not authorized by this chapter or regulations promulgated hereunder shall be unprofessional conduct by the pharmacist-in-charge and the supervising pharmacist.
  - (v) It is recognized that hospital pharmacy technicians as defined in § 17-92-602(5) are governed by the Hospital Pharmacies Act, § 17-92-601 et seq., and related Arkansas State Board of Pharmacy regulations developed pursuant to that act;

(18)

- (A) "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 and may authorize the pharmacist to substitute a therapeutically equivalent drug that is at a lower cost to the patient and communicate that authorization by any generally accepted means of communication of a prescription from a prescriber to a pharmacist.
- (B) A substitution of a therapeutically equivalent drug shall occur only after the prescriber grants such authorization for each prescription.
- (C)
- (i) Before dispensing, the pharmacist shall discuss verbally any suggested substitution with the patient and inform the patient that the patient has a right to refuse the substitution.
  - (ii) The discussion under subdivision (17)(C)(i) of this section shall include without limitation:
    - (a) Notification to the patient that the therapeutically equivalent drug does not contain the identical active ingredient present in the prescribed drug; and
    - (b) All differences in dosage and frequency between the prescribed drug and the therapeutically equivalent drug.
- (D) The pharmacist shall send notice of the substitution to the prescriber in writing or by electronic communication within twenty-four (24) hours after the drug is dispensed to the patient.
- (E) Subdivision (17)(B) of this section does not apply to specific acts of drug therapy management or disease state management delegated to a pharmacist based upon a written protocol or patient care plan approved

by a physician under § 17-92-101(16)(A)(ix);

- (19) “Proprietary medicines”, when not otherwise limited, means remedies that a certain individual or individuals have the exclusive right to manufacture or sell;
- (20) “Supervision” means under the direct charge or direction of and does not contemplate any continued absence of such supervision;
- (21) “Therapeutic class” means a group of similar drug products that have the same or similar mechanisms of action and are used to treat a specific condition;
- (22) “Therapeutically equivalent” means drug products from the same therapeutic class that if administered in appropriate amounts will provide the same therapeutic effect, identical in duration and intensity;
- (23) “Veterinarian” means a practitioner of veterinary medicine duly licensed under the laws of this or some other state; and
- (24) “Written protocol” means a physician's order, standing medical order, standing delegation order, or other order or protocol as defined by regulation of the Arkansas State Medical Board under the Arkansas Medical Practices Act, § 17-95-201 et seq., § 17-95-301 et seq., and § 17-95-401 et seq.
- (25) “Statewide protocol” means a standardized procedure or protocol approved by the Arkansas State Board of Pharmacy and the Arkansas State Medical Board authorizing a pharmacist to initiate therapy and administer or dispense, or both, a drug or device.

#### **17-92-102. Exemptions**

- (a) Nothing in this section and §§ 17-92-101(1)-(11), 17-92-103, 17-92-105, 17-92-205(b), 17-92-206(b), 17-92-303, 17-92-402, 17-92-404, 17-92-405, 17-92-409, 17-92-410, and 17-92-411(a) shall prevent the personal administration of drugs and medicines carried and kept for emergencies by licensed physicians, dentists, or veterinarians in order to supply the immediate needs of their patients while in their presence, nor shall it apply to physicians, dentists, or veterinarians compounding or dispensing their own prescriptions.
- (b) The provisions of this section and §§ 17-92-101(1)-(11), 17-92-103, 17-92-105, 17-92-205(b), 17-92-206(b), 17-92-303, 17-92-402, 17-92-404, 17-92-405, 17-92-409, 17-92-410, and 17-92-411(a) shall not apply:
  - (1) To the sale of drugs and medicines when intended for agricultural, technical, and industrial use, unless those drugs and medicines are legend drugs as defined in § 20-64-503;
  - (2) To the sales by wholesale druggists, wholesale or retail grocers, or other wholesale or retail dealers or manufacturers of proprietary medicines in original packages; or
  - (3) To the sales of those drugs commonly known as “grocers' drugs” in original packages when put up under the direction of a licensed pharmacist of this or some other state.
- (c) Further exempted from the provisions of this section and §§ 17-92-101(1)-(11), 17-92-103, 17-92-105, 17-92-205(b), 17-92-206(b), 17-92-303, 17-92-402, 17-92-404, 17-92-405, 17-92-409, 17-92-410, and 17-92-411(a) are the sale of legend drugs approved by the State Board of Optometry by licensed pharmacists to duly licensed optometrists and the possession and use of legend drugs by duly licensed optometrists as authorized by the board and by §§ 17-90-401--17-90-403.
- (d) In the event a pharmacist receives a request for a prescription refill and the pharmacist is unable to obtain refill authorization from the prescriber, the pharmacist may dispense a one-time emergency refill of the prescribed medication, provided that:

- (1) The prescription is not for a medicinal drug listed in Schedule II as defined in § 5-64-205;
- (2) The medication is essential to the maintenance of life or to the continuation of therapy;
- (3) In the pharmacist's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort;
- (4) The pharmacist properly records the dispensing; and
- (5) The dispensing pharmacist notifies the prescriber of the emergency dispensing within a reasonable time after the one-time emergency refill dispensing.

**17-92-103. Pharmacy laws**

This section and §§ 17-92-101(1)-(11), 17-92-102, 17-92-105, 17-92-205(b), 17-92-206(b), 17-92-303, 17-92-402, 17-92-404, 17-92-405, 17-92-409, 17-92-410, and 17-92-411(a) shall not be construed to repeal any portion of the pharmacy laws in force prior to June 12, 1929, unless they are in direct conflict with these sections.

**17-92-104. Privilege taxes**

Nothing in this act shall be construed to repeal or anywise interfere with the collection of the privilege taxes now levied, or that may be levied, for state, county, or city purposes on the business of hawking, peddling, or street vending of goods, wares, and merchandise.

**17-92-105. Prohibited acts--Penalties**

- (a) Violation of any part of this section and §§ 17-92-101(1)-(11), 17-92-102, 17-92-103, 17-92-205(b), 17-92-206(b), 17-92-303, 17-92-402, 17-92-404, 17-92-405, 17-92-409, 17-92-410, and 17-92-411(a) not otherwise provided for shall be a violation and shall be punished by a fine of not less than twenty-five dollars (\$25.00) nor more than three hundred dollars (\$300).
- (b) Each day of violation shall constitute a separate offense.

**17-92-106. Violations; writs of injunction**

The Arkansas State Board of Pharmacy, in its discretion and in addition to various remedies now provided by law, may apply to a court having competent jurisdiction over the parties and subject matter for a writ of injunction to restrain repetitious violations of the pharmacy laws of this state.

**17-92-107. Prosecutions- Disposition of fines.**

- (a)
  - (1) All suits for the collection of any fine or penalty prescribed in this act may be instituted in any court having jurisdiction thereof by any citizen of the county wherein the fine or penalty is incurred.
  - (2) It shall be the duty of the prosecuting attorney of the county wherein the fine or penalty is incurred to prosecute all persons incurring them when notified by any citizen of the county.
- (b)
  - (1) Upon affidavit made before any justice of the peace by any citizen of the county showing a violation of this act, the justice of the peace shall issue his or her warrant as provided by law.
  - (2) However, the Arkansas State Board of Pharmacy or any member thereof, or its authorized agent, may institute and prosecute proceedings in any county in this state for violations of this act or for the

collection of any fine or penalty prescribed in this act in any court having jurisdiction.

- (c) All fines and penalties collected under the provisions of this act shall inure to the public school fund of the school district in which the offense was committed.

**17-92-108. Fees**

- (a) The fees charged by the Arkansas State Board of Pharmacy for the various examinations, permits, licenses, certificates, credentials, and books issued by the board shall be as follows:
  - (1) The fee for examination for a license as a licensed pharmacist upon examination shall not exceed twenty-five dollars (\$25.00) plus the actual cost of the examination;
  - (2) The fee for a license as a licensed pharmacist from another state by reciprocity and without examination shall not exceed two hundred dollars (\$200);
  - (3)
    - (A) The fee for the initial license as a licensed pharmacist shall not exceed seventy-five dollars (\$75.00).
    - (B) The fee for the renewal of a license as a licensed pharmacist shall not exceed seventy-five dollars (\$75.00) per year;
  - (4)
    - (A)
      - (i) The fee for issuance of a pharmacy permit for the first time to operate an in-state pharmacy shall not exceed three hundred dollars (\$300).
      - (ii) The fee for renewal of a permit to operate an in-state pharmacy shall not exceed one hundred fifty dollars (\$150) per year.
      - (iii) When there is a change in ownership in an in-state pharmacy, a new permit must be obtained, and the fee shall not exceed one hundred fifty dollars (\$150).
    - (B)
      - (i) The fee for issuance of a permit for the first time to operate a specialty pharmacy shall not exceed three hundred dollars (\$300).
      - (ii) The fee for renewal of a permit to operate a specialty pharmacy shall not exceed one hundred fifty dollars (\$150) per year.
      - (iii) When there is a change in ownership in a specialty pharmacy, a new permit must be obtained, and the fee shall not exceed one hundred fifty dollars (\$150).
    - (C)
      - (i) The fee for issuance of a permit for the first time to operate an out-of-state pharmacy shall not exceed three hundred dollars (\$300).
      - (ii) The fee for renewal of a permit to operate an out-of-state pharmacy shall not exceed one hundred fifty dollars (\$150) per year.
      - (iii) When there is a change in ownership in an out-of-state pharmacy, a new permit must be obtained, and the fee shall not exceed one hundred fifty dollars (\$150);

- (5) The fee for a certificate as a licensed pharmacist shall not exceed ten dollars (\$10.00);
- (6) The fee for certifying grades in connection with an application for reciprocity licensure without an examination shall not exceed ten dollars (\$10.00);
- (7)
  - (A) The fee for issuance of a hospital pharmaceutical service permit shall not exceed three hundred dollars (\$300), and the fee for the renewal of a hospital pharmaceutical service permit shall not exceed one hundred fifty dollars (\$150) per year.
  - (B) When there is a change in ownership of a hospital pharmacy, a new permit must be obtained, and the fee shall not exceed one hundred fifty dollars (\$150).
  - (C)
    - (i) The fee for issuance of an ambulatory care center pharmaceutical service permit shall not exceed three hundred dollars (\$300), and the fee for the renewal of an ambulatory care center pharmaceutical service permit shall not exceed one hundred fifty dollars (\$150) per year.
    - (ii) When there is a change in ownership of an ambulatory care center pharmacy, a new permit must be obtained, and the fee shall not exceed one hundred fifty dollars (\$150);
- (8)
  - (A) The fee for issuance of an institutional pharmaceutical services permit shall not exceed thirty-five dollars (\$35.00).
  - (B) The fee for the annual renewal of an institutional pharmaceutical services permit shall not exceed thirty-five dollars (\$35.00);
- (9)
  - (A) The fee for issuance of and the reinstatement of a nursing home consultant pharmacist permit shall not exceed thirty-five dollars (\$35.00).
  - (B) The fee for the renewal of a nursing home consultant pharmacist permit shall not exceed thirty-five dollars (\$35.00) per year;
- (10)
  - (A) The fee for intern registration shall not exceed forty-five dollars (\$45.00).
  - (B) The fee for preceptor registration shall not exceed twenty dollars (\$20.00) every two (2) years;
- (11) The fee for a change of pharmacist in charge of a pharmacy or other facility as described at § 17-92-403 shall not exceed thirty-five dollars (\$35.00);
- (12) The fee for reinstatement of a pharmacist licensure shall not exceed seventy-five dollars (\$75.00) for each delinquent year up to a maximum of three hundred dollars (\$300);
- (13) The fee for the Arkansas State Board of Pharmacy law book shall not exceed twenty-five dollars (\$25.00) except to interns on initial licensure and applicants for reciprocity on a one-time basis. A copy of each edition as revised shall be provided free to each pharmacy permit holder;
- (14) The fee for a change of location inspection shall not exceed one hundred dollars (\$100);
- (15) The penalty for late payment of renewal of any permit, license, registration, or certificate shall not exceed twenty dollars (\$20.00) per month beginning the first day of the second month after expiration,

provided that if the renewal is not paid by the first day of the fourth month after expiration, the license shall be void;

- (16)
  - (A) The fee for issuance of a wholesale distributor, third-party logistics provider, manufacturer, or outsourcing facility of legend drugs and controlled substances permit shall not exceed three hundred dollars (\$300), and the renewal fee shall not exceed one hundred fifty dollars (\$150) per year.
  - (B) When there is a change in ownership of a wholesale distributor, third-party logistics provider, manufacturer, or outsourcing facility of legend drugs and controlled substances, a new permit must be obtained, and the fee shall not exceed one hundred fifty dollars (\$150);
- (17)
  - (A) The fee for the original issuance of a pharmacy technician's permit shall not exceed thirty-five dollars (\$35.00).
  - (B) The fee for the renewal of a pharmacy technician's permit shall not exceed thirty-five dollars (\$35.00) per year.
  - (C) The board may waive the fees under subdivisions (a)(17)(A) and (B) of this section if the pharmacy technician performs pharmacy technician duties as a volunteer in a charitable clinic;
- (18)
  - (A) The reinstatement fee for a pharmacy technician's permit shall not exceed forty dollars (\$40.00).
  - (B) The board may waive the fee under subdivision (a)(18)(A) of this section if the pharmacy technician performs pharmacy technician duties as a volunteer in a charitable clinic; and
- (19)
  - (A) The application fee for a license to sell, rent, offer to sell, or rent directly to patients in this state any home medical equipment, legend drugs, or medical gases shall not exceed two hundred fifty dollars (\$250).
  - (B) The license renewal fee shall not exceed one hundred twenty-five dollars (\$125).
  - (C) The change-of-ownership fee shall not exceed one hundred twenty-five dollars (\$125).
- (b) All fees for examination for a license shall be payable with the application and shall not be subject to refund.
- (c) Should any license, certificate, or registration not be renewed within ninety (90) days after expiration thereof, it may be reinstated by the board as authorized in this section upon payment of the renewal fee and reinstatement fee. However, the following are not subject to reinstatement if not renewed within ninety (90) days after expiration:
  - (1) Pharmacy permits;
  - (2) Out-of-state pharmacy permits;
  - (3) Specialty pharmacy permits;
  - (4) Hospital permits;
  - (5) Ambulatory care center pharmacy permits;

- (6) Wholesale distributors, third-party logistics providers, manufacturers, or outsourcing facilities of legend drugs or controlled substance permits, or both; and
  - (7) Suppliers of medical equipment, legend devices, and medical gas licenses.
- (d)
- (1) All retail pharmacy permits, out-of-state pharmacy permits, specialty pharmacy permits, and pharmacist licenses shall be renewed every two (2) years beginning with renewals for 2002-2003.
  - (2) All pharmacy technician permits, hospital pharmacy permits, ambulatory care center pharmaceutical services permits, wholesale distributors, third-party logistics providers, manufacturers, or outsourcing facilities of legend or controlled substance permits, wholesale distributors of medical equipment, legend devices, and medical gases permits, institutional pharmaceutical services permits, and any other permit, license, registration, or certificate issued by the board and not covered in subdivision (d)(1) of this section other than internship licenses and preceptor permits shall be renewed every two (2) years.
  - (3) The fee for any biennial renewal term will be the amount of two (2) annual renewal fees for the applicable license, permit, registration, or certification as provided in subsection (a) of this section.
  - (4) If the initial licensure, permit, certificate, or registration occurs in the first year of a biennial renewal term, the applicant shall pay the appropriate initial fee and the applicable annual fee for the license, permit, certificate, or registration for the second year in the renewal term as provided in subsection (a) of this section.
  - (5) If the initial licensure, permit, certificate, or registration occurs in the second year of a biennial renewal term, the applicant will pay only the original fee and will not be responsible for the renewal fee until the biennial renewal period for the license, permit, certificate, or registration.

**17-92-111. Construction of Acts 1997, No. 1204.**

Nothing in this act shall be construed to authorize or permit any licensed or registered pharmacist to examine, diagnose, treat, or manage diseases or conditions of the human eye, lid, adnexa, or visual system or to adapt, fill duplicate, modify, prescribe, or sell contact lenses or prescription eyeglasses.

**17-92-113. Preservation of professional responsibilities of pharmacist--Prohibitions**

- (a) As used in this section:
  - (1) "Exercise of professional responsibilities" includes without limitation a pharmacist's or pharmacy's:
    - (A) Discussing any aspect of a patient's medical condition, treatment alternatives, or plan options with the patient;
    - (B) In good faith communicating with or advocating on behalf of a patient concerning the patient's needs; or
    - (C) Asserting rights under:
      - (i) The contract with the pharmacy benefits manager; or
      - (ii) State or federal law; and

- (2) "Pharmacy benefits manager" means a non-governmental entity that administers or manages a pharmacy benefits plan or program.
- (b) A pharmacy benefits manager shall not interfere with the exercise of professional responsibilities to a patient by a pharmacist or a pharmacy.

**17-92-114. Reciprocity**

The Arkansas State Board of Pharmacy may adopt rules applicable to a pharmacy or a pharmacist licensed in another state that renders services in Arkansas that mirror qualifications, requirements, prerogatives, prohibitions, and limitations imposed by the other state on Arkansas pharmacies and pharmacists rendering services in the other state.

**17-92-115. Requirements for administering and dispensing under a statewide protocol.**

- (a) When initiating therapy and administering or dispensing, or both, under a statewide protocol, a pharmacist shall:
  - (1) Notify the primary care provider of the patient of any drug or device furnished to the patient or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider;
  - (2) Provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice, if the patient does not have a primary care provider; and
  - (3)
    - (A) Make a standardized fact sheet available to the recipient of the drug or device.
    - (B) The standardized fact sheet shall include without limitation:
      - (i) The indications and contraindications for the use of the drug or device;
      - (ii) The appropriate method for the use of the drug or device;
      - (iii) The need for medical follow up; and
      - (iv) Other appropriate information.

**17-92-116. Exemption for home peritoneal kidney dialysis.**

- (a) The provisions of §§ 17-92-101, 17-92-103, 17-92-105, 17-92-205, 17-92-206, 17-92-303, 17-92-401, 17-92-402, 17-92-404, 17-92-405, 17-92-409, 17-92-410, 17-92-411, and 17-92-902 do not apply to the sale or distribution of dialysate or devices necessary to perform home peritoneal kidney dialysis to patients with end stage renal disease if:
  - (1) The dialysate composed of dextrose or icodextrin or devices are:
    - (A) Approved or cleared by the United States Food and Drug Administration as required by federal law;
    - (B) Lawfully held by a manufacturer or a third-party logistics provider of the manufacturer that is properly registered with the Arkansas State Board of Pharmacy as a wholesale distributor or medical device provider;
    - (C) Held and delivered in original, sealed packaging from the manufacturing facility; and

- (D) Delivered only by the manufacturer or a third-party logistics provider of the manufacturer and only upon receipt of a physician's order by a licensed pharmacy and the transmittal of an order from a licensed pharmacy to the manufacturer or a third party logistics provider of the manufacturer; and
- (2) The manufacturer or a third-party logistics provider of the manufacturer delivers the dialysate or devices directly to:
  - (A) A patient with end stage renal disease or a designee for the self-administration of the dialysis therapy; or
  - (B) A healthcare provider or institution for administration or delivery of the dialysis therapy to a patient with end stage renal disease.
    - (i) The board shall retain oversight of all other drugs for home peritoneal kidney dialysis with the exception of dialysate as described in subdivision (a)(1) of this section.
    - (ii) All records of sales and distribution of dialysate to patients under this section shall be retained according to state law and rule of the board.

**17-92-117. Prescriptions for all healthcare professionals**

- (a) As used in this section, "healthcare professional" means a person who is licensed, certified, or otherwise authorized by the laws of this state to administer health care in the ordinary course of the practice of his or her profession.
- (b) A pharmacist licensed in the State of Arkansas may fill prescriptions in the State of Arkansas for any healthcare professional who has prescriptive authority to the extent of that healthcare professional's scope of practice.

**17-92-201. Members--Qualifications**

- (a) The Arkansas State Board of Pharmacy shall consist of eight (8) members, appointed by the Governor for terms of six (6) years:
  - (1) Five (5) members shall be experienced pharmacists who have been actively engaged in the practice of pharmacy for the last five (5) years immediately preceding their appointments, to be appointed by the Governor after consulting the Arkansas Pharmacists Association and subject to confirmation by the Senate;
  - (2) One (1) member shall be a minority who is a licensed practicing pharmacist in this state, to be appointed by the Governor after consulting the Pharmaceutical Section of the Arkansas Medical, Dental, and Pharmaceutical Association and subject to confirmation by the Senate; and
  - (3)
    - (A) Two (2) members of the board shall not be actively engaged in or retired from the practice of pharmacy. One (1) member shall represent consumers, and one (1) member shall be sixty (60) years of age or older and shall represent the elderly. Both shall be appointed from the state at large, subject to confirmation by the Senate. Both shall be full voting members but shall not participate in the grading of examinations.
    - (B) The two (2) positions shall not be held by the same person.

- (b) A member shall hold his or her office until his or her successor shall have been appointed and qualified.
- (c)
  - (1) In case of a vacancy from death or other cause, the Governor shall appoint a successor with qualifications as set forth in subsection (a) of this section.
  - (2) In the event that a vacancy exists in the minority position due to death, resignation, or other cause, a successor member to the position shall be appointed by the Governor for the remainder of the unexpired portion of the term in the same manner as is provided for the initial appointment.

#### **17-92-202. Members' oath**

Before entering upon the duties of the office, the members of the Arkansas State Board of Pharmacy shall take the oath prescribed by the Constitution for state officers and shall file it in the office of the Secretary of State, who shall thereupon issue to each of the board members a certificate of appointment.

#### **17-92-203. Member compensation and reimbursement**

Members of the Arkansas State Board of Pharmacy may receive expense reimbursement and stipends in accordance with § 25-16-901 et seq.

#### **17-92-204. Organization and proceedings**

- (a) Immediately after the appointment and qualification of the Arkansas State Board of Pharmacy, the members shall meet and organize as the Arkansas State Board of Pharmacy, by electing from their own number a president and secretary.
- (b)
  - (1) The board shall hold not fewer than two (2) regular meetings per annum for the examination of candidates.
  - (2) One (1) meeting may be held at the time and place of the annual meeting of the Arkansas Pharmacists Association. The other meeting shall be held at a time and place as the board may determine.
  - (3) Other meetings of the board may also be held whenever and wherever a quorum of the board, including the secretary, is present.
- (c) A majority of the board shall be a quorum for the transaction of any business.
- (d) The board may adopt such bylaws as it deems necessary to carry into execution the provisions of this act without expense to the state.

#### **17-92-205. Rules and regulations- Enforcement**

- (a)
  - (1) The Arkansas State Board of Pharmacy shall have authority to make reasonable rules and regulations, not inconsistent with law, to carry out the purposes and intentions of this chapter and the pharmacy laws of this state that the board deems necessary to preserve and protect the public health.
  - (2) The board shall by regulation establish standards for the administration of medications by licensed pharmacists, including, but not limited to, the completion of a course in the administration of medications.

- (b) It shall be the duty of the board, through officials appointed by it or under its supervision for that purpose, to enforce all the provisions of this chapter.
- (c)
  - (1) Upon written authorization by the board, the board's inspectors or other designated agents shall have authority to conduct oversight activities authorized by law, including, but not limited to, audits, investigations, inspections, licensure, or disciplinary actions, civil, administrative, or criminal proceedings or actions, or other activities necessary for appropriate oversight of the regulated activities and may enter any store, business establishment, including any hospital pharmacy, or any other facility holding a license, permit, or other authority issued by the board where drugs, medicines, chemicals, pharmaceuticals, poisons, home medical equipment, or services or other objects, services, or activities regulated by the board are manufactured, sold, dispensed, or conducted to enforce this chapter, the Uniform Controlled Substances Act, §§ 5-64-101--5-64-510, § 5-64-1001 et seq., § 5-64-1101 et seq., the Food, Drug, and Cosmetic Act, § 20-56-201 et seq., or § 20-64-501 et seq.
  - (2)
    - (A) Upon written authorization by the board, the board's inspectors and other designated agents may obtain copies of any document, prescription, drug order, or other record or physical object relevant to the board's oversight of the regulated activity.
    - (B)
      - (i) With regard to hospital pharmacies, the board's inspectors and other designated agents may also view and at the board's expense make copies of identifiable records relating to patients in patient areas of the hospital if the records are relevant to an activity regulated by the board.(ii)
      - (ii) However, should any such record be in active use or storage at the time of the board's request to examine, obtain, or copy the record, the entity having control or possession of the record shall state in writing that the record will be made available to the board at a specific date and time within two (2) working days after the board's request.
    - (C) For purposes of confidentiality, a record containing patient health information in the possession of the board under this subdivision (c)(2) shall be considered a medical record for purposes of the Freedom of Information Act of 1967, § 25-19-101 et seq.
  - (3) In any investigation or official inquiry of a potential violation of law or any administrative proceeding regarding an alleged violation of law subject to its jurisdiction, the board may issue subpoenas signed by its executive director or the director's designee for any document, prescription, drug order, or other record or physical object identified or otherwise described in the subpoena if the item is relevant and material to the inquiry, investigation, or proceeding.
  - (4) In any administrative proceeding arising from an alleged violation of law within its jurisdiction, the board may order the disclosure of any information that is relevant and material to the alleged violation.
  - (5)
    - (A) If a person has been served with a subpoena or subpoena duces tecum or has been ordered to disclose information in an administrative proceeding under this chapter and fails to comply with the order, the board may apply to the Pulaski County Circuit Court or to the circuit court of the county in which the board is conducting its investigation or hearing for an order directing that:
      - (i) The person be brought before the court; and
      - (ii) After notice and opportunity for a hearing, the person comply with the order.
    - (B) If the person violates the court's order, the court may punish the person for civil contempt.

- (C) If a person fails or refuses to make available to the board's inspectors or agents under subdivision (c)(2) of this section any document, prescription, drug order, or other record or physical object, the board may file an action in the Pulaski County Circuit Court or in the circuit court of the county in which the board is conducting its oversight activity to obtain an order, after notice and opportunity for hearing, mandating that the person make the document, prescription, drug order, or other record or physical object available to the board's representatives.
- (6) The board's inspectors and other designated agents may seize products for testing of sterility, potency, and pyrogenicity when inspecting permitted facilities.
- (d) The board shall promulgate rules limiting the amount of Schedule II narcotics that may be dispensed by licensees of the board.

**17-92-206. Issuance of bulletins- Annual report**

- (a) It shall be the duty of the Arkansas State Board of Pharmacy to issue bulletins from time to time, informing pharmacists of important United States public health regulations, service and regulatory announcements of the Bureau of Chemistry and Soils in the United States Department of Agriculture, and decisions of the United States Department of Treasury relating to the possession, use, and sale of nonbeverage United States Pharmacopoeia alcohol and to the Harrison-Wright Antinarcotic Act.
- (b) The board shall make a written report on September 1 of each year to the Governor and to the Arkansas Pharmacists Association of all its proceedings, orders, rules, requirements, and regulations, of its receipts and disbursements, including also the names of all persons licensed to practice under this chapter, and a record of permits and renewals.

**17-92-207. Maintenance of office**

The Arkansas State Board of Pharmacy shall have the authority to maintain an office, purchase supplies, etc., for the advancement of pharmacy as may in its judgment be deemed necessary to carry out the purposes of this chapter and to enforce the pharmacy laws of this state.

**17-92-208. Employees**

- (a) The Arkansas State Board of Pharmacy is authorized to make payment for services, salaries, and other purposes from the funds received by the board from issuance of licensed pharmacy permits, renewals, or certificates of licensure of licensed pharmacists, examinations, reciprocity fees, and from other moneys collected.
- (b)
  - (1) The board is authorized to employ an attorney to supervise and conduct its investigations and to institute and prosecute actions and charges for the violation of the provisions of the Arkansas Pharmacy Act, § 17-92-101 et seq.
  - (2) The attorney employed or retained by the board shall make regular reports to the Attorney General of the actions instituted or prosecuted by him or her.
  - (3) Appeals from the circuit court to the Supreme Court in matters affecting the action of the board may be handled by the office of the Attorney General.
- (c) The board is authorized to make reimbursement of the necessary and reasonable travel, board, and lodging expenses of the staff of the board incurred in the performance of their duties.

**17-92-301. License required**

- (a) No person shall perform any of the acts constituting the practice of pharmacy unless the person is:
  - (1) A licensed pharmacist;
  - (2) A student or graduate of a recognized college of pharmacy serving an internship under an internship program established and regulated by the Arkansas State Board of Pharmacy;
  - (3) A pharmacy technician performing the limited functions permitted under this chapter and regulations promulgated hereunder; or
  - (4) A hospital pharmacy technician as defined in § 17-92-602 performing the limited functions permitted under that subchapter and regulations promulgated thereunder.
- (b) No person other than a licensed pharmacist shall use the term “doctor of pharmacy” or “Pharm.D”.

**17-92-302. Unlicensed practice – Penalty.**

- (a) No person shall fill a prescription, compound medicines, or otherwise perform the function of a licensed pharmacist unless the person is:
  - (1) An Arkansas-licensed pharmacist, except students or graduates of a recognized college of pharmacy serving internship as provided by law and regulated by the Arkansas State Board of Pharmacy;
  - (2) A pharmacy technician performing the limited functions permitted under this chapter and regulations promulgated hereunder; or
  - (3) A hospital pharmacy technician as defined in § 17-92-602 performing the limited functions permitted under that subchapter and regulations promulgated thereunder.
- (b) Any person who is not an Arkansas-licensed pharmacist or a student serving internship or a pharmacy technician performing the limited functions permitted under this chapter and regulations promulgated hereunder or a hospital pharmacy technician as defined in § 17-92-602 performing the limited functions permitted under that subchapter and regulations promulgated thereunder, who shall fill a prescription, compound or dispense medicine, or otherwise perform the functions of a pharmacist, shall be guilty of a misdemeanor punishable by a fine of not less than fifty dollars (\$50.00) nor more than one hundred dollars (\$100) for the first offense and not less than one hundred dollars (\$100) or thirty (30) days' imprisonment, or both fine and imprisonment, for each succeeding offense thereafter.
- (c) Each day that the person shall fill prescriptions, compound or dispense medicines, or otherwise perform the functions of a pharmacist shall constitute a separate offense.
- (d) Any licensed pharmacist who shall aid, abet, or encourage any person to violate the provisions of this section shall have his or her license or permit revoked or suspended, within the discretion of the board.

**17-92-303. Unlawful use of professional title--Penalty**

Any person who shall take, use, or exhibit the title of licensed pharmacist, unless it has been regularly conferred upon him or her as set forth in §§ 17-92-306 and 17-92-309, shall be guilty of a violation and upon conviction shall be liable to a penalty of not less than five dollars (\$5.00) nor more than one hundred dollars (\$100).

**17-92-304. Board administration – Support services.**

- (a) The Arkansas State Board of Pharmacy shall be fully advised respecting the eligibility and qualifications of all persons whom the board admits to the examination and to whom the board grants licensure.
- (b) For this purpose the board shall secure the services of the National Association of Boards of Pharmacy and the Arkansas Pharmacists Association and shall pay for such service as the board may determine, but not to exceed one dollar (\$1.00) of each renewal fee annually paid.

**17-92-305. Application - Qualification of applicants**

- (a) Each applicant for examination as a pharmacist:
  - (1) Be not less than twenty-one (21) years of age;
  - (2) Have:
    - (A) Graduated and received the first professional undergraduate degree from a pharmacy degree program which has been approved by the Arkansas State Board of Pharmacy; or
    - (B) Graduated from a foreign college of pharmacy, completed a transcript verification program, taken and passed a college of pharmacy equivalency exam program, and completed a process of communication ability testing as defined under board regulations so that it is assured that the applicant meets standards necessary to protect public health and safety.
- (b) Each application for examination shall be made on a form to be supplied by the board and shall be filed with the board as required by board regulations.
- (c) Each application shall be accompanied by the cost of the examination plus the examination fee and certificate fee prescribed by § 17-92-108.
- (d) The examination shall be given at a time and place and in a manner set by the board.

**17-92-306. Examinations**

Upon application and at such time and place and in such manner as it may determine, the Arkansas State Board of Pharmacy shall examine or provide for examination every person who shall desire to practice pharmacy as described in §§ 17-92-101 and 17-92-402 in the State of Arkansas.

**17-92-307. Internship required**

- (a)
  - (1) Every applicant for licensure must have experience and internship in a retail pharmacy under a licensed pharmacist, approved by the Arkansas State Board of Pharmacy, before and after graduation and examination as the board shall deem necessary to maintain and preserve the reciprocal agreements with other states and territories.
  - (2) The experience and internship in a retail pharmacy under a licensed pharmacist shall be predominantly related to the selling of drugs and medical supplies, compounding prescriptions, preparing pharmaceutical preparations, and keeping records and making reports required under the state and federal statutes.
- (b) The board is directed and empowered to establish an internship program whereby students and graduates of a recognized college of pharmacy may be permitted to practice pharmacy under the direction and control of a licensed pharmacist.

### **17-92-308. Reciprocity**

- (a) The Arkansas State Board of Pharmacy, in its discretion, may license as a pharmacist, through the process of reciprocity as established by the National Association of Boards of Pharmacy, any person who is duly licensed in some other state, territory, or the District of Columbia if the territory, state, or the District of Columbia has the same general requirements for licensure as Arkansas at the time of original licensure, provided that the state, territory, or the District of Columbia in which the person is licensed shall, under like conditions, grant reciprocal licensure to a pharmacist duly licensed by examination in this state.
- (b) All applications for a reciprocal license shall be accompanied by the fee prescribed by § 17-92-108.
- (c)
  - (1) In the interim between sessions of the board and upon satisfactory evidence of the fitness as established by board regulation of an applicant for reciprocity, any member of the board, in his or her discretion, may issue a temporary certificate that shall authorize the holder to practice pharmacy as defined in § 17-92-101.
  - (2) The temporary certificate shall expire on the date of the next meeting of the board after the granting of the certificate whether that meeting is a regular meeting or a called meeting at which reciprocity is considered.

### **17-92-309. Registration and certificate**

- (a) The Arkansas State Board of Pharmacy shall register in a suitable book the names and places of residence of all persons to whom it issues certificates and the date of issuance.
- (b) The board shall issue an appropriate certificate to each person licensed. The certificate must be conspicuously displayed in every store described in this chapter.
- (c) The board may provide by regulation for issuing and waiving the renewal fee for pharmacy certificates denoting special recognition for pharmacists who have the following qualifications:
  - (1) The pharmacist graduated from a college of pharmacy approved by the board fifty (50) or more years before the date on which the certificate will be issued; or
  - (2)
    - (A) The pharmacist has held an Arkansas pharmacist license for forty-nine (49) continuous years before the date on which the certificate will be issued without any lapse in the payment of licensure fees.
    - (B) However, a pharmacist who has paid fees to reinstate an expired license shall not be deemed to have held a license for continuous years.

### **17-92-310. Failure to renew**

- (a)
  - (1)
    - (A) All retail pharmacy permits, out-of-state pharmacy permits, specialty pharmacy permits, nursing home consultant pharmacist permits, and pharmacist licenses shall expire on December 31 of the first odd-numbered year following the date of issuance.
    - (B) All preceptor permits shall expire on December 31 of the first odd-numbered year following the date of issuance.
    - (C)

- (i)
  - (a) Intern licenses issued to foreign graduates shall expire on December 31 of the second calendar year following the date of issuance.
  - (b) However, an intern license issued to a foreign graduate shall expire when the intern is issued a pharmacist license.
- (ii)
  - (a) An intern license issued to a student intern shall remain valid as long as the intern maintains active student status in a college of pharmacy approved by the Arkansas State Board of Pharmacy and for six (6) months following graduation.
  - (b) An intern license issued to a student intern shall expire six (6) months following graduation.
  - (c) An intern license issued to a student intern may be reinstated if the intern resumes active student status in a board-approved college of pharmacy and applies for reinstatement.
  - (d) An intern license issued to a student intern shall expire when the intern is issued a pharmacist license.
- (D) All pharmacy technician permits, hospital pharmacy permits, ambulatory care center pharmaceutical services permits, wholesale distributors, third-party logistics providers, manufacturers, or outsourcing facilities of legend or controlled substance permits, wholesale distributors of medical equipment, legend devices, and medical gases permits, institutional pharmaceutical services permits, List I chemical permits, and any other permit, license, registration, or certificate issued by the board and not covered in subdivisions (a)(1)(A)-(C) of this section shall expire on December 31 of the first even-numbered year following the date of the issuance of the permit, license, registration, or certificate.
- (2) Every license, permit, registration, and certificate not renewed within ninety (90) days after expiration thereof shall be void.
- (b) The penalty for late payment of renewal for pharmacists, pharmacies, wholesaler/manufacturer of legend drugs and controlled substances, hospital, institutional, and nursing home consultant permits shall be as listed in § 17-92-108, and if renewal remains unpaid on April 1 of any year, the license shall be void.
- (c) If a pharmacist's license is not renewed by April 1, the fee for reinstatement shall be as stated in § 17-92-108.
- (d) If a pharmacist's license has not been renewed for more than two (2) years, the board shall evaluate the former pharmacist to determine his or her continued ability to practice pharmacy safely with regard to the public health and safety, and the board shall establish conditions for the safe reentry into practice of the profession.

**17-92-311. Revocation, suspension, or nonrenewal – Grounds.**

- (a) The Arkansas State Board of Pharmacy may revoke or suspend an existing certificate of licensure, license, registration, or permit or may refuse to issue a certificate of licensure, license, registration, or permit if the holder or applicant, as the case may be, has committed or is found guilty by the board of any of the following acts or offenses set forth:
  - (1) The person is guilty of fraud, deceit, or misrepresentation in the practice of pharmacy;
  - (2) The person is unfit or incompetent to practice pharmacy by reason of negligent performance of his or her duties;

- (3) The person has been found guilty or pleaded guilty or nolo contendere in a criminal proceeding, regardless of whether or not the adjudication of guilt or sentence is withheld by a court of this state, another state, or the federal government for:
    - (A) Any felony listed under § 17-2-102;
    - (B) Any act involving gross immorality or which is related to the qualifications, functions, and duties of a licensee; or
    - (C) Any violation of the pharmacy or drug laws or rules of this state, or of the pharmacy or drug statutes, rules, and regulations of any other state or of the federal government;
  - (4) The person has become physically or mentally incompetent to practice pharmacy to such an extent as to endanger the public;
  - (5) The person has directly or indirectly aided or abetted the practice of pharmacy by a person not authorized to practice pharmacy by the board;
  - (6) The person has been guilty of fraud or misrepresentation in obtaining a license to practice pharmacy in the State of Arkansas as a licensed pharmacist;
  - (7) The person has been guilty of gross unprofessional or dishonorable conduct;
  - (8) The person has willfully violated any of the provisions of the pharmacy laws of the State of Arkansas;
  - (9) The person is addicted to the use of intoxicating liquors or drugs to such a degree as to render him or her unfit, in the opinion of the board, to manufacture, compound, sell, or dispense drugs or medicine;
  - (10) The person knowingly adulterated or caused to be adulterated any drugs, chemical, or medical preparations and offered those preparations for sale; or
  - (11) The person had his or her certificate of licensure, license, registration, or permit revoked, suspended, or had other disciplinary action taken, or had his or her application for a certificate of licensure, license, registration, or permit refused, revoked, or suspended, or had voluntarily or otherwise surrendered his or her certificate of licensure, license, registration, or permit after a disciplinary action was instituted by a duly authorized professional disciplinary agency of another state.
- (b) Nothing in this section should be construed as affecting the rights of any person to appeal any order of the board as now provided by the state pharmacy laws.

**17-92-312. Revocation and fine – Adulteration of drugs**

Any licensed pharmacist who shall knowingly, intentionally, and fraudulently adulterate or cause to be adulterated any drugs, chemicals, or medical preparations and offer such adulterations for sale shall be deemed guilty of a misdemeanor. Upon conviction, his or her license shall be revoked and, in addition, he or she shall be liable to a penalty of not less than five dollars (\$5.00) nor more than one hundred dollars (\$100).

**17-92-313. Revocation – Procedure**

- (a)
  - (1) Before revoking the certificate of licensure, license, registration, or permit, the Arkansas State Board of Pharmacy shall give the person ten (10) days' notice in writing to appear before the board, at the time and place as the board may direct, to show cause why his or her certificate should not be revoked.

- (2) The notice shall be signed by the Executive Director of the Arkansas State Board of Pharmacy or the executive director's designee and shall set forth in clear and concise language the nature of the charge against the person.
  - (3) Mailing a copy of the notice by registered mail, addressed to the person at his or her address appearing upon the records of the board concerning the issuance of his or her certificate or the last renewal thereof, shall be sufficient service of notice.
- (b) At the hearing:
- (1) The board shall have the power to subpoena witnesses;
  - (2) The executive director or the director's designee shall sign subpoenas;
  - (3) The President of the Arkansas State Board of Pharmacy shall have the power to administer oaths; and
  - (4) The board shall hear evidence.
- (c) If the board finds after a hearing that the certificate of licensure, license, registration, or permit should be revoked, it shall be done immediately.

#### **17-92-314. Revocation – Appeals**

Any person whose certificate of licensure, license, or permit has been revoked by the Arkansas State Board of Pharmacy as provided in this chapter may appeal from the action of the board pursuant to the Arkansas Administrative Procedure Act, § 25-15-201 et seq.

#### **17-92-315. Alternative penalties**

- (a)
- (1) Whenever the Arkansas State Board of Pharmacy has authority pursuant to applicable laws to suspend, revoke, or deny any permit, license, certificate, credential, or registration or otherwise impose penalties or sanctions on the holder thereof, the board shall have the power and authority to impose on the holder thereof any one (1) or more of the following sanctions:
    - (A) A monetary penalty not to exceed five hundred dollars (\$500) for each violation;
    - (B) Require completion of appropriate education programs or courses, or both;
    - (C) Require successful completion of an appropriate licensing examination, jurisprudence examination, credentialing examination, or any combination of the three (3) examinations;
    - (D) Place conditions or restrictions upon regulated activities of the holder of the license, permit, certificate, credential, or registration; and
    - (E) Such other requirements or penalties as may be appropriate to the circumstances of the case and which would achieve the desired disciplinary purposes, but which would not impair the public health and welfare.
  - (2) The board is authorized to file suit in either the Pulaski County Circuit Court or the circuit court of any county in which the defendant resides or does business to collect any monetary penalty assessed pursuant

to this chapter if such a penalty is not paid within the time prescribed by the board.

- (3) Upon imposition of a sanction, the board may order that the license, permit, certificate, credential, or registration be suspended until the holder thereof has complied in full with all applicable sanctions imposed pursuant to this section.
- (b)
- (1)
    - a. A monetary penalty imposed by the board shall not exceed one thousand dollars (\$1000) per violation
    - b. The board may impose a monetary penalty on a license, permit, certificate, credential, or registration holder if the license, permit, certificate, credential, or registration has been revoked by the board for such a violation.
    - c. The board may collect out-of-pocket costs of an investigation incurred by the board to conduct a disciplinary hearing.
  - (2) Each instance when a federal or state law or board rule is violated shall constitute a separate violation.
  - (3) The power and authority of the board to impose sanctions authorized in this section are not to be affected by any other civil or criminal proceeding concerning the same violation, nor shall the imposition of a penalty preclude the board from imposing other sanctions short of revocation.
- (c) Any person sanctioned by the board under this section may appeal any order of the board as now provided by the state pharmacy laws.
- (d) In addition to other sanctions authorized by this chapter, the board may also impose a civil penalty under this section against an unlicensed person or entity practicing or providing goods or services or offering to practice or provide any goods or services requiring licensure under this chapter.
- (e) The board may collect costs of inspections incurred by the board while inspecting a permitted facility that is out of state.

**17-92-316. Credential required for professional pharmacy service**

- (a)
- (1) The Arkansas State Board of Pharmacy may provide by regulation for credentialing and approval of pharmacists to practice disease state management and any other pharmacy services determined by the board to require a credential.
  - (2)
    - (A) The credentials may be issued by agencies approved by the board to pharmacists who qualify pursuant to minimum competencies, standards, objectives, and qualifications determined by the board.
    - (B) However, a credential shall not authorize the pharmacist to practice credentialed pharmacy service in Arkansas until after the board has determined that the credentialed pharmacist meets the minimum competencies, standards, objectives, and qualifications determined by the board.
- (b) The board shall adopt regulations necessary and appropriate to implement the credentialing and the board's approval of pharmacists to practice disease state management and other credentialed pharmacy services, including:

- (1) Identification of areas of credentialed pharmacy services;
  - (2) Identification of the minimum competencies, standards, objectives, and qualifications necessary for a credential and the board's approval to practice in each area of credentialed pharmacy service;
  - (3) Identification of the standards for qualifying an agency to issue credentials for areas of pharmacy services;
  - (4) The procedure and standards, which may include a practical examination, for the board's review and approval of a credential and determination of a pharmacist's qualifications to practice disease state management or other credentialed pharmacy service;
  - (5) The conversion of a credential previously issued by the board for the practice of disease state management or other pharmacy service to a credential issued by an approved credentialing agency; and
  - (6) Continuing professional education and other measures to maintain pharmacists' continuing competency in disease state management and other credentialed pharmacy services.
- (c) The board shall promulgate regulations to:
- (1) Identify areas of credentialing;
  - (2) Establish procedures for initial application and renewal;
  - (3) Define the minimum competencies and standards to be examined;
  - (4) Define the qualifications for credentialing; and
  - (5) Define required continuing education, competencies, standards, and other information necessary to implement this chapter.

**17-92-317. Criminal background checks**

- (a)
  - (1) Each applicant for a new intern or pharmacist license or a new or reinstated registration as a pharmacy technician issued by the Arkansas State Board of Pharmacy shall apply to the Identification Bureau of the Department of Arkansas State Police for a state and national criminal background check, to be conducted by the Federal Bureau of Investigation.
  - (2) However, the board may authorize the criminal background check obtained for a license or registration to be used for a subsequent application for another new license or registration issued by the board for a designated time period after the date of the original license or registration.
- (b) The criminal background check shall conform to the applicable federal standards as in effect on January 1, 2003 and shall include the taking of fingerprints.
- (c) The applicant shall sign a release of information to the board and shall be responsible to the Department of Arkansas State Police for the payment of any fee associated with the criminal background check.
- (d) Upon completion of the criminal background check, the Identification Bureau of the Department of Arkansas State Police shall forward to the board all information obtained concerning the commission by the applicant of any offense listed in subsection (e) of this section.

(e) Notwithstanding the provisions of § 17-1-103, a person is not eligible to receive or hold an intern or pharmacist license or pharmacy technician registration issued by the board if that person has pleaded guilty or nolo contendere to, or has been found guilty of, any of the following offenses, regardless of whether an adjudication of guilt or sentencing or imposition of sentence is withheld, by any court in the State of Arkansas or of any similar offense by a court in another state or of any similar offense by a federal court:

- (1) Any felony listed under § 17-2-102;
- (2) Any act involving gross immorality, dishonesty, or which is related to the qualifications, functions, and duties of a person holding the license or registration; or
- (3) Any violation of Arkansas pharmacy or drug law or regulations, including, but not limited to, this chapter, the Uniform Controlled Substances Act, § 5-64-101 et seq., and the Food, Drug, and Cosmetic Act, § 20-56-201 et seq.

(f)

- (1)
  - (A) The board may issue a nonrenewable provisional license or registration pending the results of the criminal background check.
  - (B) The nonrenewable provisional license or registration shall be valid for no more than six (6) months.
- (c) Upon receipt of information from the Identification Bureau of the Department of Arkansas State Police that the person holding the nonrenewable provisional license or registration has pleaded guilty or nolo contendere to, or has been found guilty of, any offense under subsection (e) of this section, the board shall immediately revoke the nonrenewable provisional license or registration.

(g)

- (1) The provisions of subsection (e) of this section and subdivision (f)(2) of this section may be waived by the board upon the request of:
  - (A) An affected applicant for licensure or registration; or
  - (B) The person holding a license or registration subject to revocation.
- (2) Circumstances for which a waiver may be granted shall include, but not be limited to:
  - (A) The age at which the crime was committed;
  - (B) The circumstances surrounding the crime;
  - (C) The length of time since the crime;
  - (D) Subsequent work history;
  - (E) Employment references;
  - (F) Character references; and
  - (G) Other evidence demonstrating that the applicant does not pose a threat to the public health, safety, or welfare.

(h)

- (1) Any information received by the board from the Identification Bureau of the Department of Arkansas State Police under this section shall not be available for examination except by:
    - (A) The affected applicant or the applicant's authorized representative; or
    - (B) The person whose license or registration is subject to revocation or his or her authorized representative.
  - (2) No record, file, or document shall be removed from the custody of the Department of Arkansas State Police.
- (i) Only information pertaining to the person making the request may be made available to the affected applicant or the person whose license or registration is subject to revocation.
  - (j) Rights of privilege and confidentiality established in this section shall not extend to any document created for purposes other than the criminal background check.
  - (k) The board shall adopt the necessary rules and regulations to fully implement the provisions of this section.

**17-92-401. Applicability to out-of-state operations**

- (a) A pharmacy operating outside the state that routinely ships, mails, or delivers in any manner a dispensed legend drug into Arkansas or otherwise practices pharmacy in Arkansas shall hold a pharmacy license issued by the Arkansas State Board of Pharmacy, and that part of the pharmacy operation dispensing the prescription for an Arkansas resident shall abide by Arkansas law and regulations of the board.
- (b)
  - (1) Any pharmacy operating outside the state that routinely ships, mails, or delivers in any manner a dispensed legend drug into Arkansas shall be required to have on staff in the out-of-state pharmacy an Arkansas-licensed pharmacist, who shall be designated the pharmacist-in-charge for the Arkansas out-of-state pharmacy license.
  - (2) If the out-of-state pharmacy fails to have on staff an Arkansas-licensed pharmacist due to extended illness, death, resignation, or for any other reason, the pharmacy within ten (10) calendar days shall notify the board of the fact and must within thirty (30) calendar days or such additional time at the discretion of the board not to exceed thirty (30) calendar days, either:
    - (A) Secure the services of an Arkansas-licensed pharmacist; or
    - (B) Cease to operate as a pharmacy in the State of Arkansas.
- (c) An out-of-state pharmacy that ships, mails, or delivers in any manner a dispensed legend drug into Arkansas shall designate an agent who is a resident of Arkansas for service of process and register the agent with the Secretary of State.
- (d) If under investigation for violation of this chapter, an out-of-state pharmacy shall be required to appear before the board to respond to questions concerning the investigation.
- (e) The board shall have all the powers to enforce this chapter as are granted to the board under § 17-92-101 et seq.

**17-92-402. Licensed pharmacist required**

- (a) It shall be unlawful for any person not a licensed pharmacist within the meaning of this act to conduct any

pharmacy or other facility subject to this subchapter for the purpose of retailing, compounding, dispensing medicines, or otherwise performing the practice of pharmacy as defined in § 17-92-101 in the State of Arkansas except as provided.

- (b) It shall be unlawful for the proprietor of a store or pharmacy or other facility subject to this chapter to allow any person other than a licensed pharmacist to compound or dispense the prescriptions of authorized practitioners except as an aid to and under the supervision of a licensed pharmacist as provided in this chapter.
- (c) However, any person who is not a licensed pharmacist may own or conduct a pharmacy or other facility as identified in § 17-92-403 if the owner keeps constantly in the pharmacy or other facility a licensed pharmacist subject to § 17-92-607.
- (d) Any person violating the provisions of this act shall be guilty of a violation and upon conviction shall be liable to a fine of not less than five dollars (\$5.00) nor more than one hundred dollars (\$100).

#### **17-92-403. Licensed pharmacist required--Exceptions**

- (a) No person shall operate a pharmacy or other facility dispensing prescriptions as identified in this section or be issued a pharmacy permit or other permit issued by the Arkansas State Board of Pharmacy to facilities dispensing prescriptions unless an Arkansas-licensed pharmacist-in-charge is on duty in the drugstore or pharmacy a minimum of forty (40) hours per week or as otherwise provided in this chapter or by board regulation.
- (b) In the absence of a licensed pharmacist, no one shall fill a prescription except a student serving as a graduate intern.
- (c) If the owner of any pharmacy or other facility dispensing prescriptions as identified in this section fails to have on duty a licensed pharmacist-in-charge forty (40) hours per week or as otherwise provided in this chapter due to illness, death, resignation, or for any other reason, the owner shall within five (5) days notify the board of the fact and shall within thirty (30) days or such additional time at the discretion of the board either secure the services of a licensed pharmacist-in-charge or remove all prescription legend drugs and drug signs from the pharmacy or facility as identified in this section and cease to operate as a pharmacy or facility as identified in this section.
- (d)
  - (1) The board shall provide by regulation for the issuance of permits for specialty pharmacies to which § 17-92-607 shall apply.
  - (2) The owners of specialty pharmacies shall have on duty a licensed pharmacist-in-charge whose minimum number of hours on duty shall be determined by board regulations regarding the nature of the pharmacy service provided.
  - (3) Specialty pharmacies dispensing prescriptions to in-house patients that are cared for on a twenty-four-hour-per-day basis must have a pharmacist on duty no less than forty (40) hours per week.
  - (4) The owners of specialty pharmacies shall abide by all provisions established for the employment of pharmacists in this chapter and board regulations.
  - (5) If the owner of any specialty pharmacy fails to have on duty a licensed pharmacist-in-charge as provided in subdivision (d)(2) or subdivision (d) (3) of this section due to illness, death, resignation, or for any other reason, the owner shall within five (5) days notify the board of the fact and shall within thirty (30) days, or such additional time as the board in its discretion may allow, either secure the services of a licensed pharmacist-in-charge or remove all prescription legend drugs and drug signs from the pharmacy and cease to operate the pharmacy.

- (e) The board may provide by regulation for the issuance of hospital pharmaceutical permits to pharmacists employed in hospitals under which the pharmacist-in-charge employed in a hospital may have a flexible schedule of attendance and to which the requirement of a licensed pharmacist-in-charge on duty for a minimum of forty (40) hours a week shall not apply.
- (f) The board shall provide for the issuance of ambulatory care center pharmaceutical services permits to entities so licensed by the Department of Health and that shall employ a licensed pharmacist-in-charge as provided by board regulation.
- (g) The board shall provide by regulation for the issuance of institutional pharmacy permits to governmentally funded institutions that provide inpatient pharmaceutical services to persons confined to such institutions or in which drugs are administered to inpatients on orders of practitioners authorized by law to prescribe or administer the drugs and to which the requirement that the licensed pharmacist-in-charge on duty for a minimum of forty (40) hours a week shall not apply.
- (h) The board may provide by regulation for the issuance of charitable clinic pharmacy permits to clinics operated on a nonprofit basis to furnish medical and dental care to poor and underprivileged persons and in which drugs are dispensed or administered to such persons on orders or prescriptions of practitioners authorized by law to prescribe or administer the drugs and to which the requirement of a licensed pharmacist-in-charge on duty for a minimum of forty (40) hours a week shall not apply.

**17-92-404. Pharmacy permit required**

- (a) No person shall conduct any pharmacy or other facility as identified in § 17-92-403 in which practitioners' prescriptions are compounded and drugs are retailed or dispensed and in which a licensed pharmacist-in-charge must be employed unless the pharmacy or other facility as identified in § 17-92-403 has obtained a permit issued by the Arkansas State Board of Pharmacy.
- (b)
  - (1) Keeping a pharmacy or other facility as identified in § 17-92-403 where drugs and medicines or chemicals are dispensed or sold or displayed for sale at retail or where prescriptions are compounded or which has on it a sign using the words “pharmacist”, “pharmaceutical chemist”, “apothecary”, “pharmacy”, “druggist”, “drug store”, “drugs”, or their equivalent in any language, or advertising such a store or shop as a drugstore, apothecary shop, or pharmacy by any method or means shall be prima facie evidence of the sale and dispensing of drugs.
  - (2) Unless the place so conducted holds a permit issued by the board, it shall be unlawful for any person, firm, or corporation:
    - (A) To carry on, conduct, or transact a retail business under any name that contains as a part thereof the words “drugs”, “drugstore”, “pharmacy”, “medicine”, “apothecary”, or “chemist shop” or any abbreviation, translation, extension, or variation thereof; or
    - (B) In the operation of any pharmacy or other facility as identified in § 17-92-403 in any manner by advertisement, circular, poster, telephone directory listing, sign, or otherwise, to describe or refer to the place of business conducted by such a person, firm, or corporation by such a term, abbreviation, translation, extension, or variation.
  - (3) Any person, firm, or corporation violating this subsection shall be guilty of a violation and, if a corporation, any officer thereof who participates in such a violation also shall be guilty of a violation and shall be punished by a fine of not less than twenty-five dollars (\$25.00) nor more than three hundred dollars (\$300).

- (c)
  - (1) The control of the dispensing of medicines being essential to the protection of the public health and general welfare of the people, any violation of subsection (b) of this section may be enjoined by action in any court of competent jurisdiction at the instance of the board or of the owner of any licensed pharmacy.
  - (2) Proceedings under this subsection shall be governed by rules applicable to circuit courts.

**17-92-405. Pharmacy permit--Application**

- (a)
  - (1) Upon application, the Arkansas State Board of Pharmacy shall issue a permit to maintain a pharmacy or other facility as described in § 17-92-403 or § 17-92-404 for the sale at retail or otherwise dispensing of drugs and medicines to such persons, firms, or corporations as the board may deem to be qualified to conduct such a pharmacy or other facility.
  - (2)
    - (A) The permit, to be known as a “pharmacy permit”, “specialty permit”, “hospital pharmaceutical services permit”, or “ambulatory care center pharmacy permit”, is for the compounding of practitioners' prescriptions and for the manufacture, sale, and distribution of drugs, medicines, and poisons.
    - (B) The pharmacy, specialty pharmacy, hospital pharmacy, or ambulatory care center pharmacy is to be under the direct supervision of a licensed pharmacist.
  - (3) All permits shall expire on December 31.
- (b) Application for a permit shall be made in such a manner and in such a form as the board may determine.
- (c) The permits shall at all times be displayed in a conspicuous place in the pharmacy or other facility as identified in § 17-92-403 for which the permit is issued.

**17-92-406. Repealed by Acts of 2001, Act 910, § 7, eff. Aug. 13, 2001**

**17-92-407. Revocation--Grounds**

- (a) The Arkansas State Board of Pharmacy may revoke any permit issued under this subchapter in the event the holder thereof allows any person other than an Arkansas-licensed pharmacist or those students or graduates of a college of pharmacy serving an internship to fill prescriptions, compound and dispense drugs or medicines, or otherwise perform the duties and functions of a licensed pharmacist.
- (b) Whenever any person, firm, partnership, estate, or corporation holding any permit issued under this subchapter obtains a permit by false representations or knowingly violates any of the pharmacy laws or fails to comply with the rules and regulations of the board passed by authority of the pharmacy laws, the board shall revoke the holder's pharmacy permit.
- (c) The board shall also revoke any permit issued under this subchapter when information in possession of the board shall disclose that the operations for which the permit was issued are not being conducted according to law or are being conducted so as to endanger the public health or safety.

**17-92-408. Revocation--Procedure**

The Arkansas State Board of Pharmacy shall follow the same procedure in revoking any permits issued under this

subchapter as provided for revoking certificates of licensure as set out in § 17-92-313.

**17-92-409. Pharmacy library required**

There shall be kept in every pharmacy or other facility as identified in § 17-92-403 a library consisting of books, periodicals, and computer software as required by regulations of the Arkansas State Board of Pharmacy.

**17-92-410. Records of poison sales**

- (a) The proprietor shall at all times keep in his or her place of business a record book in which shall be entered all sales of the following, other than sales to physicians, dentists, veterinarians, and sales made on prescriptions of a physician, dentist, or veterinarian: arsenious acid, hydrocyanic acid, potassium cyanide, cyanide mixture, mercury bichloride, and strychnine and its salts, except in proper dosage in pill and tablet form.
- (b)
  - (1) The record shall show in parallel columns: date of sale, name of article sold, quantity of article sold, purpose for which sold, name or initial of dispenser, and the signature and address of the purchaser. The record shall at all times during business hours be open for inspection by any police officer, sheriff, city or town representative, or any representative of the Arkansas State Board of Pharmacy and shall be preserved for a period of not less than two (2) years from the date of the last entry in the record.
  - (2) If the purchaser is a person not known to the seller, the seller shall require necessary identification to determine the true name and address of the purchaser.

**17-92-411. Prescription content and labels**

- (a) Labels on original packages shall bear the label of the distributor or manufacturer, with the proper medicinal dose, if a remedy used internally. In the case of poisons, the word "POISON" shall be displayed thereon in a conspicuous manner with the antidote for a poisonous dose.
- (b) A doctor of medicine or other person authorized to issue prescriptions, upon the request of the patient, shall indicate briefly and concisely on the prescriptions the conditions for which the medication is prescribed. Every pharmacist filling any such prescription shall include on the label of the prescription container the labeling as stated on the prescription issued.

**17-92-412. Nursing home consultant permit**

- (a)
  - (1) The Arkansas State Board of Pharmacy shall provide for the issuance of nursing home consultant permits by regulation.
  - (2) The consultant pharmacist-in-charge and the nursing home administrator shall be jointly responsible to ensure that a valid permit is posted at the facility at all times.
- (b) The board shall set by regulation the standards by which the controlled and legend drugs and devices will be maintained in the nursing home or long-term care facility.
- (c) The consultant pharmacist-in-charge, in conjunction with the nursing home administrator and director of nurses, shall ensure the proper control and accountability, storage, and proper utilization of drugs and other legend devices dispensed to patients residing in the facility according to board standards as well as those established by state and federal guidelines.

**17-92-501. Violations of provisions**

Any person licensed or otherwise permitted to practice pharmacy in this state who shall violate any provisions of this subchapter shall be subject to discipline by the Arkansas State Board of Pharmacy, including, but not limited to, revocation of such license or permission, according to procedures established by law or by regulations of the board.

### **17-92-502. Rules and regulations**

The Arkansas State Board of Pharmacy may adopt such reasonable regulations, not inconsistent with law, as it shall deem necessary to carry out the purposes and intentions of this subchapter.

### **17-92-503. Generic drug product and biological product substitutions**

- (a)
  - (1)
    - (A) Except as provided in subsection (b) of this section, when a pharmacist receives a prescription for a brand or trade name drug product or biological product, the pharmacist may dispense a generically equivalent drug product or interchangeable biological product only when there will be a cost savings for the patient.
    - (B) The pharmacist shall disclose the amount of the cost savings at the request of the patient.
  - (2) The total amount charged for the substituted generically equivalent drug product or interchangeable biological product or for dispensing the drug product shall not exceed the amount normally and regularly charged under comparable circumstances by the pharmacist for that drug product or biological product or for the dispensing of that drug product or biological product.
  - (3) A pharmacist may not dispense a drug product or interchangeable biological product with a total charge that exceeds the total charge of the drug product or biological product originally prescribed unless agreed to by the purchaser.
- (b) The pharmacist shall not dispense a generically equivalent drug product under subsection (a) of this section if:
  - (1) The prescriber, in the case of a prescription in writing signed by the prescriber, indicates in his or her own handwriting by name or initial that no substitution shall be made;
  - (2) The prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates that the prescription is to be dispensed as communicated;
  - (3) The person for whom the drug product or biological product is prescribed indicates that the prescription is to be dispensed as written or communicated; or
  - (4) The Arkansas State Board of Pharmacy has determined that the drug product or biological product should not be substituted and has notified all pharmacists of that determination.
- (c)
  - (1) The Arkansas State Board of Pharmacy shall determine which drugs are generically equivalent and which biological products are interchangeable biological products as defined in § 17-92-101, relying on standards scientifically supported and generally accepted in the field of pharmacy, and shall notify each licensed pharmacist and the Arkansas State Medical Board of this determination.
  - (2) In making this determination, the Arkansas State Board of Pharmacy may use a nationally recognized reference source that meets the requirements of this act, notifying each licensed pharmacist and the Arkansas State Medical Board of the reference source to be used and any additions or deletions the Arkansas State Board of Pharmacy may make in its discretion.
- (d)

- (1) Within five (5) business days after dispensing an interchangeable biological product that has been substituted for a biological product, the dispensing pharmacist or his or her designee shall record the specific interchangeable biological product provided to the patient, including without limitation the name of the interchangeable biological product and the manufacturer of the interchangeable biological product.
- (2) The record shall be electronically accessible to the prescriber through:
  - (A) An interoperable electronic medical records system;
  - (B) An electronic prescribing technology;
  - (C) A pharmacy benefit management system; or
  - (D) A pharmacy record.
- (3) If requested by a prescriber, a pharmacist shall communicate to the prescriber within five (5) business days using facsimile, telephone, electronic transmission, or other prevailing means that an interchangeable biological product has been dispensed.
- (4) A communication is not required when:
  - (A) An interchangeable biological product does not exist for the prescribed biological product; or
  - (B) A refill prescription for a biological product is not substituted with an interchangeable biological product on a subsequent filling of the prescription.
- (5) The pharmacist or pharmacy shall maintain a record of biological products dispensed for at least two (2) years.
- (6) Under subdivision (d)(2) of this section, the dispensing pharmacist or prescriber is not:
  - (A) Required to show proof that a prescriber has access to the record in any type of payment audit conducted by a payer or pharmacy benefit manager; or
  - (B) Subject to disciplinary action or civil penalties for failure to ensure that the record is accessible or for failure to access the record.

**17-92-504. Repealed by Acts of 2001, Act 801, § 6, eff. Aug. 13, 2001**

**17-92-505. Labeling requirements**

- (a)
  - (1) The pharmacist filling a prescription for dispensing to an ultimate patient may affix to the container a label showing:
    - (A) The pharmacy name, address, and telephone number;
    - (B) The date of dispensing;
    - (C) The serial number of the prescription;
    - (D) The name of the patient;

- (E) The name of the prescribing practitioner;
  - (F) Either:
    - (i) The trade name of the drug product, if any, or the generic name and identity of the manufacturer of the dispensed drug product, if the drug product appears generically listed on the drug formulary list as established by this subchapter; or
    - (ii) In the case of a biological product, the trade name of the biological product, if any, or the proper name of the biological product and identity of the manufacturer of the dispensed biological product;
  - (G) The strength per unit dose of the medication;
  - (H) The quantity of the medication; and
  - (I) Directions for use.
- (2) If a pharmacist dispenses a generically equivalent product or interchangeable biological product, the person for whom the medication is prescribed shall be informed before dispensing or the label should appropriately indicate the substitution.
  - (3) This subsection does not apply to the dispensing of medication to inpatients in hospitals.
  - (4) In the case of dispensing a drug product or biological product, the prescribing practitioner may indicate that the name, manufacturer, and strength of the medication dispensed shall be deleted from the label.
- (b) An authorized person who fills a prescription for dispensing to an ultimate patient shall affix to the container a label showing:
    - (1) The trade name of the medication or the generic name of the medication unless directed to the contrary by the prescribing practitioner; or
    - (2) The trade name, if any, or the proper name of the biological product unless directed to the contrary by the prescribing practitioner.

**17-92-506. Available drug product and biological product lists.**

- (a)
  - (1) A pharmacist may display, within the confines of the pharmacy, lists of available drug products and biological products, other than controlled substances, and current charges for the drug products or biological products or for the dispensing of the drug products or biological products in specified quantities.
  - (2) Upon request, a pharmacy may make such lists available to its customers and other members of the public.
- (b) The Arkansas State Board of Pharmacy shall maintain on the website of the board a link to the lists of all interchangeable biological products approved by the United States Food and Drug Administration.

**17-92-507. Maximum Allowable Cost Lists**

- (a) As used in this section:
- (1)
    - (A) "Maximum Allowable Cost List" means a listing of drugs or other methodology used by a pharmacy benefits manager, directly or indirectly, setting the maximum allowable payment to a pharmacy or pharmacist for a generic drug, brand-name drug, biologic product, or other prescription drug.
    - (B) "Maximum Allowable Cost List" includes without limitation:
      - (i) Average acquisition cost, including national average drug acquisition cost;
      - (ii) Average manufacturer price;
      - (iii) Average wholesale price;
      - (iv) Brand effective rate or generic effective rate;
      - (v) Discount indexing;
      - (vi) Federal upper limits;
      - (vii) Wholesale acquisition cost; and
      - (viii) Any other term that a pharmacy benefits manager or a healthcare insurer may use to establish reimbursement rates to a pharmacist or pharmacy for pharmacist services;
  - (2) "Pharmaceutical wholesaler" means a person or entity that sells and distributes prescription pharmaceutical products, including without limitation a full line of brand-name, generic, and over-the-counter pharmaceuticals, and that offers regular and private delivery to a pharmacy;
  - (3) "Pharmacist" means a licensed pharmacist as defined in § 17-92-101;
  - (4) "Pharmacist services" means products, goods, and any combination of products, goods, and services, provided as a part of the practice of pharmacy as defined in § 17-92-101;
  - (5) "Pharmacy" means the same as in § 17-92-101;
  - (6) "Pharmacy acquisition cost" means the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy's billing invoice;
  - (7) "Pharmacy benefits manager" means an entity that administers or manages a pharmacy benefits plan or program;
  - (8) "Pharmacy benefits manager affiliate" means a pharmacy or pharmacist that directly or indirectly, through one (1) or more intermediaries, owns or controls, is owned or controlled by, or is under common ownership or control with a pharmacy benefits manager; and
  - (9) "Pharmacy benefits plan or program" means a plan or program that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services to individuals who reside in or are employed in this state.
- (b) Before a pharmacy benefits manager places or continues a particular drug on a Maximum Allowable Cost List, the drug:
- (1) If the drug is a generically equivalent drug as defined in § 17-92-101, shall be listed as therapeutically equivalent and pharmaceutically equivalent "A" or "B" rated in the United States Food and Drug Administration's most recent version of the "Orange Book" or "Green Book" or have an NR or NA rating by Medi-Span, Gold Standard, or a similar rating by a nationally recognized reference;
  - (2) Shall be available for purchase by each pharmacy in the state from national or regional wholesalers operating in Arkansas; and

- (3) Shall not be obsolete.
- (c) A pharmacy benefits manager shall:
  - (1) Provide access to its Maximum Allowable Cost List to each pharmacy subject to the Maximum Allowable Cost List;
  - (2) Update its Maximum Allowable Cost List on a timely basis, but in no event longer than seven (7) calendar days from an increase of ten percent (10%) or more in the pharmacy acquisition cost from sixty percent (60%) or more of the pharmaceutical wholesalers doing business in the state or a change in the methodology on which the Maximum Allowable Cost List is based or in the value of a variable involved in the methodology;
  - (3) Provide a process for each pharmacy subject to the Maximum Allowable Cost List to receive prompt notification of an update to the Maximum Allowable Cost List; and
  - (4)
    - (A)
      - (i) Provide a reasonable administrative appeal procedure to allow pharmacies to challenge maximum allowable cost list and reimbursements made under a maximum allowable cost list for a specific drug or drugs as:
        - (a) Not meeting the requirements of this section; or
        - (b) Being below the pharmacy acquisition cost.
      - (ii) The reasonable administrative appeal procedure shall include the following:
        - (a) A dedicated telephone number, email address, and website for the purpose of submitting administrative appeals;
        - (b) The ability to submit an administrative appeal directly to the pharmacy benefits manager regarding the pharmacy benefits plan or program or through a pharmacy service administrative organization; and
        - (c) No less than thirty (30) business days to file an administrative appeal.
    - (B) The pharmacy benefits manager shall respond to the challenge under subdivision (c)(4)(A) of this section within thirty (30) business days after receipt of the challenge.
    - (C) If a challenge is under subdivision (c)(4)(A) of this section, the pharmacy benefits manager shall within thirty (30) business days after receipt of the challenge either:
      - (i) If the appeal is upheld:
        - (a) Make the change in the maximum allowable cost list payment to at least the pharmacy acquisition cost;
        - (b) Permit the challenging pharmacy or pharmacist to reverse and rebill the claim in question;
        - (c) Provide the National Drug Code number that the increase or change is based on to the pharmacy or pharmacist; and

- (d) Make the change under subdivision (c)(4)(C)(i)(a) of this section effective for each similarly situated pharmacy as defined by the payor subject to the Maximum Allowable Cost List;
  - (ii) If the appeal is denied, provide the challenging pharmacy or pharmacist the National Drug Code number and the name of the national or regional pharmaceutical wholesalers operating in Arkansas that have the drug currently in stock at a price below the Maximum Allowable Cost List; or
  - (iii) If the National Drug Code number provided by the pharmacy benefits manager is not available below the pharmacy acquisition cost from the pharmaceutical wholesaler from whom the pharmacy or pharmacist purchases the majority of prescription drugs for resale, then the pharmacy benefits manager shall adjust the Maximum Allowable Cost List above the challenging pharmacy's pharmacy acquisition cost and permit the pharmacy to reverse and rebill each claim affected by the inability to procure the drug at a cost that is equal to or less than the previously challenged maximum allowable cost.
- (d)
  - (1) A pharmacy benefits manager shall not reimburse a pharmacy or pharmacist in the state an amount less than the amount that the pharmacy benefits manager reimburses a pharmacy benefits manager affiliate for providing the same pharmacist services.
  - (2) The amount shall be calculated on a per unit basis based on the same generic product identifier or generic code number.
- (e) A pharmacy or pharmacist may decline to provide the pharmacist services to a patient or pharmacy benefits manager if, as a result of a Maximum Allowable Cost List, a pharmacy or pharmacist is to be paid less than the pharmacy acquisition cost of the pharmacy providing pharmacist services.
- (f)
  - (1) This section does not apply to a Maximum Allowable Cost List maintained by the Arkansas Medicaid Program or the Employee Benefits Division of the Department of Finance and Administration.
  - (2) This section shall apply to the pharmacy benefits manager employed by the Arkansas Medicaid Program or the Employee Benefits Division if, at any time, the Arkansas Medicaid Program or the Employee Benefits Division engages the services of a pharmacy benefits manager to maintain a Maximum Allowable Cost List.
- (g)
  - (1) A violation of this section is a deceptive and unconscionable trade practice under the Deceptive Trade Practices Act, § 4-88-101 et seq., and a prohibited practice under the Arkansas Pharmacy Benefits Manager Licensure Act, § 23-92-501 et seq., and the Trade Practices Act, § 23-66-201 et seq.
  - (2) This section is not subject to § 4-88-113(f)(1)(B).

**17-92-601. Citation**

This subchapter may be cited as the “Hospital Pharmacies Act”.

**17-92-602. Definitions**

As used in this subchapter:

- (1) "Board" means the Arkansas State Board of Pharmacy;
- (2) "Hospital" means a hospital as defined in § 20-9-201;
- (3) "Hospital employee" means any individual employed by a hospital whose compensation for services or labor actually performed for a hospital is reflected on the payroll records of a hospital;
- (4) "Hospital pharmacy" means the place or places in which drugs, chemicals, medicines, prescriptions, or poisons are prepared for distribution and administration for the use or benefit of patients in a hospital. The "hospital pharmacy" may also provide pharmacy services to patients in a "swing bed" within the hospital that may periodically swing back and forth from being a short-term acute hospital bed to a longer-term nursing home bed. The "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 for other persons in emergency situations;
- (5) "Hospital pharmacy technicians" means persons other than licensed pharmacists who perform duties in conjunction with the overall hospital medication distribution system for inpatients; and
- (6) "Licensed pharmacist" means any person licensed to practice pharmacy by the board.

#### **17-92-604. Regulatory authority**

- (a) The Arkansas State Board of Pharmacy shall adopt, promulgate, and enforce rules and standards as may be necessary to the regulation of the operation of a hospital pharmacy and for the accomplishment of all other purposes of this subchapter.
- (b) The board may modify, amend, or rescind the rules and standards, provided the modification, amendment, or rescission does not in any manner defeat the purposes of this subchapter.

#### **17-92-605. Hospital pharmacy license- Services permitted**

- (a) All hospital pharmacies shall be licensed by the Arkansas State Board of Pharmacy as provided for by this subchapter. The hospital pharmacy license shall be issued in the name of the hospital.
- (b) Any hospital receiving a permit shall advise the board of the name of:
  - (1) The hospital administrator or other person assuming responsibility for the general administration of the hospital;
  - (2) The director of the pharmacy, or other person assuming responsibility for the general operation of the hospital pharmacy, who shall be a licensed pharmacist; and
  - (3) All other licensed pharmacists employed by the hospital in its hospital pharmacy.
- (c) The hospital and the director of pharmacy shall be required to report to the board any change in licensed pharmacist personnel.
- (d) Upon the receipt of a hospital pharmacy license, a hospital pharmacy may provide the following pharmaceutical services:
  - (1) Prepare for distribution and administration of drugs, chemicals, medicines, prescriptions, or poisons for

the use or benefit of the patients in the hospital as set forth in § 17-92-602(4); and

- (2) Compound or dispense drugs, chemicals, medicines, prescriptions, or poisons for the use or benefit of the hospital's employees, members of the immediate families of hospital employees, patients being discharged, and other persons in emergency situations.

#### **17-92-606. Hospital pharmaceutical permit**

Any hospital pharmacy holding a hospital pharmaceutical permit issued by the Arkansas State Board of Pharmacy pursuant to § 17-92-403 on March 28, 1975, shall be deemed to be licensed pursuant to this subchapter until the permit shall expire.

#### **17-92-607. Unlawful for hospital to hold licensed pharmacy permit – Exceptions**

- (a) It shall be unlawful for any nonprofit, tax exempt, or governmentally funded hospital to acquire direct or indirect interest in or otherwise hold directly or indirectly a licensed pharmacy permit pursuant to the provisions of § 17-92-405, for the sale at retail of drugs and medicines.
- (b) However, nothing contained in this section shall be construed to prohibit any hospital having a direct or indirect interest in or otherwise holding either directly or indirectly a permit prior to March 28, 1975, from continuing to have an interest in or holding the permit. Nothing contained in this section shall be construed to prohibit any hospital so holding a permit prior to March 28, 1975, from receiving a renewal of the permit.

#### **17-92-701. Definitions**

As used in this subchapter:

- (1) “Board” means the Arkansas State Board of Pharmacy;
- (2) “Board-approved intervenors” means persons trained in intervention and designated by the board to implement the intervention process when necessary;
- (3) “Committee” means a committee appointed by the board to formulate and administer the impaired pharmacists program;
- (4) “Impaired pharmacist” means a pharmacist who is unable to practice pharmacy with reasonable skill, competency, or safety to the public because of substance abuse;
- (5) “Impaired pharmacist program” means a plan approved by the board for intervention, treatment, and rehabilitation of an impaired pharmacist;
- (6) “Intervention” means a process whereby an allegedly impaired pharmacist is confronted by the board or board-approved intervenors who provide documentation that a problem exists and attempt to convince the pharmacist to seek evaluation and treatment;
- (7) “Rehabilitation” means the process whereby an impaired pharmacist advances in an impaired pharmacist program to an optimal level of competence to practice pharmacy without endangering the public; and
- (8) “Verification” means a process whereby alleged professional impairment is identified or established.

#### **17-92-702. Administration**

- (a) The Arkansas State Board of Pharmacy may appoint a committee to organize and administer a program that

shall fulfill two (2) functions:

- (1) The program shall serve as a diversion program to which the board may refer licensees when appropriate in lieu of or in addition to other disciplinary action; and
  - (2) The program shall also be a source of treatment or referral for pharmacists who, on a strictly voluntary basis, desire to avail themselves of its services.
- (b) The board may appoint a committee of five (5) persons who are recovering pharmacists to serve three-year terms with the initial members appointed to staggered terms.

#### **17-92-703. Functions**

The functions of the committee shall include:

- (1) Evaluation of pharmacists who request participation in the program;
- (2) Review and designation of treatment facilities and services to which pharmacists in the program may be referred;
- (3) Receipt and review of information relating to the participation of pharmacists in the program;
- (4) Assisting the pharmacists' professional association in publicizing the program; and
- (5) Preparation of reports for the Arkansas State Board of Pharmacy.

#### **17-92-704. Board review**

The Arkansas State Board of Pharmacy shall review the activities of the committee. As part of this evaluation, the board may review files of all participants in the impaired pharmacist program. The board shall also resolve complaints voiced regarding the impaired pharmacist program.

#### **17-92-705. Notification of procedures, rights, and responsibilities – Failure to comply.**

- (a) The Arkansas State Board of Pharmacy shall inform each pharmacist referred to the program by board action of the procedures followed in the program, of the rights and responsibilities of the pharmacist in the program, and of the possible consequences of noncompliance with the program.
- (b) The board shall be informed of the failure of a pharmacist to comply with any treatment provision of a program if the committee determines that the resumption of the practice of pharmacy would pose a threat to the health and safety of the public.
- (c) Participation in a program under this section shall not be a defense to any disciplinary action which may be taken by the board. Further, no provision of this section shall preclude the board from commencing disciplinary action against a licensee who is terminated from a program pursuant to this section.
- (d) The board shall be informed when pharmacists who enter the program resume professional practice.

#### **17-92-706. Funding**

- (a)
  - (1) The Arkansas State Board of Pharmacy may provide up to fifty thousand dollars (\$50,000) per year to the committee for the program.

(2) The board may provide to the committee at any time the moneys authorized under subdivision (a)(1) of this section.

(b) Documentation of the use of these funds shall be provided quarterly to the board for review and comment.

#### **17-92-707. Liability**

(a) All persons acting on behalf of the Arkansas State Board of Pharmacy in the impaired pharmacist program under this section shall be considered officers or employees of the State of Arkansas for purposes of:

(1) Immunity from civil liability pursuant to § 19-10-301 et seq.; and

(2) Payment of actual damages on behalf of state officers or employees pursuant to § 21-9-201 et seq.

(b) All patient records shall be confidential and shall not be subject to public inspection except pursuant to an order of a court of competent jurisdiction. However, the records may be introduced as evidence in any relevant proceedings before the board and shall be produced upon board request.

#### **17-92-801. Powers and duties of Arkansas State Board of Pharmacy**

(a) The Arkansas State Board of Pharmacy shall provide that hospital pharmacy technicians as in § 17-92-602(5) and pharmacy technicians as in § 17-92-101(16)(C), and hereinafter referred to as pharmacy technicians, register with or be certified by the board, or both.

(b) The board may provide reasonable qualifications for a person to be certified as a pharmacy technician or registered as a pharmacy technician, or both, including, without limitation, the education, training, and testing that the board deems necessary to preserve and protect the public health.

(c) The board may suspend or revoke the registration of any person certified as a pharmacy technician or registered as a pharmacy technician, or both, but only after an opportunity for a hearing before the board upon reasonable notice to the person in writing.

(d) Grounds for suspension or revocation of registration or certification as a pharmacy technician, or both, are the following:

(1) Violation of any law or regulation regarding the practice of pharmacy;

(2) Violation of any law or regulation regarding legend drugs or controlled substances; or

(3) Violation of any regulation adopted by the board regarding pharmacy technicians.

#### **17-92-901. Definitions**

As used in this subchapter:

(1) “Home medical equipment, legend device, and medical gas supplier” means a person licensed to supply home medical equipment, medical gases, or legend devices, or any combination thereof, to patients on an order from medical practitioners licensed to order, use, or administer these products and to other licensed suppliers of home medical equipment, medical gases, or legend devices, or any combination thereof;

(2) “Home medical equipment services” means the delivery, installation, maintenance, replacement, or instruction, or any combination thereof, in the use of medical equipment used by a sick or disabled individual to allow the individual to be maintained in a noninstitutional environment;

- (3) “Legend device” means a device which, because of any potential for harmful effect or the method of its use, is not safe except under the supervision of a practitioner;
- (4)
- (A) “Medical equipment” means technologically sophisticated medical devices, including, but not limited to:
- (i) Oxygen and oxygen delivery systems;
  - (ii) Ventilators;
  - (iii) Respiratory disease management devices;
  - (iv) Electronic and computer-driven wheelchairs and seating systems;
  - (v) Apnea monitors;
  - (vi) Transcutaneous electrical nerve stimulator units;
  - (vii) Low air loss cutaneous pressure management devices;
  - (viii) Sequential compression devices;
  - (ix) Neonatal home phototherapy devices;
  - (x) Feeding pumps;
  - (xi) Electrically powered hospital beds; and
  - (xii) Infusion pumps.
- (B) “Medical equipment” does not include:
- (i) Medical equipment used or dispensed in the normal course of treating patients by hospitals, hospices, nursing facilities, or home health agencies;
  - (ii) Medical equipment used or dispensed by health care professionals licensed in Arkansas, provided that the professional is practicing within the scope of that professional's practice act;
  - (iii) Upper and lower extremity prosthetics and related orthotics; or
  - (iv) Canes, crutches, walkers, bathtub grab bars, standard wheelchairs, commode chairs, and bath benches;
- (5) “Medical gas” means those gases and liquid oxygen intended for human consumption; and
- (6) “Order” means an order issued by a licensed medical practitioner legally authorized to order medical gases or legend devices, or both.

**17-92-902. License required**

- (a)
- (1) No person or entity subject to licensure shall sell or rent or offer to sell or rent directly to patients in this state any home medical equipment, legend devices, or medical gases, or any combination thereof, unless the person or entity is licensed as required by this subchapter.

- (2) The licensure requirements of this subchapter will apply to all companies, agencies, and other business entities that are in the business of supplying medical equipment to patients in their residences and that bill the patient or the patient's insurance, Medicare, Medicaid, or other third-party payor for the rent or sale of that equipment.
- (b)
- (1) The application for a license shall be on a form furnished by the Arkansas State Board of Pharmacy and shall be accompanied by payment of the fee prescribed by § 17-92-108.
  - (2) The board shall require a separate license for each facility directly or indirectly owned or operated within this state by the same person or business entity within this state, or for a parent entity with divisions, subdivisions, subsidiaries, or affiliate companies, or any combination thereof, when operations are conducted at more than one (1) location and there exists joint ownership and control among all the entities.
- (c)
- (1) All licenses issued under this subchapter shall expire on December 31 of each calendar year.
  - (2)
    - (A) Each application for renewal of the license must be made on or before December 31 of each year.
    - (B) Penalties for late payment include:
      - (i) A twenty-dollar penalty if not paid by February 1 of each year; and
      - (ii) A forty-dollar penalty if not paid by March 1 of each year.
    - (C) The license shall be considered null and void if the fee is not paid by April 1 of each year.
- (d) Wholesale distributors licensed under § 20-64-501 et seq. may exchange those licenses for licenses issued under this subchapter without payment of additional fees.
- (e) Each license issued hereunder shall be displayed by the holder thereof in a conspicuous place.

**17-92-903. Exemption from license and permit requirements**

- (a) The licensure requirements of this subchapter and any retail pharmacy permit requirements that may apply to the distribution or provision of legend medical gases, medical equipment, legend devices, and medical supplies, except legend drugs, do not apply to the following unless the following have a separate company, corporation, division, or other business entity that is in the business of providing medical equipment for sale or rent to a patient at his or her home as covered by this subchapter:
- (1) Home health agencies;
  - (2) Hospitals;
  - (3) Manufacturers and wholesale distributors when not selling directly to the patient;
  - (4) Health care practitioners legally eligible to prescribe or order home medical equipment, medical gases, and legend devices;
  - (5) Medical doctors, physical therapists, respiratory therapists, occupational therapists, speech pathologists, optometrists, chiropractors, and podiatrists who use home medical equipment or legend devices, or both,

to treat patients;

- (6) Nurses who use but do not sell home medical equipment or legend devices, or both, to their patients;
  - (7) Pharmacies;
  - (8) Hospice programs;
  - (9) Nursing homes;
  - (10) Veterinarians;
  - (11) Dentists; and
  - (12) Emergency medical services.
- (b) Although excluded from a separate licensure requirement for medical equipment, pharmacies shall be subject to the same rules and regulations for the sale or rental of medical equipment covered by this subchapter.

**17-92-904. Supply order required**

- (a) Home medical equipment, legend device, and medical gas suppliers shall not supply medical gases or legend devices to a patient without an order.
- (b)
  - (1) Orders may be issued for institutional, medical practitioner, and individual patient use.
  - (2) It is also recognized that oxygen, liquid oxygen, and legend devices may be used in emergencies by trained individuals.
  - (3) Nothing in this subchapter shall prohibit the prehospital emergency administration of oxygen by licensed health care providers, emergency medical technicians, first responders, firefighters, law enforcement officers, and other emergency personnel trained in the proper use of emergency oxygen.

**17-92-905. Labeling**

- (a) Medical gases shall be labeled in compliance with existing federal and state laws.
- (b) All legend devices shall be labeled in compliance with existing federal and state laws.

**17-92-906. Regulations**

- (a)
  - (1) The Arkansas State Board of Pharmacy shall adopt regulations for the distribution of home medical equipment, legend devices, and medical gases which promote the public health and welfare and which comply with, at least, the minimum standards, terms, and conditions of federal laws and federal regulations.
  - (2) The regulations shall include, without limitation:
    - (A) Minimum information from each home medical equipment, legend device, and medical gas supplier required for licensing and renewal of licenses;

- (B) Minimum qualifications of persons who engage in the distribution of these products;
  - (C) Appropriate education or experience, or both, of persons employed in distribution of these products who assume responsibility for positions related to compliance with state licensing requirements;
  - (D) Minimum requirements for the storage and handling of these products;
  - (E) Minimum requirements for the establishment and maintenance of distribution records for these products; and
  - (F) Federal and state labeling requirements.
- (b) State regulations shall not apply to the following:
- (1) Home health agencies;
  - (2) Hospitals;
  - (3) Manufacturers and wholesale distributors when not selling directly to the patient;
  - (4) Health care practitioners legally eligible to prescribe or order home medical equipment, medical gases, and legend devices;
  - (5) Medical doctors, physical therapists, respiratory therapists, occupational therapists, speech pathologists, optometrists, chiropractors, and podiatrists who use home medical equipment or legend devices, or both, to treat patients;
  - (6) Nurses who use but do not sell home medical equipment or legend devices, or both, to their patients;
  - (7) Hospice programs;
  - (8) Nursing homes; and
  - (9) Veterinarians.
- (c) No regulations promulgated to implement this subchapter shall be effective until they have been reviewed by the House Committee on Public Health, Welfare, and Labor and the Senate Committee on Public Health, Welfare, and Labor or appropriate subcommittees thereof.

**17-92-907. Manufacture, shipment, or sale of medical gases.**

- (a) The manufacture within this state, shipment into this state, or sale or offer for sale within this state of medical gases shall not be subject to § 20-56-211(11)(C).
- (b)
  - (1) Pursuant to this subchapter, the dispensing of medical gases does not require a retail pharmacy permit.
  - (2) The sale of medical gases directly to patients shall not be subject to § 20-56-211(11)(C) or § 20-64-504.

**17-92-908. Revocation or suspension of license**

The Arkansas State Board of Pharmacy may revoke or suspend licenses or may refuse to issue any license under this subchapter if the holder or applicant has committed or is found guilty by the board of any of the following:

- (1) Violation of any federal, state, or local law or regulation relating to medical equipment, medical gases, and medical supplies, except legend drugs and legend devices;
- (2) Violation of any provisions of this subchapter or any regulation promulgated hereunder; or
- (3) Commission of an act or engaging in a course of conduct which constitutes a clear and present danger to the public health and safety.

#### **17-92-1001. Title**

This subchapter may be known and cited as the “Arkansas Internet Prescription Consumer Protection Act”.

#### **17-92-1002. Purpose**

The purpose of this subchapter is to require Internet pharmacies to:

- (1) Make certain disclosures on their Internet sites;
- (2) List the principals, pharmacists, and physicians associated with the Internet sites; and
- (3) Include amending licensing requirements for pharmacists and physicians to address prescribing and dispensing medication via the Internet.

#### **17-92-1003. Definitions**

As used in this subchapter:

- (1) “Deliver” means the actual, constructive, or attempted transfer from one (1) person to another of any drug whether or not an agency relationship exists;
- (2) “Dispense” means to deliver prescription medication to the ultimate user or research subject pursuant to the lawful order of a practitioner or pursuant to the prescription of a mid-level practitioner;
- (3) “Distribute” means to deliver, other than by administering or dispensing, any drug;
- (4) “Electronic mail” means any message transmitted through the international network of interconnected government, educational, and commercial computer networks, including without limitation messages transmitted from or to any address affiliated with an Internet site;
- (5) “Foreign entity” means any corporation, limited liability company, or other body corporate organized under the law of any jurisdiction other than the State of Arkansas;
- (6) “Internet broker” means an entity that serves as an agent or intermediary or other capacity that causes the Internet to be used to bring together a buyer and seller to engage in the dispensing of prescription-only drugs;
- (7) “Internet site” means a specific location on the international network of interconnected government, educational, and commercial computer networks that is determined by Internet protocol numbers, by a domain name, or by both, including without limitation domain names that use the designations “.com”, “.edu”, “.gov”, “.org”, and “.net”;
- (8) “Person” means any individual, corporation, partnership, limited liability company, limited liability partnership, limited partnership, association, joint venture, or any other legal or commercial entity, whether foreign or

domestic;

- (9) “Pharmacist” means any natural person licensed under this subchapter to practice pharmacy;
- (10) “Pharmacy”, “drug store”, or “apothecary” means premises, laboratory, area, or other place:
- (A) Where drugs are offered for sale, where the profession of pharmacy is practiced, and where prescriptions are compounded and dispensed;
  - (B) Which has displayed upon it or within it the words “pharmacist”, “pharmaceutical chemist”, “pharmacy”, “apothecary”, “drugstore”, “druggist”, “drugs”, “drug sundries”, or any of these words or combination of these words; or
  - (C) Where the characteristic symbols of pharmacy or the characteristic prescription sign “Rx” may be exhibited;
- (11) “Practitioner” means:
- (A) A person licensed to practice medicine and surgery, dentistry, podiatry, veterinary medicine, or optometry licensed under the optometry law as a therapeutic licensee or diagnostic and therapeutic licensee; or
  - (B) A scientific investigator or other person authorized by law to use a prescription-only drug in teaching or chemical analysis or to conduct research with respect to a prescription-only drug;
- (12) “Premises” means the portion of any building or structure leased, used, or controlled by the licensee in the conduct of the business registered by the Arkansas State Board of Pharmacy at the address for which the registration was issued;
- (13)
- (A) “Prescription-only drug” means any drug, whether intended for use by man or animal, required by federal or state law to be dispensed only pursuant to a written or oral prescription or order of a practitioner or that is restricted to use by practitioners only.
  - (B) “Prescription-only drug” does not mean contact lenses;
- (14)
- (A) “Prescription order” means:
    - (i) An order to be filled by a pharmacist for prescription medication issued and signed by a practitioner or a mid-level practitioner in the authorized course of professional practice; or
    - (ii) An order transmitted to a pharmacist through word of mouth, note, telephone, or other means of communication directed by the practitioner or mid-level practitioner.
  - (B) In the absence of a prior and proper patient-practitioner relationship, “prescription order” does not include an order for a prescription-only drug issued solely in response to:
    - (i) An Internet questionnaire;
    - (ii) An Internet consultation; or
    - (iii) A telephonic consultation; and
- (15) “Proper practitioner-patient relationship” means that before the issuance of a prescription, a practitioner,

physician, or other prescribing health professional performs a history and in-person physical examination of the patient adequate to establish a diagnosis and to identify underlying conditions or contraindications to the treatment recommended or provided unless:

- (A) The prescribing practitioner is consulting at the specific request of another practitioner who:
  - (i) Maintains an ongoing relationship with the patient;
  - (ii) Has performed an in-person physical examination of the patient; and
  - (iii) 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; or
- (C) The relationship is established through telemedicine pursuant to the Telemedicine Act, § 17-80-401 et seq.

#### **17-92-1004. Requirements for Internet sales**

- (a) A pharmacy operating within or outside Arkansas shall not sell, dispense, distribute, deliver, or participate in the sale, dispensing, distribution, or delivery of a prescription-only drug to any consumer in this state through an Internet site or by electronic mail unless:
  - (1) All Internet sites and electronic mail used by the person for purposes of sales or delivery of a prescription-only drug are in compliance with all requirements of federal law applicable to the Internet site or electronic mail;
  - (2)
    - (A) The pharmacy that sells, dispenses, distributes, or delivers the prescription-only drug is in compliance with all requirements of relevant state law.
    - (B) The pharmacy shall be properly regulated by the Arkansas State Board of Pharmacy to engage in the practice of pharmacy pursuant to § 17-92-101 et seq.;
  - (3) The pharmacist who fills the prescription order is in compliance with subsection (c) of this section;
  - (4)
    - (A) Any pharmacy that participates in the sale of a prescription-only drug is in compliance with subsection (d) of this section.
    - (B) Any pharmacy that participates in the sale of a prescription-only drug is in compliance with an Arkansas prescription drug monitoring program, if an Arkansas prescription drug monitoring program exists;
  - (5)
    - (A) The pharmacy, if a foreign entity, is registered with the Secretary of State and is in compliance with all requirements for foreign corporations provided in any applicable state law.
    - (B) Nothing in this subdivision (a)(5) shall be construed to authorize any corporation to engage in the practice of medicine contrary to any applicable Arkansas law; and
  - (6) Any practitioner who sells, dispenses, distributes, or delivers the prescription-only drug is in compliance with all requirements of relevant state law.
- (b) Any practitioner who writes a prescription order through an Internet site or electronic mail for a consumer

physically located in this state who is not an established patient shall be licensed by the applicable licensing board and in compliance with all applicable laws.

- (c) A pharmacist practicing within or outside Arkansas may not fill a prescription order to dispense a prescription-only drug to a patient if the pharmacist knows or reasonably should have known under the circumstances that the prescription order was issued:
  - (1) On the basis of:
    - (A) An Internet questionnaire;
    - (B) An Internet consultation; or
    - (C) A telephonic consultation; and
  - (2) Without a valid prior patient-practitioner relationship.
- (d)
  - (1) An Internet broker operating within or outside Arkansas may participate in the sale of a prescription-only drug in this state only if the Internet broker knows that the pharmacist who dispenses the drug has complied with the requirements of subsection (c) of this section.
  - (2) The board shall report to the Attorney General any violations of subdivision (d)(1) of this section.

#### **17-92-1005. Requirements for Internet sites**

No pharmacy shall sell, dispense, distribute, deliver, or participate in the sale, dispensing, distribution, or delivery of any prescription-only drug to any consumer in this state if any part of the transaction was conducted through an Internet site unless the Internet site displays in a clear and conspicuous manner the:

- (1) Name of each pharmacy that causes the sale, dispensing, or delivery of a prescription-only drug to any consumer in this state;
- (2) Address of the principal place of business of each pharmacy that causes the sale, dispensing, or delivery of a prescription-only drug to any consumer in this state;
- (3) Telephone number of each pharmacy that causes the sale, dispensing, or delivery of a prescription-only drug to any consumer or other person in this state; and
- (4) Pharmacy's:
  - (A) Permit number assigned by the Arkansas State Board of Pharmacy; or
  - (B) Certification by the National Association of Boards of Pharmacy as a Verified Internet Pharmacy Practice Sites site and the Verified Internet Pharmacy Practice Sites seal with a link to the National Association of Boards of Pharmacy's verification site.

#### **17-92-1006. Disclaimers or limitations of liabilities**

- (a) No pharmacy that sells, dispenses, distributes, delivers, prescribes, or participates in the sale, dispensing, or delivery of any prescription-only drug to any consumer in this state, if the consumer submitted the purchase order for the prescription-only drug through an Internet site or by electronic mail, may disclaim, limit, or waive any liability to which the pharmacy otherwise is subject under law for the act or practice of selling, dispensing, or delivering prescription-only drugs.

- (b) Any disclaimer, limitation, or waiver in violation of this section is void.
- (c) Any attempt to make any disclaimer, limitation, or waiver in violation of this section is a violation of this subchapter.

**17-92-1007. Enforcement**

Any violation of this subchapter is an unconscionable act or practice under § 4-88-107.

**17-92-1101. Purpose**

It is the purpose of this subchapter to:

- (1) Improve the health of needy Arkansans through a prescription drug redispensing program that authorizes charitable clinic pharmacies to redispense medicines that would otherwise be destroyed; and
- (2) Reaffirm the existing broad latitude of the Arkansas State Board of Pharmacy to protect the safety of the prescription drug supply in this state.

**17-92-1102. Definitions**

As used in this subchapter:

- (1) “Charitable clinic” means a charitable nonprofit corporation or a facility organized as a not-for-profit corporation under §§ 4-28-201--4-28-206 and 4-28-209--4-28-224 that:
  - (A) Holds a valid exemption from federal income taxation issued pursuant to section 501(a) of the Internal Revenue Code;
  - (B) Is listed as an exempt organization under section 501(c)(3) of the Internal Revenue Code;
  - (C) Provides advice, counseling, diagnosis, treatment, surgery, care, or services relating to the preservation or maintenance of health on an outpatient basis for a period of less than twenty-four (24) consecutive hours to persons not residing or confined at the facility;
  - (D) May charge an administrative fee or request a donation not to exceed ten dollars (\$10.00) per visit; and
  - (E) Has a licensed outpatient pharmacy;
- (2) “Charitable clinic pharmacy” means the practice of a pharmacy at a site where prescriptions are dispensed by a charitable clinic free of charge to appropriately screened and qualified indigent patients;
- (3) “Controlled substances” means substances defined by the Uniform Controlled Substances Act, §§ 5-64-101--5-64-510;
- (4) “Indigent” means a person with an income that is below two hundred percent (200%) of the federal poverty level;
- (5) “Nursing facility” means the same as under § 20-10-1401;
- (6)
  - (A)
    - (i) “Prescription drug” means a drug limited by section 503(b)(1) of the Federal Food, Drug, and

Cosmetic Act, 21 U.S.C. § 301 et seq., to being dispensed by or upon a medical practitioner's prescription because the drug is:

- (a) Habit-forming;
  - (b) Toxic or having potential for harm; or
  - (c) Limited in its use to use under a practitioner's supervision by the new drug application for the drug.
- (ii) The product label of a legend drug is required to contain the statement:
- (a) "CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION"; or
  - (b) "Rx only".
- (iii) The drug is 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) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., if certain specified conditions are met.
- (B) "Prescription drug" does not include controlled substances; and
- (7) "Properly transferred" means the storage, handling, and distribution of the drug under this subchapter in:
- (A) Accordance with the label; and
  - (B) Its dispensed, sealed, tamper-evident single-user unit.

**17-92-1103. Prescription drug redispensing program**

- (a) The prescription drug redispensing program established by this subchapter shall be a pilot program to determine the efficacy of redispensing prescription drugs to indigent patients.
- (b) In cooperation with the Department of Health and the Department of Human Services, the Arkansas State Board of Pharmacy shall develop and implement the program consistently with public health and safety through which unused prescription medications other than controlled substances may be transferred from a nursing facility to a charitable clinic pharmacy for the purpose of distributing the medication to Arkansas residents who are indigent.
- (c) In cooperation with the Department of Health and the Department of Human Services, the board shall monitor the program and submit to the General Assembly two (2) reports along with any recommendations or findings, as follows:
  - (1) The first report shall be submitted on or before January 1, 2006; and
  - (2) The second report shall be submitted on or before October 1, 2006.
- (d) Participation in the program by any entity, including individuals, pharmacies, charitable clinics, charitable clinic pharmacies, nursing facilities, and drug manufacturers, shall be voluntary.

**17-92-1104. Donations of unused prescription drugs**

- (a)
  - (1) A charitable clinic may accept for redispensing prescription drugs obtained from a nursing facility by the

- clinic pharmacy for relabeling and dispensing free of charge and pursuant to a valid prescription order to an indigent patient.
- (2) The donor patient shall be considered to be the owner of the prescription drug and entitled to donate the prescription drug for use by a charitable clinic.
- (b)
- (1)
- (A)
- (i) Any nursing home may enter into a contract with any charitable clinic for the transfer of prescription drugs under this section.
- (ii) No prescription drugs may be transferred without a contract.
- (B) A contract entered into under subdivision (b)(1)(A) of this section shall:
- (i) Be approved by the Arkansas State Board of Pharmacy, in cooperation with the Department of Health and the Department of Human Services; and
- (ii) Set out procedures for ensuring a safe chain of custody to protect the safety of all transferred drugs.
- (C) The contract may specify that the charitable clinic will:
- (i) Define a specified set of prescription drugs that will be transferred from the nursing home to the charitable clinic;
- (ii) Request from time to time the transfer of particular prescription drugs;
- (iii) Receive all the prescription drugs that the nursing home is authorized to transfer under this section; or
- (iv) Make such other provisions as may be approved by the board.
- (2) The pharmacist-in-charge at the charitable clinic shall be responsible for determining the description of the prescription drugs that will be included in the contract.
- (c) Donations of prescription drugs to a charitable clinic pharmacy shall meet the following requirements:
- (1)
- (A) The charitable clinic pharmacy accepts the prescription drugs only in their original sealed and tamper-evident packaging.
- (B) However, the charitable clinic pharmacy may accept prescription drugs packaged in single-unit doses or blister packs with the outside packaging opened if the single-unit dose packaging remains intact;
- (2) A pharmacist of the charitable clinic pharmacy determines that the prescription drug is not adulterated or misbranded and is safe to dispense;
- (3) No product of which the integrity cannot be assured is accepted for redispensing by the pharmacist of the charitable clinic pharmacy;
- (4) The prescription drugs are physically transferred from the nursing facility to a charitable clinic pharmacy

by a person authorized by the board to pick up the prescription drugs for the charitable clinic;

- (5)
    - (A) The donor executes a form stating that the donor is authorized to donate the prescription drugs and intends to voluntarily donate them to a charitable clinic pharmacy.
    - (B) The nursing facility retains the donor form along with other acquisition records;
  - (6) The donor patient's name, prescription number, and any other identifying marks are obliterated from the packaging before the nursing facility sends the prescription drug to the charitable clinic;
  - (7) The drug name, strength, and expiration date remain on the prescription drug package label;
  - (8) The redispensed prescription drug is assigned the same expiration date as on the original package;
  - (9) Expired prescription drugs accepted by a charitable clinic pharmacy are not redispensed and are destroyed according to the charitable clinic pharmacy's destruction procedures; and
  - (10) The charitable clinic pharmacy accepts no controlled substances.
- (d)
- (1) If a nursing facility that releases prescription drugs to a charitable clinic receives notice from a pharmacy that a prescription drug has been recalled, the nursing facility shall inform the clinic of the recall.
  - (2) If a charitable clinic receives a recall notification from a nursing facility, the clinic shall perform a uniform destruction of all of the recalled prescription drug in the facility.
- (e) No prescription drug dispensed through a charitable clinic pharmacy shall be eligible for reimbursement from the state Medicaid program.
- (f) Indigent patients receiving prescription drugs through the prescription drug redispensing program shall sign a waiver form releasing the nursing facility, the donor, and the donor's estate from liability.
- (g) The board shall promulgate rules to develop:
- (1) Forms and procedures for authorizations and certifications required under subdivision (c)(4) of this section;
  - (2) The donor consent form required under subdivision (c)(5) of this section;
  - (3) The waiver forms required under subsection (f) of this section; and
  - (4)
    - (A) Specific requirements for a charitable clinic pharmacy or other specialty pharmacy for the medically indigent as defined by rules of the board to qualify for participation in and to participate in the prescription drug redispensing program.
    - (B) On request, the board shall provide the information required under subdivision (g)(4)(A) of this section to charitable clinics.
- (h)
- (1) The following persons and entities that participate in the prescription drug redispensing program shall not be subject to any professional disciplinary action or criminal prosecution for actions taken under the prescription drug redispensing program:

- (A) The donor and the donor's estate;
  - (B) A nursing facility;
  - (C) The prescribing physician, physician's assistant, registered nurse, advanced practice nurse, or nurse practitioner;
  - (D) Pharmacists and pharmacy technicians except when the board has promulgated regulations dealing specifically with the prescription drug redispensing program;
  - (E) The charitable clinic;
  - (F) The Department of Health;
  - (G) The Department of Human Services; or
  - (H) The board.
- (2) Participation in the prescription drug redispensing program shall not be used as an independent basis for a claim of liability in tort or other civil action against any person or entity, including, but not limited to:
- (A) The donor and the donor's estate;
  - (B) A nursing facility;
  - (C) The prescribing physician, physician's assistant, nurse practitioner, or nurse;
  - (D) The charitable clinic;
  - (E) The charitable clinic pharmacy acting in conformity with board regulations;
  - (F) The pharmacist who originally dispensed the donated prescription drugs acting in conformity with board regulations;
  - (G) A pharmacist dispensing donated prescription drugs acting in conformity with board regulations;
  - (H) The Department of Health;
  - (I) The Department of Human Services; or
  - (J) The board.
- (3)
- (A) In the absence of bad faith, a prescription drug manufacturer shall not be subject to criminal prosecution or liability in tort or other civil action for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a prescription drug manufactured by the prescription drug manufacturer that is donated by any person under the prescription drug redispensing program, including, but not limited to, liability for failure to provide:
    - (i) Product or consumer package insert information; or
    - (ii) The expiration date of the donated prescription drug.

(B) Subdivision (h)(3)(A) of this section does not apply to a previously undisclosed product defect.

**17-92-1105. Sample drug use not restricted**

Nothing in this subchapter shall restrict the use of samples by a physician or advanced practice nurse during the course of working at a charitable clinic whether or not the clinic has a licensed outpatient pharmacy.

**17-92-1106. Resale prohibited**

Nothing in this subchapter shall be construed to provide for the resale of prescription drugs by any person or entity.

**17-92-1107. Applicability**

Nothing in this subchapter applies to any questions of liability arising outside the scope of the prescription drug redispensing program.

**17-92-1201. Arkansas Pharmacy Audit Bill of Rights**

- (a) This subchapter shall be known and may be cited as the “Arkansas Pharmacy Audit Bill of Rights”.
- (b) Notwithstanding any other law, when an audit of the records of a pharmacy is conducted by a managed care company, an insurance company, a third-party payor, or any entity that represents responsible parties such as companies or groups, the audit shall be conducted in accordance with the following bill of rights:
  - (1) The entity conducting the initial on-site audit shall give the pharmacy notice at least one (1) week before conducting the initial on-site audit for each audit cycle;
  - (2) Any audit that involves clinical or professional judgment shall be conducted by or in consultation with a pharmacist;
  - (3)
    - (A)
      - (i) Any clerical or recordkeeping error, such as a typographical error, scrivener's error, or computer error, regarding a required document or record shall not in and of itself constitute fraud.
      - (ii) However, a claim arising under subdivision (b)(3)(A)(i) of this section may be subject to recoupment.
    - (B) A claim arising under subdivision (b)(3)(A)(i) of this section is not subject to criminal penalties without proof of intent to commit fraud;
  - (4) A pharmacy may use the records of a hospital, physician, or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug;
  - (5)
    - (A) A finding of an overpayment or underpayment may be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs.
    - (B) However, recoupment of claims under subdivision (b)(5)(A) of this section shall be based on the actual overpayment unless the projection for overpayment or underpayment is part of a settlement by the pharmacy;
  - (6)

- (A) Where an audit is for a specifically identified problem that has been disclosed to the pharmacy, the audit shall be limited to claims that are identified by prescription number.
  - (B) For an audit other than described in subdivision (b)(6)(A) of this section, an audit shall be limited to twenty-five (25) prescriptions that have been randomly selected.
  - (C) If an audit reveals the necessity for a review of additional claims, the audit shall be conducted on site.
  - (D) Except for audits initiated under subdivision (b)(6)(A) of this section, an entity shall not initiate an audit of a pharmacy more than two (2) times in a calendar year;
- (7)
- (A) A recoupment shall not be based on:
    - (i) Documentation requirements in addition to or exceeding requirements for creating or maintaining documentation prescribed by the Arkansas State Board of Pharmacy; or
    - (ii)
      - (a) A requirement that a pharmacy or pharmacist perform a professional duty in addition to or exceeding professional duties prescribed by the Arkansas State Board of Pharmacy.
      - (b) This subdivision (b)(7) applies only to audits of claims submitted for payment on or after January 1, 2012
  - (B) Subdivisions (b)(7)(A)(i) and (ii) do not apply in cases of Food and Drug Administration regulation or drug manufacturer safety programs;
- (8) Recoupment shall only occur following the correction of a claim and shall be limited to amounts paid in excess of amounts payable under the corrected claim;
- (9) Except for Medicare claims, approval of drug, prescriber, or patient eligibility upon adjudication of a claim shall not be reversed unless the pharmacy or pharmacist obtained the adjudication by fraud or misrepresentation of claim elements;
- (10) Each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies audited by the entity;
- (11) A pharmacy shall be allowed at least thirty (30) days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit;
- (12) The period covered by an audit shall not exceed twenty-four (24) months from the date the claim was submitted to or adjudicated by a managed care company, an insurance company, a third-party payor, or any entity that represents such companies or groups;
- (13) Unless otherwise consented to by the pharmacy, an audit shall not be initiated or scheduled during the first seven (7) calendar days of any month due to the high volume of prescriptions filled during that time;
- (14)
- (A) The preliminary audit report shall be delivered to the pharmacy within one hundred twenty (120) days after conclusion of the audit.
  - (B) A final audit report shall be delivered to the pharmacy within six (6) months after receipt of the

preliminary audit report or the final appeal as provided for in subsection (c) of this section, whichever is later; and

- (15) Notwithstanding any other provision in this subsection, the agency conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits.
- (c) Recoupments of any disputed funds shall only occur after final internal disposition of the audit, including the appeals process as set forth in subsection (d) of this section.
- (d)
  - (1) Each entity conducting an audit shall establish an appeals process under which a pharmacy may appeal an unfavorable preliminary audit report to the entity.
  - (2) If, following the appeal, the entity finds that an unfavorable audit report or any portion of the unfavorable audit report is unsubstantiated, the entity shall dismiss the audit report or the unsubstantiated portion of the audit report without any further proceedings.
- (e) Each entity conducting an audit shall provide a copy of the final audit report to the plan sponsor after completion of any review process.
- (f)
  - (1) The full amount of any recoupment on an audit shall be refunded to the responsible party.
  - (2) Except as provided in subsection (f)(3) of this section, a charge or assessment for an audit shall not be based, directly or indirectly, on amounts recouped.
  - (3) Subsection (f)(2) does not prevent the entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if both the following conditions are met:
    - (A) The responsible party and the entity have a contract that explicitly states the percentage charge or assessment to the responsible party; and
    - (B) A commission or other payment to an agent or employee of the entity conducting the audit is not based, directly or indirectly on amounts recouped.
- (g) This section does not apply to any audit, review, or investigation that involves alleged fraud, willful misrepresentation, or abuse, including without limitation:
  - (1) Medicaid fraud as defined in § 5-55-111;
  - (2) Abuse or fraud as defined in § 20-77-1702; or
  - (3) Insurance fraud.