Board of Pharmacy Law Book – Acts
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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 it existed on January 1, 2019;

(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 Arkansas State Board of Pharmacy certifying that the pharmacist has met the standards of competency established by the Arkansas State Board of Pharmacy for 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 healthcare outcomes and quality of care, and when possible, to control healthcare 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 Pharmacopeia – 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) "HIV" means the human immunodeficiency virus or any other identified causative agent of acquired immunodeficiency syndrome (AIDS);

(8) "Interchangeable biological product" means a biological product that is interchangeable as defined by 42 U.S.C. § 262(i)(3), as it existed on January 1, 2019;

(9)

(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;

(10) "Medicine" means a drug or preparation of drugs in suitable form for use as a curative or remedial substance;

(11) "Optometrist" means a practitioner of optometry duly licensed under the laws of this state;

(12) "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;

(13) “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 Pharmacopeia – National Formulary or another nationally recognized compendium;

(14) “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;

(15) “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;

(16) “Physician” means a practitioner of medicine duly licensed under the laws of this or some other state;

(17) “Poisons” means any drug, chemical, medicine, or preparation liable to be destructive to adult human life in quantities of sixty (60) grains or less;

(18)

(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) A pharmacist may prescribe, administer, deliver, distribute, or dispense medications that treat adverse reactions associated with the administration of vaccines and immunizations, vaccines, and immunizations to or for a person three (3) years of age or older.

(d) A pharmacist who prescribes and administers vaccines and immunizations other than for influenza or coronavirus 2019 (COVID-19) to a person who is three (3) years of age to six (6) years of age shall:

(1) Participate in the federal Vaccines for Children Program; and

(2) Inform the person who is three (3) years of age to six (6) years of age and adult caregivers accompanying the person who is three (3) years of age to six (6) years of age of the importance of a well-child visit with a pediatrician or other licensed primary care provider and recommend a well-child visit at least yearly.

(e)

(1) A pharmacist may administer medications other than medications that treat adverse reactions associated with the administration of vaccines and immunizations, vaccines, and immunizations under a patient-specific order or prescription or general written protocol.

(2) The administration of the medication under subdivision (18)(A)(i)(e)(1) of this section is subject to reporting to the prescribing physician, if applicable.

(f) A general written protocol and patient-specific orders or prescriptions under subdivision (18)(A)(i)(e) of this section 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.

(g) Under a statewide protocol, a pharmacist may initiate therapy and administer or dispense, or both, drugs that include Naloxone, nicotine replacement therapy products, oral contraceptives, HIV pre-exposure prophylaxis, and HIV post-exposure prophylaxis;

(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 (18)(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 (18)(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)

(a) Providing pharmacy care.

(b) A pharmacist may treat the following conditions within the framework of a statewide written protocol:

(1) Influenza;

(2) Pharyngitis caused by streptococcus A; or

(3) Other health conditions that can be screened utilizing the waived test under the Clinical Laboratory Improvement Amendments of 1988, that may be adopted by rule of the Arkansas State Board of Pharmacy, in consultation with and upon approval of the Arkansas State Medical Board.

(c) A pharmacist shall only treat conditions for which the pharmacist has tested and that are approved under subdivision (18)(A)(x)*(b)* of this section.

(d)

(1) The Arkansas State Board of Pharmacy, with consultation and upon approval of the Arkansas State Medical Board, shall adopt by rule:

(A) A formulary of medicinal drugs that a pharmacist may prescribe for treatment of conditions listed in subdivision (18)(A)(x)*(b)* of this section; and

(B) A written statewide protocol for conditions listed in subdivision (18)(A)(x)*(b)* of this section, which shall include without limitation the age of people that can be treated and medications to be used to treat people under this subdivision.

(2) The formulary shall include medicinal drugs approved by the United States Food and Drug Administration which are indicated for treatment of these conditions, including without limitation any over-the-counter medication.

(3) The formulary shall not include any controlled substance in Schedules I — IV or 21 U.S.C. § 812, as existing on January 1, 2021.

(e) A pharmacist may write a prescription for over-the-counter medications, supplies, and devices; and

(xi) Providing pharmacokinetic services.

(B) The provisions of subdivisions (18)(A) and (18)(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 Arkansas State Board of Pharmacy rules under the direct, personal supervision of a licensed pharmacist under rules 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.

(ii) A pharmacy technician may administer vaccines and immunizations to a person three (3) years of age or older if delegated to do so by a supervising pharmacist, but may not administer other medications.

(iii) 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.

(iv) Pharmacy products prepared by pharmacy technicians shall be verified for accuracy by the supervising pharmacist before release for patient use, and the verification shall be documented.

(v) The use of pharmacy technicians in a manner not authorized by this chapter or rules promulgated hereunder shall be unprofessional conduct by the pharmacist-in-charge and the supervising pharmacist.

(vi) It is recognized that hospital pharmacy technicians as defined in § 17-92-602(4) are governed by the Hospital Pharmacies Act, § 17-92-601 et seq., and related Arkansas State Board of Pharmacy rules developed under the Hospital Pharmacies Act, § 17-92-601 et seq.;

(19)

(A)

(i) “Prescription” means an order for medicine or medicines usually written as a formula by a physician, optometrist, dentist, veterinarian, or other licensed medicinal practitioner.

(ii) A prescription 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 an equal or lower cost to the patient and communicate that authorization by any generally accepted means of communication of a prescription from a prescriber to a pharmacist.

(B)

(i) A pharmacist whose practice is located within this state may substitute one (1) medication for a therapeutically equivalent medication.

(ii) However, a pharmacist shall not substitute one (1) medication for a therapeutically equivalent medication if:

(a) A prescription is in writing and the prescriber indicates in his or her own handwriting by name or initial that no substitution is to be made;

(b) A prescription is not in writing and the prescriber expressly indicates that the prescription is to be dispensed as communicated; or

(c) The Arkansas State Board of Pharmacy has determined that a therapeutically equivalent medication should not be substituted and has notified all pharmacists of that determination.

(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 (19)(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 (19)(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 subdivision (18)(A)(ix) of this section;

(20) "Proprietary medicines", when not otherwise limited, means remedies that a certain individual or individuals have the exclusive right to manufacture or sell;

(21) "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;

(22) "Supervision" means under the direct charge or direction of and does not contemplate any continued absence of such supervision;

(23) "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;

(24) "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;

(25) "Veterinarian" means a practitioner of veterinary medicine duly licensed under the laws of this or some other state; and

(26) "Written protocol" means a physician's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Arkansas State Medical Board under the Arkansas Medical Practices Act, § 17-95-201 et seq., § 17-95-301 et seq., and § 17-95-401 et seq.

17-92-102. Exemptions.

(a) Nothing in this section and § 17-92-101, § 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, § 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;

(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; or

(4) To the sale or shipping of antibiotics and microbials for veterinary medical use directly from a wholesaler, distributor, pharmacy, or farm store to a client if the veterinary drugs and medicine are dispensed based only on a prescription of a licensed veterinarian who has an existing veterinary-client-patient relationship with the client.

(c) Further exempted from the provisions of this section and § 17-92-101, § 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 unaffected.

This section and § 17-92-101, § 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 before June 12, 1929, unless they are in direct conflict with these sections.

17-92-104. Privilege tax unaffected.

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 hawking, peddling, or street vending of good, wares, and merchandise.

17-92-105. Prohibited acts – Penalties.

(a) Violation of any part of this section and § 17-92-101, § 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. Injunctions.

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) [Repealed.]

(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 – Definitions.

(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 nongovernmental 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 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.

(b)

(1) In addition to the requirements under subsection (a) of this section, when initiating therapy and administering or dispensing, or both, oral contraceptives under a statewide protocol, a pharmacist shall:

(A) Complete a training program related to oral contraceptives that has been approved by the Arkansas State Board of Pharmacy;

(B)

(i) Screen a patient seeking oral contraceptives to assess whether the patient has been seen by a primary care provider or women's healthcare provider within the previous six (6) months.

(ii) If the patient has not been seen by a primary care provider or women's healthcare provider within the previous six (6) months, the pharmacist shall:

(a) Provide the patient with a referral to a local primary care provider or women's healthcare provider; and

(b) Not dispense more than a six-month supply of oral contraceptives or the equivalent number of refills to the patient until the patient has been seen by a primary care provider or women's healthcare provider.

(iii) A pharmacist shall not provide the patient with a referral to a licensed abortion provider.

(iv) The board shall adopt screening assessment procedures and questionnaires to be used by pharmacists throughout the state;

(C)

(i) Explain verbally to the patient the possible effects of an oral contraceptive, including without limitation the death of an unborn child and possible health complications or adverse reactions as printed by the United States Food and Drug Administration.

(ii) The patient and pharmacist shall sign an informed consent form that documents the explanation described in subdivision (b)(1)(C)(i) of this section and place the form in the patient's medical record;

(D) Report the following information to the Department of Health:

(i) The number of women who receive oral contraceptives without a prescription; and

(ii) The age of the women who receive oral contraceptives without a prescription;

(E) Provide a standardized information sheet about the oral contraceptive dispensed to the patient; and

(F) Write a summary of consultation to be maintained in the patient's medical record.

(2) A pharmacist shall only initiate therapy and administer or dispense, or both, oral contraceptives under a statewide protocol to an individual who is eighteen (18) years of age or older.

(c)

(1) In addition to the requirements under subsection (a) of this section, when initiating therapy and administering or dispensing, or both, for HIV pre-exposure prophylaxis or HIV post-exposure prophylaxis, or both, under a statewide protocol, a pharmacist shall:

(A) Within twelve (12) months of initiating therapy and administering or dispensing, or both, complete a training program approved by the board on the use of HIV pre-exposure prophylaxis and HIV post-exposure prophylaxis, which shall include information about:

(i) Financial assistance programs for HIV pre-exposure prophylaxis and HIV post-exposure prophylaxis; and

(ii) Relevant federal guidelines regarding HIV pre-exposure prophylaxis and HIV post-exposure prophylaxis; and

(B) Not permit a patient to waive consultation for HIV pre-exposure prophylaxis or HIV post-exposure prophylaxis.

(2) Under a statewide protocol, a pharmacist shall dispense at least a thirty-day supply and up to a sixty-day supply of HIV pre-exposure prophylaxis if:

(A)

(i) The patient is HIV-negative as documented by a negative HIV test result obtained within the previous seven (7) days from:

(a) An HIV antigen/antibody test;

(b) An HIV antibody-only test; or

(c) A rapid, point-of-care fingerstick blood test approved by the United States Food and Drug Administration.

(ii) If the test results are not transmitted directly to the pharmacist, the pharmacist shall verify the test results.

(iii) If the patient tests positive for HIV infection, the pharmacist shall direct the patient to a primary care provider and provide a list of providers and clinics in the region.

(iv) If the patient does not provide evidence of a negative HIV test, the pharmacist shall test and administer an HIV test and interpret the test results;

(B) The patient does not report:

(i) Any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms; and

(ii) Usage of any contraindicated medication;

(C) The pharmacist provides counseling to the patient on the ongoing use of HIV pre-exposure prophylaxis, which shall include education about:

(i) Side effects;

(ii) Safety during pregnancy and breastfeeding;

(iii) Adherence to recommended dosing;

(iv) The importance of timely testing and treatment for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of childbearing capacity; and

(v) The requirement that subsequent prescriptions for HIV pre-exposure prophylaxis be issued by a primary care provider; and

(D) To the extent possible, the pharmacist documents the services provided by the pharmacist in the patient record system shared with the primary care provider.

(3) Under a statewide protocol, a pharmacist shall dispense a course of HIV post-exposure prophylaxis if the pharmacist:

(A) Screens the patient and determines that the exposure to HIV occurred within the previous seventy-two (72) hours and that the patient otherwise meets the clinical criteria for HIV post-exposure prophylaxis;

(B) Provides HIV testing or determines that the patient is:

(i) Willing to undergo HIV testing consistent with federal guidelines; or

(ii) Unwilling to undergo HIV testing but otherwise eligible for HIV post-exposure prophylaxis;

(C) Provides counseling to the patient on the ongoing use of HIV post-exposure prophylaxis, which shall include education about:

(i) Side effects;

(ii) Safety during pregnancy and breastfeeding;

(iii) Adherence to recommended dosing;

(iv) The importance of timely testing and treatment for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of childbearing capacity; and

(v) The availability of HIV pre-exposure prophylaxis for a person who is at a substantial risk of acquiring HIV; and

(D) To the extent possible, documents the services provided by the pharmacist in the patient record system shared with the primary care provider.

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.

(b)

(1) 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.

(2) 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 - Definition

(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.

17-92-118. Point-of-care treatment.

A pharmacist who tests for conditions under § 17-92-101(18)(A)(x) shall:

(1) Hold a license to practice pharmacy in this state;

(2) Report a diagnosis or suspected existence of influenza to the Department of Health;

(3) Furnish patient records to a healthcare practitioner designated by the patient upon the request of the patient; and

(4) Maintain records of all patients receiving services under this section for two (2) years.

17-92-119. Prescription delivery standards – Definition.

(a) As used in this section, "home delivery services" means providing medications from a pharmacy licensed in this state to a patient through any means other than the patient picking up the medication at the physical pharmacy location, including shipping, mailing, or delivering in any manner a dispensed legend drug.

(b)

(1) The Arkansas State Board of Pharmacy shall promulgate and maintain rules defining the standard of care for pharmacies and pharmacists that provide home delivery services in this state.

(2) If a pharmacy or pharmacist owns or controls, is owned or controlled by, or is under ownership or control with an insurance company, pharmacy benefits manager, pharmaceutical manufacturer, pharmaceutical wholesaler, or pharmacy benefits manager affiliate, then the pharmacy, including any common ownership or controlling entities, or pharmacist, shall not require that a patient receive his or her prescriptions through home delivery services.

(c) A pharmacy or pharmacist is not prohibited from charging a nominal fee for any home delivery service if the nominal fee is charged to the patient with his or her express consent.

(d) The board may modify delivery standards to accommodate changes in technology and for other reasons.

17-92-120. New prescription requests and new refill requests from prescriber.

(a) A pharmacy, pharmacist, employee of a pharmacy, or entity that owns or controls, is owned or controlled by, or is under ownership or control with an insurance company, health clinic, rural health center, federally qualified health center, pharmacy benefits manager, pharmaceutical manufacturer, pharmaceutical wholesaler, or pharmacy benefits manager affiliate shall not request or solicit:

(1) Refill requests for prescription medications from a prescriber for a patient who has not previously filled prescriptions with the pharmacy without express written consent for each individual prescription requested; or

(2) New prescription medications from a prescriber for a patient who has not previously filled prescriptions with the pharmacy without express written consent for each individual prescription requested.

(b)

(1) When a physician or other licensed prescriber authorizes or provides new prescriptions or refill medications to a pharmacy that is not physically located in this state or to a pharmacy that utilizes common carriers to deliver medications through the mail for a new patient who has not previously received pharmacist services or prescriptions filled through that pharmacy, that pharmacy shall:

(A) Establish a professional relationship between a pharmacist and the patient by telephone or telemedicine consult;

(B) Obtain express consent to provide pharmacist services before any prescription medication's being processed, filled, mailed, or delivered to a patient; and

(C) Include communication to the patient about:

(i) The address and physical city and state of the pharmacy;

(ii) The name of the licensed pharmacist who will be providing services;

(iii) The telephone number and website for the pharmacy;

(iv) Expectations for time of delivery of prescription medications; and

(v) Disclosure of any conflicts of interest, including common ownership of the pharmacy by a healthcare insurer, pharmacy benefits manager, medical clinic, federal qualified health center, rural health center, hospital, pharmaceutical wholesaler, or pharmaceutical manufacturer.

(2) If the conditions within subdivision (b)(1) of this section are not met, then the pharmacy and pharmacist shall not fill, bill, dispense, or mail any prescription medications to the patient.

(c) This section does not prohibit:

(1) A physician licensed in this state or any other prescriber licensed in this state from issuing new prescriptions or prescription refills to any licensed pharmacy in this state or out of state that a patient wishes to use; or

(2) A pharmacy licensed in this state or out of this state from requesting prescription transfers from another licensed pharmacy as directed by a patient.

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, Inc. 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) If 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.

(d) [Repealed.]

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 Arkansas 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. Members – Compensation.

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 of the Arkansas State Board of Pharmacy, 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 – Enforcement.

(a)

(1) The Arkansas State Board of Pharmacy shall have authority to make reasonable rules, 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 rule 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 the Department of Health for that purpose, to enforce all the provisions of this chapter.

(c)

(1) Upon written authorization by the board, the department'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 et seq., § 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 department'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 department's inspectors and other designated agents may also view and at the department'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) 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 the Executive Director of the Arkansas State Board of Pharmacy or the executive 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 department'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 Natural Resources Conservation Service in the United States Department of Agriculture, and decisions of the United States Department of the 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 Secretary of the Department of Health and to the Arkansas Pharmacist's Association of all its proceedings, orders, rules, and requirements 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.

17-92-208. Authorization for payment to the Department of Health

(a) The Arkansas State Board of Pharmacy may make payment to the Department of Health 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 department may 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 Hospital Pharmacies Act, § 17-92-601 et seq.

(2) The attorney employed or retained by the department may 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 may 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 rules promulgated hereunder; or

(4) A hospital pharmacy technician as defined in § 17-92-602 performing the limited functions permitted under that subchapter and rules 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 rules promulgated hereunder; or

(3) A hospital pharmacy technician as defined in § 17-92-602 performing the limited functions permitted under that subchapter and rules 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 rules promulgated hereunder or a hospital pharmacy technician as defined in § 17-92-602 performing the limited functions permitted under that subchapter and rules 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 shall:

(1) Be not less than twenty-one (21) years of age; and

(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 rules 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 rules.

(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 rule 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 rule 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, 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, and institutional permits shall be as listed in § 17-92-108, and if renewal remains unpaid by April 1 of the 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 United States Government for:

(A) Any felony listed under § 17-3-102;

(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 United States 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 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 a 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 executive 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 ($1,000) 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 rule for credentialing and approval of pharmacists to practice 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 as a result of meeting the minimum competencies, standards, objectives, and qualifications determined by the board.

(B) However, a credential shall not authorize the pharmacist to practice credentialed pharmacy services 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 rules necessary and appropriate to implement the credentialing and the board's approval of pharmacists to practice 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 credentialed pharmacy services;

(5) The conversion of a credential previously issued by the board for the practice of pharmacy services to a credential issued by an approved credentialing agency; and

(6) Continuing professional education and other measures to maintain pharmacists' continuing competency in credentialed pharmacy services.

(c) The board shall promulgate rules 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 check.

(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 Division 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 Division 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 Division 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 § 17-3-102;

(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 rules, 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.

(2) Upon receipt of information from the Identification Bureau of the Division 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 Division 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 division.

(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 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 rules 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 rule.

(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 rule 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 rules 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 rules.

(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 rule 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 rule.

(g) The board shall provide by rule 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 rule 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. Hospital pharmacy continuity of care endorsement.

(a) The Arkansas State Board of Pharmacy may issue a hospital pharmacy continuity of care endorsement to a healthcare organization that is licensed as a hospital in this state and that has a hospital pharmaceutical services permit.

(b) A hospital pharmacy continuity of care endorsement shall allow a hospital to sell drugs and medications at retail for emergency room patients or patients upon discharge from the hospital for off premises, personal use in an outpatient setting for either up to a thirty-one (31) day supply or a single commercially available package size that is used as a continuation of or supplement to hospital or emergency room treatment.

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 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 rules 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 contents 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 pharmacist.

(a) A nursing home consultant pharmacist and the nursing home administrator shall be jointly responsible to ensure that a pharmacist license is posted at the facility at all times.

(b) The Arkansas State Board of Pharmacy shall set by rule 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 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 standards established by state and federal guidelines.

17-92-413. Disclosure of ownership interest or possible conflicts of interest required – Prohibition of data mining.

A pharmacy, pharmacist, physician, employee, or entity that owns or controls, is owned or controlled by, or is under ownership or control with an insurance company, health clinic, hospital, rural health center, federally qualified health center, pharmacy benefits manager, pharmaceutical manufacturer, pharmaceutical wholesaler, or pharmacy benefits manager that provides a pharmacy benefits plan or program, including prescription drug coverage, or contracts with a third party for prescription drug services under a health benefit plan shall:

(1) Disclose to the consumer any ownership interest or possible conflicts of interest with a pharmacy benefits manager, healthcare insurer, or healthcare payor; and

(2) Not access and utilize patient information, including either medical information in patient charts or billing claims information, to market or contact patients in order to solicit the transfer of the patient to a particular pharmacy.

17-92-501. Penalty.

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 rules of the board.

17-92-502. Rules.

The Arkansas State Board of Pharmacy may adopt such reasonable rules, 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 or biological 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 or interchangeable biological 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 benefits 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 payor or pharmacy benefits 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.

17-92-505. Labeling.

(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 – Definitions.

(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 services, or 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 made 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 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 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 as listed on the Maximum Allowable Cost List; or

(iii) If the National Drug Code 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 as listed on 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.

(2) This section shall apply to the pharmacy benefits manager employed by the Arkansas Medicaid Program or the division if, at any time, the Arkansas Medicaid Program or the 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. Short title.

This subchapter may be cited as the "Hospital Pharmacies Act".

17-92-602. Definitions

As used in this subchapter:

(1) "Hospital" means a hospital as defined in § 20-9-201;

(2) "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;

(3) "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;

(4) "Hospital pharmacy technicians" means persons other than licensed pharmacists who perform duties in conjunction with the overall hospital medication distribution system for inpatients; and

(5) "Licensed pharmacist" means any person licensed to practice pharmacy by the Arkansas State Board of Pharmacy.

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(3); 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)

(1) However, this section does not prohibit any hospital having a direct or indirect interest in or otherwise holding either directly or indirectly a permit before March 28, 1975, from continuing to have an interest in or holding the permit.

(2) This section does not prohibit any hospital so holding a permit before March 28, 1975, from receiving a renewal of the permit.

(3) This section does not prohibit dispensing drugs or medications through a hospital pharmacy continuity of care endorsement or to hospital employees and students.

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 before 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 before March 28, 1975, from receiving a renewal of the permit.

17-92-701. Definitions.

As used in this subchapter:

(1) “Board-approved intervenors” means persons trained in intervention and designated by the Arkansas State Board of Pharmacy to implement the intervention process when necessary;

(2) “Impaired pharmacist” means a pharmacist who is unable to practice pharmacy with reasonable skill, competency, or safety to the public because of substance abuse;

(3) “Impaired pharmacist program” means a plan approved by the board for intervention, treatment, and rehabilitation of an impaired pharmacist;

(4) “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;

(5) “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

(6) “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 and pharmacy technicians as in § 17-92-101(18)(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 rule regarding the practice of pharmacy;

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

(3) Violation of any rule 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 healthcare 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) Healthcare 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 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 healthcare 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. Rules.

(a)

(1) The Arkansas State Board of Pharmacy shall adopt rules 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 rules 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 rules 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) Healthcare 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 rules 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 rule 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;

(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 in-need 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 et seq.;

(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 Arkansas 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 rules 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 rules;

(F) The pharmacist who originally dispensed the donated prescription drugs acting in conformity with board rules;

(G) A pharmacist dispensing donated prescription drugs acting in conformity with board rules;

(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) of this section do not apply in cases of United States 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 subdivision (f)(3) of this section, a charge or assessment for an audit shall not be based, directly or indirectly, on amounts recouped.

(3) Subdivision (f)(2) of this section 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.

(h) The Insurance Commissioner shall:

(1) Administer and enforce this subchapter; and

(2) Promulgate rules to implement the purposes and requirements of this subchapter.

Miscellaneous Statutes Related to Pharmacy

Professions Generally – General Provisions

17-1-103. Registration, certification, and licensing for criminal offenders.

(a)

(1) It is the policy of the State of Arkansas to encourage and contribute to the rehabilitation of criminal offenders and to assist them in the assumption of the responsibilities of citizenship.

(2) The public is best protected when offenders are given the opportunity to secure employment or to engage in a meaningful trade, occupation, or profession.

(b)

(1)

(A) Subject to the provisions of subdivision (b)(2) of this section in determining eligibility under this section, a board, commission, department, or an agency may take into consideration conviction of certain crimes that have not been annulled, expunged, or pardoned.

(B) However, such convictions shall not operate as an automatic bar to registration, certification, or licensing for any trade, profession, or occupation.

(2) The following criminal records shall not be used, distributed, or disseminated in connection with an application for a registration, license, or certificate:

(A) Records of arrest not followed by a valid felony conviction by the courts;

(B) Convictions that have been annulled or expunged or pardoned by the Governor; and

(C) Misdemeanor convictions, except misdemeanor sex offenses and misdemeanors involving violence.

(c) The board, commission, department, or agency shall state explicitly in writing the reasons for a decision that prohibits the applicant from practicing the trade, occupation, or profession if the decision is based, in whole or in part, on conviction of a felony.

(d) For the purposes of this section, completion of the following shall be deemed prima facie evidence of sufficient rehabilitation:

(1) Probation, parole, or post-release supervision; and

(2) A period of five (5) years after final discharge or release from any term of imprisonment in the state penitentiary without any subsequent conviction.

(e) Any complaints concerning the violation of this section shall be adjudicated in accordance with the procedure set forth in the Arkansas Administrative Procedure Act, § 25-15-201 et seq., for administrative and judicial review.

(f)

(1) This section shall apply to any board, commission, department, agency, or any other body that deals in licensing or regulating a profession, trade, or occupation in the State of Arkansas.

(2) It shall be the duty of the Secretary of State to make this section known to any board, commission, department, or agency affected by this section.

(g) This section shall not apply to teacher licensure or certification or nursing licensure and certification as governed by §§ 6-17-410 and 17-87-312 respectively.

Occupational Criminal Background Checks

17-3-102. Licensing restrictions based on criminal records.

(a) An individual is not eligible to receive or hold a license issued by a licensing entity if that individual has pleaded guilty or nolo contendere to or been found guilty of any of the following offenses 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, unless the conviction was lawfully sealed under the Comprehensive Criminal Record Sealing Act of 2013, § 16-90-1401 et seq., or otherwise previously sealed, pardoned or expunged under prior law:

(1) Capital murder as prohibited in § 5-10-101;

(2) Murder in the first degree and second degree as prohibited in §§ 5-10-102 and 5-10-103;

(3) Manslaughter as prohibited in § 5-10-104;

(4) Negligent homicide as prohibited in § 5-10-105;

(5) Kidnapping as prohibited in § 5-11-102;

(6) False imprisonment in the first degree as prohibited in § 5-11-103;

(7) Permanent detention or restraint as prohibited in § 5-11-106;

(8) Robbery as prohibited in § 5-12-102;

(9) Aggravated robbery as prohibited in § 5-12-103;

(10) Battery in the first degree as prohibited in § 5-13-201;

(11) Aggravated assault as prohibited in § 5-13-204;

(12) Introduction of a controlled substance into the body of another person as prohibited in § 5-13-210;

(13) Aggravated assault upon a law enforcement officer or an employee of a correctional facility as prohibited in § 5-13-211, if a Class Y felony;

(14) Terroristic threatening in the first degree as prohibited in § 5-13-301;

(15) Rape as prohibited in § 5-14-103;

(16) Sexual indecency with a child as prohibited in § 5-14-110, if the offense is a felony;

(17) Sexual extortion as prohibited in § 5-14-113;

(18) Sexual assault in the first degree, second degree, third degree, and fourth degree as prohibited in §§ 5-14-124 — 5-14-127;

(19) Incest as prohibited in § 5-26-202;

(20) Offenses against the family as prohibited in §§ 5-26-303 — 5-26-306;

(21) Endangering the welfare of an incompetent person in the first degree as prohibited in § 5-27-201;

(22) Endangering the welfare of a minor in the first degree as prohibited in § 5-27-205;

(23) Permitting the abuse of a minor as prohibited in § 5-27-221;

(24) Engaging children in sexually explicit conduct for use in visual or print media, transportation of minors for prohibited sexual conduct, pandering or possessing visual or print media depicting sexually explicit conduct involving a child, or use of a child or consent to use of a child in a sexual performance by producing, directing, or promoting a sexual performance by a child, as prohibited in §§ 5-27-303 — 5-27-305, 5-27-402, and 5-27-403;

(25) Possession or use of child sexual abuse material as prohibited in § 5-27-603;

(26) Computer exploitation of a child in the first degree as prohibited in § 5-27-605;

(27) Felony adult abuse as prohibited in § 5-28-103;

(28) Theft of property as prohibited in § 5-36-103;

(29) Theft by receiving as prohibited in § 5-36-106;

(30) Arson as prohibited in § 5-38-301;

(31) Burglary as prohibited in § 5-39-201;

(32) Felony violation of the Uniform Controlled Substances Act, § 5-64-101 et seq., as prohibited in the former § 5-64-401, and §§ 5-64-419 — 5-64-442;

(33) Promotion of prostitution in the first degree as prohibited in § 5-70-104;

(34) Stalking as prohibited in § 5-71-229;

(35) Criminal attempt, criminal complicity, criminal solicitation, or criminal conspiracy, as prohibited in §§ 5-3-201, 5-3-202, 5-3-301, and 5-3-401, to commit any of the offenses listed in this subsection; and

(36) All other crimes referenced in this title.

(b)

(1) If an individual has been convicted of a crime listed in subsection (a) or subsection (e) of this section, a licensing entity may waive disqualification or revocation of a license based on the conviction if a request for a waiver is made by:

(A) An affected applicant for a license; or

(B) The individual holding a license subject to revocation.

(2) A basis upon which a waiver may be granted includes without limitation:

(A) The age at which the offense was committed;

(B) The circumstances surrounding the offense;

(C) The length of time since the offense was committed;

(D) Subsequent work history since the offense was committed;

(E) Employment references since the offense was committed;

(F) Character references since the offense was committed;

(G) Relevance of the offense to the occupational license; and

(H) Other evidence demonstrating that licensure of the applicant does not pose a threat to the health or safety of the public.

(3) The waiver requirements of this section are not required for a renewal of a license if an individual has been convicted of a crime listed in subsection (a) of this section and has either:

(A) Completed the waiver requirements of this section at his or her initial licensure;

(B) Been licensed in this state before the enactment of subsection (a) of this section; or

(C) Attended a professional or occupational school, program, or training in pursuit of an occupational license before the enactment of subsection (a) of this section and would have been qualified to hold an occupational license on or before July 24, 2019.

(c) If an individual has a valid criminal conviction for an offense that could disqualify the individual from receiving a license, the disqualification shall not be considered for more than five (5) years from the date of conviction or incarceration or on which probation ends, whichever date is the latest, if the individual:

(A) Was not convicted for committing a violent or sexual offense; and

(B) Has not been convicted of any other offense during the five-year disqualification period.

(d) A licensing entity shall not, as a basis upon which a license may be granted or denied:

(1) Use vague or generic terms, including without limitation the phrases "moral turpitude" and "good character"; or

(2) Consider arrests without a subsequent conviction.

(e) Due to the serious nature of the offenses, the following shall result in disqualification for licensure, regardless of the date of conviction or the date on which probation or incarceration ends unless a waiver is granted under subsection (b) of this section:

(1) Capital murder as prohibited in § 5-10-101;

(2) Murder in the first degree as prohibited in § 5-10-102 and murder in the second degree as prohibited in § 5-10-103;

(3) Kidnapping as prohibited in § 5-11-102;

(4) Aggravated assault upon a law enforcement officer or an employee of a correctional facility as prohibited in § 5-13-211, if a Class Y felony;

(5) Rape as prohibited in § 5-14-103;

(6) Sexual extortion as prohibited in § 5-14-113;

(7) Sexual assault in the first degree as prohibited in § 5-14-124 and sexual assault in the second degree as prohibited in § 5-14-125;

(8) Incest as prohibited in § 5-26-202;

(9) Endangering the welfare of an incompetent person in the first degree as prohibited in § 5-27-201;

(10) Endangering the welfare of a minor in the first degree as prohibited in § 5-27-205;

(11) Adult abuse that constitutes a felony as prohibited in § 5-28-103;

(12) Arson as prohibited in § 5-38-301; and

(13) Engaging children in sexually explicit conduct for use in visual or print media, transportation of minors for prohibited sexual conduct, pandering or possessing visual or print media depicting sexually explicit conduct involving a child, or use of a child or consent to use of a child in a sexual performance by producing, directing, or promoting a sexual performance by a child, as prohibited in §§ 5-27-303 — 5-27-305, 5-27-402, and 5-27-403.

(f) This chapter does not preclude a licensing entity from taking emergency action against a licensee as authorized under § 25-15-211 for the sake of public health, safety, or welfare.

(g) The disqualification for an offense listed in subsection (a) of this section and the disqualification for an offense listed in subsection € of this section do not apply to:

(1) An individual who holds a valid license on July 24, 2019;

(2) An individual who holds a valid license on or before July 24, 2019, but failed to renew his or her license for any reason; or

(3) An individual who was a student on or before July 24, 2019, in a professional or occupational school, program, or training in pursuit of an occupational license and would have been qualified to hold an occupational license on or before July 24, 2019.

(h) This section does not apply to licensure or certification:

(1) Of professions not governed by this title;

(2) Of polygraph examiners and voice stress analysis examiners under § 17-39-101 et seq.;

(3) Of private investigators and private security agencies under the Private Security Agency, Private Investigator, and School Security Licensing and Credentialing Act, § 17-40-101 et seq.; or

(4) Of body artists under § 17-26-601 et seq.

Medical Professions – General Provisions

17-80-102. Subpoena power of boards — Enforcement.

(a)

(1) The licensing and disciplining boards of the professions of the healing arts provided in this subtitle shall have the power to issue subpoenas and bring before the board as a witness any person in this state.

(2) The secretary or the investigative officer of the board shall issue a subpoena upon the request of any party to a proceeding pending before the board or at the request of the board.

(3) The writ shall be directed to the sheriff of the county where the witness resides or may be found.

(4) The writ may require the witness to bring with him or her any book, writing, or other thing under his or her control which he or she is bound by law to produce in evidence.

(5) Service of the writ shall be in the manner as now provided by statute for the service of subpoenas in civil cases.

(b)

(1) A witness who has been served by subpoena in the manner provided by law and who shall have been paid or tendered the legal fees for travel and attendance as provided by law shall be obligated to attend for examination of the trial of the cause pending before the board.

(2) In the event a witness shall have been served with subpoenas as herein provided and fails to attend the hearing in obedience to the subpoena, the board may apply to the circuit court of the county wherein the board is having its meeting for an order causing the arrest of the witness and directing that the witness be brought before the court.

(3) The court shall have the power to punish the disobedient witness for contempt as now provided by law in the trial of civil cases.

(4) The disobedient witness shall be liable in damages for nonattendance to the trial or hearing as provided by Rev. Stat., ch. 158, § 9 [superseded].

17-80-103. Immunity of board members and individuals acting on behalf of boards including expert witnesses.

A member of a board or any individual acting on behalf of the board of any profession or occupation classified under the laws of the State of Arkansas as a profession of the healing arts, including an expert witness testifying or offering opinions, or both, regarding an administrative proceeding before a board of a profession or occupation classified as a profession of the healing arts, is not liable in damages to any person for slander, libel, defamation of character, breach of any privileged communication, or otherwise for any action taken or recommendation made within the scope of the functions of the board if the board member or the individual acting on behalf of the board, including an expert witness testifying or offering opinions, or both, regarding an administrative proceeding before a board of a profession or occupation classified as a profession of the healing arts, acts without malice and in the reasonable belief that the action or recommendation is warranted by the facts known to him or her after a reasonable effort is made to obtain the facts on which the action is taken or the recommendation is made.

17-80-104. Continuing education requirements.

(a) The regulatory boards of the professions or occupations classified by the laws of the State of Arkansas as professions of the healing arts and for whom the General Assembly has heretofore established regulatory boards empowered to license persons who practice under conditions of licensure authorized by the General Assembly are authorized to adopt rules requiring the continuing education of the persons licensed by the board.

(b) All rules establishing requirements for continuing education under the provisions of this section shall be adopted in the manner and method set out in the Arkansas Administrative Procedure Act, § 25-15-201 et seq., for the adoption of rules.

(c) The regulatory boards shall establish by rule the number of hours of credit and the manner and methods of obtaining the hours of credit by its licensee.

(d) In the event a licensee of the board does not complete the continuing education established by the board under the provisions of this section, the board is empowered to deny renewal of the license held by the licensee or after proper hearing take such action as it considers just and proper to compel compliance with its rules requiring continuing education.

Uniform Controlled Substances Act

Definitions

5-64-101. Definitions.

As used in this chapter:

(1) "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means to the body of a patient or research subject by:

(A) A practitioner; or

(B) The patient or research subject at the direction and in the presence of the practitioner;

(2)

(A) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser.

(B) "Agent" does not include a common or contract carrier, public warehouseman, or employee of the common or contract carrier or warehouseman;

(3)

(A) "Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestin, and corticosteroid that promotes muscle growth.

(B)

(i) "Anabolic steroid" does not include an anabolic steroid that is expressly intended for administration through an implant to cattle or another nonhuman species and that has been approved by the Secretary of the Department of Health for such administration.

(ii) If any person prescribes, dispenses, or distributes a steroid described in subdivision (3)(B)(i) of this section for human use, the person is considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this subdivision (3);

(4) "Controlled substance" means a drug, substance, or immediate precursor in Schedules I through VI;

(5)

(A) "Counterfeit substance" means a noncontrolled substance, that by overall dosage unit appearance including color, shape, size, markings, packaging, labeling, and overall appearance or upon the basis of representations made to the recipient, purports to be a controlled substance or to have the physical or psychological effect associated with a controlled substance.

(B) In determining whether a substance is a "counterfeit substance", the following factors shall be utilized and a finding of any two (2) of these factors constitutes prima facie evidence that the substance is a "counterfeit substance":

(i) A statement made by an owner or by anyone else in control of the substance concerning the nature of the substance, its use, or effect;

(ii) The physical appearance of the finished product containing the noncontrolled substance is substantially the same as that of a specific controlled substance;

(iii) The noncontrolled substance is unpackaged or is packaged in a manner normally used for the illegal delivery of a controlled substance;

(iv) The noncontrolled substance is not labeled in accordance with 21 U.S.C. § 352 or 21 U.S.C. § 353;

(v) The person delivering, attempting to deliver, or causing delivery of the noncontrolled substance states or represents to the recipient that the noncontrolled substance may be resold at a price that substantially exceeds the value of the substance;

(vi) An evasive tactic or action utilized by the owner or person in control of the substance to avoid detection by a law enforcement authority; or

(vii) A prior conviction, if any, of an owner, or anyone in control of the object under a state or federal law related to a controlled substance or fraud;

(6) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one (1) person to another of a controlled substance or counterfeit substance in exchange for money or anything of value, whether or not there is an agency relationship;

(7) "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the controlled substance for that delivery;

(8) "Dispenser" means a practitioner who dispenses;

(9) "Distribute" means to deliver other than by administering or dispensing a controlled substance;

(10) "Distributor" means a person who distributes;

(11)

(A) "Drug" means a substance:

(i) Recognized as a drug in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them;

(ii) Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(iii) Other than food intended to affect the structure or any function of the body of humans or animals; and

(iv) Intended for use as a component of any article specified in subdivision (11)(A)(i), subdivision (11)(A)(ii), or subdivision (11)(A)(iii) of this section.

(B) "Drug" does not include a device or its components, parts, or accessories;

(12)

(A) "Drug paraphernalia" means any equipment, product, and material of any kind that are used, intended for use, or designed for use in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance in violation of this chapter.

(B) "Drug paraphernalia" includes, but is not limited to:

(i) A kit used, intended for use, or designed for use in planting, propagating, cultivating, growing, or harvesting any species of plant that is a controlled substance or from which a controlled substance can be derived;

(ii) A kit used, intended for use, or designed for use in manufacturing, compounding, converting, producing, processing, or preparing a controlled substance;

(iii) An isomerization device used, intended for use, or designed for use in increasing the potency of any species of plant that is a controlled substance;

(iv) Testing equipment used, intended for use, or designed for use in identifying or in analyzing the strength, effectiveness, or purity of a controlled substance;

(v) A scale or balance used, intended for use, or designed for use in weighing or measuring a controlled substance;

(vi) A diluent or adulterant, such as quinine hydrochloride, mannitol, mannite, dextrose, and lactose used, intended for use, or designed for use in cutting a controlled substance;

(vii) A separation gin or sifter used, intended for use, or designed for use in removing a twig or seed from, or in otherwise cleaning or refining, marijuana;

(viii) A blender, bowl, container, spoon, or mixing device used, intended for use, or designed for use in compounding a controlled substance;

(ix) A capsule, balloon, envelope, or other container used, intended for use, or designed for use in packaging a small quantity of a controlled substance;

(x) A container or other object used, intended for use, or designed for use in storing or concealing a controlled substance;

(xi) A hypodermic syringe, needle, or other object used, intended for use, or designed for use in parenterally injecting a controlled substance into the human body; and

(xii) An object used, intended for use, or designed for use in ingesting, inhaling, or otherwise introducing a controlled substance into the human body, such as:

(a) A metal, wooden, acrylic, glass, stone, plastic, or ceramic pipe with or without a screen, permanent screen, hashish head, or punctured metal bowl;

(b) A water pipe;

(c) A carburetion tube or device;

(d) A smoking or carburetion mask;

(e) A roach clip, meaning an object used to hold burning material, such as a marijuana cigarette that has become too small or too short to be held in the hand;
(f) A miniature cocaine spoon or cocaine vial;

(g) A chamber pipe;

(h) A carburetor pipe;

(i) An electric pipe;

(j) An air-driven pipe;

(k) A chillum;

(l) A bong;

(m) An ice pipe or chiller; and

(n) An aluminum foil boat.

(C) In determining whether an object is "drug paraphernalia", a court or other authority shall consider, in addition to any other logically relevant factor, the following:

(i) A statement by an owner or by anyone in control of the object concerning its use;

(ii) A prior conviction, if any, of an owner or of anyone in control of the object under any state or federal law relating to any controlled substance;

(iii) The proximity of the object in time and space to a direct violation of this chapter;

(iv) The proximity of the object to a controlled substance;

(v) The existence of any residue of a controlled substance on the object;

(vi)

(a) Direct or circumstantial evidence of the intent of an owner or of anyone in control of the object to deliver it to a person whom he or she knows, or should reasonably know, intends to use the object to facilitate a violation of this chapter.

(b) The innocence of an owner or of anyone in control of the object as to a direct violation of this chapter does not prevent a finding that the object is intended for use or designed for use as "drug paraphernalia";

(vii) An oral or written instruction provided with the object concerning its use;

(viii) Descriptive materials accompanying the object that explain or depict its use;

(ix) National and local advertising concerning the object's use;

(x) The manner in which the object is displayed for sale;

(xi) Whether the owner or anyone in control of the object is a legitimate supplier of a like or related item to the community, such as a licensed distributor or dealer of a tobacco product;

(xii) Direct or circumstantial evidence of the ratio of sales of the objects to the total sales of the business enterprise;

(xiii) The existence and scope of legitimate uses for the object in the community; and

(xiv) Expert testimony concerning the object's use;

(D) "Drug paraphernalia" does not include a disposable, single -use test strip that can detect the presence of fentanyl or fentanyl analogs in a substance;

(13) "Fentanyl" means the opioid known as fentanyl, an analog of fentanyl that is a fentanyl-related controlled substance, and any chemical structure modification to fentanyl or a fentanyl analog, including without limitation the isomers, esters, ethers, and salts of fentanyl;

(14) "Immediate precursor" means a substance that the secretary has found to be and by rule designates as being the principal compound commonly used or produced primarily for use, and that is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture;

(15)

(A) "Manufacture" means the production, preparation, propagation, compounding, conversion, or processing of a controlled substance, either directly or indirectly by extraction from a substance of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.

(B) "Manufacture" includes any packaging or repackaging of a controlled substance or labeling or relabeling of a controlled substance's container.

(C) However, "manufacture" does not include the preparation or compounding of a controlled substance by an individual for his or her own use or the preparation, compounding, packaging, or labeling of a controlled substance:

(i) By a practitioner as an incident to his or her administering or dispensing of a controlled substance in the course of his or her professional practice; or

(ii) By a practitioner or by his or her authorized agent under his or her supervision for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale;

(16)

(A) "Marijuana" means:

(i) Any part and any variety or species, or both, of the Cannabis plant that contains THC (Tetrahydrocannabinol) whether growing or not;

(ii) The seeds of the plant;

(iii) The resin extracted from any part of the plant; and

(iv) Every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or resin.

(B) "Marijuana" does not include:

(i) The mature stalks of the plant;

(ii) Fiber produced from the stalks;

(iii) Oil or cake made from the seeds of the plant;

(iv) Any other compound, manufacture, salt, derivative, mixture, or preparation of the:

(a) Mature stalks, except the resin extracted from the mature stalks;

(b) Fiber;

(c) Oil; or

(d) Cake;

(v) The sterilized seed of the plant that is incapable of germination; or

(vi) Hemp-derived cannabidiol that:

(a) Contains not more than three-tenths of one percent (0.3%) of delta-9 tetrahydrocannabinol (THC) on a dry weight basis as verified by a nationally accredited laboratory for quality, purity, and accuracy standards; and

(b) Is not approved by the United States Food and Drug Administration for marketing as a medication;

(17)

(A)

(i) "Narcotic drug" means any drug that is defined as a narcotic drug by order of the secretary.

(ii) In the formulation of a definition of "narcotic drug", the secretary shall:

(a) Include any drug that he or she finds is narcotic in character and by reason of being narcotic is dangerous to the public health or is promotive of addiction-forming or addiction-sustaining results upon the user that threaten harm to the public health, safety, or morals; and

(b) Take into consideration the provisions of the federal narcotic laws as they exist from time to time and shall amend the definitions so as to keep them in harmony with the definitions prescribed by the federal narcotic laws, so far as is possible under the standards established in this subdivision (17) and under the policy of this chapter.

(B) "Narcotic drug" also means any of the following, whether produced directly or indirectly by extraction from a substance of vegetable origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(i)

(a) Opium, opiates, a derivative of opium or opiates, including their isomers, esters, and ethers whenever the existence of the isomers, esters, ethers, and salts is possible within the specific chemical designation.

(b) "Narcotic drug" does not include an isoquinoline alkaloid of opium;

(ii) Poppy straw and concentrate of poppy straw;

(iii) Coca leaves, except coca leaves and extracts of coca leaves from which cocaines, ecgonine, and derivatives of ecgonine or their salts have been removed;

(iv) Cocaine, its salts, optical and geometric isomers, and salts of isomers;

(v) Ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(vi) Any compound, mixture, or preparation that contains any quantity of any substance referred to in subdivisions (17)(B)(i)-(v) of this section;

(18) "Noncontrolled substance" means any liquid, substance, or material not listed in Schedules I through VI of the Schedules of Controlled Substances promulgated by the secretary;

(19) "Person" means an individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity;

(20) "Practitioner" means:

(A) A physician, dentist, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state; and

(B) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state;

(21) "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance;

(22) "State" when applied to a part of the United States, includes any state, district, commonwealth, territory, insular possession thereof, and any area subject to the legal authority of the United States of America; and

(23) "Ultimate user" means a person who lawfully possesses a controlled substance for:

(A) The person's own use;

(B) The use of a member of the person's household; or

(C) Administering to an animal owned by the person or by a member of his or her household.

Designation of Controlled Substances

5-64-201. Secretary's Duties

(a)

(1)

(A)

(i) The Secretary of the Department of Health shall administer this chapter and may add a substance to or delete or reschedule any substance enumerated in a schedule under the procedures of the Arkansas Administrative Procedure Act, § 25-15-201 et seq.

(ii) The secretary may promulgate without action or approval of the State Board of Health an emergency rule under the procedures of the Arkansas Administrative Procedure Act, § 25-15-201 et seq., that adds a substance to or deletes a substance from a schedule or reschedules a substance.

(iii) If the secretary adds, deletes, or reschedules a substance through an emergency rule under the procedures of the Arkansas Administrative Procedure Act, § 25-15-201 et seq., the emergency rule may be effective for no longer than one hundred eighty (180) days.

(B) However, the secretary shall not delete any substance from a schedule in effect on July 20, 1979, without prior approval by the Legislative Council.

(2) In making a determination regarding a substance, the secretary shall consider the following:

(A) The actual or relative potential for abuse;

(B) The scientific evidence of its pharmacological effect, if known;

(C) The state of current scientific knowledge regarding the substance;

(D) The history and current pattern of abuse;

(E) The scope, duration, and significance of abuse;

(F) The risk to public health;

(G) The potential of the substance to produce psychic or physiological dependence liability; and

(H) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

(b) After considering the factors enumerated in subsection (a) of this section, the secretary shall make findings with respect to the factors and issue a rule controlling the substance if he or she finds the substance has a potential for abuse.

(c) If the secretary designates a substance as an immediate precursor, a substance that is a precursor of the controlled precursor is not subject to control solely because it is a precursor of the controlled precursor.

(d)

(1) If any substance is designated as a controlled substance under federal law and notice of the designation is given to the secretary, the secretary shall similarly control the substance under this chapter after the expiration of thirty (30) days from publication in the Federal Register of a final order designating a substance as a controlled substance unless within that thirty-day period the secretary objects to inclusion.

(2)

(A) If the secretary objects to inclusion, the secretary shall publish the reasons for objection and afford any interested party an opportunity to be heard.

(B) At the conclusion of the hearing, the secretary shall publish his or her decision.

(C) Any person aggrieved by a decision of the secretary is entitled to judicial review in the Pulaski County Circuit Court.

(3) Upon publication of objection to inclusion under this chapter by the secretary, control under this chapter is stayed until the secretary publishes his or her decision or, if judicial review is sought, the inclusion is stayed until adjudication of the judicial review.

(4) If notice has been given to the secretary that the United States Food and Drug Administration has designated, rescheduled, or descheduled a marijuana-derived substance under federal law and approved for marketing the marijuana-derived substance as a prescription medication, the secretary shall consider the designation, rescheduling, or descheduling of the marijuana-derived substance under this chapter.

(e) Authority to control under this section does not extend to distilled spirits, wine, malt beverages, or tobacco.

(f) The secretary shall schedule gamma-hydroxybutyrate and its known precursors and analogs in a manner consistent with the procedures outlined in this section.

5-64-202. Nomenclature.

A controlled substance listed or to be listed in a schedule shall be included by whatever official, common, usual chemical, or trade name designated.

5-64-203. Criteria for Schedule I.

The Secretary of the Department of Health shall place a substance in Schedule I if he or she finds that the substance has:

(1) High potential for abuse; and

(2) No accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision.

5-64-204. Substances in Schedule I.

(a) In addition to any substance placed in Schedule I by the Secretary of the Department of Health under § 5-64-203, any material, compound, mixture, or preparation, whether produced directly or indirectly from a substance of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, that contains any quantity of the following substances, or that contains any of the following substances' analogs, salts, isomers, and salts of isomers when the existence of the analogs, salts, isomers, and salts of isomers is possible within the specific chemical designation, with the following chemical structure is included in Schedule I:

(1) 4-Methylmethcathinone (Mephedrone);

(2) Methylenedioxypyrovalerone (MDPV);

(3) 3,4-Methylenedioxy-N-methylcathinone (Methylone);

(4) 4-Methoxymethcathinone;

(5) 3-Fluoromethcathinone;

(6) 4-Fluoromethcathinone; or

(7) A compound, unless listed in another schedule or a legend drug, that is structurally derived from 2-Amino-1-phenyl-1-propanone by modification or by substitution:

(A) In the phenyl ring to any extent with alkyl, alkoxy, alkylenedioxy, haloalkyl or halide substituents, whether or not further substituted in the phenyl ring by one (1) or more other univalent substituents;

(B) At the 3-position with an alkyl substituent; or

(C) At the nitrogen atom with alkyl or dialkyl groups, or by inclusion of the nitrogen atom in a cyclic structure.

(b) The Secretary of the Department of Health shall not delete a controlled substance listed in this section from Schedule I.

5-64-205. Criteria for Schedule II.

The Secretary of the Department of Health shall place a substance in Schedule II if he or she finds that:

(1) The substance has high potential for abuse;

(2) The substance has currently accepted medical use in treatment in the United States or currently accepted medical use with severe restrictions; and

(3) The abuse of the substance may lead to severe psychic or physical dependence.

5-64-206. [Reserved.]

5-64-207. Criteria for Schedule III.

The Secretary of the Department of Health shall place a substance in Schedule III if he or she finds that:

(1) The substance has a potential for abuse less than the substances listed in Schedules I and II;

(2) The substance has currently accepted medical use in treatment in the United States; and

(3) Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

5-64-208. [Reserved.]

5-64-209. Criteria for Schedule IV.

The Secretary of the Department of Health shall place a substance in Schedule IV if he or she finds that:

(1) The substance has a low potential for abuse relative to substances in Schedule III;

(2) The substance has currently accepted medical use in treatment in the United States; and

(3) Abuse of the substance may lead to limited physical dependence or psychological dependence relative to the substances in Schedule III.

5-64-210. Substances in Schedule IV.

Schedule IV includes any material, compound, mixture, or preparation that contains any quantity of tramadol or that contains any of tramadol's salts, isomers, or salts of isomers.

5-64-211. Criteria for Schedule V.

The Secretary of the Department of Health shall place a substance in Schedule V if he or she finds that:

(1) The substance has low potential for abuse relative to the controlled substances listed in Schedule IV;

(2) The substance has currently accepted medical use in treatment in the United States; and

(3) The substance has limited physical dependence or psychological dependence liability relative to the controlled substances listed in Schedule IV.

5-64-212. Substances in Schedule V.

(a) An ephedrine combination product, pseudoephedrine, and phenylpropanolamine, as defined in § 5-64-1105, are designated Schedule V controlled substances in addition to the drugs and other substances listed in Schedule V of the List of Controlled Substances for the State of Arkansas promulgated by the Secretary of the Department of Health.

(b) The Schedule V classification does not apply to:

(1) An exempt product described in § 5-64-1103(b)(1); or

(2) Any ephedrine or pseudoephedrine in liquid, liquid capsule, or liquid gel capsule form described in § 5-64-1103(b)(2).

(c) The secretary may reschedule a product described in subdivision (b)(1) or subdivision (b)(2) of this section if it is determined that the conversion of the active ingredient in the product into methamphetamine or its salts or precursors is feasible.

(d) A wholesale distributor with exclusive rights to distribute pseudoephedrine to only licensed pharmacies is exempt from Schedule V requirements for the storage and distribution of pseudoephedrine.

5-64-213. Schedule VI established.

(a) There is established a Schedule VI for the classification of those substances that are determined to be inappropriately classified by placing them in Schedules I through V.

(b) Schedule VI includes a controlled substance listed or to be listed by whatever official name, common or usual name, chemical name, or trade name designated.

5-64-214. Criteria for Schedule VI.

The Secretary of the Department of Health shall place a substance in Schedule VI if he or she finds that:

(1) The substance is not currently accepted for medical use in treatment in the United States;

(2) There is lack of accepted safety for use of the drug or other substance even under direct medical supervision;

(3) The substance has relatively high psychological or physiological dependence liability, or both; and

(4) Use of the substance presents a definite risk to public health.

5-64-215. Substances in Schedule VI.

(a) In addition to any substance placed in Schedule VI by the Secretary of the Department of Health under § 5-64-214, any material, compound, mixture, or preparation, whether produced directly or indirectly from a substance of vegetable origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, that contains any quantity of the following substances, or that contains any of their salts, isomers, and salts of isomers when the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation, is included in Schedule VI:

(1) Marijuana;

(2) Tetrahydrocannabinols, unless the tetrahydrocannabinol is:

(A) Contained in hemp-derived cannabidiol;

(B) Not more than three-tenths of one percent (0.3%) of delta-9 tetrahydrocannabinol the hemp-derived cannabidiol on a dry weight basis as verified by a nationally accredited laboratory for quality, purity, and accuracy standards; and

(C) Not approved by the United States Food and Drug Administration for marketing as a medication;

(3) A synthetic equivalent of:

(A) The substance contained in the Cannabis plant; or

(B) The substance contained in the resinous extractives of the genus Cannabis;

(4) Salvia divinorum or Salvinorin A, which includes all parts of the plant presently classified botanically as Salvia divinorum, whether growing or not, the seeds of the plant, any extract from any part of the plant, and every compound, manufacture, derivative, mixture, or preparation of the plant, its seeds, or its extracts, including salts, isomers, and salts of isomers when the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation;

(5) Synthetic substances, derivatives, or their isomers in the chemical structural classes described below in subdivisions (a)(5)(A)-(J) of this section and also specific unclassified substances in subdivision (a)(5)(K) of this section. Compounds of the structures described in this subdivision (a)(5), regardless of numerical designation of atomic positions, are included in this subdivision (a)(5). The synthetic substances, derivatives, or their isomers included in this subdivision (a)(5) are:

(A)

(i) Tetrahydrocannabinols, including without limitation the following:

(a) Delta-1 cis or trans tetrahydrocannabinol, otherwise known as delta-9 cis or trans tetrahydrocannabinol, and its optical isomers;

(b) Delta-6 cis or trans tetrahydrocannabinol, otherwise known as delta-8 cis or trans tetrahydrocannabinol, and its optical isomers;

(c) Delta-3,4 cis or trans tetrahydrocannabinol, otherwise known as delta-6a,10a cis or trans tetrahydrocannabinol, and its optical isomers;

(d) Delta-10 cis or trans tetrahydrocannabinol, and its optical isomers;

(e) Delta-8 tetrahydrocannabinol acetate ester;

(f) Delta-9 tetrahydrocannabinol acetate ester;

(g) Delta-6a,10a tetrahydrocannabinol acetate ester;

(h) Delta-10 tetrahydrocannabinol acetate ester;

(i) A product derived from industrial hemp that was produced as a result of a synthetic chemical process that converted the industrial hemp or a substance contained in the industrial hemp into delta-8 delta-9, delta-6a,10a, or delta-10 tetrahydrocannabinol including their respective acetate esters; and

(j) Any other psychoactive substance derived therein.

(ii) Dronabinol in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the United States Food and Drug Administration is not a tetrahydrocannabinol under this subdivision (a)(5)(A);

(B) Naphthoylindoles, or any compound structurally derived from 3-(1-naphthoyl)indole or 1H-indol-3-yl-(1-naphthyl)methane by substitution at the nitrogen atom of the indole ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent, including without limitation the following:

(i) JWH-007, or 1-pentyl-2-methyl-3-(1-naphthoyl)indole;

(ii) JWH-015, or 1-Propyl-2-methyl-3-(1-naphthoyl)indole;

(iii) JWH-018, or 1-Propyl-3-(1-naphthoyl)indole;

(iv) JWH-019, or 1-Hexyl-3-(1-naphthoyl)indole;

(v) JWH-073, or 1-Butyl-3-(1-naphthoyl)indole;

(vi) JWH-081, or 1-Pentyl-3-(4-methoxy-1-naphthoyl)indole;

(vii) JWH-098, or 1-pentyl-2-methyl-3-(4-methoxy-1-naphthoyl)indole;

(viii) JWH-122, or 1-Pentyl-3-(4-methyl-1-naphthoyl)indole;

(ix) JWH-164, or 1-pentyl-3-(7-methoxy-1-naphthoyl)indole;

(x) JWH-200, or 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole;

(xi) JWH-210, or 1-Pentyl-3-(4-ethyl-1-naphthoyl)indole;

(xii) JWH-398, or 1-Pentyl-3-(4-chloro-1-naphthoyl)indole;

(xiii) AM-2201, or 1-(5-fluoropentyl)-3-(1-naphthoyl)indole;

(xiv) MAM2201, or (1-(5-fluoropentyl)-1H-indol-3-yl)(4-methyl-1-naphthalenyl)-methanone; and

(xv) EAM2201, or (1-(5-fluoropentyl)-1H-indol-3-yl)(4-ethyl-1-naphthalenyl)-methanone;

(C) Naphthylmethylindoles, or any compound structurally derived from an H-indol-3-yl-(1-naphthyl) methane by substitution at the nitrogen atom of the indole ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent, including without limitation the following:

(i) JWH-175, or 1-Pentyl-1H-indol-3-yl-(1-naphthyl)methane; and

(ii) JWH-184, or 1-Pentyl-1H-3-yl-(4-methyl-1-naphthyl)methane;

(D) Naphthoylpyrroles, or any compound structurally derived from 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent, including without limitation JWH-307, or (5-(2-fluorophenyl)-1-pentylpyrrol-3-yl)-naphthalen-1-ylmethanone;

(E) Naphthylmethylindenes, or any compound structurally derived from 1-(1-napthylmethyl)indene with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent, including without limitation JWH-176, or E-1-[1-(1-Naphthalenylmethylene)-1H-inden-3-yl]pentane;

(F) Phenylacetylindoles, or any compound structurally derived from 3-phenylacetylindole by substitution at the nitrogen atom of the indole ring with alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent, including without limitation the following:

(i) JWH-201, or 2-(4-methoxyphenyl)-1-(1-pentylindol-3-yl)ethanone;

(ii) JWH-203, or 1-Pentyl-3-(2-chlorophenylacetyl)indole;

(iii) JWH-250, or 1-Pentyl-3-(2-methoxyphenylacetyl)indole;

(iv) JWH-251, or 1-Pentyl-3-(2-methylphenylacetyl)indole; and

(v) RCS-8, or 1-(2-cyclohexylethyl)-3-(2-methoxyphenylacetyl)indole;

(G) Cyclohexylphenols, or any compound structurally derived from 2-(3-hydroxycyclohexyl)phenol by substitution at the 5-position of the phenolic ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not substituted in the cyclohexyl ring to any extent, including without limitation the following:

(i) CP 47,497 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol;

(ii) Cannabicyclohexanol or CP 47,497 C8 homologue, or 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol; and

(iii) CP 55,940, or 5-(1,1-dimethylheptyl)-2-[(1R,2R)-5-hydroxy-2-(3-hydroxypropyl)cyclohexyl]-phenol;

(H) Benzoylindoles, or any compound structurally derived from a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent, including without limitation the following:

(i) AM-694, or 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole;

(ii) RCS-4, or 1-Pentyl-3-(4-methoxybenzoyl)indole;

(iii) WIN-48,098 or Pravadoline, or (4-Methoxyphenyl)-[2-methyl-1-(2-(4-morpholinyl)ethyl) indol-3-y]methanone;

(iv) AM-2233, or 1-[(N-methylpiperidin-2-yl)methyl]-3-(2-iodobenzoyl)indole; and

(v) RCS-4 (C4 homologue) or (4-methoxyphenyl)(1-butyl-1H-indol-3-yl)-methanone;

(I) Adamantoylindoles, or Adamantoylindazoles, including Adamantyl Carboxamide Indoles and Adamantyl Carboxamide Indazoles, or any compound structurally derived from 3-(1-adamantoyl) indole, 3-(1-adamantoyl) indazole, or 3-(2-adamantoyl)indole by substitution at a nitrogen atom of the indole or indazole ring with alkyl, haloalkyl, alkenyl, cyanoalkyl, hydroxyalkyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl) ethyl, whether or not further substituted in the indole or indazole ring to any extent and whether or not substituted in the adamantyl ring to any extent, including without limitation the following:

(i) AM-1248, or 1-adamantyl-[1-[(1-methylpiperidin-2-yl)methyl]indol-3-yl]methanone;

(ii) AB-001, or 1-adamantyl-(1-pentylindol-3-yl)methanone;

(iii) 2NE1, or 1-pentyl-3-(1-adamantylamido)indole;

(iv) JWH-018 adamantyl carboxamide, or 1-pentyl-N-tricyclo[3.3.1.13,7]dec-1-yl-1H-indole-3-carboxamide;

(v) AKB-48, or N-(1-adamantyl)-pentyl-1H-indazole-3-carboxamide;

(vi) 5F-AKB-48, or N-((3s,5s,7s)-adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide; and

(vii) STS-135, or N-(1-adamantyl)-1-(5-fluoropentyl)indole-3-carboxamide;

(J) Tetramethylcyclopropylcarbonylindoles or any compound structurally derived from 3-(2,2,3,3-tetramethylcyclopropylcarbonyl) indole by substitution at the nitrogen atom of the indole ring with alkyl, haloalkyl, alkenyl, cyanoalkyl, hydroxyalkyl, cycloalkylmethyl, cycloalkylethyl, (N-methylpiperidin-2-yl)methyl or 2-(4-morpholinyl) ethyl, whether or not further substituted in the indole ring to any extent, including without limitation the following:

(i) UR-144, or (1-pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone;

(ii) XLR-11, or [1-(5-fluoropentyl)-1H-indol-3-yl]-(2,2,3,3-tetramethylcyclopropyl)methanone;

(iii) A-796,260, or [1-(2-morpholin-4-yl-ethyl)-1H-indol-3-yl]-(2,2,3,3-tetramethylcyclopropyl)methanone;

(iv) 5-Chloro-UR-144, or ([-(5-chloropentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone;

(v) 5-Bromo-UR-144, or [1-(5-bromopentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone; and

(vi) A-834,735, or 1-(tetrahydropyran-4-ylmethyl)-1H-indol-3-yl]-(2,2,3,3-tetramethylcyclopropyl)methanone; or

(K) Unclassified Synthetic Cannabinoids, including without limitation the following:

(i) CP 50556-1 hydrochloride, or [(6S,6aR,9R,10aR)-9-hydroxy-6-methyl-3-[(2R)-5-phenylpentan-2-yl]oxy-5,6,6a,7,8,9,10,10a-octahydrophenanthridin-1-yl] acetate;

(ii) HU-210, or (6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol;

(iii) HU-211, or Dexanabinol,(6aS,10aS)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol;

(iv) Dimethylheptylpyran or DMHP;

(v) WIN55,212-2, or 2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl-1-naphthalenylmethanone;

(vi) URB597, or [3-(3-carbamoylphenyl)phenyl] N-cyclohexylcarbamate;

(vii) URB754, or 6-methyl-2-[(4-methylphenyl)amino]-1-benzoxazin-4-one;

(viii) AKB-48, or N-(1-adamantyl)-1-pentylindazole-3-carboxamide;

(ix) CB-13, or 1-naphthalenyl[4-(pentyloxy)-1-naphthalenyl]-methanone;

(x) URB602, or cyclohexyl N-(3-phenylphenyl)carbamate;

(xi) PB-22, or quinolin-8-yl 1-(5-pentyl)-1H-indole-3-carboxylate;

(xii) 5F-PB-22, or quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate;

(xiii) BB-22, or quinolin-8-yl 1-(cyclohexylmethyl)-1H-indole-3-carboxylate;

(xiv) NNEI (MN-24), or N-1-naphthalenyl-1-pentyl-1H-indole-3-carboxamide; and

(xv) 5F-NNEI, or 1-(5-fluoropentyl)-N-(naphthalen-1-yl)-1H-indole-3-carboxamide; or

(6) A synthetic substance, derivative, or its isomers with:

(A) Similar chemical structure to any substance described in subdivisions (a)(1)-(5) of this section; or

(B) Similar pharmacological effects to any substance described in subdivisions (a)(1)-(5) of this section.

(b) However, except as provided under subsection (c) of this section, the secretary shall not delete a controlled substance listed in this section from Schedule VI.

(c) A prescription drug approved by the United States Food and Drug Administration under 21 U.S.C. § 355 is excluded from Schedule VI unless the secretary objects under § 5-64-201.

(d) This section does not prohibit the continuous transportation through Arkansas of the plant Cannabis sativa L., and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than three-tenths of one percent (0.3%) on a dry weight basis, produced in accordance with 7 U.S.C. § 1639o et seq.

5-64-216. Schedule Revisions.

The Secretary of the Department of Health shall revise and republish the schedules annually.

Regulation of Distribution

5-64-305. Powers of Arkansas State Board of Pharmacy – Sale of nonnarcotic drugs.

(a)

(1) Nothing contained in this chapter shall affect the licensing or regulation of pharmacists or pharmacies in this state by the Arkansas State Board of Pharmacy.

(2) The board may also inventory and destroy any outdated or unwanted controlled substance at the request of a licensee of the board with proper record of the destruction provided to appropriate agencies.

(3) The board is given primary but not exclusive jurisdiction in the enforcement application of this chapter to the board's licensees.

(b) Nothing in this chapter is deemed to prohibit the sale of a nonnarcotic proprietary drug if the nonnarcotic proprietary drug, under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., or the Food, Drug, and Cosmetic Act, § 20-56-201 et seq., may be lawfully sold over the counter without a prescription.

5-64-306. Offenses relating to records.

It is unlawful for any person to refuse or fail to make, keep, or furnish any record, notification, order form, statement, invoice, or information required under this chapter.

5-64-307. Order forms.

(a) A controlled substance in Schedule I or Schedule II shall be distributed by a practitioner to another practitioner only pursuant to an order form.

(b) Compliance with the provisions of federal law respecting an order form is deemed compliance with this section.

5-64-308. Prescriptions. [Effective until contingent effective date as stated in Acts 2019, No. 447, § 2]

(a) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, no controlled substance in Schedule II may be dispensed without the written prescription of a practitioner or the oral, faxed, or electronic prescription of a practitioner, if issued in compliance with federal law and regulations.

(b)

(1) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included in Schedule III or Schedule IV that is a prescription drug shall not be dispensed without a written or oral prescription of a practitioner or the faxed or electronic prescription of a practitioner, if issued in compliance with federal law and regulations.

(2) The prescription shall not be filled or refilled more than six (6) months after the date of the prescription or be refilled more than five (5) times unless renewed by the practitioner.

(c) A controlled substance included in Schedule V shall not be distributed or dispensed other than for a medical purpose.

5-64-308. Prescriptions – Mandatory electronic prescribing. [Effective on contingent effective date as stated in Acts 2019, No. 447, § 2]

(a) A prescription for a controlled substance included in Schedule III or Schedule IV shall not be filled or refilled more than six (6) months after the date of the prescription or be refilled more than five (5) times unless renewed by the practitioner.

(b) A controlled substance included in Schedule V shall not be distributed or dispensed other than for a medical purpose.

(c) Except as provided in subsection (d) of this section, a practitioner shall not issue a prescription for a controlled substance included in Schedule II through Schedule VI unless the prescription is made by electronic prescription from the practitioner issuing the prescription to a pharmacy.

(d) A practitioner may issue a prescription for a controlled substance included in Schedule II through Schedule VI by written, oral, or faxed method if issued:

(1) By:

(A) A veterinarian; or

(B) A practitioner:

(i) To be dispensed by a pharmacy located outside of the state;

(ii) For a controlled substance for which the United States Food and Drug Administration requires the prescription to contain certain elements that are not captured through electronic prescribing methods;

(iii) For the dispensing of a nonpatient-specific prescription under a standing order, approved protocol for drug therapy, collaborative drug management or comprehensive medication management, or in response to a public health emergency or other circumstances in which the practitioner may issue a nonpatient-specific prescription;

(iv) For a controlled substance under a research protocol;

(v)

(a) Who has received a waiver or a renewal of a waiver for a specified time period from the electronic prescription requirement due to economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstances demonstrated by the practitioner.

(b) A practitioner who has received a waiver from the United States Department of Health and Human Services shall have a valid waiver in this state; or

(vi) Under circumstances in which the practitioner reasonably determines that obtaining the controlled substances in a timely manner is impractical through electronic prescription and the delay would adversely impact the medical condition of the patient;

(2) In circumstances in which electronic prescribing is not available due to temporary technological or electrical failure; or

(3) When the practitioner and the dispenser are the same entity.

(e)

(1) A pharmacist or pharmacy that receives a written, oral, or faxed prescription for a controlled substance included in Schedule I through Schedule VI is not required to verify that the prescription properly falls under one (1) of the exceptions listed in subsection (d) of this section.

(2) A pharmacist may continue to dispense a controlled substance from an otherwise valid written, oral, or faxed prescription that is consistent with state law or rules or federal law and regulations.

(f) In addition to other penalties available under this chapter, a licensing board of a practitioner may impose a civil penalty of two hundred fifty dollars ($250) per violation of this section.

(g) This section does not apply to prescriptions written by a prescriber employed by or working under a professional services contract for the Division of Correction or the Division of Community Correction.

Records of Transactions

5-64-1005. Exemptions.

The provisions of § 5-64-1001 do not apply to any of the following:

(1) Any pharmacist or other authorized person who sells or furnishes a substance upon the prescription of a physician, dentist, podiatrist, or veterinarian;

(2) Any physician, dentist, podiatrist, or veterinarian who administers or furnishes a substance to his or her patient;

(3) Any manufacturer or wholesaler licensed by the Arkansas State Board of Pharmacy that sells, transfers, or otherwise furnishes a substance to a licensed pharmacy, physician, dentist, podiatrist, or veterinarian; or

(4) Any sale, transfer, furnishing, or receipt by a retail distributor of any drug that contains any ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and that is sold, transferred, or furnished over the counter without a prescription pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., or regulations adopted under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., if:

(A) The drug is sold in a blister pack of not more than three grams (3g) of ephedrine, pseudoephedrine, or phenylpropanolamine base, each blister containing not more than two (2) dosage units;

(B) The use of a blister pack is technically unfeasible, the drug is packaged in a unit dose packet or pouch;

(C) The drug is an exempted product described in § 5-64-1103(b)(1), or the product contains ephedrine or pseudoephedrine in liquid, liquid capsule, or liquid gel capsule form described in § 5-64-1103(b)(2), and is sold in a package size of not more than three grams (3g) of ephedrine or pseudoephedrine base; and

(D) The total quantity of the sale is not greater than three (3) packages or five grams (5g) of ephedrine or nine grams (9g) of pseudoephedrine, whichever is smaller.

5-64-1006. Suspicious transaction reports.

(a) Any pharmacy, manufacturer, wholesaler, or retail distributor that is required to keep records under this subchapter and that sells, transfers, or otherwise furnishes ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, optical isomers, and salts of optical isomers, alone or in a mixture, to any person in this state in a suspicious transaction shall report the transaction in writing to the Arkansas State Board of Pharmacy.

(b) Any person who does not submit a report as required by subsection (a) of this section is guilty of a Class A misdemeanor.

(c) As used in this section, "suspicious transaction" means a sale or transfer to which either of the following applies:

(1) The circumstances of the sale or transfer would lead a reasonable person to believe that the substance is likely to be used for the purpose of unlawfully manufacturing a controlled substance in violation of this chapter based on such factors as:

(A) The amount involved;

(B) The method of payment;

(C) The method of delivery; and

(D) Past dealings with the person acquiring the substance; or

(2) The transaction involves payment for ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, optical isomers, and salts of optical isomers, alone or in a mixture, in cash or money orders totaling more than two hundred dollars ($200).

(d)

(1) The board shall adopt by rule criteria for determining whether a transaction is a suspicious transaction, taking into consideration the recommendations in Appendix A, Report to the United States Attorney General by the Suspicious Orders Task Force, under the Comprehensive Methamphetamine Control Act of 1996, Pub. L. No. 104-237.

(2) In addition to any other penalty provided for in this section, the board may impose a civil penalty for a violation of subsection (a) of this section not to exceed ten thousand dollars ($10,000) per violation.

Ephedrine and Other Nonprescription Drugs

5-64-1101. Possession – Penalty.

(a) It is unlawful for any person to possess more than five grams (5g) of ephedrine or nine grams (9g) of pseudoephedrine or phenylpropanolamine, or their salts, optical isomers, and salts of optical isomers, alone or in a mixture, except:

(1) Any pharmacist or other authorized person who sells or furnishes ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, optical isomers, and salts of optical isomers, upon the prescription of a physician, dentist, podiatrist, veterinarian, or other healthcare professional with prescriptive authority, or as authorized pursuant to § 5-64-1103;

(2) A product exempted under § 5-64-1103(b)(1) and (2), without a prescription, pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., or regulations adopted under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., if the person possesses a sales and use tax permit issued by the Department of Finance and Administration;

(3) Any physician, dentist, podiatrist, veterinarian, or other healthcare professional with prescriptive authority who administers or furnishes ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, optical isomers, and salts of optical isomers to his or her patient; or

(4)

(A) Any manufacturer, wholesaler, or distributor licensed by the Arkansas State Board of Pharmacy that meets one (1) of the requirements in subdivision (a)(4)(B) of this section and sells, transfers, or otherwise furnishes ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, optical isomers, and salts of optical isomers to:

(i) A licensed pharmacy, physician, dentist, podiatrist, veterinarian, or other healthcare professional with prescriptive authority; or

(ii) Any person who possesses a sales and use tax permit issued by the department.

(B)

(i) The manufacturer, wholesaler, or distributor shall hold or store the substance in a facility that meets the packaging requirements of § 5-64-1005(4)(A)-(C).

(ii) The manufacturer, wholesaler, or distributor shall sell, transfer, or otherwise furnish only to a healthcare professional identified in subdivisions (a)(1) and (a)(3) of this section.

(b) Possession of more than five grams (5g) of ephedrine or more than nine grams (9g) of pseudoephedrine or phenylpropanolamine, or their salts, optical isomers, and salts of optical isomers constitutes prima facie evidence of the intent to manufacture methamphetamine or another controlled substance in violation of this subchapter unless the person qualifies for an exemption listed in subsection (a) of this section.

(c) Any person who violates a provision of this section is guilty of a Class D felony.

5-64-1102. Possession with purpose to manufacture – Unlawful distribution.

(a)

(1) It is unlawful for a person to possess ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, optical isomers, or salts of optical isomers with a purpose to manufacture methamphetamine.

(2) A person who violates subdivision (a)(1) of this section upon conviction is guilty of a:

(A) Class D felony if the quantity of substances listed in subdivision (a)(1) of this section is capable of producing ten grams (10g) or less of methamphetamine; or

(B) Class B felony if the quantity of substances listed in subdivision (a)(1) of this section is capable of producing more than ten grams (10g) of methamphetamine.

(b)

(1) It is unlawful for a person to possess ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, optical isomers, or salts of optical isomers in a quantity capable of producing twenty-eight grams (28g) or more of a Schedule I or Schedule II controlled substance that is a narcotic drug or methamphetamine with a purpose to manufacture methamphetamine.

(2) A person who violates subdivision (b)(1) of this section upon conviction is guilty of a Class B felony.

(c)

(1) It is unlawful for a person to sell, transfer, distribute, or dispense any product containing ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers if the person:

(A) Knows that the purchaser will use the product as a precursor to manufacture methamphetamine or another controlled substance; or

(B) Sells, transfers, distributes, or dispenses the product with reckless disregard as to how the product will be used.

(2) A person who violates subdivision (c)(1) of this section upon conviction is guilty of a Class D felony.

5-64-1103. Sales limits.

(a) It is unlawful for any person, other than a person or entity described in § 5-64-1101(a)(3) and (4), to knowingly sell, transfer, or otherwise furnish in a single transaction a product containing ephedrine, pseudoephedrine, or phenylpropanolamine except in a licensed pharmacy by a licensed pharmacist or a registered pharmacy technician.

(b) Unless the product has been rescheduled pursuant to § 5-64-212(c), this section does not apply to a retail distributor sale for personal use of a product:

(1) That the Department of Health, in collaboration with the Arkansas State Board of Pharmacy, upon application of a manufacturer, exempts by rule from this section because the product has been formulated in such a way as to effectively prevent the conversion of the active ingredient into methamphetamine or its salts or precursors; or

(2) Containing ephedrine or pseudoephedrine in liquid, liquid capsule, or liquid gel capsule form if the drug is dispensed, sold, transferred, or otherwise furnished in a single transaction limited to no more than three (3) packages, with any single package containing not more than ninety-six (96) liquid capsules or liquid gel capsules or not more than three grams (3g) of ephedrine or pseudoephedrine base.

(c)

(1)

(A) Except under a valid prescription, before dispensing a product containing ephedrine, pseudoephedrine, or phenylpropanolamine that is not exempt under subdivision (b)(1) or subdivision (b)(2) of this section, a pharmacist shall make a professional determination as to whether or not there is a legitimate medical and pharmaceutical need for the product containing ephedrine, pseudoephedrine, or phenylpropanolamine.

(B) The determination under subdivision (c)(1)(A) of this section may be based on factors, including without limitation:

(i) Prior medication-filling history;

(ii) Patient screening; and

(iii) Other tools that provide professional reassurance to the pharmacist that a legitimate medical and pharmaceutical need exists.

(2) The board may:

(A) Adopt rules regarding determinations made under subdivision (c)(1) of this section;

(B) Review determinations made under subdivision (c)(1) of this section; and

(C) Take appropriate disciplinary action as required.

(3) This subsection does not prohibit a pharmacist from dispensing a product containing ephedrine, pseudoephedrine, or phenylpropanolamine to a person who:

(A) Has not utilized the services of the pharmacist frequently; or

(B) Has not established a pharmacist-patient relationship with the pharmacist before the instance of dispensing.

(d) Except under a valid prescription, it is unlawful for a licensed pharmacist to dispense or a registered pharmacy technician to knowingly sell, transfer, or otherwise furnish in a single transaction:

(1) More than three (3) packages of one (1) or more products that contain ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers;

(2) Any single package of any product that contains ephedrine, pseudoephedrine, or phenylpropanolamine, that contains more than ninety-six (96) pills, tablets, gelcaps, capsules, or other individual units or more than three grams (3g) of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, or a combination of any of these substances, whichever is smaller;

(3) Any product containing ephedrine, pseudoephedrine, or phenylpropanolamine, unless:

(A) The product is sold in a package size of not more than three grams (3g) of ephedrine, pseudoephedrine, or phenylpropanolamine base and is packaged in a blister pack, each blister containing not more than two (2) dosage units;

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

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

(4)

(A) Any product containing ephedrine, pseudoephedrine, or phenylpropanolamine to any person under eighteen (18) years of age, unless the person is purchasing an exempt product under subdivision (b)(1) or subdivision (b)(2) of this section.

(B) The person making the sale shall require proof of age from the purchaser.

(e)

(1)

(A) A person who violates subsection (a) or subsection (d) of this section for a first or second offense upon conviction is guilty of a Class A misdemeanor and also may be subject to a civil fine not to exceed five thousand dollars ($5,000).

(B) A person who violates subsection (a) or subsection (d) of this section for a third offense upon conviction is guilty of a Class D felony and also may be subject to a civil fine not to exceed five thousand dollars ($5,000).

(C) A person who violates subsection (a) or subsection (d) of this section for a fourth or subsequent offense upon conviction is guilty of a Class C felony and also may be subject to a civil fine not to exceed ten thousand dollars ($10,000).

(2) A plea of guilty or nolo contendere to or a finding of guilt under a penal law of the United States or another state that is equivalent to subsection (a) or subsection (d) of this section is considered a previous offense for purposes of this subsection.

(3)

(A) The prosecuting attorney may waive any civil penalty under this section if a person establishes that he or she acted in good faith to prevent a violation of this section, and the violation occurred despite the exercise of due diligence.

(B) In making this determination, the prosecuting attorney may consider evidence that an employer trained employees how to sell, transfer, or otherwise furnish substances specified in this subchapter in accordance with applicable laws.

(f)

(1)

(A) It is unlawful for any person, other than a person or entity described in § 5-64-1101(a), to knowingly purchase, acquire, or otherwise receive in a single transaction:

(i) More than three (3) packages of one (1) or more products that the person knows to contain ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers; or

(ii) Any single package of any product that the person knows to contain ephedrine, pseudoephedrine, or phenylpropanolamine, that contains more than ninety-six (96) pills, tablets, gelcaps, capsules, or other individual units or more than three grams (3g) of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, or a combination of any of these substances, whichever is smaller.

(B) It is unlawful for any person, other than a person or entity described in § 5-64-1101(a), to knowingly purchase, acquire, or otherwise receive more than five grams (5g) of ephedrine or nine grams (9g) of pseudoephedrine or phenylpropanolamine within any thirty-day period.

(2)

(A) A person who violates subdivision (f)(1)(A) or subdivision (f)(1)(B) of this section for a first or second offense upon conviction is guilty of a Class A misdemeanor.

(B) A person who violates subdivision (f)(1)(A) or subdivision (f)(1)(B) of this section for a third offense upon conviction is guilty of a Class D felony.

(C) A person who violates subdivision (f)(1)(A) or subdivision (f)(1)(B) of this section for a fourth or subsequent offense upon conviction is guilty of a Class C felony.

(3) A plea of guilty or nolo contendere to or a finding of guilt under a penal law of the United States or another state that is equivalent to subdivision (f)(1)(A) or subdivision (f)(1)(B) of this section is considered a previous offense for the purposes of this subsection.

(g) This section does not prohibit a person under eighteen (18) years of age from possessing and selling a product described in subsections (a) and (b) of this section as an agent of the minor's employer acting within the scope of the minor's employment.

5-64-1104. Sales records – Entering transactions into real-time electronic logbook – Purchaser's proof of identity.

(a) A pharmacy shall:

(1) Maintain a written or electronic log or receipts of transactions involving the sale of ephedrine, pseudoephedrine, or phenylpropanolamine; and

(2) Enter any transaction required to be maintained by this section into the real-time electronic logbook maintained by the Arkansas Crime Information Center under § 5-64-1106.

(b) A person purchasing, receiving, or otherwise acquiring ephedrine, pseudoephedrine, or phenylpropanolamine shall:

(1) Produce current and valid proof of identity; and

(2) Sign a written log or an electronic log or a receipt that documents the date of the transaction, the name of the person, and the quantity of ephedrine, pseudoephedrine, or phenylypropanolamine purchased, received, or otherwise acquired.

(c) The requirements of subsection (a) of this section and subdivision (b)(2) of this section are satisfied by entering the information required to be produced into the real-time electronic logbook maintained by the Arkansas Crime Information Center under § 5-64-1106.

5-64-1111. Liability of pharmacy or pharmacist.

(a) A pharmacy in this state is not liable civilly for a sale of ephedrine, pseudoephedrine, or phenylpropanolamine that occurs at another pharmacy in this state.

(b) A pharmacy or pharmacist is not civilly liable for a determination made under § 5-64-1103(c) or for any refusal to dispense, sell, transfer, or otherwise furnish ephedrine, pseudoephedrine, or phenylpropanolamine based on a determination of age or identity.

Insurance Policies – Prescription Drug Benefits

23-79-149. Prescription drug benefits.

(a) As used in this section, "insurance policy" means any individual, group, or blanket policy, contract, or evidence of coverage written, issued, amended, delivered, or renewed in this state, or which provides such insurance for residents of this state, by an insurance company, hospital medical corporation, or health maintenance organization.

(b) No insurance company, hospital medical corporation, or health maintenance organization issuing insurance policies in this state shall contract with a pharmacist, pharmacy, pharmacy distributor, or wholesale drug distributor, nonresident or otherwise, to provide benefits under such insurance policies for the shipment or delivery of a dispensed legend drug into the State of Arkansas, unless the pharmacist, pharmacy, or distributor has been granted a license or permit from the Arkansas State Board of Pharmacy to operate in the State of Arkansas.

(c)

(1) Each insurance policy shall apply the same coinsurance, co-payment, and deductible factors to covered drug prescriptions filled by a pharmacy provider who participates in the insurance policy's network if the provider meets the contract's explicit product cost determination.

(2) Nothing in this subsection shall be construed to prohibit the insurance policy from applying different coinsurance, copayment, and deductible factors between and among generic and brand name drugs.

(d) Insurance policies shall not set a limit on the quantity of drugs which an enrollee may obtain at any one (1) time with a prescription, unless the limit is applied uniformly to all pharmacy providers in the insurance policy's network.

(e)

(1) For the purpose of this subsection, "maintenance drug" means a drug prescribed by a practitioner who is licensed to prescribe drugs and used to treat a medical condition for a period greater than thirty (30) days.

(2) Insurance policies shall not insist or mandate any provider to change an enrollee's maintenance drug, unless the prescribing provider and enrollee agree to such a change.

(3) Notwithstanding other provisions of law to the contrary, insurance policies that change an enrollee's maintenance drug without the consent of the provider and enrollee shall be liable to the provider or enrollee, or both, for any damages resulting from the change.

(f) The Insurance Commissioner shall enforce the provisions of this section and shall impose and collect a penalty of one thousand dollars ($1,000) for the first violation of this section and a penalty of five thousand dollars ($5,000) for each subsequent violation of this section. In addition, the commissioner shall have all the powers to enforce this section as are granted to the commissioner elsewhere in the Arkansas Insurance Code.

(g) The commissioner shall have all the powers to enforce this section, including, but not limited to, ensuring that the different coinsurance, copayment, and deductible factors applicable between and among generic and brand name drugs are reasonable, as are granted to the commissioner elsewhere in the Arkansas Insurance Code.

Coverage for Diabetes Treatment

23-79-601. Definitions.

As used in this subchapter:

(1) "Diabetes self-management training" means instruction in an inpatient or outpatient setting including medical nutrition therapy relating to diet, caloric intake and diabetes management, excluding programs the primary purposes of which are weight reduction, which enables diabetic patients to understand the diabetic management process and daily management of diabetic therapy as a method of avoiding frequent hospitalizations and complications when the instruction is provided in accordance with a program in compliance with the National Standards for Diabetes Self-Management Education and Support as developed by the American Diabetes Association;

(2) "Healthcare insurer" means any insurance company, fraternal benefit society, hospital and medical services corporation, or health maintenance organization issuing or delivering a health insurance policy subject to any of the following laws:

(A) The Arkansas Insurance Code;

(B) Section 23-74-101 et seq., relating to fraternal benefit societies;

(C) Section 23-75-101 et seq., pertaining to hospital medical service corporations;

(D) Section 23-76-101 et seq., pertaining to health maintenance organizations; and

(E) Any successor law of the foregoing; and

(3) "Health insurance policy" means a group insurance policy, contract, or plan or an individual policy, contract, or plan which provides medical coverage on an expense incurred, service, or prepaid risk-sharing basis. The term includes, but is not limited to, a policy, contract, or plan issued by an entity subject to any of the following laws:

(A) The Arkansas Insurance Code;

(B) Section 23-74-101 et seq., relating to fraternal benefit societies;

(C) Section 23-75-101 et seq., pertaining to hospital medical service corporations;

(D) Section 23-76-101 et seq., pertaining to health maintenance organizations; and

(E) Any successor law of the foregoing.

23-79-602. Diabetes self-management training – Licensed providers – Prescription by physician.

(a) Every health insurance policy shall include coverage for a one-per-lifetime training program per insured for diabetes self-management training when medically necessary as determined by a physician and when provided by an appropriately licensed healthcare professional upon certification by the healthcare professional providing the training that the insured patient has successfully completed the training.

(b) Every healthcare insurer shall offer, in addition to the one-lifetime-training program provided in subsection (a) of this section, additional diabetes self-management training in the event that a physician prescribes additional diabetes self-management training and it is medically necessary because of a significant change in the insured's symptoms or conditions.

(c) A licensed healthcare professional shall only provide diabetes self-management training within his or her scope of practice after having demonstrated expertise in diabetes care and treatment and after having completed an educational program required by his or her licensing board when that program is in compliance with the National Standards for Diabetes Self-Management Education and Support as developed by the American Diabetes Association.

(d) Diabetes self-management training shall be provided only upon prescription by a physician licensed under the Arkansas Medical Practices Act, § 17-95-201 et seq., § 17-95-301 et seq., and § 17-95-401 et seq.

(e) Nothing in this subchapter shall be construed to prohibit healthcare insurers from selectively negotiating contracts with qualified providers of diabetes self-management training programs.

23-79-603. Requirements.

(a) Every health insurance policy shall include medical coverage for medically necessary equipment, supplies, and services for the treatment of Type I diabetes, Type II diabetes, and gestational diabetes, when prescribed by a physician licensed under § 17-95-201 et seq.

(b) The coverage required by this section shall be consistent with that established for other services covered by a given health insurance policy in regard to any of the following:

(1) Deductibles, coinsurance, other patient cost-sharing amounts or out-of-pocket limits; or

(2) Prior authorization or other utilization review requirements or processes.

23-79-604. Exclusions.

This subchapter shall not be construed as prohibiting a health insurance policy from excluding from coverage diabetes self-management training or equipment or supplies and related services for the treatment of Type I diabetes, Type II diabetes, or gestational diabetes when the training, equipment, supplies, and services are not medically necessary, provided that the medical necessity determination is made in accordance with generally accepted standards of the medical profession and other applicable laws and rules.

23-79-605. Rules.

The State Insurance Department shall develop and promulgate rules to implement the provisions of this subchapter.

23-79-606. Applicability – Delivery within state.

(a) This subchapter shall apply to any health insurance policy that is delivered, issued for delivery, renewed, extended, or modified in this state on or after August 1, 1997.

(b) If a health insurance policy provides coverage or benefits to an Arkansas resident, the health insurance policy shall be deemed to be delivered in this state within the meaning of this subchapter, regardless of whether the healthcare insurer or other entity that provides the coverage is located within or outside of Arkansas.

23-79-607. Applicability – Exceptions.

(a) This subchapter shall not apply to:

(1) Long-term care plans;

(2) Disability income plans;

(3) Short-term nonrenewable individual health insurance policies that expire after six (6) months;

(4) Medical payments under homeowner or automobile insurance policies; and

(5) Workers' compensation insurance.

Arkansas Coverage for Early Refills of Prescription Eye Drops Act

23-79-2201. Title.

This subchapter shall be known and may be cited as the "Arkansas Coverage for Early Refills of Prescription Eye Drops Act".

23-79-2202. Definitions.

As used in this subchapter:

(1) "Covered person" means a person who is and continues to remain eligible for coverage under a health benefit plan and is covered under the health benefit plan;

(2)

(A) "Health benefit plan" means:

(i) An individual, blanket, or group plan, policy, or contract for healthcare services issued or delivered by a healthcare insurer; and

(ii) Any health benefit program receiving state or federal appropriations from the State of Arkansas, including the Arkansas Medicaid Program and the Arkansas Works Program, or any successor program.

(B) "Health benefit plan" includes:

(i) Indemnity and managed care plans; and

(ii) Nonfederal governmental plans as defined in 29 U.S.C. § 1002(32), as it existed on January 1, 2021.

(C) "Health benefit plan" does not include:

(i) A disability income plan;

(ii) A credit insurance plan;

(iii) Insurance coverage issued as a supplement to liability insurance;

(iv) A medical payment under automobile or homeowners insurance plans;

(v) A health benefit plan provided under Arkansas Constitution, Article 5, § 32, the Workers' Compensation Law, § 11-9-101 et seq., or the Public Employee Workers' Compensation Act, § 21-5-601 et seq.;

(vi) A plan that provides only indemnity for hospital confinement;

(vii) An accident-only plan;

(viii) A specified disease plan;

(ix) A long-term-care-only plan;

(x) A dental-only plan; or

(xi) A vision-only plan;

(3) “Healthcare insurer” means an entity subject to the insurance laws of this state or the jurisdiction of the Insurance Commissioner that contracts or offers to contract to provide health insurance coverage, including without limitation an insurance company, a health maintenance organization, a hospital medical service corporation, a self-insured governmental or church plan in this state, or the Arkansas Medicaid Program;

(4) “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; and

(5) “Prescription eye drops” means a prescription topical eye medication that is delivered through eye drops and is used to treat a chronic condition of the eye.

23-79-2203. Prescription eye drops – Early refills – Requirements.

A healthcare insurer that provides coverage for prescription eye drops under a health benefit plan shall provide coverage for early refills of prescription eye drops to a covered person on and after January 1, 2022, if:

(1) For a thirty-day supply:

(A) The amount of time has passed after which a covered person should have used seventy percent (70%) of the dosage of the prescription eye drops according to a healthcare professional's instructions on the prescription; or

(B) Twenty-two (22) days have passed from:

(i) The original date the prescription eye drops were distributed to a covered person; or

(ii) The date the most recent refill of the prescription eye drops was distributed to a covered person;

(2) The healthcare professional indicates on the original prescription that additional quantities of the prescription eye drops are needed;

(3) A refill request of a covered person for prescription eye drops does not exceed the number of additional quantities needed as described in subdivision (2) of this section; and

(4) The prescription eye drops prescribed by a healthcare professional are a covered benefit under the health benefit plan of the covered person.

Food, Drug, and Cosmetic Act

20-56-201. Title.

This subchapter may be cited as the "Food, Drug, and Cosmetic Act".

20-56-202. Definitions.

As used in this subchapter, unless the context otherwise requires:

(1) "Abandoned drug" means a drug which:

(A) Is in the possession or control of a person who is without authority under law to possess, purchase, or sell;

(B) In its present circumstances presents a danger to the public health or safety;

(C) Is not properly controlled by the person who by law has authority to possess, purchase, or sell the drug;

(D) Is the subject of a recall order by the United States Food and Drug Administration but has not been returned within a reasonable time after the publication of that order;

(E) Is adulterated, misbranded, or a new drug as defined in this subchapter or a drug intended solely for investigational use and approved by the United States Food and Drug Administration as such for which there is no approval in effect; or

(F) Is otherwise rendered unsafe for use as a result of fire, flood, or other natural disaster;

(2) "Advertisement" means all representations disseminated in any manner, or by any means other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics;

(3) The representation of a drug, in its labeling or advertisement, as an antiseptic shall be considered to be a representation that it is a germicide except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or other use which involves prolonged contact with the body;

(4) "Board" means the State Board of Health;

(5) "Contaminated with filth" applies to any food, drug, device, or cosmetic not securely protected from dust, dirt, and, as far as may be necessary and by all reasonable means, from all foreign or injurious contaminations;

(6) "Cosmetic" means:

(A) Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance; and

(B) Articles intended for use as a component of any such articles, except that the term shall not include soap;

(7) "Counterfeit substance" means a drug which, or the container or labeling of which, without authorization bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who, in fact, manufactured, processed, packed, or distributed the drug and which thereby falsely purports or is represented to be the product of or to have been packed or distributed by another drug manufacturer, processor, packer, or distributor;

(8) "Device", except when used in subdivision (16)(B) of this section, and in § 20-56-209(6), § 20-56-211(3), § 20-56-213(3), and § 20-56-215, means instruments, apparatus, and contrivances, including their components, parts, and accessories which are intended:

(A) For use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; or

(B) To affect the structure or any function of the bodies of humans or other animals;

(9) "Drug" means:

(A) Articles recognized in the official *United States Pharmacopoeia*, the official *Homeopathic Pharmacopoeia of the United States*, the official *National Formulary*, or in any supplement to any of them;

(B) Articles intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(C) Articles other than food intended to affect the structure or any function of the bodies of humans or other animals; and

(D) Articles intended for use as a component of any article specified in subdivisions (9)(A)-(C) of this section, but does not include devices or their components, parts, or accessories;

(10) "Federal act" means the Federal Food, Drug, and Cosmetic Act;

(11) "Food" means:

(A) Articles used for food or drink for humans or other animals;

(B) Chewing gum; and

(C) Articles used for components of any such article;

(12) "Human growth hormone" means somatrem, somatropin, or an analogue of either of them;

(13) "Human growth hormone" includes both cadaver source and biosynthetic human growth hormones;

(14) "Immediate container" does not include package liners;

(15) "Label" means a display of written, printed, or graphic matter upon the immediate container of any article. A requirement made by or under authority of this subchapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless the word, statement, or other information also appears on the outside container or wrapper, if there is any, of the retail package of the article, or is easily legible through the outside container or wrapper;

(16)

(A) "Labeling" means all labels and other written, printed, or graphic matter upon an article or any of its containers or wrappers, or accompanying the article.

(B) If any article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then, in determining whether the labeling or advertisement is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device, sound, or in any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of the representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual;

(17) "New drug" means:

(A) Any drug the composition of which is such that the drug is not generally recognized among experts who are qualified by scientific training and experience to evaluate the safety of drugs as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof; or

(B) Any drug the composition of which is such that the drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions;

(18) "Official compendium" means the official *United States Pharmacopoeia*, the official *Homeopathic Pharmacopoeia of the United States*, the official *National Formulary*, or any supplement to any of them; and

(19) "Person" includes an individual, partnership, corporation, or association.

20-56-203. Applicability.

The provisions of this subchapter regarding the selling of food, drugs, devices, or cosmetics shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession, and holding of any such article for sale and includes the sale, dispensing, and giving of any such article and the supplying or applying of the articles in the conduct of any food, drug, or cosmetic establishment.

20-56-204. Notice of minor violations.

Nothing in this subchapter shall be construed as requiring the State Board of Health to report for the institution of proceedings under this subchapter any minor violations of this subchapter whenever the board believes that the public interest will be adequately served under the circumstances by a suitable written notice or warning to the violators.

20-56-205. Penalties – Exceptions.

(a) Any person who violates any of the provisions of this subchapter shall be guilty of a misdemeanor and for such offense shall, upon conviction, be fined an amount not to exceed five hundred dollars ($500), or shall be sentenced to not more than one (1) year's imprisonment, or both fine and imprisonment, in the discretion of the court. For each subsequent offense and conviction thereof, the person shall be fined not less than one thousand dollars ($1,000) or sentenced to one (1) year's imprisonment, or both fine and imprisonment, in the discretion of the court.

(b) No person shall be subject to the penalties of subsection (a) of this section for having violated § 20-56-215(1) or § 20-56-215(3) if he or she establishes a guaranty or undertaking, signed by and containing the name and address of the person residing in the State of Arkansas from whom he or she received in good faith the article, to the effect that the article is not adulterated or misbranded within the meaning of this subchapter and designating this subchapter.

(c) No publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, but not including the manufacturer, packer, distributor, or seller of the article to which a false advertisement relates, shall be liable under this section by reason of the dissemination by him, her, or it of the false advertisement unless he, she, or it has refused, on the request of the State Board of Health, to furnish the board the name and post office address of the manufacturer, packer, distributor, seller, or advertising agency residing in the State of Arkansas who caused him, her, or it to disseminate the advertisement.

(d)

(1) Except as provided in subdivision (d)(2) of this section, any person who distributes or possesses with intent to distribute any human growth hormone or counterfeit substance purporting to be a human growth hormone for any use in humans other than the treatment of disease pursuant to the order of a physician shall be deemed guilty of a Class D felony.

(2) Any person who distributes or possesses with the intent to distribute to an individual under eighteen (18) years of age, any human growth hormone or counterfeit substance purporting to be a human growth hormone for any use in humans other than the treatment of disease pursuant to the order of a physician shall be deemed guilty of a Class C felony.

(3) Possession by any person of more than two hundred (200) capsules or tablets or more than sixteen cubic centimeters (16 cm^3) of human growth hormone or counterfeit substance purporting to be a human growth hormone shall create a rebuttable presumption that the person possesses such substances with the intent to deliver in violation of this subsection. However, this presumption may be overcome by the submission of evidence sufficient to create a reasonable doubt that the person charged possessed the substance with intent to deliver.

20-56-206. Duty of prosecuting attorney.

It shall be the duty of each prosecuting attorney to whom the State Board of Health reports any violation of this subchapter to cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law.

20-56-207. Injunctions authorized.

In addition to the remedies provided in § 20-56-205, the State Board of Health is authorized to apply to the proper circuit court for, and the court shall have jurisdiction, upon hearing and for cause shown, to grant, a temporary or permanent injunction restraining any person from violating any provision of § 20-56-215, whether or not there exists an adequate remedy at law.

20-56-208. Adulterated food.

A food shall be deemed to be adulterated:

(1)

(A) If the food bears or contains any poisonous or deleterious substance which may render the food injurious to health.

(B) However, if the substance is not an added substance, the food shall not be considered adulterated under subdivision (1)(A) of this section if the quantity of the substance in the food does not ordinarily render the food injurious to health;

(2) If the food bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of § 20-56-218;

(3) If the food consists, in whole or in part, of a diseased, contaminated, filthy, putrid, or decomposed substance, or if the food is otherwise unfit for human consumption;

(4) If the food has been produced, prepared, packed, or held under insanitary conditions where the food may have become contaminated with filth, or where the food may have been rendered diseased, unwholesome, or injurious to health;

(5) If the food is the product of a diseased animal or an animal that has died otherwise than by slaughter or that has been fed, or has otherwise fed upon, the uncooked offal of other animals;

(6) If the food's container is composed, in whole or in part, of any poisonous or deleterious substance which may render the food injurious to health;

(7) If any valuable constituent has been, in whole or in part, omitted or abstracted from the food;

(8) If any substance has been substituted wholly or in part for the food;

(9) If damage or inferiority has been concealed in any manner;

(10) If any substance has been added, mixed, or packed with the food to increase the food's bulk or weight, to reduce the food's quality or strength, or to make the food appear better or of greater value than the food is;

(11)

(A) If the food is confectionery and the food bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of one percent (4/10 of 1%), harmless natural wax not in excess of four-tenths of one percent (4/10 of 1%), harmless natural gum, and pectin.

(B) However, this subdivision (11) shall not apply to:

(i) Confectionery containing less than five percent (5%) by volume of alcohol, if the alcohol is in a nonliquid form as a result of being mixed with other substances; or

(ii) Chewing gum containing harmless nonnutritive masticatory substances; or

(12) If the food bears or contains a coal tar color other than one from a batch which has been certified under authority of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301.

20-56-209. Misbranded food.

A food shall be deemed to be misbranded:

(1) If its labeling is false or misleading in any particular;

(2) If it is offered for sale under the name of another food;

(3) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated;

(4) If its container is so made, formed, or filled as to be misleading;

(5) If in package form, unless it bears a label containing:

(A) The name and place of business of the manufacturer, packer, or distributor; and

(B) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, provided that reasonable variations shall be permitted, and exemptions as to small packages shall be established by rules prescribed by the State Board of Health;

(6) If any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness, as considered as compared with other words, statements, designs, or devices in the labeling, and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(7) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by rules or regulations as provided by § 20-56-219 or by the Federal Food, Drug, and Cosmetic Act, unless:

(A) It conforms to the definition and standard; and

(B) Its label bears the name of the food specified in the definition and standard, and, insofar as may be required by rules or regulations, the common names of optional ingredients other than spices, flavoring, and coloring present in the food;

(8) If it purports to be or is represented as:

(A) A food for which a standard of quality has been prescribed by rules or regulations as provided in § 20-56-219 or by the Federal Food, Drug, and Cosmetic Act and its quality falls below the standard, unless its label bears, in such manner and form as the rules or regulations specify, a statement that it falls below the standard; or

(B) A food for which a standard of fill of container has been prescribed by rules or regulations as provided by § 20-56-219, and it falls below the standard of fill of container applicable thereto unless its label bears, in such manner and form as the rules or regulations specify, a statement that it falls below the standard;

(9) If it is not subject to the provisions of subdivision (7) of this section, unless it bears labeling clearly giving:

(A) The common or usual name of the food, if there is any; and

(B)

(i) In case it is fabricated from two (2) or more ingredients, the common or usual name of each ingredient, except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each.

(ii) However, to the extent that compliance with the requirements of subdivision (9)(B)(i) of this section is impractical or results in deception or unfair competition, exemptions shall be established by rules promulgated by the board;

(10) If it purports to be or is represented for special dietary uses unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the board determines to be, and by rules prescribed as necessary in order to fully inform purchasers as to its value for such uses;

(11) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative unless it bears labeling stating that fact, provided that to the extent that compliance with the requirements of this subdivision (11) is impracticable, exemptions shall be established by rules promulgated by the board; and

(12) If it is a product intended as an ingredient of another food and, when used according to the directions of the purveyor, will result in the final food product's being adulterated or misbranded.

20-56-210. Adulterated drug or device.

A drug or device shall be deemed to be adulterated:

(1)

(A) If it consists in whole or in part of any filthy, putrid, or decomposed substance;

(B) If it has been produced, prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health;

(C) If it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(D) If it is a drug and it bears or contains, for purposes of coloring only, a coal tar color other than one from a batch certified under the authority of the Federal Food, Drug, and Cosmetic Act;

(2) If it purports to be or is represented as a drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in the compendium. The determination as to strength, quality, or purity of the drug or device shall be made in accordance with the tests or methods of assay set forth in the compendium, or in the absence of or inadequacy of the tests or methods of assay, those prescribed under authority of the Federal Food, Drug, and Cosmetic Act. No drug defined in an official compendium shall be deemed to be adulterated under this subdivision (2) because it differs from the standard of strength, quality, or purity set forth in the compendium if its difference in strength, quality, or purity from the standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia;

(3) If it is not subject to the provisions of subdivision (2) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess; or

(4) If it is a drug and any substance has been:

(A) Mixed or packed therewith so as to reduce its quality or strength; or

(B) Substituted wholly or in part therefor.

20-56-211. Misbranded drug or device.

A drug or device shall be deemed to be misbranded:

(1) If its labeling is false or misleading in any particular;

(2) If in package form unless it bears a label containing:

(A) The name and place of business of the manufacturer, packer, or distributor. However, in the case of any drug subject to subdivision (11) of this section, the label shall contain the name and place of business of the manufacturer of the final dosage form of the drug and, if different, the name and place of business of the packer or distributor thereof; and

(B) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. Reasonable variations shall be permitted, and exemptions as to small packages shall be established, by rules prescribed by the State Board of Health;

(3) If any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness, as compared with other words, statements, designs, or devices in the labeling, and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(4) If it is for use by humans and contains any quantity of narcotic or hypnotic substance, alpha-sucaine, barbituric acid, beta-sucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, or sulphonmethane, or any chemical derivative of such substances, which derivative has been designated as habit-forming by regulations promulgated under § 502(d) [repealed] of the Federal Food, Drug, and Cosmetic Act unless its label bears the name and quantity or proportion of the substance or derivative and in juxtaposition therewith the statement "Warning — May be habit-forming";

(5) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears:

(A) The common or usual name of the drug, if there is any; and

(B) In case it is fabricated from two (2) or more ingredients, the common or usual name of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, glucosides, mercury, ouabain, stophanthin, strychnine, thyroid, or any derivative or preparation of any such substances contained therein. However, to the extent that compliance with the requirements of this subdivision (5)(B) is impracticable, exemptions shall be established by rules promulgated by the board;

(6) Unless its labeling bears:

(A) Adequate directions for use; and

(B) Such adequate warning against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users. However, where any requirement of subdivision (6)(A) of this section as applied to any drug or device is not necessary for the protection of the public health, the board shall promulgate rules exempting the drug or device from the requirements;

(7) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein. However, the method of packing may be modified with the consent of the board. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia;

(8) If it has been found by the board to be a drug liable to deterioration, unless it is packaged in such form and manner and its label bears a statement of such precautions as the board shall by rule require as necessary for the protection of public health. No such rules shall be established for any drug recognized in an official compendium until the board shall have informed the appropriate body charged with the revision of the compendium of the need for the packaging or labeling requirements and the body shall have failed within a reasonable time to prescribe the requirements;

(9)

(A) If it is a drug and its container is so made, formed, or filled as to be misleading.

(B) If it is an imitation of another drug.

(C) If it is offered for sale under the name of another drug;

(10) If it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof; or

(11) If it is a drug other than those covered by Acts 1951, No. 184 [repealed], and intended for use by humans which:

(A) Is a habit-forming drug to which subdivision (4) of this section applies;

(B) Because of its toxicity or other potentiality for harmful effect, or the method of use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a physician, dentist, or veterinarian; or

(C) Is limited by an effective application under § 505 [repealed] of the Federal Food, Drug, and Cosmetic Act to use under professional supervision by a physician, dentist, or veterinarian unless it is dispensed only:

(i) Upon a written prescription of a physician, dentist, or veterinarian; or

(ii)

(a) By refilling a written or oral prescription if the refilling is authorized by the prescriber.

(b) However, a drug dispensed by filling or refilling a written prescription of a physician, dentist, or veterinarian is exempt from the requirements of this section except subdivisions (1) and (9) of this section if the drug bears a label containing:

(1) The name and address of the dispenser;

(2) The serial number and date of the prescription or its filling;

(3) The name of the prescriber;

(4) If stated in the prescription, the name of the patient; and

(5) The directions for use and cautionary statements, if any, contained in the prescription.

(c) This exemption does not apply to a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail.

20-56-212. Adulterated cosmetic.

A cosmetic shall be deemed to be adulterated:

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling or advertisement thereof, or under such conditions of use as are customary or usual. However, this provision shall not apply to coal tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution — This product contains ingredients which may cause skin irritation on certain individuals, and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness", and the labeling of which bears adequate direction for such preliminary testing. For the purposes of this subdivision (1) and subdivision (5) of this section, the term "hair dye" shall not include eyelash dyes or eyebrow dyes;

(2) If it consists in whole or part of any filthy, putrid, or decomposed substance;

(3) If it has been produced, prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health;

(4) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(5) If it is not a hair dye and it bears or contains a coal tar color other than one from a batch which has been certified under authority of the Federal Food, Drug, and Cosmetic Act.

20-56-213. Misbranded cosmetic.

A cosmetic shall be deemed to be misbranded:

(1) If its labeling is false or misleading in any particular;

(2) If in package form unless it bears a label containing:

(A) The name and place of business of the manufacturer, packer, or distributor; and

(B) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, provided that reasonable variations shall be permitted and exemptions as to small packages shall be established by rules prescribed by the State Board of Health;

(3) If any word, statement, or other information required by or under authority of this subchapter to appear on the label is not prominently placed thereon with such conspicuousness, as compared with other words, statements, designs, or devices, in the labeling and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; or

(4) If its container is so made, formed, or filled as to be misleading.

20-56-214. False or misleading advertisement.

(a) An advertisement of a food, drug, device, or cosmetic shall be deemed to be false if it is false or misleading in any particular.

(1)

(A) For the purpose of this subchapter, the advertisement of a drug or device shall also be deemed to be false if the advertisement represents the drug or device to have any effect on any of the following diseases or conditions:

(i) Albuminuria;

(ii) Appendicitis;

(iii) Arteriosclerosis;

(iv) Blood poison;

(v) Bone disease;

(vi) Bright's disease;

(vii) Cancer;

(viii) Carbuncles;

(ix) Cholecystitis;

(x) Diabetes;

(xi) Diphtheria;

(xii) Dropsy;

(xiii) Erysipelas;

(xiv) Gallstones;

(xv) Heart and vascular diseases;

(xvi) High blood pressure;

(xvii) Mastoiditis;

(xviii) Measles;

(xix) Meningitis;

(xx) Mumps;

(xxi) Nephritis;

(xxii) Otitis media;

(xxiii) Paralysis;

(xxiv) Pneumonia;

(xxv) Poliomyelitis or infantile paralysis;

(xxvi) Prostate gland disorders;

(xxvii) Pyelitis;

(xxviii) Scarlet fever;

(xxix) Sexual impotence;

(xxx) Sexually transmitted disease;

(xxxi) Sinus infection;

(xxxii) Smallpox;

(xxxiii) Tuberculosis;

(xxxiv) Tumors;

(xxxv) Typhoid; or

(xxxvi) Uremia.

(B) An advertisement of a drug or device shall not be deemed to be false under this subsection if the advertisement is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of the drug or device.

(2) However, whenever the State Board of Health determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named in subdivision (b)(1)(A) of this section, the board shall by rule authorize the advertisement of drugs having curative or therapeutic effect for the disease, subject to such conditions and restrictions as the board may deem necessary in the interests of public health.

(3) This subsection shall not be construed as indicating that self-medication for diseases other than those named herein is safe or efficacious.

20-56-215. Prohibited acts.

The following acts and the causing thereof within the State of Arkansas are prohibited:

(1) The manufacture or sale, delivery, holding, or offering for sale of any food, drug, device, or cosmetic that is adulterated, misbranded, or abandoned;

(2) The adulteration, misbranding, or abandoning of any food, drug, device, or cosmetic;

(3) The receipt in commerce of any food, drug, device, or cosmetic knowing it to be adulterated, misbranded, or abandoned, and the delivery or proffered delivery thereof for pay or otherwise;

(4) The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of § 20-56-217;

(5) The dissemination of any false advertisement;

(6) The refusal to permit entry or inspection or to permit the taking of a sample, as authorized by § 20-56-220;

(7) The giving of a guaranty or undertaking which is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the State of Arkansas from whom he or she received in good faith the food, drug, device, or cosmetic;

(8) The removal or disposal of a detained or embargoed article in violation of § 20-56-216;

(9) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic if the act is done while the article is held for sale and results in the article's being misbranded; and

(10) Forging, counterfeiting, simulating, falsely representing or, without proper authority, using any mark, stamp, tag, label, or other identification device authorized or required by rules promulgated under the provisions of this subchapter.

20-56-216. Adulterated, misbranded, or abandoned food, drug, device, or cosmetic – Procedures.

(a)

(1) Whenever an authorized agent of the State Board of Health finds or has probable cause to believe that any food, drug, device, or cosmetic is adulterated, so misbranded, or abandoned as to be dangerous or fraudulent within the meaning of this subchapter, he or she shall affix to the article a tag or other appropriate marking giving notice that the article is, or is suspected of being, adulterated, misbranded, or abandoned and has been detained or embargoed and warning all persons not to move, transfer from one (1) place to another, remove, or dispose of the article by sale or otherwise until written permission or order for movement, transfer, removal, or disposal is given by the agent or the court.

(2) It shall be unlawful for any person to move, transfer, remove, or dispose of the detained or embargoed article by sale or otherwise without permission.

(b)

(1) When an article detained or embargoed under subsection (a) of this section has been found by an agent to be adulterated, misbranded, or abandoned, the agent shall petition the judge of the circuit court in whose jurisdiction the article is detained or embargoed for a libel for condemnation of the article.

(2) When the agent has found that an article so detained or embargoed is not adulterated, misbranded, or abandoned, then he or she shall remove the tag or other marking.

(c)

(1) If the court finds that a detained or embargoed article is adulterated, misbranded, or abandoned, then the article, after entry of the decree, shall be destroyed at the expense of the claimant when under the supervision of the agent of the board. All court costs and fees and storage and other proper expenses shall be taxed against the claimant of the article or his or her agent.

(2) When the adulteration, misbranding, or abandoning can be corrected by proper labeling or processing of the article, the court, after entry of the decree and after costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that the article shall be so labeled or processed, has been executed, may direct that the article be delivered to the claimant thereof for labeling or processing under the supervision of an agent of the board.

(3) The expense of the supervision shall be paid by the claimant.

(4) The bond shall be returned to the claimant of the article upon representation to the court by the board that the article is no longer in violation of this subchapter and that the expenses of the supervision have been paid.

(d) Whenever the board or any of its authorized agents shall find in any room, building, vehicle of transportation, or other structure any meat, seafood, poultry, vegetable, fruit, or other perishable articles which are unsound or contain any filthy, decomposed, or putrid substance or which may be poisonous or deleterious to health or otherwise unsafe, those articles being declared to be a nuisance, the board or its authorized agent shall immediately condemn or destroy those articles or in any other manner render those articles unsalable as human food.

20-56-217. Contamination with microorganisms.

(a) Whenever the State Board of Health finds after investigation that the distribution in Arkansas of any class of food may, by reason of contamination with microorganisms during manufacture, processing, or packing thereof in any locality, be injurious to health and that the injurious nature cannot be adequately determined after the articles have entered commerce, it then, and in that case only, shall promulgate rules providing for the issuance of permits to manufacturers, processors, or packers of the class of food in the locality. To these permits shall be attached such conditions governing the manufacture, processing, or packing of the class of food for such temporary period of time as may be necessary to protect the public health. After the effective date of the rules and during the temporary period, no person shall introduce or deliver for introduction into commerce any food manufactured, processed, or packed by any manufacturer, processor, or packer unless the manufacturer, processor, or packer holds a permit issued by the board as provided by the rules.

(b) The board is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of the permit. The board shall, immediately after prompt hearing and an inspection of the establishment, reinstate the permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

(c) Any officer or employee designated by the board shall have access to any factory or establishment, the operator of which holds a permit from the board, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for the inspection shall be grounds for suspension of the permit until access is freely given by the operator.

20-56-218. Poisonous or deleterious substance – Rules for use.

(a) Any poisonous or deleterious substance added to any food, except where the substance is required in the production thereof or cannot be avoided by good manufacturing practice, shall be deemed to be unsafe for purposes of the application of § 20-56-208(2), but when the substance is so required or cannot be so avoided, the State Board of Health shall promulgate rules limiting the quantity therein or thereon to such extent as the board finds necessary for the protection of the public health. Any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of § 20-56-208(2).

(b) While such a rule is in effect limiting the quantity of any substance in the case of any food, the food shall not, by reason of bearing or containing any added amount of the substance not in excess of the limit established by rule, be considered to be adulterated within the meaning of § 20-56-208(1).

(c) In determining the quantity of the added substance to be tolerated in or on different articles of food, the board shall take into account the extent to which the use of the substance is required or cannot be avoided in the production of each article and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

20-56-219. State Board of Health – Authority to regulate.

(a)

(1) The authority to promulgate rules for the efficient enforcement of this subchapter is vested in the State Board of Health.

(2) The board is authorized to make the rules promulgated under this subchapter conform, insofar as practicable, with those promulgated under the Federal Food, Drug, and Cosmetic Act.

(b)

(1) Before promulgating any rules contemplated by § 20-56-209(10), § 20-56-211(4), § 20-56-211(6)-(8), § 20-56-214(b), § 20-56-217, or subsection (c) of this section, the board shall give appropriate notice of the proposal and of the time and place for a hearing.

(2) The rule so promulgated shall become effective on a date fixed by the board which shall not be before thirty (30) days after its promulgation.

(3) The rule may be amended or repealed in the same manner as is provided for its adoption, except that, in the case of a rule amending or repealing a rule, the board, to such an extent as it deems necessary in order to prevent undue hardship, may disregard the foregoing provisions regarding notice, hearing, or effective date.

(c)

(1) Whenever in the judgment of the board such action will promote honesty and fair dealing in the interest of consumers, the board shall promulgate rules fixing and establishing for any food or class of food a reasonable definition and standard of identity or reasonable standard of quality or fill of container.

(2) In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the board shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label.

(3) The definitions and standards so promulgated shall conform so far as practicable to the definitions and standards promulgated under authority of the Federal Food, Drug, and Cosmetic Act.

20-56-220. State Board of Health – Inspectors.

(a) The State Board of Health or its authorized agent shall have free access at all reasonable hours to any factory, warehouse, or establishment in which foods, drugs, devices, or cosmetics are manufactured, processed, packed, or held for introduction into commerce or to enter any vehicle being used to transport or hold such foods, drugs, devices, or cosmetics in commerce, for the purpose of:

(1) Inspecting the factory, warehouse, establishment, or vehicle to determine if any of the provisions of this subchapter are being violated; and

(2) Securing samples or specimens of any food, drug, device, or cosmetic after paying or offering to pay for the samples.

(b) It shall be the duty of the board to make or cause to be made examinations of samples secured under the provisions of this section to determine whether or not any provision of this subchapter is being violated.

20-56-221. State Board of Health – Publication and dissemination of information.

(a) The State Board of Health may cause reports to be published summarizing all judgments, decrees, and court orders which have been rendered under this subchapter, including the nature of the charge and the disposition thereof.

(b) The board may also cause to be disseminated such information regarding food, drugs, devices, and cosmetics as the board deems necessary in the interest of the public health and the protection of the consumer against fraud.

(c) Nothing in this section shall be construed to prohibit the board from collecting, reporting, and illustrating the results of the investigations of the board.

20-56-222. State Board of Health – Enforcement of subchapter.

(a) The enforcement of the provisions of this subchapter and all acts ancillary to it shall be the duty of the Division of Environmental Health Protection of the Department of Health.

(b) The State Board of Health is authorized to appoint the necessary personnel to properly administer this subchapter.

20-56-223. State Board of Health – Enforcement of federal law.

The State Board of Health is authorized to confer and cooperate with the United States Food and Drug Administration in the enforcement of the Federal Food, Drug, and Cosmetic Act as it may apply to food, liquor, drugs, and cosmetic products received in this state from other states, territories, or foreign countries.

Controlled Substances and Legend Drugs

20-64-501. Applicability

Nothing in this subchapter shall apply to the sale of chemicals or poisons for use for nonmedical purposes, or for uses as insecticides or biologics or medicine used for the cure, mitigation, or prevention of disease of animals or fowl, and uses for agricultural use which comply with the requirements of the Federal Food, Drug, and Cosmetic Act and all amendments thereto unless those products are prescription drugs under this subchapter.

20-64-502. Construction.

(a) This subchapter shall be construed to repeal only those provisions of the pharmacy laws of Arkansas in direct and specific conflict herewith.

(b) The provisions of this subchapter shall otherwise be cumulative to the pharmacy laws of Arkansas.

20-64-503. Definitions.

As used in this subchapter, unless the context otherwise requires:

(1) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing;

(2) "Blood component" means that part of blood separated by physical or mechanical means;

(3) [Repealed.]

(4) "Controlled substance" means those substances, drugs, or immediate precursors listed in Schedules I through VI of the Uniform Controlled Substances Act, § 5-64-101 et seq., and revised by the Secretary of the Department of Health pursuant to his or her authority under §§ 5-64-214 — 5-64-216;

(5) "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug;

(6)

(A) "Legend drug" means a drug limited by section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act to being dispensed by or upon a medical practitioner's prescription because the drug is:

(i) Habit-forming;

(ii) Toxic or having potential for harm; or

(iii) Limited in its use to use under a practitioner's supervision by the new drug application for the drug.

(B) The product label of a legend drug is required to contain the statement: "CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION".

(C) A legend drug includes prescription drugs subject to the requirement of section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act which shall be exempt from section 502(f)(1) if certain specified conditions are met;

(7) "Manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug;

(8) “Person” includes individual, partnership, corporation, business firm, and association;

(9) “Prescription drug” means controlled substances, legend drugs, and veterinary legend drugs as defined herein;

(10) “Veterinary legend drugs” means drugs defined in 21 C.F.R. § 201.105 and bearing a label required to bear the cautionary statement: “CAUTION: FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF A LICENSED VETERINARIAN”;

(11) “Wholesale distribution” means the distribution of prescription drugs to persons other than consumers or patients but does not include:

(A) Intracompany sales;

(B) The purchase or other acquisition by a hospital or other healthcare entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or healthcare entities that are members of the organizations;

(C) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(D) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other healthcare entities that are under common control. For the purposes of this section, “common control” means the power to direct or cause the direction of the management and policies of a person or an organization whether by ownership of stock or voting rights, by contract, or otherwise;

(E) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this section, “emergency medical reasons” includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(F) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

(G) The distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(H) The sale, purchase, or trade of blood components intended for transfusion; and

(12) “Wholesale distributor” means any person engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers' own-label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; prescription drug repackagers; physicians; dentists; veterinarians; birth control and other clinics; individuals; hospitals; nursing homes and their providers; health maintenance organizations and other healthcare providers; and retail and hospital pharmacies that conduct wholesale distributions. A wholesale drug distributor shall not include any for-hire carrier or person or entity hired solely to transport prescription drugs.

20-64-504. Sales – Permit required.

It shall be unlawful for any person to sell or offer for sale by advertisement, circular, letter, sign, oral solicitation, or any other means any prescription drug unless the person holds and possesses a permit authorizing the sale as provided by this subchapter.

20-64-505. Wholesale distributor – Permit required.

(a) Every wholesale distributor who shall engage in the wholesale distribution of prescription drugs, to include without limitation, manufacturing in this state, shipping into this state, or selling or offering to sell in this state, shall register annually with the Arkansas State Board of Pharmacy by application for a permit on a form furnished by the board and accompanied by a fee of two hundred dollars ($200). The board may require a separate license for each facility directly or indirectly owned or operated by the same business entity within this state, or for a parent entity with divisions, subdivisions, subsidiaries, or affiliate companies within this state when operations are conducted at more than one (1) location and there exists joint ownership and control among all the entities.

(b)

(1) The permit may be renewed annually at a renewal permit fee of one hundred dollars ($100).

(2) All permits issued under this section shall expire on December 31 of each calendar year.

(3) Each application for the renewal of the permit must be made on or before December 31 of each year, at which time the previous permits shall become null and void.

(c) Each permit issued hereunder shall be displayed by the holder thereof in a conspicuous place.

20-64-506. Wholesale distributors – Shipment to certain licensed professionals.

(a) All wholesale distributors must, before shipping to a recipient in this state any prescription drug as defined in this subchapter, ascertain that the person to whom shipment is made is either a physician licensed by the Arkansas State Medical Board, a licensed doctor of dentistry, a licensed doctor of veterinary medicine, a licensed doctor of podiatric medicine, a hospital licensed by the State Board of Health, a licensed wholesale distributor as defined in this subchapter, a pharmacy licensed by the Arkansas State Board of Pharmacy, or other entity authorized by law to purchase or possess prescription drugs.

(b) No wholesale distributor shall ship any prescription drug to any person after receiving written notice from the Arkansas State Board of Pharmacy that the person no longer holds a registered pharmacy permit or is not a licensed physician, dentist, veterinarian, or hospital.

20-64-507. Rules.

(a) The Arkansas State Board of Pharmacy shall adopt rules for the wholesale distribution of prescription drugs which promote the public health and welfare and which comply with the minimum standards, terms, and conditions of the Prescription Drug Marketing Act and federal regulations, including without limitations 21 C.F.R. § 205, for licensing by state authorities of persons who engage in the wholesale distribution in interstate commerce of prescription drugs. The rules shall include without limitation:

(1) Minimum information from each wholesale distributor required for licensing and renewal of licenses;

(2) Minimum qualifications of persons who engage in the wholesale distribution of prescription drugs;

(3) Appropriate education or experience, or both, of persons employed in wholesale distribution of prescription drugs who assume responsibility for positions related to compliance with state licensing requirements;

(4) Minimum requirements for the storage and handling of prescription drugs; and

(5) Minimum requirements for the establishment and maintenance of prescription drug distribution records.

(b) In the event that this subchapter or rules promulgated under this subchapter conflict with the federal Prescription Drug Marketing Act or federal regulations, the federal Prescription Drug Marketing Act or federal regulations shall control.

(c) The board shall appoint an advisory committee composed of seven (7) members, one (1) of whom shall be a representative of a pharmacy but who shall not be a member of the board, three (3) of whom shall be representatives of wholesale drug distributors, and three (3) of whom shall be representatives of drug manufacturers. The committee shall review and make recommendations to the board on the merit of all rules dealing with pharmacy distributors, wholesale drug distributors, and drug manufacturers which are proposed by the board.

20-64-508. Revocation or suspension of licenses.

The Arkansas State Board of Pharmacy may revoke or suspend an existing license or may refuse to issue a 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, rule, or regulation relating to drugs;

(2) Violation of any provisions of this subchapter or any rule 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.

20-64-509. Penalties.

(a) After notice and hearing, whenever the Arkansas State Board of Pharmacy has found a licensee to have committed any act enumerated in § 20-64-508, the board shall have the power to impose a civil penalty and may order the license to be suspended until the penalty is paid.

(b) Before imposing any civil penalty, the board shall determine that the public health and welfare would not be impaired by the imposition of the penalty and that payment of the penalty will achieve the desired disciplinary purposes.

(c) No penalty imposed by the board shall exceed one thousand dollars ($1,000) per violation, nor shall the board impose a penalty on a licensee where the license has been revoked by the board for a violation.

(d) Each instance where a federal, state, or local law or regulation is violated shall constitute a separate violation.

(e) The power and authority of the board to impose penalties is 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.

20-64-510. Hearing procedures.

The procedure for notice, hearing, and appeals therefrom shall be that of the Arkansas State Board of Pharmacy set forth in § 17-92-313, and that of the Arkansas Administrative Procedure Act, § 25-15-201 et seq.

20-64-511. Violations.

A person violating any provision of this subchapter shall be guilty of a Class A misdemeanor.

20-64-512. Inspection of records.

(a)

(1) The Arkansas State Board of Pharmacy may conduct inspections upon all premises purporting or appearing to be used by a person licensed under this subchapter.

(2) The board in its discretion may accept a satisfactory inspection by the United States Food and Drug Administration or a state agency of another state which the board determines to be comparable to that made by the United States Food and Drug Administration or the board.

(b) A licensed person may keep records at a central location apart from the principal office of the licensee or the location at which the drugs were stored and from which they are distributed.

20-64-513. Injunctive powers.

The Arkansas State Board of Pharmacy may, in its discretion and in addition to various remedies provided by law under this subchapter, apply to a court having competent jurisdiction over the parties and subject matter for a writ of injunction to restrain violations of this subchapter or of any conduct which constitutes a clear and present danger to the public health and safety.

Administrative Procedure Act

25-15-201. Title.

This subchapter shall be known and cited as the "Arkansas Administrative Procedure Act".

25-15-202. Definitions.

As used in this subchapter:

(1)

(A) "Adjudication" means an agency process for the formulation of an order.

(B) "Adjudication" does not include inmate disciplinary proceedings conducted by the Division of Correction and the Division of Community Correction;

(2)

(A) "Agency" means a board, commission, department, officer, or other authority of the government of the State of Arkansas, whether within, or subject to review by, another agency, except the General Assembly, the courts, and the Governor.

(B) The word "agency" shall include the Division of Child Care and Early Childhood Education and the Child Care Appeal Review Panel for purposes of administrative appeal.

(C)

(i) Except as provided in subdivision (2)(C)(ii) of this section, the word "agency" shall not include the Arkansas Public Service Commission, the Arkansas Pollution Control and Ecology Commission, the Workers' Compensation Commission, and the Division of Workforce Services, as the existing laws governing those agencies provide adequate administrative procedures for those agencies.

(ii) The word "agency" as used in §§ 25-15-216 and 25-15-218 shall include the Arkansas Public Service Commission, the Arkansas Pollution Control and Ecology Commission, the Workers' Compensation Commission, and the Division of Workforce Services.

(D) This subchapter does not repeal delegations of authority as provided by law;

(3) "Financial impact statement" means a realistic statement of a new or increased cost or obligation of complying with a proposed rule to a:

(A) Private individual, entity, and business; and

(B) State, county, and municipal government;

(4) "License" includes an agency permit, certificate, approval, registration, charter, or similar form of permission required by law;

(5) "Licensing" means an agency process respecting the grant, denial, renewal, revocation, suspension, annulment, withdrawal, limitation, or amendment of a license;

(6) "Order" means the final disposition of an agency in any matter other than rulemaking, including licensing and rate making, in which the agency is required by law to make its determination after notice and hearing;

(7) "Party" means a person or agency named or admitted as a party, or properly seeking and entitled as of right to be admitted as a party, in an agency proceeding;

(8) "Person" means an individual, partnership, corporation, association, or public or private organization of any character;

(9)

(A) "Rule" means an agency statement of general applicability and future effect that implements, interprets, or prescribes law or policy, or describes the organization, procedure, or practice of an agency and includes, but is not limited to, the amendment or repeal of a prior rule.

(B) "Rule" does not mean:

(i) A statement that concerns the internal management of a state agency and that does not affect the private rights or procedures available to the public;

(ii) A declaratory order or ruling issued under § 25-15-206 or other provision of law applicable to the state agency issuing the declaratory order or ruling;

(iii) Intra-agency memoranda;

(iv) A medical code within the Arkansas Medicaid Program that is issued by the Centers for Medicare & Medicaid Services, including without limitation:

(a) Current Procedural Terminology codes;

(b) Healthcare Common Procedure Coding System codes;

(c) International Classification of Diseases codes;

(d) National Uniform Billing Committee Official UB-04 Data Specifications Manual codes; and

(e) National Correct Coding Initiative codes;

(v) The addition of formatting to one (1) or more rules, including without limitation one (1) or more sections of the Code of Arkansas Rules, in order to create a handbook, manual, pamphlet, or other similar publication for the purpose of packaging or distributing materials for public use, including without limitation the addition of:

(a) A cover or title page;

(b) A table of contents; or

(c) An index;

(vi) A technical correction under § 25-15-218; or

(vii)

(a) Unless required by law to be promulgated as a rule, a form developed by an agency to implement or interpret a rule.

(b) A form under subdivision (9)(B)(vii)(a) of this section shall not contain language that otherwise meets the definition of a rule under subdivision (9)(A) of this section unless:

(1) The language is derived from an existing law or rule; and

(2) A citation to the existing law or rule is included on the form; and

(viii) An internal policy or the internal guidelines of a state agency related to a cybersecurity incident involving, or a cyberattack on, a state agency; and

(10) "Rulemaking" means an agency process for the formulation, amendment, or repeal of a rule.

25-15-203. Rules – Required rules – Public inspection.

(a) In addition to other rulemaking requirements imposed by law, each agency shall:

(1) Adopt as a rule a description of its organization, stating the general course and method of its operations, including the methods whereby the public may obtain information or make submissions or requests;

(2) Adopt rules of practice setting forth the nature and requirements of all formal and informal procedures available, including a description of all forms and instructions used by the agency;

(3) Make available for public inspection all rules and all other written statements of policy or interpretations formulated, adopted, or used by the agency in the discharge of its functions; and

(4) Make available for public inspection all orders, decisions, and opinions.

(b) No agency rule, order, or decision shall be valid or effective against any person or party, nor may it be invoked by the agency for any purpose, until it has been filed and made available for public inspection as required in this subchapter. This provision shall not apply in favor of any person or party with actual knowledge of an agency rule, order, or decision.

(c) To the extent possible, a rule shall be written in plain language.

25-15-204. Rules – Procedure for adoption.

(a) Prior to the adoption, amendment, or repeal of a rule, the agency shall:

(1)

(A)

(i) Give at least thirty (30) days' notice of its intended action.

(ii) The thirty-day period shall begin on the first day of the publication of notice.

(B) The notice shall include:

(i) A statement of the terms or substance of the intended action or a description of the subjects and issues involved; and

(ii) The time, location, and manner in which an interested person may present his or her position on the intended action of the agency or on the issues related to the intended action of the agency.

(C) The notice shall be mailed to:

(i) A person specified by law; and

(ii) A person who has requested advance notice of rulemaking proceedings.

(D) Unless otherwise provided by law, the notice shall be published:

(i) In a newspaper of general daily circulation for three (3) consecutive days and, when appropriate, in those trade, industry, or professional publications that the agency may select.

(ii) By the Secretary of State on the internet for thirty (30) days under § 25-15-218.

(E)

(i) If enacted legislation requires or results in more than one (1) agency adopting, amending, or repealing rules on a similar subject matter, the agencies may publish a combined notice for all rules.

(ii) The combined notice shall:

(a) Include:

(1) The names of all agencies involved in the collective filing; and

(2) The time, location, and manner in which an interested person may present his or her position on the intended action of each agency or on the issues related to the intended action of each agency; and

(b) Meet the requirements of subdivisions (a)(1)(C) and (D) of this section;

(2)

(A) Afford all interested persons reasonable opportunity to submit written data, views, or arguments, orally or in writing.

(B) The agency shall grant an opportunity for an oral hearing if requested by twenty-five (25) persons, by a governmental subdivision or agency, or by an association having at least twenty-five (25) members.

(C) The agency shall fully consider all written and oral submissions respecting the proposed rule before finalizing the language of the proposed rule and filing the proposed rule as required by subsection (e) of this section.

(D) If an interested person requests a statement of the reasons for and against the adoption of a rule before adoption or within thirty (30) days after adoption, the agency shall issue a concise statement of the principal reasons for and against its adoption, incorporating its reasons for overruling the considerations urged against its adoption.

(E) When rules are required by law to be made on the record after opportunity for an agency hearing, the provisions of that law shall apply in place of this subdivision (a)(2).

(F) Agencies that publish a combined notice as described in subdivision (a)(1)(E) of this section may hold a joint public hearing when required by law or otherwise desired by the agencies; and

(3) Consider the following factors:

(A) Whether the agency is required by statute to adopt the proposed rule, whether by a specific date, and whether the agency has discretion to promulgate rules;

(B) Other statutes relevant to the proposed rule and its alternatives;

(C) The specific nature and significance of the problem the agency addresses with the proposed rule, including without limitation:

(i) The nature and degree of the risks the problem poses;

(ii) The priority of addressing those risks as opposed to other matters or activities within the agency's jurisdiction;

(iii) Whether the problem warrants new agency action; and

(iv) The countervailing risks that may be posed by alternative rules for the agency;

(D) Whether existing rules have created or contributed to the problem the agency is addressing with the proposed rule, and whether those rules could be amended or repealed to address the problem in whole or in part;

(E) Reasonable alternatives to the proposed rule, including without limitation:

(i) Adopting no rule;

(ii) Amending or repealing existing rules; and

(iii) Other potential responses that could be taken instead of agency action;

(F) The financial impact of the proposed rule; and

(G) Any other factor relevant to the need for and alternatives to the proposed rule.

(b)

(1) An agency shall not adopt, amend, or repeal a rule unless the rule is based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule.

(2) An agency shall adopt the least costly rule considered under this section, unless:

(A) The additional benefits of the more costly rule justify its additional cost;

(B) The agency explains its reason for adoption of the more costly rule in writing;

(C) The reason is based on the interests of public health, safety, or welfare; and

(D) The reason is within the scope of the agency's statutory authority.

(c)

(1) If an agency finds that imminent peril to the public health, safety, or welfare or compliance with a federal law or regulation requires adoption of a rule upon less than thirty (30) days' notice and states in writing its reasons for that finding, it may proceed without prior notice or hearing, or upon any abbreviated notice and hearing that it may choose, to adopt an emergency rule.

(2) An agency shall not file an emergency rule with the Secretary of State for adoption until the emergency rule has been approved under § 10-3-309.

(3) Except as provided in § 5-64-201, the rule may be effective for no longer than one hundred twenty (120) days.

(4) If, after the expiration of the effective period of an emergency rule, an agency wishes to adopt a successive emergency rule that is identical or substantially similar to the expired emergency rule, the agency shall not adopt the successive emergency rule earlier than thirty (30) days after the expiration of the emergency rule.

(d)

(1) A person may petition an agency for the issuance, amendment, or repeal of a rule.

(2) Within thirty (30) days after submission of a petition, the agency shall:

(A) Deny the petition, stating in writing its reasons for the denial; or

(B) Initiate rulemaking proceedings.

(e)

(1)

(A) An agency shall file with the Secretary of State and the Legislative Council a:

(i) Copy of each rule, including without limitation an emergency rule, proposed by the agency;

(ii) Financial impact statement for the proposed rule;

(iii) Notice for the adoption, amendment, or repeal of any rule required to be published on the internet under this section;

(iv) Statement setting forth the reason for the proposed rule; and

(v) Summary of the proposed rule.

(B) An agency shall file with the Arkansas State Library a copy of each rule, including without limitation an emergency rule, finalized by the agency and a financial impact statement for the rule.

(C) A rule shall be filed in compliance with this section and with §§ 10-3-309 and 25-15-218.

(2) The Secretary of State shall keep a register of the rules open to public inspection, and it shall be a permanent register.

(3) If the purpose of a state agency rule is to implement a federal rule or regulation, the financial impact statement shall include:

(A) The cost to implement the federal rule or regulation; and

(B) The additional cost of the state rule.

(4)

(A) If a financial impact statement reveals a new or increased cost or obligation of at least one hundred thousand dollars ($100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined, the agency shall file written findings at the time of filing the financial impact statement.

(B) The written findings shall be filed simultaneously with the financial impact statement and shall include without limitation:

(i) A statement of the rule's basis and purpose;

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

(iii) A description of the factual evidence that:

(a) Justifies the agency's need for the proposed rule; and

(b) Describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;

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

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

(vi)

(a) A statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule.

(b) If existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and

(vii) An agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule, including without limitation whether:

(a) The rule is achieving the statutory objectives;

(b) The benefits of the rule continue to justify its costs; and

(c) The rule can be amended or repealed to reduce costs while continuing to achieve the statutory objections.

(f) An agency shall not file a final rule with the Secretary of State for adoption unless the final rule has been approved under § 10-3-309.

(g)

(1)

(A) Each rule adopted by an agency is effective ten (10) days after filing of the final rule with the Secretary of State unless a later date is specified by law or in the rule itself.

(B) A final rule shall not be filed until the thirty-day public comment period required under subdivision (a)(1)(A) of this section has expired.

(C)

(i) After the expiration of the thirty-day public comment period and before the effective date of the rule, the agency promulgating the rule shall take appropriate measures to make the final rule known to the persons who may be affected by the rule.

(ii) Appropriate measures shall include without limitation posting the following information on the agency's website:

(a) The final rule;

(b) Copies of all written comments submitted to the agency regarding the rule;

(c) A summary of all written and oral comments submitted to the agency regarding the rule and the agency's response to those comments;

(d) A summary of the financial impact of the rule; and

(e) The proposed effective date of the final rule.

(2)

(A)

(i) However, an emergency rule may become effective immediately upon filing or at a stated time less than ten (10) days after filing if the agency finds that this effective date is necessary because of imminent peril to the public health, safety, or welfare.

(ii) The agency's finding, a brief statement of the reasons for the finding, and the financial impact statement shall be filed with the rule.

(B) The agency shall take appropriate measures to make emergency rules known to the persons who may be affected by the emergency rules.

(3) To ensure that the Code of Arkansas Rules is updated when a rule goes into effect, the Secretary of State shall work with the Bureau of Legislative Research to implement and maintain a system that notifies the Bureau of Legislative Research when a final rule is filed with the Secretary of State, including without limitation notification of the date the final rule:

(A) Was filed with the Secretary of State; and

(B) Will become effective.

(h) A rule adopted after June 30, 1967, is not valid unless adopted and filed in substantial compliance with this section.

(i)

(1) In a proceeding that questions the existence of imminent peril to the public health, safety, or welfare, a written finding by an agency that adopting an emergency rule was necessary to avoid the loss of federal funding or certification establishes a prima facie case of the existence of imminent peril to the public health, safety, or welfare.

(2) The burden of proof shifts to the challenger to rebut the existence of the condition by a preponderance of the evidence.

25-15-205. Rules – The Arkansas Register.

(a)

(1) The Secretary of State shall compile, index, and publish on its website a document to be known as "The Arkansas Register".

(2) The register shall contain:

(A) A copy of each rule, including without limitation an emergency rule, proposed by an agency;

(B) A financial impact statement for the proposed rule;

(C) The notice for the adoption, amendment, or repeal of any rule required to be published on the internet under § 25-15-204;

(D) A statement setting forth the reason for the proposed rule; and

(E) A summary of the proposed rule.

(3) The inclusion of a direct link to an electronic version of the information under subdivision (a)(2) of this section shall satisfy the requirements of this section.

(4)

(A) The Secretary of State may omit from publication in the register any rule in which publication would be unduly cumbersome, expensive, or otherwise impractical.

(B) If a rule is omitted from publication under subdivision (a)(4)(A) of this section, the register shall indicate where and how a copy of the omitted rule may be obtained.

(b) The Secretary of State shall update the register at least monthly no later than the first Tuesday of every month, setting forth a synopsis of rules filed by agencies.

(c)

(1) If requested, a printed copy of the register shall be furnished to all state agencies and other persons at prices fixed by the Secretary of State to cover publication and mailing costs.

(2) Proceeds from the sale of the register shall be deposited into the Constitutional Officers Fund and the State Central Services Fund in the State Treasury.

(d) A progress report on publication and distribution shall be provided to the Legislative Council annually.

25-15-206. Rules – Declaratory Orders.

Each agency shall provide by rule for the filing and prompt disposition of petitions for declaratory orders as to the applicability of any rule, statute, or order enforced by it. These declaratory orders shall have the same status as agency orders in cases of adjudication.

25-15-207. Rules – Actions for declaratory judgments.

(a) The validity or applicability of a rule may be determined in an action for declaratory judgment if it is alleged that the rule, or its threatened application, injures or threatens to injure the plaintiff in his or her person, business, or property.

(b) The action may be brought in the circuit court of any county in which the plaintiff resides or does business or in Pulaski County Circuit Court.

(c) The agency shall be made defendant in that action.

(d) A declaratory judgment may be rendered whether or not the plaintiff has requested the agency to pass upon the validity or applicability of the rule in question.

25-15-208. Administrative adjudication – Procedures generally.

(a) In every case of adjudication:

(1) All parties shall be afforded an opportunity for hearing after reasonable notice;

(2) The notice shall include:

(A) A statement of the time, place, and nature of the hearing;

(B) A statement of the legal authority and jurisdiction under which the hearing is to be held; and

(C) A short and plain statement of the matters of fact and law asserted;

(3) In every case of adjudication wherein an agency seeks to revoke, suspend, or otherwise sanction a license or permit holder, the agency or its attorney, upon the request of the license or permit holder, must provide the following information prior to conducting a hearing of adjudication:

(A) The names and addresses of persons whom the agency intends to call as witnesses at any hearing;

(B) Any written or recorded statements and the substance of any oral statements made by the license or permit holder, or a copy of the same;

(C) Any reports or statements of experts, made in connection with the particular case, including results of physical or mental examinations, scientific tests, experiments, or comparisons, or copies of the same;

(D) Any books, papers, documents, photographs, or tangible objects which the agency intends to use in any hearing or which were obtained from or belong to the license or permit holder, or copies of the same;

(E) Disclosure shall not be required of research or records, correspondence, reports, or memoranda to the extent that they contain the opinions, theories, or conclusions of the attorney for the agency or members of his or her staff or other state agents;

(4) Opportunity shall be afforded all parties to respond and present evidence and argument on all issues involved;

(5) The record shall include:

(A) All pleadings, motions, and intermediate rulings;

(B) Evidence received or considered, including, on request of any party, a transcript of oral proceedings or any part thereof;

(C) A statement of matters officially noticed;

(D) Offers of proof, objections, and rulings thereon;

(E) Proposed findings and exceptions thereto; and

(F) All staff memoranda or data submitted to the hearing officer or members of an agency in connection with their consideration of the case;

(6) Findings of fact shall be based exclusively on the evidence and on matters officially noticed;

(7)

(A) If the agency is authorized by law to issue subpoenas for the attendance and testimony of witnesses and the production of documents or things, then any party shall to the same extent be so authorized, and the agency shall issue a subpoena forthwith on written application thereof.

(B) A subpoena may be served in the manner as now provided for by statute or rule for the service of subpoenas in civil cases or by any form of mail addressed to the person to be served with a return receipt requested and delivery restricted to the addressee or agent of the addressee.

(b) Nothing in this subchapter shall prohibit informal disposition by stipulation, settlement, consent order, or default.

25-15-209. Administrative adjudication – Communication by decision maker.

(a) Unless required for the disposition of ex parte matters authorized by law, members or employees of an agency assigned to render a decision or to make final or proposed findings of fact or conclusions of law in any case of adjudication shall not communicate, directly or indirectly, in connection with any issue of fact with any person or party nor, in connection with any issue of law, with any party or his or her representative, except upon notice and opportunity for all parties to participate.

(b) An agency member may:

(1) Communicate with other members of the agency; and

(2) Have the aid and advice of one (1) or more personal assistants.

25-15-210. Administrative adjudication – Decisions.

(a) When, in a case of adjudication, a majority of the officials of the agency who are to render the decision have not heard the case or read the record, the decision, if adverse to a party other than the agency, shall not be made until a proposal for decision is served upon the parties and an opportunity is afforded to each party adversely affected to file exceptions and present briefs and oral argument to the officials who are to render the decision. The proposal for decision shall contain a statement of the reasons therefor and of each issue of fact or law necessary thereto, prepared by the person who conducted the hearing.

(b)

(1) In every case of adjudication, a final decision or order shall be in writing or stated in the record.

(2) A final decision shall include findings of fact and conclusions of law, separately stated. Findings of fact, if set forth in statutory language, shall be accompanied by a concise and explicit statement of the underlying facts supporting the findings. If, in accordance with agency rules, a party submitted proposed findings of fact, the decision shall include a ruling upon each proposed finding.

(c)

(1) Parties shall be served either personally or by mail with a copy of any decision or order.

(2) In addition to the manner of service provided under subdivision (c)(1) of this section, administrative adjudication decisions made by the Department of Human Services may be served electronically by email if the party consents.

25-15-211. Administrative adjudication – Licenses – Definition.

(a) When the grant, denial, or renewal of a license is required by law to be preceded by notice and an opportunity for hearing, the provisions of this subchapter concerning cases of adjudication apply.

(b) When a licensee has made timely and sufficient application for the renewal of a license or a new license with reference to any activity of a continuing nature, the existing license shall not expire until the application has been finally determined by the agency and, in case the application is denied or the terms of the new license limited, until the last day for seeking review of the agency order, or a later date fixed by order of the reviewing court.

(c) No revocation, suspension, annulment, or withdrawal of any license is lawful unless the agency gives notice by mail to the licensee of facts or conduct warranting the intended action and unless the licensee is given an opportunity to show compliance with all lawful requirements for the retention of the license. If the agency finds that public health, safety, or welfare imperatively requires emergency action and incorporates a finding to that effect in its order, summary suspension of a license may be ordered pending proceedings for revocation or other action, which proceedings shall be promptly instituted and determined.

(d)

(1) A complaint filed by an offender with a state licensing board or state licensing agency against a licensee of the board or agency shall not be heard by the board or agency unless the complaint is accompanied by appropriately verified documentation showing that the offender has exhausted all administrative remedies under the Division of Correction grievance procedure.

(2) For purposes of this section, "offender" means any person sentenced to the Division of Correction or sentenced to the Division of Correction for judicial transfer to the Division of Community Correction or any person confined in a community correction center as a condition of probation, suspended imposition of sentence, or post-prison transfer.

25-15-212. Administrative adjudication – Judicial review.

(a) In cases of adjudication, any person, except an inmate under sentence to the custody of the Division of Correction, who considers himself or herself injured in his or her person, business, or property by final agency action shall be entitled to judicial review of the action under this subchapter. Nothing in this section shall be construed to limit other means of review provided by law.

(b)

(1) Proceedings for review shall be instituted by filing a petition within thirty (30) days after service upon petitioner of the agency's final decision in:

(A) The circuit court of any county in which the petitioner resides or does business; or

(B) Pulaski County Circuit Court.

(2) Copies of the petition shall be served upon the agency and all other parties of record in accordance with the Arkansas Rules of Civil Procedure.

(3) In its discretion, the court may permit other interested persons to intervene.

(c) The filing of the petition does not automatically stay enforcement of the agency decision, but the agency or reviewing court may do so upon such terms as may be just. However, on review of disciplinary orders issued by professional licensing boards governing professions of the healing arts, the reviewing court, only after notice and hearing, may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of review proceedings.

(d)

(1) Within thirty (30) days after service of the petition or within such further time as the court may allow but not exceeding an aggregate of ninety (90) days, the agency shall transmit to the reviewing court the original or a certified copy of the entire record of the proceeding under review.

(2) The cost of the preparation of the record shall be borne by the agency. However, the cost of the record shall be recovered from the appealing party if the agency is the prevailing party.

(3) By stipulation of all parties to the review proceeding, the record may be shortened. Any party unreasonably refusing to stipulate to limit the record may be taxed by the court for the additional costs.

(4) The court may require or permit subsequent corrections or additions to the record.

(e) If review proceedings have been instituted in two (2) or more circuit courts with respect to the same order, the agency concerned shall file the record in the court in which a proceeding was first instituted. The other courts in which the proceedings are pending shall thereupon transfer them to the court in which the record has been filed.

(f) If before the date set for hearing, application is made to the court for leave to present additional evidence and the court finds that the evidence is material and that there were good reasons for failure to present it in the proceeding before the agency, the court may order that the additional evidence be taken before the agency upon any conditions which may be just. The agency may modify its findings and decision by reason of the additional evidence and shall file that evidence and any modifications, new findings, or decisions with the reviewing court.

(g) The review shall be conducted by the court without a jury and shall be confined to the record, except that in cases of alleged irregularities in procedure before the agency not shown in the record, testimony may be taken before the court. The court shall, upon request, hear oral argument and receive written briefs.

(h) The court may affirm the decision of the agency or remand the case for further proceedings. It may reverse or modify the decision if the substantial rights of the petitioner have been prejudiced because the administrative findings, inferences, conclusions, or decisions are:

(1) In violation of constitutional or statutory provisions;

(2) In excess of the agency's statutory authority;

(3) Made upon unlawful procedure;

(4) Affected by other error or law;

(5) Not supported by substantial evidence of record; or

(6) Arbitrary, capricious, or characterized by abuse of discretion.

(i) Any agency order which is affirmed or affirmed in part by the court shall be a final judgment subject to writ of garnishment or execution to the extent it is affirmed.

25-15-213. Hearings generally.

In every case of adjudication, and in cases of rule making in which rules are required by law to be made on the record after opportunity for an agency hearing, and in cases of rule making in which, pursuant to § 25-15-204(a)(2), the agency shall direct that oral testimony be taken or a hearing held:

(1) Any person compelled to appear before any agency or representative thereof shall have the right to be accompanied and advised by counsel. Every party shall have the right to appear in person or by counsel;

(2)

(A) There shall preside at the hearing:

(i) The agency;

(ii) One (1) or more members of the agency; or

(iii) One (1) or more examiners or referees designated by the agency.

(B) All presiding officers and all officers participating in decisions shall conduct themselves in an impartial manner and may at any time withdraw if they deem themselves disqualified.

(C) Any party may file an affidavit of personal bias or disqualification. The affidavit shall be ruled on by the agency and granted if timely, sufficient, and filed in good faith;

(3)

(A) Presiding officers shall have power, pursuant to published procedural rules of the agency:

(i) To issue subpoenas if the agency is authorized by law to issue them;

(ii) To administer oaths and affirmations;

(iii) To maintain order;

(iv) To rule upon all questions arising during the course of a hearing or proceeding;

(v) To permit discovery by deposition or otherwise;

(vi) To hold conferences for the settlement or simplification of issues;

(vii) To make or recommend decisions; and

(viii) Generally to regulate and guide the course of the pending proceeding.

(B) In any proceeding before any agency, if any person refuses to respond to a subpoena, refuses to take the oath or affirmation as a witness or thereafter refuses to be examined, or refuses to obey any lawful order of an agency contained in its decision rendered after hearing, the agency or the presiding officer of the agency hearing may apply to the circuit court of the county where the proceedings were held or are being held or to the circuit court of the county where a petition for judicial review was filed for an order directing that person to take the requisite action or to otherwise comply with the order

of the agency. The court shall issue the order in its discretion. Should any person willfully fail to comply with an order so issued, the court shall punish him or her as for contempt;

(4) Except as otherwise provided by law, the proponent of a rule or order shall have the burden of proof. Irrelevant, immaterial, and unduly repetitious evidence shall be excluded. Any other oral or documentary evidence, not privileged, may be received if it is of a type commonly relied upon by reasonably prudent people in the conduct of their affairs. Objections to evidentiary offers may be made and shall be noted of record. When a hearing will be expedited and the interests of the parties will not be substantially prejudiced, any part of the evidence may be received in written form;

(5) Parties shall have the right to conduct such cross examination as may be required for a full and true disclosure of the facts; and

(6) Official notice may be taken of judicially cognizable facts and of generally recognized technical or scientific facts within the agency's specialized knowledge. Parties shall be notified of material so noticed, including any staff memoranda or data, and shall be afforded a reasonable opportunity to show the contrary.

25-15-214. Failure of agency to act – Action by injured party.

In any case of rule making or adjudication, if an agency shall unlawfully, unreasonably, or capriciously fail, refuse, or delay to act, any person who considers himself or herself injured in his or her person, business, or property by the failure, refusal, or delay may bring suit in the circuit court of any county in which he or she resides or does business, or in Pulaski County Circuit Court, for an order commanding the agency to act.

25-15-215. Model rules.

(a)

(1) The Attorney General shall publish model rules of procedure for use by agencies.

(2) The model rules shall include general functions and duties commonly performed by agencies.

(a)

(1) Each agency created after August 13, 2001, shall adopt, in accordance with the provisions of this subchapter, those model rules that are practicable.

(2) Any agency that adopts a rule of procedure that differs from the model rule, in conjunction with adopting the rule of procedure, shall state the reason why the relevant portions of the model rules are impracticable.

25-15-216. Review of agency rules.

(a)

(1) As soon as is practicable after each regular session and fiscal session of the General Assembly, each agency shall review any newly enacted laws to determine whether:

(A) Any existing rule should be repealed or amended; or

(B) Any new rule should be adopted.

(2) At the conclusion of each review, the agency shall adopt a written report of the result of the review.

(3) A copy of each report shall be maintained as a public record by the agency.

(b)

(1) If an agency determines that a newly enacted law requires the repeal or amendment of an existing rule or the adoption of a new rule and the newly enacted law does not provide a specific date for the repeal, amendment, or adoption of the rule, the final version of the new, amended, or repealed rule shall be filed for adoption with the Secretary of State:

(A) On or before June 1 of the following year, if the newly enacted law results from a regular or fiscal session of the General Assembly;

(B) On or before the one hundred eightieth day following sine die adjournment, if the newly enacted law results from a special session of the General Assembly; or

(C) If approval of a rule under § 10-3-309 has not occurred by the date under subdivision (b)(1)(A) or subdivision (b)(1)(B) of this section, as soon as practicable after approval under § 10-3-309.

(2) An agency shall file the proposed rule with the Legislative Council, or the Joint Budget Committee if the General Assembly is in regular, fiscal, or extraordinary session, under § 10-3-309 sufficiently in advance of the date under subdivision (b)(1)(A) or subdivision (b)(1)(B) of this section so that the Legislative Council or Joint Budget Committee may consider the rule for approval before the appropriate date.

(3)

(A) No later than sixty (60) days following the sine die adjournment of a regular session of the General Assembly, the Bureau of Legislative Research shall file with the Legislative Council a report identifying the rules required by newly enacted laws that it has determined shall be filed for adoption on or before June 1 of the year following a regular session of the General Assembly.

(B) The report under subdivision (b)(3)(A) of this section shall only include rules specifically required by a newly enacted law.

(C) An agency shall promulgate a rule it determines is required under subdivision (a)(1) of this section regardless of whether the rule appears on the report under subdivision (b)(3)(A) of this section.

(4) The executive head of an agency or his or her designee shall provide monthly written updates on the agency's progress in promulgating a rule it determines is required under subdivision (a)(1) of this section, including without limitation a rule identified in the report under subdivision (b)(3)(A) of this section, to the Legislative Council or its appropriate subcommittee until the final version of the new, amended, or repealed rule is filed for adoption with the Secretary of State on or before the required date under subdivision (b)(1) of this section.

(5)

(A)

(i) If an agency fails to file the final version of the new, amended, or repealed rule for adoption as required by subdivision (b)(1) of this section, the executive head of the agency at issue or his or her designee shall appear before the Legislative Council or its appropriate subcommittee on a monthly basis until the final version of the new, amended, or repealed rule is filed for adoption with the Secretary of State.

(ii) If the rule the agency failed to file under subdivision (b)(5)(A)(i) of this section resulted from a newly enacted law at a regular session of the General Assembly, the executive head of the agency at issue or his or her designee shall appear before the Legislative Council or its appropriate subcommittee on a monthly basis until the final version of the new, amended, or repealed rule is filed for adoption with the Secretary of State if the final version of the new, amended, or repealed rule has not been filed for adoption by June 1 of the year following the regular session of the General Assembly. An appearance under this subdivision (b)(5)(A)(ii) shall be in lieu of a monthly written update under subdivision (b)(4) of this section.

(B) When appearing before the Legislative Council or its appropriate subcommittee, the executive head of the agency at issue or his or her designee shall:

(i) Describe why the agency has been unable to comply with subdivision (b)(1) of this section;

(ii) Provide an update on the current status of the necessary rule changes;

(iii) Describe the steps the agency is taking to address the failure to comply with subdivision (b)(1) of this section; and

(iv) Provide an anticipated date for when the final version of the new, amended, or repealed rule will be filed for adoption with the Secretary of State.

(C)

(i) An agency shall not be required to appear before the Legislative Council or its appropriate subcommittee under this subdivision (b)(5) if the newly enacted law requiring the new, amended, or repealed rule is the subject of litigation.

(ii) The agency shall provide written notification to the Legislative Council or its appropriate subcommittee of the litigation involving the newly enacted law and update the written notification when the litigation is resolved.

(c)

(1) If a newly enacted law specifically requires the adoption of a rule by an agency and the agency believes that a rule is not necessary for the operation of the newly enacted law, it may submit a written request to the Legislative Council or its appropriate subcommittee:

(A) Notifying the Legislative Council or its appropriate subcommittee of the agency's intent to not adopt the required rule; and

(B) Requesting that the rule it believes is not necessary be excluded from the requirements of subdivisions (b)(3)-(5) of this section.

(2) The Legislative Council or its appropriate subcommittee may exclude an agency from the requirements of subdivisions (b)(3)-(5) of this section if it determines that the required rule is not necessary, including without limitation determining that the required rule would merely restate the newly enacted law.

25-15-217. Alternative sanctions.

(a)

(1) Each agency which may suspend, revoke, or deny a license for acts or omissions or other conduct as provided by law may impose alternative sanctions set forth in subsection (b) of this section.

(2) The penalties set forth in subsection (b) of this section shall be supplemental to any agency's authority to impose penalties upon any person or entity under the agency's jurisdiction.

(b) Each agency may impose on any person or entity under the agency's jurisdiction:

(1) A monetary penalty not to exceed five hundred dollars ($500) for each violation;

(2) A requirement that the person complete appropriate education programs or courses, or both;

(3) A requirement that the person or entity successfully complete:

(A) A licensing examination;

(B) A credentialing examination; or

(C) Any other examination required in order to obtain a permit, license, registration, or credential;

(4) Conditions or restrictions upon regulated activities of the holder of a license, permit, certificate, credential, registration, or other authority; and

(5) Other requirements or penalties as may be appropriate under the circumstances of the case and which would achieve the agency's desired disciplinary purposes, but which would not impair the public health and welfare.

(c) The agency may file suit to collect any monetary penalty assessed pursuant to this subchapter, if the penalty is not paid within the time prescribed by the agency, in either Pulaski County Circuit Court or the circuit court of any county in which the person or entity under the agency's jurisdiction:

(1) Resides; or

(2) Does business.

(d) Upon imposition of a sanction against a person or entity under the agency's jurisdiction, the agency may order that the license, permit, certification, credential, or registration be suspended until the person or entity has complied in full with all applicable sanctions imposed pursuant to this section.

(e)

(1) Each violation shall constitute a separate violation.

(2) The power and authority of the agency to impose a sanction authorized in this section shall not be affected by any other civil or criminal proceeding concerning the same violation.

Rules Pertaining to Arkansas Prescription Drug Monitoring Program

Section I – Authority

The following rules have been hereby promulgated pursuant to Arkansas Code Annotated § 20-7-613.

Section II – Purpose

The purpose of these rules is to protect the state health system and the citizens of Arkansas by:

(1) Enhancing patient care by providing prescription monitoring information that will ensure legitimate use of controlled substances in health care, including palliative care, research, and other medical pharmacological uses;

(2) Helping curtail the misuse and abuse of controlled substances;

(3) Assisting in combating illegal trade in and diversion of controlled substances; and

(4) Enabling access to prescription information by practitioners, law enforcement agents, and other authorized individuals and agencies and to make prescription information available to practitioners, law enforcement agents, and other authorized individuals and agencies in other states.

Section III – Definitions

As used in this section:

(1) "Arkansas Medicaid prescription drug program" means:

(A) The prescription drug program that is a portion of the Title XIX Medicaid program for the State of Arkansas;

(B) The Arkansas Medicaid prescription drug program includes any entity contracted with the Arkansas Medicaid prescription drug program and to which the Arkansas Medicaid Program has granted authority.

(2) "Certified law enforcement prescription drug diversion investigator" means a certified law enforcement officer assigned by his or her law enforcement agency to investigate prescription drug diversion and who has completed a certification course in prescription drug diversion approved by the Arkansas Prescription Drug Advisory Committee and certified by the Arkansas Commission on Law Enforcement Standards and Training and who may access the Arkansas Prescription Drug Monitoring Program for prescriptions dispensed in Arkansas.

(3) "Controlled substance" means a drug, substance, or immediate precursor in Schedules II-V;

(4) "Delegate" means an agent or employee of the prescriber or dispenser to whom the prescriber or dispenser has delegated the task of accessing the data described in this subsection, but only if the agent or employee has been granted access by a delegate account, and for whose actions the authorizing prescriber or dispenser retains accountability.

(5) "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including without limitation, the prescribing, administering, packaging, labeling, or compounding necessary to prepare the controlled substance for that delivery;

(6)

(A) "Dispenser" means a practitioner who dispenses.

(B) "Dispenser" does not include:

(i) A licensed hospital pharmacy when it is distributing controlled substances for the purpose of outpatient services, inpatient hospital care, or at the time of discharge from a hospital, except for a pharmacy owned by a hospital that has a retail pharmacy permit when the pharmacy is distributing controlled substances directly to the public;

(ii) A wholesale distributor of Schedule II-Schedule V controlled substances; or

(iii) A practitioner or other authorized person who administers a controlled substance;

(7) "Drug overdose" means an acute condition resulting from the consumption or use of a controlled substance, or dangerous drug, or combination of a controlled substance and other intoxicants by an individual, causing signs, including without limitation:

(i) Extreme physical illness;

(ii) Decreased level of consciousness;

(iii) Respiratory depression;

(iv) Coma;

(v) Mania; or

(vi) Death.

(8) "Exchangeability" means the ability of the program to electronically share reported information with another state's prescription monitoring program if the information concerns the dispensing of a controlled substance either:

(A) To a patient who resides in the other state; or

(B) Prescribed by a practitioner whose principal place of business is located in the other state;

(C) To a patient in which the practitioner believes an out of state search is warranted.

(9) "Hospice" or "hospice care" means an autonomous, centrally administered, medically directed, coordinated program providing a continuum of home, outpatient, and home-like inpatient care for the terminally ill patient and family, employing an interdisciplinary team to assist in providing palliative and supportive care to meet the special needs arising out of the physical, emotional, spiritual, social and economic stresses which are experienced during the final stages of illness and during dying and bereavement, with such care being available 24 hours a day, 7 days a week and provided on the basis of need regardless of ability to pay.

(10) "Investigation" means an active inquiry that is being conducted with a reasonable, good faith belief that the inquiry:

(A) Could lead to the filing of administrative, civil, or criminal proceedings; or

(B) Is ongoing and continuing and a reasonable, good faith anticipation exists for securing an arrest or prosecution in the foreseeable future;

(11) "Opioid" means a drug or medication that relieves pain, including without limitation:

(A) Hydrocodone;

(B) Oxycodone;

(C) Morphine

(D) Codeine;

(E) Heroin;

(F) Fentanyl

(12) "Palliative care" means patient-centered and family-centered medical care offered throughout the continuum of an illness that optimizes quality of life by anticipating, preventing, and treating the suffering caused by a serious illness to address physical, emotional, social, and spiritual needs and facilitate patient autonomy, access to information, and choice, including without limitation:

(A) Discussion of the patient's goals for treatment;

(B) Discussions of treatment options appropriate to the patient, including hospice care, if needed; and

(C) Comprehensive pain and symptom management

(13) "Patient" means the person or animal who is the ultimate user of a controlled substance for whom a lawful prescription is issued and for whom a controlled substance is lawfully dispensed;

(14) "Practitioner" means:

(A) A physician, dentist, veterinarian, advanced practice nurse, physician assistant, pharmacist, scientific investigator, or other person licensed, registered, or otherwise permitted to prescribe, distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state; and

(B) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state;

(15) "Prescribe" means to issue a direction or authorization, by prescription, permitting a patient lawfully to obtain a controlled substance;

(16) "Prescriber" means a practitioner or other authorized person who prescribes a Schedule II, III, IV, or V controlled substance;

(17) "Prescription" means a controlled substance lawfully prescribed and subsequently dispensed.

(18) "Prescription drug monitoring program" means a program that collects, manages, analyzes, and provides information regarding Schedule II, III, IV, and V controlled substances as provided under the Uniform Controlled Substances Act, § 5-64-101 et seq., §§ 5-64-1101 – 5-64-1103, the Food, Drug, and Cosmetic Act, § 20-56-201 et seq., or §§ 20-64-501 – 20 64-513;

(19) "Qualified law enforcement agency" means a law enforcement agency that has a certified law enforcement prescription drug diversion investigator and a chief, sheriff, or law enforcement chief executive officer who have successfully completed a certification course in prescription drug diversion approved by the commission.

(20) "Schedule II" means controlled substances that are placed in Schedule II under § 5-64-205;

(21) "Schedule III" means controlled substances that are placed in Schedule III under § 5-64-207;

(22) "Schedule IV" means controlled substances that are placed in Schedule IV under § 5-64-209;

(23) "Schedule V" means controlled substances that are placed in Schedule V under § 5-64-211;

(24) "Ultimate user" means a person who lawfully possesses a controlled substance for:

(A) The person's own use;

(B) The use of a member of the person's household; or

(C) Administering to an animal owned by a person or by a member of the person's household.

Section IV – Requirements for the Prescription Drug Monitoring Program

(a) The State Board of Health shall create the Prescription Drug Monitoring Program upon the Department of Health's procuring adequate funding to establish the program.

(b)

(1) Each dispenser shall submit to the department information regarding each Schedule II, III, IV, or V controlled substance dispensed.

(2) A dispenser located outside Arkansas and licensed and registered by the Arkansas State Board of Pharmacy shall submit to the department information regarding each Schedule II, III, IV, or V controlled substance prescription dispensed to an ultimate user whose address is within Arkansas.

(A) A federal dispenser located in the state of Arkansas or located outside Arkansas may submit to the department information regarding each Schedule II, III, IV or V controlled substance dispensation to an ultimate user whose address is within Arkansas.

(3) The board shall create a controlled substances database for the Prescription Drug Monitoring Program.

(c) Each dispenser required to report under subsection (b) of this section shall submit to the department by electronic means, or other methods approved by the Prescription Drug Monitoring Program, information that shall include without limitation the following:

(1) The dispenser's identification number;

(2) The date the prescription was filled;

(3) The prescription number;

(4) Whether the prescription is new or is a refill;

(5) The National Drug Code number for the controlled substance that is dispensed;

(6) The quantity of the controlled substance dispensed;

(7) The number of days' supply dispensed;

(8) The number of refills ordered;

(9)

(A) A patient identifier.

(B) A patient identifier shall not be a social security number or a driver's license number;

(10) The patient's name;

(11) The patient's address;

(12) The patient's date of birth;

(13) The patient's gender;

(14) The prescriber's identification number;

(15) The date the prescription was issued by the prescriber; and

(16) The source of the payment for the prescription.

(d) If the prescription dispensed is for an animal patient, the prescription shall be reported as follows:

(1) The prescription shall be identified as an animal/veterinary patient;

(2) The owner of the animal/veterinary patient shall be reported to the department by first name, last name, and date of birth;

(3) The animal/veterinary patient shall be reported.

(e)

(1) Except as required in subdivision (e)(2) of this section, practitioners are encouraged to access or check the information in the controlled substance database created under this section before prescribing, dispensing, providing medication reconciliation, or administering medications.

(2)

(A) A prescriber shall check the information in the Prescription Drug Monitoring Program when prescribing:

(i) An opioid from Schedule II or Schedule III for every time prescribing the medication to a patient; and

(ii) A benzodiazepine medication for the first time prescribing the medication to a patient.

(B) A licensing board that licenses practitioners who have the authority to prescribe shall adopt rules requiring the practitioners to check the information in the Prescription Drug Monitoring Program as described in subdivision (e)(2) of this section.

(C) This subdivision (e)(2) does not apply to:

(i) A practitioner administering a controlled substance:

(a) Immediately before or during surgery;

(b) During recovery from a surgery while in a healthcare facility;

(c) In a healthcare facility; or

(d) Necessary to treat a patient in an emergency situation at the scene of an emergency, in a licensed ground ambulance or air ambulance, or in the intensive care unit of a licensed hospital;

(ii) A practitioner prescribing or administering a controlled substance to:

(a) A palliative care or hospice patient; or

(b) A resident in a licensed nursing home facility; or

(iii) Situations in which the Prescription Drug Monitoring Program is not accessible due to technological or electrical failure.

(D) The State Board of Health may amend, by rule, the exemptions listed in subdivision (e)(2)(C) of this section upon a recommendation from the Secretary of the Department of Health and a showing that the exemption or lack of exemption is unnecessarily burdensome or has created a hardship.

(3) A licensed oncologist shall check the Prescription Drug Monitoring Program when prescribing to a patient on an initial malignant episodic diagnosis and every three (3) months following the diagnosis while continuing treatment.

(f) This section does not prohibit licensing boards from requiring practitioners to access or check the information in the controlled substance database as a part of a review of the practitioner's professional practice.

(g)

(1) Each dispenser shall submit the required information in accordance with the Standard for Prescription Monitoring Programs of the American Society for Automation in Pharmacy (ASAP) Version 4 Release 2 September 2011, incorporated by reference, or other format approved by the Prescription Drug Monitoring Program.

(2) Data shall be submitted via CD-ROM, a secure File Transfer Protocol (FTP), Virtual Private Network (VPN), https: or other methods approved by the Prescription Drug Monitoring Program.

(3) A dispenser shall report the controlled substance dispensing information records required under Arkansas Code Annotated §§ 20-7-601 to -614 and these rules no later than the next business day after the date of dispensing. Veterinarians shall report dispensing information every thirty days. If controlled substances were not dispensed for the reporting period, the dispenser shall submit a Zero Report in accordance with ASAP Version 4 Release 2 September 2011, or other format approved by the Prescription Drug Monitoring Program.

(4) The department or the department's contractor shall notify a dispenser of an error in data reporting. Upon receiving notification of an error in data reporting, the dispenser shall take appropriate measures to correct the error and transmit the corrected data to the department or the department's contractor within 14 days of being notified of the error.

(h) The department's process for patients to address errors, inconsistencies, and other matters in their record as maintained under this section, including in cases of breach of privacy and security shall comply with Sections 261 through 264 of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104-191 (the Administrative Simplification provisions) and regulations 45 CFR Parts 160 and 164 ("the HIPAA Security and Privacy Rule") and the HITECH (Health Information Technology for Economic and Clinical Health) Act as enacted by the American Recovery and Reinvestment Act (ARRA) of 2009 (Pub. L. 111-5), pursuant to Title XIII of Division A and Title IV of Division B.

(i) The department shall limit access to only those employees whose access is reasonably necessary to carry out this section.

(j) A certified law enforcement prescription drug diversion investigator shall provide to the department the following information in order to be granted access to the Prescription Drug Monitoring Program:

(1) The identification credentials assigned by the department; and

(2) The case number of the investigation submitted on the investigator's law enforcement agency letterhead.

(3) The badge number of the investigator.

(4) A copy of the investigator's certification from the Arkansas Commission of Law Enforcement Standards and Training course in prescription drug diversion.

(k)

(1) A qualified law enforcement agency shall submit to the department an annual report of the data accessed by all certified law enforcement prescription drug diversion investigators in the qualified law enforcement agency, including without limitation:

(A) Written verification that the inquiries were part of a lawful prescription drug diversion investigation as provided to the department through the case number of the investigation; and

(B) The disposition of the investigation.

(2) The department shall:

(A) Create a verification form for use under subdivision (k)(l) of this section; and

(B) Make the verification form available annually to the qualified law enforcement agency.

(3)

(A) The verification form under subdivision (k)(l) of this section shall be submitted to the department within thirty (30) days of receipt of the form by the qualified law enforcement agency.

(B) Failure to submit a verification form under subdivision (k)(3)(A) of this section shall result in the immediate suspension of the access to the database by the qualified law enforcement agency and its certified law enforcement prescription drug diversion investigators until a determination is made by the department to allow continued access.

Section V – Prescription Drug Monitoring Program Advisory Committee

(a) The State Board of Health shall create the Prescription Drug Monitoring Program Advisory Committee upon the Department of Health's procuring adequate funding to establish the Prescription Drug Monitoring Program.

(b) The mission of the advisory committee is to consult with and advise the Department of Health on matters related to the establishment, maintenance, operation, and evaluation of the Prescription Drug Monitoring Program.

(c) The committee shall consist of:

(1) One (1) representative designated by each of the following organizations:

(A) The Arkansas Academy of Physician Assistants;

(B) The Arkansas Association of Chiefs of Police;

(C) The Arkansas Drug Director;

(D) The Arkansas Medical Society;

(E) The Arkansas Nurses Association;

(F) The Arkansas Optometric Association;

(G) The Arkansas Osteopathic Medical Association;

(H) The Arkansas Pharmacists Association;

(I) The Arkansas Podiatric Medical Association;

(J) The Arkansas Prosecuting Attorneys Association;

(K) The Arkansas Sheriffs Association;

(L) The Arkansas State Dental Association;

(M) The Arkansas Veterinary Medical Association;

(N) The State Board of Health;

(O) The Arkansas Public Defender Commission; and

(P) A mental health provider or certified drug and alcohol counselor; and

(2) One (1) consumer appointed by the Governor.

(3) The chair of the Arkansas State Medical Board or his or her designee who is also a member of the Arkansas State Medical Board; and

(4) The chair of the Arkansas State Board of Dental Examiners or his or her designee who is also a member of the Arkansas State Board of Dental Examiners.

Section VI – Confidentiality

(a) Prescription information submitted to the Department of Health pursuant to Arkansas Code Annotated §§ 20-7-60l to - 614 and these rules is confidential and not subject to the Freedom of Information Act of 1967, § 25-19-101 et seq.

(b)

(1) The controlled substances database and all information contained in the controlled substances database and any records maintained by the department or by an entity contracting with the department that is submitted to, maintained, or stored as a part of the controlled substances database is privileged and confidential, is not a public record, and is not subject to subpoena or discovery in a civil proceeding.

(2) Information in the controlled substances database may be accessed by:

(A) A certified law enforcement officer pursuant to a criminal investigation but only after the law enforcement officer obtains a search warrant signed by a judge that demonstrates probable cause to believe that a violation of federal or state criminal law has occurred, that specified information contained in the database would assist in the investigation of the crime, and that the specified information should be released to the certified law enforcement officer;

(B) A regulatory body engaged in the supervision of activities of licensing or regulatory boards of practitioners authorized to prescribe or dispense controlled substances;

(C) A person or entity investigating a case involving breaches of privacy involving the database or its records.

(D) A certified law enforcement prescription drug diversion investigator of a qualified law enforcement agency; or

(E) A practitioner within the Arkansas Medicaid prescription drug program; or

(F) The Department of Human Services or the Crimes Against Children Division of the Department of Arkansas State Police if:

(i) The purpose of the database access is related to an investigation under the Child Maltreatment Act, § 12-18-101 et seq., and not pursuant to a criminal investigation by a certified law enforcement officer; and

(ii) The Department of Human Services has obtained a court order to access the database under § 12-18-621.

(G) The Office of Medicaid Inspector General for review and investigation of fraud, waste, and abuse within the Arkansas Medicaid prescription drug program if access is limited to beneficiaries of the Arkansas Medicaid prescription drug program.

(c) This section does not apply to information, documents, or records created or maintained in the regular course of business of a pharmacy, medical, dental, optometric, or veterinary practitioner, or other entity covered by Arkansas Code Annotated §§ 20-7-601 to -614 and these rules, and all information, documents, or records otherwise available from original sources are not immune from discovery or use in a civil proceeding merely because the information contained in the records was reported to the controlled substances database under Arkansas Code Annotated §§ 20-7-601 to -614 and these rules.

(d) The department shall establish and enforce policies and procedures to ensure that the privacy and confidentiality of patients are maintained and that patient information collected, recorded, transmitted, and stored is protected and not disclosed to persons except as listed in Section VII - Providing Prescription Monitoring Information. The department's policies shall comply with Sections 261 through 264 of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104-191 (the Administrative Simplification provisions) and regulations 45 CFR Parts 160 and 164 ("the HIPAA Security and Privacy Rule") and the HITECH (Health Information Technology for Economic and Clinical Health) Act as enacted by the American Recovery and Reinvestment Act (ARRA) of 2009 (Pub. L. 111-5), pursuant to Title XIII of Division A and Title IV of Division B.

(e) The Prescription Drug Monitoring Program shall establish and maintain a process for verifying the credentials and authorizing the use of prescription information by individuals and agencies listed in Section VII - Providing Prescription Monitoring Information. The application to access prescription information shall include information as needed by the department to verify the applicant's authority to use prescription information in compliance with Section VII.

Section VII – Providing Prescription Monitoring Information

(a)

(1)

(A)

(i) The Department of Health shall review the Prescription Drug Monitoring Program information, including without limitation a review to identify information that appears to indicate whether a person is obtaining prescriptions in a manner that may represent misuse or abuse of controlled substances based on prescribing criteria determined by the Secretary of the Department of Health upon consultation with the Prescription Drug Monitoring Program Advisory Committee.

(ii) The prescribing criteria shall be posted on the website of the department and be available in print upon request.

(B) If the information appears to indicate misuse or abuse may have occurred, the department shall notify the practitioners and dispensers who have prescribed or dispensed in the following manner:

(i) The department shall provide quarterly reports to the individual practitioners and dispensers; and

(ii) If after twelve (12) months of providing quarterly reports to the practitioners and dispensers, the information appears to indicate misuse or abuse may be continuing, the department shall send a report to the licensing boards of the practitioner or dispenser who prescribed or dispensed the prescription.

(iii) If the department is notified of a drug overdose of an Arkansas resident, the department may notify any practitioner in whose authority any applicable controlled substance prescription(s) was dispensed within an applicable period prior to the overdose as determined by the Secretary of Health, or any practitioner that may prescribe or dispense a controlled substance within one year of drug overdose.

(C) If information of misuse or abuse is identified, the department shall notify the practitioners and dispensers who prescribed or dispensed the prescriptions and the Little Rock, Arkansas Office of Diversion Control of the United States Drug Enforcement Administration.

(D) On or before January 1, 2019, the department shall contract with a vendor to make the Prescription Drug Program interactive and to provide same-day reporting in real-time, if funding and technology are available.

(2)

(A) The department may:

(i) Review the Prescription Drug Monitoring Program information, including without limitation a review to identify information that appears to indicate whether a prescriber or dispenser may be prescribing or dispensing prescriptions in a manner that may represent misuse or abuse of a controlled substance; and

(ii) Require prescribers or dispensers, or both, to provide physical copies of written or electronic prescriptions upon request to validate data submitted to the program in order to evaluate the information reported by the program.

(B) If information of misuse or abuse is identified, the department may notify the professional licensing board of the prescriber or dispenser only after the relevant professional licensing board has provided the department with the parameters for triggering a notification from the department to the professional licensing board.

(C) The department shall develop algorithms within the controlled substance database that would alert a practitioner if his or her patient is being prescribed opioids by more than three (3) physicians within any thirty-day period, if funding is available.

(3)

(A) A prescriber who has been found by his or her licensing board to be in violation of a rule or law involving prescription drugs shall be required by the appropriate licensing board to register with the Prescription Drug Monitoring Program and access patient information before writing a prescription for an opioid.

(B) The licensing board, in its discretion, may remove this requirement after a period of time if the board deems removal of the requirement appropriate.

(b) The department shall provide information in the Prescription Drug Monitoring Program upon request and at no cost only to the following persons:

(1)

(A) A person authorized to prescribe or dispense controlled substances for the purpose of providing medical or pharmaceutical care for his or her patients or for reviewing information regarding prescriptions that are recorded as having been issued or dispensed by the requester;

(B) A Delegate;

(2) A patient who requests his or her own prescription monitoring information;

(3) A parent or legal guardian of a minor child who requests the minor child's Prescription Drug Monitoring Program information;

(4)

(A) A designated representative of a professional licensing board of the professions of the healing arts representing health care disciplines whose licensees are prescribers pursuant to an investigation of a specific individual, entity, or business licensed or permitted by that board.

(B) Except as permitted by subsection (a)(2) of this section, the department shall provide information under subsection (b)(4)(A) of this section only if the requesting board states in writing that the information is necessary for an investigation;

(5) The State Medical Examiner as authorized by law to investigate causes of deaths for cases under investigation pursuant to his or her official duties and responsibilities;

(6) Local, state, and federal law enforcement or prosecutorial officials engaged in the administration, investigation, or enforcement of the laws governing controlled substances required to be submitted under Arkansas Code Annotated §§ 20-7-601 to 614 and these rules pursuant to the agency's official duties and responsibilities; and

(7) Personnel of the department for purposes of administration and enforcement of Arkansas Code Annotated § 20-7-607 and this section.

(c) Information collected under Arkansas Code Annotated §§ 20-7-601 to -614 and these rules shall be maintained for three (3) years.

(d) The department may provide patient, prescriber, or dispenser information to public or private entities for statistical, research, or educational purposes after encrypting or removing any patient's name, street name and number, patient identification number, month and day of birth, and prescriber or dispenser information that could be used to identify individual patients, persons who received prescriptions.

(e) The department may provide information in the Prescription Drug Monitoring Program to insurance carriers for the purpose of verifying prescriber or dispenser registration for individuals that are part of the health plan's network of providers.

Section VIII – Information Exchange with Other Prescription Drug Monitoring Programs

(a) The Department of Health may provide prescription monitoring information to federal prescription drug monitoring programs or other states' prescription drug monitoring programs, and the information may be used by those programs consistent with Arkansas Code Annotated §§ 20-7-601 to -614 and these rules.

(b) The department may request and receive prescription monitoring information from federal prescription drug monitoring programs or other states' prescription drug monitoring programs and may use the information pursuant to Arkansas Code Annotated §§ 20-7-601 to -614 and these rules.

(c) The department may develop the capability to transmit information to other prescription drug monitoring programs and receive information from other prescription drug monitoring programs employing the standards of exchangeability.

(d) The department may enter into written agreements with federal prescription drug monitoring programs or other states' prescription drug monitoring programs for the purpose of describing the terms and conditions for sharing of prescription information consistent with Arkansas Code Annotated §§ 20-7-601 to -614 and these rules.

Section IX – Authority to Contract

(a) The Department of Health may contract with another agency of this state or with a private vendor, as necessary, to ensure the effective operation of the Prescription Drug Monitoring Program.

(b) A contractor shall be bound to comply with the provisions regarding confidentiality of prescription information as outlined in Arkansas Code Annotated §§ 20-7-601 to -614 and these rules and shall be subject to the penalties specified in Arkansas Code Annotated §§ 20-7-601 to -614 and these rules for unlawful acts.

Section X – Authority to Seek Funding

(a) The Department of Health may make application for, receive, and administer grant funding from public or private sources for the development, implementation, or enhancement of the Prescription Drug Monitoring Program.

(b) A fee shall not be levied against practitioners for the purpose of funding or complying with the Prescription Drug Monitoring Program.

Section XI – Unlawful Acts and Penalties

(a)

(1) It is unlawful for a dispenser to purposely fail to submit prescription monitoring information as required under Arkansas Code Annotated §§ 20-7-601 to -614 and these rules.

(2) A violation of subdivision (a)(1) of this section is a Class B misdemeanor.

(b)

(1) It is unlawful for a dispenser to purposely submit fraudulent prescription information.

(2) A violation of subdivision (b)(1) of this section is a Class D felony.

(c)

(1) It is unlawful for a person authorized to receive prescription monitoring information to purposely disclose the information in violation of Arkansas Code Annotated §§ 20 7-601 to -614 and these rules.

(2) A violation of subdivision (c)(1) of this section is a Class C felony.

(d)

(1) It is unlawful for a person authorized to receive prescription drug monitoring program information to use such information in a manner or for a purpose in violation of Arkansas Code Annotated §§ 20-7-601 to -614 and these rules.

(2) A violation of subsection (d)(1) of this section is a Class C felony.

(e)

(1) It is unlawful for a person to knowingly obtain, use, or disclose or attempt to obtain, use, or disclose information by fraud or deceit from the Prescription Drug Monitoring Program or from a person authorized to receive information from the Prescription Drug Monitoring Program under Arkansas Code Annotated §§ 20-7-601 to -614 and these rules.

(2) A violation of subdivision (e)(1) of this section is a Class C felony.

(f) In addition to the criminal penalties provided in this section, a dispenser or practitioner who uses or discloses confidential information received from the Prescription Drug Monitoring Program in a manner or for a purpose in violation of Arkansas Code Annotated §§ 20-7-601 to -614 and these rules may be subject to disciplinary action by the dispenser's or practitioner's licensing board.

(g) In addition to the criminal penalties provided in this section, a law enforcement officer who uses or discloses confidential information received from the Prescription Drug Monitoring Program in a manner or for a purpose in violation of Arkansas Code Annotated §§ 20-7-601 to -614 and these rules may be subject to disciplinary action by the law enforcement officer's agency or department.

(h) Arkansas Code Annotated §§ 20-7-601 to -614 and these rules do not limit a person whose privacy has been compromised unlawfully under this section from bringing a civil action to address the breach of privacy or to recover all damages to which the person may be entitled per violation, including attorney's fees and costs.

(i) A practitioner who purposely fails to access the Prescription Drug Monitoring Program as required by § 20-7-604(d) is subject to disciplinary action by the licensing board of the practitioner.

Section XII – Privacy Rights Protected

Arkansas Code Annotated §§ 20-7-601 to -614 and these rules do not give authority to any person, agency, corporation, or other legal entity to invade the privacy of any citizen as defined by the General Assembly, the courts, or the United States Constitution or the Constitution of the State of Arkansas other than to the extent provided in these rules and Arkansas Code Annotated §§ 20-7-601 to -614.

Section XIII – Effective Date

(a) The Prescription Drug Monitoring Program shall become operational March 1, 2013, if full funding is available under Arkansas Code Annotated § 20-7-610 and Section X.

(b) The Secretary of the Department of Health may suspend operation of the program if adequate funding under Arkansas Code Annotated § 20-7-610 and Section X ceases.

Section XIV – Severability

If any provision of these rules or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of these rules which can give effect without the invalid provisions or applications, and to this end the provisions hereto are declared severable.

Section XV – Repeal

All rules and parts of rules in conflict are hereby repealed.