LAWS AND REGULATIONS

July 2019

Asa Hutchinson, Governor

John Clay Kirtley, Pharm.D.
Executive Director

Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201
Phone: (501) 682-0190
Fax: (501) 682-0195
asbp@arkansas.gov
www.pharmacyboard.arkansas.gov

Arkansas State Board of Pharmacy Members:

Deborah Mack, P.D.
President, Bentonville

Lenora Newsome, P.D.
Vice President/Secretary, Smackover

Steve Bryant, P.D.
Member, Batesville

Rebecca Mitchell, Pharm.D.
Member, Greenbrier

Lynn Crouse, Pharm.D.
Member, Lake Village

Brian Jolly, Pharm.D.
Member, Beebe

Carol Rader, RN
Public Member, Fort Smith

Amy Fore, MHSA, FACMPE, FACHE
Public Member, Fort Smith

Board of Pharmacy Law Book - Acts
Table of Contents

Pharmacy Practice Act A

17-92-101	Definitions……	1-4
17-92-102	Exemptions……..	4-5
17-92-103	Pharmacy laws unaffected……...	5
17-92-104	Privilege tax unaffected……..	5
17-92-105	Prohibited acts – Penalties……...	6
17-92-106	Injunctions……	6
17-92-107	Prosecutions – Disposition of fines…….	6
17-92-108	Fees……..	6-10
17-92-109	Prescriptions for optometrists……..	10
17-92-110	Prescriptive authority of advance practice nurses……	10
17-92-111	Construction of Acts 1997, No. 1204……..	10
17-92-112	Prescriptions for physician assistants…….	10
17-92-201	Members – Qualifications……	11
17-92-202	Members – Oath……	11
17-92-203	Members – Compensation……..	11
17-92-204	Organization and proceedings…….	12
17-92-205	Rules and regulations – Enforcement……..	12-13
17-92-206	Issuance of bulletins – Annual Reports……...	14
17-92-207	Maintenance of office……..	14
17-92-208	Employees……	14
17-92-209	Medications Administration Advisory Committee……..	15
17-92-301	License Required…….	15
17-92-302	Unlicensed practice – Penalty…….	15-16
17-92-303	Unlawful use of professional title – Penalty……	16
17-92-304	Board administration – Support services…….	16
17-92-305	Application – Qualification of applicants……	16-17
17-92-306	Examinations……	17
17-92-307	Internship required……...	17
17-92-308	Reciprocity……...	17-18
17-92-309	Registration and certificate……..	18
17-92-310	Failure to renew……...	18-19
17-92-311	Revocation, suspension, or non-renewal – Grounds……	19-20
17-92-312	Revocation and fine – Adulteration of drugs……...	20
17-92-313	Revocation – Procedure……...	20
17-92-314	Revocation – Appeals……..	20
17-92-315	Alternative penalties……	20-21
17-92-316	Credential required for professional pharmacy service……...	21-22
17-92-317	Criminal Background Checks……..	22-24
17-92-401	Applicability to out-of-state operations……...	24-25
17-92-402	Licensed pharmacist required……..	25
17-92-403	Licensed pharmacist required – Exceptions……	25-27
17-92-404	Pharmacy permit required……	27

17-92-405	Pharmacy permit – Application……...	27-28
17-92-407	Revocation – Grounds……..	28
17-92-408	Revocation – Procedure……...	28
17-92-409	Pharmacy library required……	28-29
17-92-410	Records of poison sales……	29
17-92-411	Prescription contents and labels……...	29
17-92-412	Nursing home consultant permit……..	29-30
17-92-501	Penalty……..	30
17-92-502	Rules and regulations……...	30
17-92-503	Generic substitutions……	30-31
17-92-505	Labeling……	31
17-92-506	Price Lists…….	31
17-92-601	Short title……..	32
17-92-602	Definitions……	32
17-92-603	Advisory Committee for Hospital Pharmacies……	32
17-92-604	Regulatory authority……	32-33
17-92-605	Hospital pharmacy license – Services permitted…….	33
17-92-606	Hospital pharmaceutical permit……...	34
17-92-607	Unlawful for hospital to hold licensed pharmacy permit – Exemptions……..	34
17-92-701	Definitions……	34
17-92-702	Administration……..	34-35
17-92-703	Functions……..	35
17-92-704	Board review……	35
17-92-705	Notification of procedures, rights, and responsibilities – Failure to comply……..	35
17-92-706	Funding……	35-36
17-92-707	Liability……	36
17-92-801	Powers and duties of Arkansas State Board of Pharmacy……...	36
17-92-901	Definitions……	36-37
17-92-902	License required……...	37-38
17-92-903	Exemption from license and permit requirements……...	38-39
17-92-904	Supply order required……..	39
17-92-905	Labeling……	39
17-92-906	Regulations……...	39-40
17-92-907	Manufacture, shipment, or sale of medical gases……	40
17-92-908	Revocation or suspension of license……	40-41
17-92-909	Advisory committee to the board…….	41
17-92-1001	Title……..	41
17-92-1002	Purpose…….	41
17-92-1003	Definitions……	41-43
17-92-1004	Requirements for Internet sales……	43
17-92-1005	Requirements for Internet sites……	43-44
17-92-1006	Disclaimers or limitations of liabilities……	44
17-92-1007	Enforcement…….	44

Miscellaneous Statutes Related to Pharmacy B

17-1-103	Registration, certification, and licensing for criminal offenders……...	1
17-80-102	Subpoena power of boards – Enforcement……..	1-2
17-80-103	Immunity of board members……	2
17-80-104	Continuing education requirements…….	2-3

Uniform Controlled Substances Act C

5-64-101	Definitions……	1-6
5-64-201	Director's duties……...	6-7
5-64-202	Nomenclature……...	7
5-64-203	Criteria for Schedule I……..	7
5-64-205	Criteria for Schedule II…….	7
5-64-207	Criteria for Schedule III……...	7
5-64-209	Criteria for Schedule IV……...	8
5-64-211	Criteria for Schedule V……	8
5-64-213	Schedule VI established……...	8
5-64-214	Criteria for Schedule VI……...	8
5-64-215	Substances in Schedule VI……...	8-9
5-64-216	Schedule revisions……	9
5-64-307	Order forms……..	9
5-64-308	Written prescriptions……	9
5-64-1005	Exemptions……...	9-10
5-64-1006	Suspicious order reports……...	10-11
5-64-1101	Possession – Penalty……	11
5-64-1102	Possession with intent to manufacture – Unlawful distribution……	11-12
5-64-1003	Retail sales limit……...	12-14

Insurance Policies – Prescription Drug Benefits D

23-79-149	Prescription drug benefits……	1
23-79-601	Definitions……	2
23-79-602	Diabetes self-management training – Licensed providers – Prescription by physician…….	2-3
23-79-603	Requirements……	3
23-79-604	Exclusions……	3
23-79-605	Regulations……...	3
23-79-606	Applicability – Delivery within state……...	3-4
23-79-607	Applicability – Exceptions……...	4

Food, Drug, and Cosmetic Act E

20-56-201	Title……..	1
20-56-202	Definitions……	1-3
20-56-203	Applicability…….	3
20-56-204	Notice of minor violations……	3
20-56-205	Penalties – Exceptions……..	3-4
20-56-206	Duty of prosecuting attorney……	4
20-56-207	Injunction authorized……	4-5
20-56-208	Adulterated food……..	5-6
20-56-209	Misbranded food……...	6-7
20-56-210	Adulterated drug or device……...	7-8
20-56-211	Misbranded drug or device……...	8-10
20-56-212	Adulterated cosmetic……	10-11
20-56-213	Misbranded cosmetic……	11
20-56-214	False or misleading advertisement……...	11-12
20-56-215	Prohibited acts……..	12
20-56-216	Adulterated, misbranded, or abandoned food, drug, device, or cosmetic – Procedures……..	13-14
20-56-217	Contamination with microorganisms……...	14
20-56-218	Poisonous or deleterious substance – Regulation for use…….	14-15
20-56-219	State Board of Health – Authority to regulate……..	15
20-56-220	State Board of Health – Inspection……...	15-16
20-56-221	State Board of Health – Publication and dissemination of information……...	16
20-56-222	State Board of Health – Enforcement of subchapter……	16
20-56-223	State Board of Health – Enforcement of federal law……...	16

Controlled Substances and Legend Drugs F

20-64-501	Applicability…….	1
20-64-502	Construction…….	1
20-64-503	Definitions……	1-3
20-64-504	Sales – Permit required…….	3
20-64-505	Wholesale distributor – Permit required……..	3
20-64-506	Wholesale distributors – Shipment to certain licensed professionals…….	3
20-64-507	Regulations……...	4
20-64-508	Revocation or suspension of licenses……...	4
20-64-509	Penalties……	4-5
20-64-510	Hearing procedures……...	5
20-64-511	Violations…….	5
20-64-512	Inspection of records……	5
20-64-513	Injunctive powers…….	5

Administrative Procedures Act G

25-15-201	Title……..	1
25-15-202	Definitions……	1-2
25-15-203	Rules – Required rules – Public inspection……..	2
25-15-204	Rules – Procedure for adoption……	2-4
25-15-205	Rules – "The Arkansas Register"…….	4-5
25-15-206	Rules – Declaratory orders……...	5
25-15-207	Rules – Actions for declaratory judgments……..	5
25-15-208	Administrative adjudication – Procedures generally……	5-6
25-15-209	Administrative adjudication – Communication by decision maker……	6
25-15-210	Administrative adjudication – Decisions…….	6-7
25-15-211	Administrative adjudication – Licenses……...	7
25-15-212	Administrative adjudication – Judicial Review……	8-9
25-15-213	Hearings generally……	9-10
25-15-214	Failure of agency to act – Action by injured party……...	10
25-15-215	Model rules……...	10-11
25-15-216	Review of agency rules……	11
25-15-217	Alternative sanctions……	11-12

Pharmacy Practice Act

17-92-101. Definitions

As used in this chapter:

(1) "Biological product" means a biological product as defined by 42 U.S.C. 262(i)(1), as existing on January 1, 2019; and;

(2) “Credentialing” means the issuance of or approval by the Arkansas State Board of Pharmacy of a credential issued to a pharmacist by an agency approved by the board certifying that the pharmacist has met the standards of competency established by the Arkansas State Board of Pharmacy for disease state management or other pharmacy services necessitating a credential;

(3) “Dentist” means a practitioner of dentistry duly licensed under the laws of this or some other state;

(4)

(A) “Disease state management” means a strategy that utilizes a team-oriented, multidisciplinary approach to improve health care outcomes and quality of care, and when possible, to control health care cost through management of targeted chronic disease states.

(B) Disease state management focuses on improving health care from prevention to diagnosis and treatment to ongoing follow-up.

(C) Disease state management will involve, but not be limited to, patient education, self-care techniques, and outpatient drug therapy management pursuant to a patient care plan;

(5) “Drug” shall include all medicines and preparations recognized in the United States Pharmacopoeia or the National Formulary as substances intended to be used for the care, mitigation, or prevention of disease of either man or other animals;

(6) “Generically equivalent” means a drug that is pharmaceutically and therapeutically equivalent to the drug prescribed;

(7) "Interchangeable biological product" means a biological product that is interchangeable as defined by 42 U.S.C. 262(i)(3), as existing on January 1, 2019.

(8)

(A) “Licensed pharmacist” means a person holding a license under the provisions of this chapter.

(B) A “licensed pharmacist” shall be considered an individual healthcare provider;

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

(10) “Optometrist” means a practitioner of optometry duly licensed under the laws of this state;

(11) “Patient care plan” means a written course of action that is patient- or physician- or pharmacist-specific and disease-specific for helping a patient to achieve outcomes that improve a patient's quality of life;

(12) “Pharmaceutically equivalent” means drug products that have identical amounts of the same active chemical ingredients in the same dosage form and that meet the identical, compendious, or other applicable standards of strength, quality, and purity according to the United States Pharmacopoeia or another nationally recognized

compendium;

(13) “Pharmacy” means the place licensed by the Arkansas State Board of Pharmacy in which drugs, chemicals, medicines, prescriptions, and poisons are compounded, dispensed, or sold at retail;

(14) “Pharmacy care” means the process by which a pharmacist in consultation with the prescribing practitioner identifies, resolves, and prevents potential and actual drug-related problems and optimizes patient therapy outcomes through the responsible provision of drug therapy or disease state management for the purpose of achieving any of the following definite outcomes that improve a patient's quality of life:

(A) Cure of disease;

(B) Elimination or reduction of a patient's symptomology;

(C) Arresting or slowing a disease process; or

(D) Preventing a disease or symptomology;

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

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

(17)

(A) “Practice of pharmacy” means the healthcare provider profession of:

(i)

(a) Dispensing, selling, distributing, transferring possession of, vending, bartering, or, in accordance with rules adopted by the Arkansas State Board of Pharmacy, administering drugs, medicines, poisons, or chemicals that under the laws of the United States or the State of Arkansas may be sold or dispensed only on the prescription and order of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

(b) Except as limited by rules adopted by the Arkansas State Board of Pharmacy, a pharmacist has the ability to administer medications.

(c) Influenza vaccines and influenza immunizations may be administered to a person seven (7) years of age and older under a general written protocol.

(d) Vaccines and immunizations other than influenza vaccines and influenza immunizations may be administered to a person from seven (7) years of age to eighteen (18) years of age general written protocol required under § 20-15-1203 if written consent of the parent or legal guardian of the minor is obtained before the administration of the vaccine or immunization.

(e) Vaccines and immunizations other than influenza vaccines and influenza immunizations may be administered to a person eighteen (18) years of age or older under a general written protocol.

(f) Medications other than vaccines and immunizations may be administered to a person seven (7) years of age or older under a patient-specific order or prescription and subject to reporting of the administration to the prescribing physician.

(g) A general written protocol under subdivisions (16)(A)(i)(c) and (e) of this section and patient-specific orders or prescriptions under subdivisions (16)(A)(i)(d) and (f) shall be from a

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

(h) Under a statewide protocol, a pharmacist may initiate therapy and administer or dispense, or both, drugs that include Naloxone and nicotine replacement therapy products;

(ii) Placing, packing, pouring, or putting into a container for dispensing, sale, distribution, transfer of, possession of, vending, or bartering any drug, medicine, poison, or chemical that under the laws of the United States or the State of Arkansas may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals;

(iii) Placing in or affixing upon any container described in subdivision (16)(A)(ii) of this section a label required to be placed upon drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals;

(iv) Preparing, typing, or writing labels to be placed in or affixed on any container described in subdivision (16)(A)(ii) of this section, which label is required to be placed upon drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals;

(v) Interpreting prescriptions for drugs, medicines, poisons, or chemicals issued by practitioners authorized by law to prescribe drugs, medicines, poisons, or chemicals that may be sold or dispensed only on prescription;

(vi) Selecting, taking from, and replacing upon shelves in the prescription department of a pharmacy or apothecary drugs, medicines, chemicals, or poisons that are required by the laws of the United States or the State of Arkansas to be sold or dispensed only on prescription of a practitioner authorized by law to prescribe them;

(vii) Compounding, mixing, preparing, or combining drugs, medicines, chemicals, or poisons that under the laws of the United States or the State of Arkansas may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe them;

(viii) Advising and providing information concerning utilization of drugs and devices and participation in drug utilization reviews;

(ix)

(a) Performing a specific act of drug therapy management or disease state management delegated to a pharmacist for an individual patient based upon a written protocol or a patient care plan approved by a physician, who shall be licensed in this state under the Arkansas Medical Practices Act, § 17-95-201 et seq., § 17-95-301 et seq., and § 17-95-401 et seq.

(b) Drug therapy management shall not include the selection of drug products not prescribed by the physician unless the drug products are either named in the physician-initiated protocol or the physician-approved patient care plan;

(x) Providing pharmacy care; and

(xi) Providing pharmacokinetic services.

(B) The provisions of subdivisions (16)(A) and (16)(C) of this section shall not apply to employees of wholesale drug companies or other drug distributors who do not fill prescriptions or sell or dispense drugs to the consumer.

(C)

(i) The Arkansas State Board of Pharmacy may permit pharmacy technicians other than pharmacists or interns to perform some or all of those functions described in board regulations under the direct, personal supervision of a licensed pharmacist pursuant to regulations defining the minimum qualifications of such employees, the ratio of pharmacy technicians to supervising pharmacists, and the scope of the duties, practices, and procedures that the Arkansas State Board of Pharmacy determines will promote the delivery of competent, professional pharmaceutical services and promote the public health and welfare. Nothing in this chapter shall be construed as allowing pharmacy technicians to administer medications.

(ii) The conduct of a pharmacy technician is the responsibility of the pharmacist-in-charge and supervising pharmacist of the pharmacy who shall not permit the employee to perform any act, task, or function that involves the exercise of independent judgment by the employee.

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

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

(v) It is recognized that hospital pharmacy technicians as defined in § 17-92-602(5) are governed by the Hospital Pharmacies Act, § 17-92-601 et seq., and related Arkansas State Board of Pharmacy regulations developed pursuant to that act;

(18)

(A) "Prescription" means an order for medicine or medicines usually written as a formula by a physician, optometrist, dentist, veterinarian, or other licensed medicinal practitioner. It contains the names and quantities of the desired substance, with instructions to the pharmacist for its preparation and to the patient for the use of the medicine at a particular time and may authorize the pharmacist to substitute a therapeutically equivalent drug that is at a lower cost to the patient and communicate that authorization by any generally accepted means of communication of a prescription from a prescriber to a pharmacist.

(B) A substitution of a therapeutically equivalent drug shall occur only after the prescriber grants such authorization for each prescription.

(C)

(i) Before dispensing, the pharmacist shall discuss verbally any suggested substitution with the patient and inform the patient that the patient has a right to refuse the substitution.

(ii) The discussion under subdivision (17)(C)(i) of this section shall include without limitation:

(a) Notification to the patient that the therapeutically equivalent drug does not contain the identical active ingredient present in the prescribed drug; and

(b) All differences in dosage and frequency between the prescribed drug and the therapeutically equivalent drug.

(D) The pharmacist shall send notice of the substitution to the prescriber in writing or by electronic communication within twenty-four (24) hours after the drug is dispensed to the patient.

(E) Subdivision (17)(B) of this section does not apply to specific acts of drug therapy management or disease state management delegated to a pharmacist based upon a written protocol or patient care plan approved

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

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

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

(21) "Therapeutic class" means a group of similar drug products that have the same or similar mechanisms of action and are used to treat a specific condition;

(22) "Therapeutically equivalent" means drug products from the same therapeutic class that if administered in appropriate amounts will provide the same therapeutic effect, identical in duration and intensity;

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

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

(25) "Statewide protocol" means a standardized procedure or protocol approved by the Arkansas State Board of Pharmacy and the Arkansas State Medical Board authorizing a pharmacist to initiate therapy and administer or dispense, or both, a drug or device.

17-92-102. Exemptions

(a) Nothing in this section and §§ 17-92-101(1)-(11), 17-92-103, 17-92-105, 17-92-205(b), 17-92-206(b), 17-92-303, 17-92-402, 17-92-404, 17-92-405, 17-92-409, 17-92-410, and 17-92-411(a) shall prevent the personal administration of drugs and medicines carried and kept for emergencies by licensed physicians, dentists, or veterinarians in order to supply the immediate needs of their patients while in their presence, nor shall it apply to physicians, dentists, or veterinarians compounding or dispensing their own prescriptions.

(b) The provisions of this section and §§ 17-92-101(1)-(11), 17-92-103, 17-92-105, 17-92-205(b), 17-92-206(b), 17-92-303, 17-92-402, 17-92-404, 17-92-405, 17-92-409, 17-92-410, and 17-92-411(a) shall not apply:

(1) To the sale of drugs and medicines when intended for agricultural, technical, and industrial use, unless those drugs and medicines are legend drugs as defined in § 20-64-503;

(2) To the sales by wholesale druggists, wholesale or retail grocers, or other wholesale or retail dealers or manufacturers of proprietary medicines in original packages; or

(3) To the sales of those drugs commonly known as "grocers' drugs" in original packages when put up under the direction of a licensed pharmacist of this or some other state.

(c) Further exempted from the provisions of this section and §§ 17-92-101(1)-(11), 17-92-103, 17-92-105, 17-92-205(b), 17-92-206(b), 17-92-303, 17-92-402, 17-92-404, 17-92-405, 17-92-409, 17-92-410, and 17-92-411(a) are the sale of legend drugs approved by the State Board of Optometry by licensed pharmacists to duly licensed optometrists and the possession and use of legend drugs by duly licensed optometrists as authorized by the board and by §§ 17-90-401--17-90-403.

(d) In the event a pharmacist receives a request for a prescription refill and the pharmacist is unable to obtain refill authorization from the prescriber, the pharmacist may dispense a one-time emergency refill of the prescribed medication, provided that:

(1) The prescription is not for a medicinal drug listed in Schedule II as defined in § 5-64-205;

(2) The medication is essential to the maintenance of life or to the continuation of therapy;

(3) In the pharmacist's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort;

(4) The pharmacist properly records the dispensing; and

(5) The dispensing pharmacist notifies the prescriber of the emergency dispensing within a reasonable time after the one-time emergency refill dispensing.

17-92-103. Pharmacy laws

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

17-92-104. Privilege taxes

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

17-92-105. Prohibited acts--Penalties

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

(b) Each day of violation shall constitute a separate offense.

17-92-106. Violations; writs of injunction

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

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

(a)

(1) All suits for the collection of any fine or penalty prescribed in this act may be instituted in any court having jurisdiction thereof by any citizen of the county wherein the fine or penalty is incurred.

(2) It shall be the duty of the prosecuting attorney of the county wherein the fine or penalty is incurred to prosecute all persons incurring them when notified by any citizen of the county.

(b)

(1) Upon affidavit made before any justice of the peace by any citizen of the county showing a violation of this act, the justice of the peace shall issue his or her warrant as provided by law.

(2) However, the Arkansas State Board of Pharmacy or any member thereof, or its authorized agent, may institute and prosecute proceedings in any county in this state for violations of this act or for the

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

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

17-92-108. Fees

(a) The fees charged by the Arkansas State Board of Pharmacy for the various examinations, permits, licenses, certificates, credentials, and books issued by the board shall be as follows:

(1) The fee for examination for a license as a licensed pharmacist upon examination shall not exceed twenty-five dollars ($25.00) plus the actual cost of the examination;

(2) The fee for a license as a licensed pharmacist from another state by reciprocity and without examination shall not exceed two hundred dollars ($200);

(3)

(A) The fee for the initial license as a licensed pharmacist shall not exceed seventy-five dollars ($75.00).

(B) The fee for the renewal of a license as a licensed pharmacist shall not exceed seventy-five dollars ($75.00) per year;

(4)

(A)

(i) The fee for issuance of a pharmacy permit for the first time to operate an in-state pharmacy shall not exceed three hundred dollars ($300).

(ii) The fee for renewal of a permit to operate an in-state pharmacy shall not exceed one hundred fifty dollars ($150) per year.

(iii) When there is a change in ownership in an in-state pharmacy, a new permit must be obtained, and the fee shall not exceed one hundred fifty dollars ($150).

(B)

(i) The fee for issuance of a permit for the first time to operate a specialty pharmacy shall not exceed three hundred dollars ($300).

(ii) The fee for renewal of a permit to operate a specialty pharmacy shall not exceed one hundred fifty dollars ($150) per year.

(iii) When there is a change in ownership in a specialty pharmacy, a new permit must be obtained, and the fee shall not exceed one hundred fifty dollars ($150).

(C)

(i) The fee for issuance of a permit for the first time to operate an out-of-state pharmacy shall not exceed three hundred dollars ($300).

(ii) The fee for renewal of a permit to operate an out-of-state pharmacy shall not exceed one hundred fifty dollars ($150) per year.

(iii) When there is a change in ownership in an out-of-state pharmacy, a new permit must be obtained, and the fee shall not exceed one hundred fifty dollars ($150);

(5) The fee for a certificate as a licensed pharmacist shall not exceed ten dollars ($10.00);

(6) The fee for certifying grades in connection with an application for reciprocity licensure without an examination shall not exceed ten dollars ($10.00);

(7)

(A) The fee for issuance of a hospital pharmaceutical service permit shall not exceed three hundred dollars ($300), and the fee for the renewal of a hospital pharmaceutical service permit shall not exceed one hundred fifty dollars ($150) per year.

(B) When there is a change in ownership of a hospital pharmacy, a new permit must be obtained, and the fee shall not exceed one hundred fifty dollars ($150).

(C)

(i) The fee for issuance of an ambulatory care center pharmaceutical service permit shall not exceed three hundred dollars ($300), and the fee for the renewal of an ambulatory care center pharmaceutical service permit shall not exceed one hundred fifty dollars ($150) per year.

(ii) When there is a change in ownership of an ambulatory care center pharmacy, a new permit must be obtained, and the fee shall not exceed one hundred fifty dollars ($150);

(8)

(A) The fee for issuance of an institutional pharmaceutical services permit shall not exceed thirty-five dollars ($35.00).

(B) The fee for the annual renewal of an institutional pharmaceutical services permit shall not exceed thirty-five dollars ($35.00);

(9)

(A) The fee for issuance of and the reinstatement of a nursing home consultant pharmacist permit shall not exceed thirty-five dollars ($35.00).

(B) The fee for the renewal of a nursing home consultant pharmacist permit shall not exceed thirty-five dollars ($35.00) per year;

(10)

(A) The fee for intern registration shall not exceed forty-five dollars ($45.00).

(B) The fee for preceptor registration shall not exceed twenty dollars ($20.00) every two (2) years;

(11) The fee for a change of pharmacist in charge of a pharmacy or other facility as described at § 17-92-403 shall not exceed thirty-five dollars ($35.00);

(12) The fee for reinstatement of a pharmacist licensure shall not exceed seventy-five dollars ($75.00) for each delinquent year up to a maximum of three hundred dollars ($300);

(13) The fee for the Arkansas State Board of Pharmacy law book shall not exceed twenty-five dollars ($25.00) except to interns on initial licensure and applicants for reciprocity on a one-time basis. A copy of each edition as revised shall be provided free to each pharmacy permit holder;

(14) The fee for a change of location inspection shall not exceed one hundred dollars ($100);

(15) The penalty for late payment of renewal of any permit, license, registration, or certificate shall not exceed twenty dollars ($20.00) per month beginning the first day of the second month after expiration,

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

(16)

(A) The fee for issuance of a wholesale distributor, third-party logistics provider, manufacturer, or outsourcing facility of legend drugs and controlled substances permit shall not exceed three hundred dollars ($300), and the renewal fee shall not exceed one hundred fifty dollars ($150) per year.

(B) When there is a change in ownership of a wholesale distributor, third-party logistics provider, manufacturer, or outsourcing facility of legend drugs and controlled substances, a new permit must be obtained, and the fee shall not exceed one hundred fifty dollars ($150);

(17)

(A) The fee for the original issuance of a pharmacy technician's permit shall not exceed thirty-five dollars ($35.00).

(B) The fee for the renewal of a pharmacy technician's permit shall not exceed thirty-five dollars ($35.00) per year.

(C) The board may waive the fees under subdivisions (a)(17)(A) and (B) of this section if the pharmacy technician performs pharmacy technician duties as a volunteer in a charitable clinic;

(18)

(A) The reinstatement fee for a pharmacy technician's permit shall not exceed forty dollars ($40.00).

(B) The board may waive the fee under subdivision (a)(18)(A) of this section if the pharmacy technician performs pharmacy technician duties as a volunteer in a charitable clinic; and

(19)

(A) The application fee for a license to sell, rent, offer to sell, or rent directly to patients in this state any home medical equipment, legend drugs, or medical gases shall not exceed two hundred fifty dollars ($250).

(B) The license renewal fee shall not exceed one hundred twenty-five dollars ($125).

(C) The change-of-ownership fee shall not exceed one hundred twenty-five dollars ($125).

(b) All fees for examination for a license shall be payable with the application and shall not be subject to refund.

(c) Should any license, certificate, or registration not be renewed within ninety (90) days after expiration thereof, it may be reinstated by the board as authorized in this section upon payment of the renewal fee and reinstatement fee. However, the following are not subject to reinstatement if not renewed within ninety (90) days after expiration:

(1) Pharmacy permits;

(2) Out-of-state pharmacy permits;

(3) Specialty pharmacy permits;

(4) Hospital permits;

(5) Ambulatory care center pharmacy permits;

(6) Wholesale distributors, third-party logistics providers, manufacturers, or outsourcing facilities of legend drugs or controlled substance permits, or both; and

(7) Suppliers of medical equipment, legend devices, and medical gas licenses.

(d)

(1) All retail pharmacy permits, out-of-state pharmacy permits, specialty pharmacy permits, and pharmacist licenses shall be renewed every two (2) years beginning with renewals for 2002-2003.

(2) All pharmacy technician permits, hospital pharmacy permits, ambulatory care center pharmaceutical services permits, wholesale distributors, third-party logistics providers, manufacturers, or outsourcing facilities of legend or controlled substance permits, wholesale distributors of medical equipment, legend devices, and medical gases permits, institutional pharmaceutical services permits, and any other permit, license, registration, or certificate issued by the board and not covered in subdivision (d)(1) of this section other than internship licenses and preceptor permits shall be renewed every two (2) years.

(3) The fee for any biennial renewal term will be the amount of two (2) annual renewal fees for the applicable license, permit, registration, or certification as provided in subsection (a) of this section.

(4) If the initial licensure, permit, certificate, or registration occurs in the first year of a biennial renewal term, the applicant shall pay the appropriate initial fee and the applicable annual fee for the license, permit, certificate, or registration for the second year in the renewal term as provided in subsection (a) of this section.

(5) If the initial licensure, permit, certificate, or registration occurs in the second year of a biennial renewal term, the applicant will pay only the original fee and will not be responsible for the renewal fee until the biennial renewal period for the license, permit, certificate, or registration.

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

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

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

(a) As used in this section:

(1) “Exercise of professional responsibilities” includes without limitation a pharmacist's or pharmacy's:

(A) Discussing any aspect of a patient's medical condition, treatment alternatives, or plan options with the patient;

(B) In good faith communicating with or advocating on behalf of a patient concerning the patient's needs; or

(C) Asserting rights under:

(i) The contract with the pharmacy benefits manager; or

(ii) State or federal law; and

(2) "Pharmacy benefits manager" means a non-governmental entity that administers or manages a pharmacy benefits plan or program.

(b) A pharmacy benefits manager shall not interfere with the exercise of professional responsibilities to a patient by a pharmacist or a pharmacy.

17-92-114. Reciprocity

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

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

(a) When initiating therapy and administering or dispensing, or both, under a statewide protocol, a pharmacist shall:

(1) Notify the primary care provider of the patient of any drug or device furnished to the patient or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider;

(2) Provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice, if the patient does not have a primary care provider; and

(3)

(A) Make a standardized fact sheet available to the recipient of the drug or device.

(B) The standardized fact sheet shall include without limitation:

(i) The indications and contraindications for the use of the drug or device;

(ii) The appropriate method for the use of the drug or device;

(iii) The need for medical follow up; and

(iv) Other appropriate information.

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

(a) The provisions of §§ 17-92-101, 17-92-103, 17-92-105, 17-92-205, 17-92-206, 17-92-303, 17-92-401, 17-92-402, 17-92-404, 17-92-405, 17-92-409, 17-92-410, 17-92-411, and 17-92-902 do not apply to the sale or distribution of dialysate or devices necessary to perform home peritoneal kidney dialysis to patients with end stage renal disease if:

(1) The dialysate composed of dextrose or icodextrin or devices are:

(A) Approved or cleared by the United States Food and Drug Administration as required by federal law;

(B) Lawfully held by a manufacturer or a third-party logistics provider of the manufacturer that is properly registered with the Arkansas State Board of Pharmacy as a wholesale distributor or medical device provider;

(C) Held and delivered in original, sealed packaging from the manufacturing facility; and

(D) Delivered only by the manufacturer or a third-party logistics provider of the manufacturer and only upon receipt of a physician's order by a licensed pharmacy and the transmittal of an order from a licensed pharmacy to the manufacturer or a third party logistics provider of the manufacturer; and

(2) The manufacturer or a third-party logistics provider of the manufacturer delivers the dialysate or devices directly to:

(A) A patient with end stage renal disease or a designee for the self-administration of the dialysis therapy; or

(B) A healthcare provider or institution for administration or delivery of the dialysis therapy to a patient with end stage renal disease.

(i) The board shall retain oversight of all other drugs for home peritoneal kidney dialysis with the exception of dialysate as described in subdivision (a)(1) of this section.

(ii) All records of sales and distribution of dialysate to patients under this section shall be retained according to state law and rule of the board.

17-92-117. Prescriptions for all healthcare professionals

(a) As used in this section, "healthcare professional" means a person who is licensed, certified, or otherwise authorized by the laws of this state to administer health care in the ordinary course of the practice of his or her profession.

(b) A pharmacist licensed in the State of Arkansas may fill prescriptions in the State of Arkansas for any healthcare professional who has prescriptive authority to the extent of that healthcare professional's scope of practice.

17-92-201. Members--Qualifications

(a) The Arkansas State Board of Pharmacy shall consist of eight (8) members, appointed by the Governor for terms of six (6) years:

(1) Five (5) members shall be experienced pharmacists who have been actively engaged in the practice of pharmacy for the last five (5) years immediately preceding their appointments, to be appointed by the Governor after consulting the Arkansas Pharmacists Association and subject to confirmation by the Senate;

(2) One (1) member shall be a minority who is a licensed practicing pharmacist in this state, to be appointed by the Governor after consulting the Pharmaceutical Section of the Arkansas Medical, Dental, and Pharmaceutical Association and subject to confirmation by the Senate; and

(3)

(A) Two (2) members of the board shall not be actively engaged in or retired from the practice of pharmacy. One (1) member shall represent consumers, and one (1) member shall be sixty (60) years of age or older and shall represent the elderly. Both shall be appointed from the state at large, subject to confirmation by the Senate. Both shall be full voting members but shall not participate in the grading of examinations.

(B) The two (2) positions shall not be held by the same person.

(b) A member shall hold his or her office until his or her successor shall have been appointed and qualified.

(c)

(1) In case of a vacancy from death or other cause, the Governor shall appoint a successor with qualifications as set forth in subsection (a) of this section.

(2) In the event that a vacancy exists in the minority position due to death, resignation, or other cause, a successor member to the position shall be appointed by the Governor for the remainder of the unexpired portion of the term in the same manner as is provided for the initial appointment.

17-92-202. Members' oath

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

17-92-203. Member compensation and reimbursement

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

17-92-204. Organization and proceedings

(a) Immediately after the appointment and qualification of the Arkansas State Board of Pharmacy, the members shall meet and organize as the Arkansas State Board of Pharmacy, by electing from their own number a president and secretary.

(b)

(1) The board shall hold not fewer than two (2) regular meetings per annum for the examination of candidates.

(2) One (1) meeting may be held at the time and place of the annual meeting of the Arkansas Pharmacists Association. The other meeting shall be held at a time and place as the board may determine.

(3) Other meetings of the board may also be held whenever and wherever a quorum of the board, including the secretary, is present.

(c) A majority of the board shall be a quorum for the transaction of any business.

(d) The board may adopt such bylaws as it deems necessary to carry into execution the provisions of this act without expense to the state.

17-92-205. Rules and regulations- Enforcement

(a)

(1) The Arkansas State Board of Pharmacy shall have authority to make reasonable rules and regulations, not inconsistent with law, to carry out the purposes and intentions of this chapter and the pharmacy laws of this state that the board deems necessary to preserve and protect the public health.

(2) The board shall by regulation establish standards for the administration of medications by licensed pharmacists, including, but not limited to, the completion of a course in the administration of medications.

(b) It shall be the duty of the board, through officials appointed by it or under its supervision for that purpose, to enforce all the provisions of this chapter.

(c)

(1) Upon written authorization by the board, the board's inspectors or other designated agents shall have authority to conduct oversight activities authorized by law, including, but not limited to, audits, investigations, inspections, licensure, or disciplinary actions, civil, administrative, or criminal proceedings or actions, or other activities necessary for appropriate oversight of the regulated activities and may enter any store, business establishment, including any hospital pharmacy, or any other facility holding a license, permit, or other authority issued by the board where drugs, medicines, chemicals, pharmaceuticals, poisons, home medical equipment, or services or other objects, services, or activities regulated by the board are manufactured, sold, dispensed, or conducted to enforce this chapter, the Uniform Controlled Substances Act, §§ 5-64-101--5-64-510, § 5-64-1001 et seq., § 5-64-1101 et seq., the Food, Drug, and Cosmetic Act, § 20-56-201 et seq., or § 20-64-501 et seq.

(2)

(A) Upon written authorization by the board, the board's inspectors and other designated agents may obtain copies of any document, prescription, drug order, or other record or physical object relevant to the board's oversight of the regulated activity.

(B)

(i) With regard to hospital pharmacies, the board's inspectors and other designated agents may also view and at the board's expense make copies of identifiable records relating to patients in patient areas of the hospital if the records are relevant to an activity regulated by the board.(ii)

(ii) However, should any such record be in active use or storage at the time of the board's request to examine, obtain, or copy the record, the entity having control or possession of the record shall state in writing that the record will be made available to the board at a specific date and time within two (2) working days after the board's request.

(C) For purposes of confidentiality, a record containing patient health information in the possession of the board under this subdivision (c)(2) shall be considered a medical record for purposes of the Freedom of Information Act of 1967, § 25-19-101 et seq.

(3) In any investigation or official inquiry of a potential violation of law or any administrative proceeding regarding an alleged violation of law subject to its jurisdiction, the board may issue subpoenas signed by its executive director or the director's designee for any document, prescription, drug order, or other record or physical object identified or otherwise described in the subpoena if the item is relevant and material to the inquiry, investigation, or proceeding.

(4) In any administrative proceeding arising from an alleged violation of law within its jurisdiction, the board may order the disclosure of any information that is relevant and material to the alleged violation.

(5)

(A) If a person has been served with a subpoena or subpoena duces tecum or has been ordered to disclose information in an administrative proceeding under this chapter and fails to comply with the order, the board may apply to the Pulaski County Circuit Court or to the circuit court of the county in which the board is conducting its investigation or hearing for an order directing that:

(i) The person be brought before the court; and

(ii) After notice and opportunity for a hearing, the person comply with the order.

(B) If the person violates the court's order, the court may punish the person for civil contempt.

(C) If a person fails or refuses to make available to the board's inspectors or agents under subdivision (c)(2) of this section any document, prescription, drug order, or other record or physical object, the board may file an action in the Pulaski County Circuit Court or in the circuit court of the county in which the board is conducting its oversight activity to obtain an order, after notice and opportunity for hearing, mandating that the person make the document, prescription, drug order, or other record or physical object available to the board's representatives.

(6) The board's inspectors and other designated agents may seize products for testing of sterility, potency, and pyrogenicity when inspecting permitted facilities.

(d) The board shall promulgate rules limiting the amount of Schedule II narcotics that may be dispensed by licensees of the board.

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

(a) It shall be the duty of the Arkansas State Board of Pharmacy to issue bulletins from time to time, informing pharmacists of important United States public health regulations, service and regulatory announcements of the Bureau of Chemistry and Soils in the United States Department of Agriculture, and decisions of the United States Department of Treasury relating to the possession, use, and sale of nonbeverage United States Pharmacopoeia alcohol and to the Harrison-Wright Antinarcotic Act.

(b) The board shall make a written report on September 1 of each year to the Governor and to the Arkansas Pharmacists Association of all its proceedings, orders, rules, requirements, and regulations, of its receipts and disbursements, including also the names of all persons licensed to practice under this chapter, and a record of permits and renewals.

17-92-207. Maintenance of office

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

17-92-208. Employees

(a) The Arkansas State Board of Pharmacy is authorized to make payment for services, salaries, and other purposes from the funds received by the board from issuance of licensed pharmacy permits, renewals, or certificates of licensure of licensed pharmacists, examinations, reciprocity fees, and from other moneys collected.

(b)

(1) The board is authorized to employ an attorney to supervise and conduct its investigations and to institute and prosecute actions and charges for the violation of the provisions of the Arkansas Pharmacy Act, § 17-92-101 et seq.

(2) The attorney employed or retained by the board shall make regular reports to the Attorney General of the actions instituted or prosecuted by him or her.

(3) Appeals from the circuit court to the Supreme Court in matters affecting the action of the board may be handled by the office of the Attorney General.

(c) The board is authorized to make reimbursement of the necessary and reasonable travel, board, and lodging expenses of the staff of the board incurred in the performance of their duties.

17-92-301. License required

(a) No person shall perform any of the acts constituting the practice of pharmacy unless the person is:

(1) A licensed pharmacist;

(2) A student or graduate of a recognized college of pharmacy serving an internship under an internship program established and regulated by the Arkansas State Board of Pharmacy;

(3) A pharmacy technician performing the limited functions permitted under this chapter and regulations promulgated hereunder; or

(4) A hospital pharmacy technician as defined in § 17-92-602 performing the limited functions permitted under that subchapter and regulations promulgated thereunder.

(b) No person other than a licensed pharmacist shall use the term “doctor of pharmacy” or “Pharm.D”.

17-92-302. Unlicensed practice – Penalty.

(a) No person shall fill a prescription, compound medicines, or otherwise perform the function of a licensed pharmacist unless the person is:

(1) An Arkansas-licensed pharmacist, except students or graduates of a recognized college of pharmacy serving internship as provided by law and regulated by the Arkansas State Board of Pharmacy;

(2) A pharmacy technician performing the limited functions permitted under this chapter and regulations promulgated hereunder; or

(3) A hospital pharmacy technician as defined in § 17-92-602 performing the limited functions permitted under that subchapter and regulations promulgated thereunder.

(b) Any person who is not an Arkansas-licensed pharmacist or a student serving internship or a pharmacy technician performing the limited functions permitted under this chapter and regulations promulgated hereunder or a hospital pharmacy technician as defined in § 17-92-602 performing the limited functions permitted under that subchapter and regulations promulgated thereunder, who shall fill a prescription, compound or dispense medicine, or otherwise perform the functions of a pharmacist, shall be guilty of a misdemeanor punishable by a fine of not less than fifty dollars ($50.00) nor more than one hundred dollars ($100) for the first offense and not less than one hundred dollars ($100) or thirty (30) days' imprisonment, or both fine and imprisonment, for each succeeding offense thereafter.

(c) Each day that the person shall fill prescriptions, compound or dispense medicines, or otherwise perform the functions of a pharmacist shall constitute a separate offense.

(d) Any licensed pharmacist who shall aid, abet, or encourage any person to violate the provisions of this section shall have his or her license or permit revoked or suspended, within the discretion of the board.

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

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

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

(a) The Arkansas State Board of Pharmacy shall be fully advised respecting the eligibility and qualifications of all persons whom the board admits to the examination and to whom the board grants licensure.

(b) For this purpose the board shall secure the services of the National Association of Boards of Pharmacy and the Arkansas Pharmacists Association and shall pay for such service as the board may determine, but not to exceed one dollar ($1.00) of each renewal fee annually paid.

17-92-305. Application - Qualification of applicants

(a) Each applicant for examination as a pharmacist:

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

(2) Have:

(A) Graduated and received the first professional undergraduate degree from a pharmacy degree program which has been approved by the Arkansas State Board of Pharmacy; or

(B) Graduated from a foreign college of pharmacy, completed a transcript verification program, taken and passed a college of pharmacy equivalency exam program, and completed a process of communication ability testing as defined under board regulations so that it is assured that the applicant meets standards necessary to protect public health and safety.

(b) Each application for examination shall be made on a form to be supplied by the board and shall be filed with the board as required by board regulations.

(c) Each application shall be accompanied by the cost of the examination plus the examination fee and certificate fee prescribed by § 17-92-108.

(d) The examination shall be given at a time and place and in a manner set by the board.

17-92-306. Examinations

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

17-92-307. Internship required

(a)

(1) Every applicant for licensure must have experience and internship in a retail pharmacy under a licensed pharmacist, approved by the Arkansas State Board of Pharmacy, before and after graduation and examination as the board shall deem necessary to maintain and preserve the reciprocal agreements with other states and territories.

(2) The experience and internship in a retail pharmacy under a licensed pharmacist shall be predominantly related to the selling of drugs and medical supplies, compounding prescriptions, preparing pharmaceutical preparations, and keeping records and making reports required under the state and federal statutes.

(b) The board is directed and empowered to establish an internship program whereby students and graduates of a recognized college of pharmacy may be permitted to practice pharmacy under the direction and control of a licensed pharmacist.

17-92-308. Reciprocity

(a) The Arkansas State Board of Pharmacy, in its discretion, may license as a pharmacist, through the process of reciprocity as established by the National Association of Boards of Pharmacy, any person who is duly licensed in some other state, territory, or the District of Columbia if the territory, state, or the District of Columbia has the same general requirements for licensure as Arkansas at the time of original licensure, provided that the state, territory, or the District of Columbia in which the person is licensed shall, under like conditions, grant reciprocal licensure to a pharmacist duly licensed by examination in this state.

(b) All applications for a reciprocal license shall be accompanied by the fee prescribed by § 17-92-108.

(c)

(1) In the interim between sessions of the board and upon satisfactory evidence of the fitness as established by board regulation of an applicant for reciprocity, any member of the board, in his or her discretion, may issue a temporary certificate that shall authorize the holder to practice pharmacy as defined in § 17-92-101.

(2) The temporary certificate shall expire on the date of the next meeting of the board after the granting of the certificate whether that meeting is a regular meeting or a called meeting at which reciprocity is considered.

17-92-309. Registration and certificate

(a) The Arkansas State Board of Pharmacy shall register in a suitable book the names and places of residence of all persons to whom it issues certificates and the date of issuance.

(b) The board shall issue an appropriate certificate to each person licensed. The certificate must be conspicuously displayed in every store described in this chapter.

(c) The board may provide by regulation for issuing and waiving the renewal fee for pharmacy certificates denoting special recognition for pharmacists who have the following qualifications:

(1) The pharmacist graduated from a college of pharmacy approved by the board fifty (50) or more years before the date on which the certificate will be issued; or

(2)

(A) The pharmacist has held an Arkansas pharmacist license for forty-nine (49) continuous years before the date on which the certificate will be issued without any lapse in the payment of licensure fees.

(B) However, a pharmacist who has paid fees to reinstate an expired license shall not be deemed to have held a license for continuous years.

17-92-310. Failure to renew

(a)

(1)

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

(B) All preceptor permits shall expire on December 31 of the first odd-numbered year following the date of issuance.

(C)

(i)

(a) Intern licenses issued to foreign graduates shall expire on December 31 of the second calendar year following the date of issuance.

(b) However, an intern license issued to a foreign graduate shall expire when the intern is issued a pharmacist license.

(ii)

(a) An intern license issued to a student intern shall remain valid as long as the intern maintains active student status in a college of pharmacy approved by the Arkansas State Board of Pharmacy and for six (6) months following graduation.

(b) An intern license issued to a student intern shall expire six (6) months following graduation.

(c) An intern license issued to a student intern may be reinstated if the intern resumes active student status in a board-approved college of pharmacy and applies for reinstatement.

(d) An intern license issued to a student intern shall expire when the intern is issued a pharmacist license.

(D) All pharmacy technician permits, hospital pharmacy permits, ambulatory care center pharmaceutical services permits, wholesale distributors, third-party logistics providers, manufacturers, or outsourcing facilities of legend or controlled substance permits, wholesale distributors of medical equipment, legend devices, and medical gases permits, institutional pharmaceutical services permits, List I chemical permits, and any other permit, license, registration, or certificate issued by the board and not covered in subdivisions (a)(1)(A)-(C) of this section shall expire on December 31 of the first even-numbered year following the date of the issuance of the permit, license, registration, or certificate.

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

(b) The penalty for late payment of renewal for pharmacists, pharmacies, wholesaler/manufacturer of legend drugs and controlled substances, hospital, institutional, and nursing home consultant permits shall be as listed in § 17-92-108, and if renewal remains unpaid on April 1 of any year, the license shall be void.

(c) If a pharmacist's license is not renewed by April 1, the fee for reinstatement shall be as stated in § 17-92-108.

(d) If a pharmacist's license has not been renewed for more than two (2) years, the board shall evaluate the former pharmacist to determine his or her continued ability to practice pharmacy safely with regard to the public health and safety, and the board shall establish conditions for the safe reentry into practice of the profession.

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

(a) The Arkansas State Board of Pharmacy may revoke or suspend an existing certificate of licensure, license, registration, or permit or may refuse to issue a certificate of licensure, license, registration, or permit if the holder or applicant, as the case may be, has committed or is found guilty by the board of any of the following acts or offenses set forth:

(1) The person is guilty of fraud, deceit, or misrepresentation in the practice of pharmacy;

(2) The person is unfit or incompetent to practice pharmacy by reason of negligent performance of his or her duties;

(3) The person has been found guilty or pleaded guilty or nolo contendere in a criminal proceeding, regardless of whether or not the adjudication of guilt or sentence is withheld by a court of this state, another state, or the federal government for:

(A) Any felony listed under § 17-2-102;

(B) Any act involving gross immorality or which is related to the qualifications, functions, and duties of a licensee; or

(C) Any violation of the pharmacy or drug laws or rules of this state, or of the pharmacy or drug statutes, rules, and regulations of any other state or of the federal government;

(4) The person has become physically or mentally incompetent to practice pharmacy to such an extent as to endanger the public;

(5) The person has directly or indirectly aided or abetted the practice of pharmacy by a person not authorized to practice pharmacy by the board;

(6) The person has been guilty of fraud or misrepresentation in obtaining a license to practice pharmacy in the State of Arkansas as a licensed pharmacist;

(7) The person has been guilty of gross unprofessional or dishonorable conduct;

(8) The person has willfully violated any of the provisions of the pharmacy laws of the State of Arkansas;

(9) The person is addicted to the use of intoxicating liquors or drugs to such a degree as to render him or her unfit, in the opinion of the board, to manufacture, compound, sell, or dispense drugs or medicine;

(10) The person knowingly adulterated or caused to be adulterated any drugs, chemical, or medical preparations and offered those preparations for sale; or

(11) The person had his or her certificate of licensure, license, registration, or permit revoked, suspended, or had other disciplinary action taken, or had his or her application for a certificate of licensure, license, registration, or permit refused, revoked, or suspended, or had voluntarily or otherwise surrendered his or her certificate of licensure, license, registration, or permit after a disciplinary action was instituted by a duly authorized professional disciplinary agency of another state.

(b) Nothing in this section should be construed as affecting the rights of any person to appeal any order of the board as now provided by the state pharmacy laws.

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

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

17-92-313. Revocation – Procedure

(a)

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

(2) The notice shall be signed by the Executive Director of the Arkansas State Board of Pharmacy or the executive director's designee and shall set forth in clear and concise language the nature of the charge against the person.

(3) Mailing a copy of the notice by registered mail, addressed to the person at his or her address appearing upon the records of the board concerning the issuance of his or her certificate or the last renewal thereof, shall be sufficient service of notice.

(b) At the hearing:

(1) The board shall have the power to subpoena witnesses;

(2) The executive director or the director's designee shall sign subpoenas;

(3) The President of the Arkansas State Board of Pharmacy shall have the power to administer oaths; and

(4) The board shall hear evidence.

(c) If the board finds after a hearing that the certificate of licensure, license, registration, or permit should be revoked, it shall be done immediately.

17-92-314. Revocation – Appeals

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

17-92-315. Alternative penalties

(a)

(1) Whenever the Arkansas State Board of Pharmacy has authority pursuant to applicable laws to suspend, revoke, or deny any permit, license, certificate, credential, or registration or otherwise impose penalties or sanctions on the holder thereof, the board shall have the power and authority to impose on the holder thereof any one (1) or more of the following sanctions:

(A) A monetary penalty not to exceed five hundred dollars ($500) for each violation;

(B) Require completion of appropriate education programs or courses, or both;

(C) Require successful completion of an appropriate licensing examination, jurisprudence examination, credentialing examination, or any combination of the three (3) examinations;

(D) Place conditions or restrictions upon regulated activities of the holder of the license, permit, certificate, credential, or registration; and

(E) Such other requirements or penalties as may be appropriate to the circumstances of the case and which would achieve the desired disciplinary purposes, but which would not impair the public health and welfare.

(2) The board is authorized to file suit in either the Pulaski County Circuit Court or the circuit court of any county in which the defendant resides or does business to collect any monetary penalty assessed pursuant

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

(3) Upon imposition of a sanction, the board may order that the license, permit, certificate, credential, or registration be suspended until the holder thereof has complied in full with all applicable sanctions imposed pursuant to this section.

(b)

(1)

a. A monetary penalty imposed by the board shall not exceed one thousand dollars ($1000) per violation

b. The board may impose a monetary penalty on a license, permit, certificate, credential, or registration holder if the license, permit, certificate, credential, or registration has been revoked by the board for such a violation.

c. The board may collect out-of-pocket costs of an investigation incurred by the board to conduct a disciplinary hearing.

(2) Each instance when a federal or state law or board rule is violated shall constitute a separate violation.

(3) The power and authority of the board to impose sanctions authorized in this section are not to be affected by any other civil or criminal proceeding concerning the same violation, nor shall the imposition of a penalty preclude the board from imposing other sanctions short of revocation.

(c) Any person sanctioned by the board under this section may appeal any order of the board as now provided by the state pharmacy laws.

(d) In addition to other sanctions authorized by this chapter, the board may also impose a civil penalty under this section against an unlicensed person or entity practicing or providing goods or services or offering to practice or provide any goods or services requiring licensure under this chapter.

(e) The board may collect costs of inspections incurred by the board while inspecting a permitted facility that is out of state.

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

(a)

(1) The Arkansas State Board of Pharmacy may provide by regulation for credentialing and approval of pharmacists to practice disease state management and any other pharmacy services determined by the board to require a credential.

(2)

(A) The credentials may be issued by agencies approved by the board to pharmacists who qualify pursuant to minimum competencies, standards, objectives, and qualifications determined by the board.

(B) However, a credential shall not authorize the pharmacist to practice credentialed pharmacy service in Arkansas until after the board has determined that the credentialed pharmacist meets the minimum competencies, standards, objectives, and qualifications determined by the board.

(b) The board shall adopt regulations necessary and appropriate to implement the credentialing and the board's approval of pharmacists to practice disease state management and other credentialed pharmacy services, including:

(1) Identification of areas of credentialed pharmacy services;

(2) Identification of the minimum competencies, standards, objectives, and qualifications necessary for a credential and the board's approval to practice in each area of credentialed pharmacy service;

(3) Identification of the standards for qualifying an agency to issue credentials for areas of pharmacy services;

(4) The procedure and standards, which may include a practical examination, for the board's review and approval of a credential and determination of a pharmacist's qualifications to practice disease state management or other credentialed pharmacy service;

(5) The conversion of a credential previously issued by the board for the practice of disease state management or other pharmacy service to a credential issued by an approved credentialing agency; and

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

(c) The board shall promulgate regulations to:

(1) Identify areas of credentialing;

(2) Establish procedures for initial application and renewal;

(3) Define the minimum competencies and standards to be examined;

(4) Define the qualifications for credentialing; and

(5) Define required continuing education, competencies, standards, and other information necessary to implement this chapter.

17-92-317. Criminal background checks

(a)

(1) Each applicant for a new intern or pharmacist license or a new or reinstated registration as a pharmacy technician issued by the Arkansas State Board of Pharmacy shall apply to the Identification Bureau of the Department of Arkansas State Police for a state and national criminal background check, to be conducted by the Federal Bureau of Investigation.

(2) However, the board may authorize the criminal background check obtained for a license or registration to be used for a subsequent application for another new license or registration issued by the board for a designated time period after the date of the original license or registration.

(b) The criminal background check shall conform to the applicable federal standards as in effect on January 1, 2003 and shall include the taking of fingerprints.

(c) The applicant shall sign a release of information to the board and shall be responsible to the Department of Arkansas State Police for the payment of any fee associated with the criminal background check.

(d) Upon completion of the criminal background check, the Identification Bureau of the Department of Arkansas State Police shall forward to the board all information obtained concerning the commission by the applicant of any offense listed in subsection (e) of this section.

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

(1) Any felony listed under § 17-2-102;

(2) Any act involving gross immorality, dishonesty, or which is related to the qualifications, functions, and duties of a person holding the license or registration; or

(3) Any violation of Arkansas pharmacy or drug law or regulations, including, but not limited to, this chapter, the Uniform Controlled Substances Act, § 5-64-101 et seq., and the Food, Drug, and Cosmetic Act, § 20-56-201 et seq.

(f)

(1)

(A) The board may issue a nonrenewable provisional license or registration pending the results of the criminal background check.

(B) The nonrenewable provisional license or registration shall be valid for no more than six (6) months.

(c) Upon receipt of information from the Identification Bureau of the Department of Arkansas State Police that the person holding the nonrenewable provisional license or registration has pleaded guilty or nolo contendere to, or has been found guilty of, any offense under subsection (e) of this section, the board shall immediately revoke the nonrenewable provisional license or registration.

(g)

(1) The provisions of subsection (e) of this section and subdivision (f)(2) of this section may be waived by the board upon the request of:

(A) An affected applicant for licensure or registration; or

(B) The person holding a license or registration subject to revocation.

(2) Circumstances for which a waiver may be granted shall include, but not be limited to:

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

(B) The circumstances surrounding the crime;

(C) The length of time since the crime;

(D) Subsequent work history;

(E) Employment references;

(F) Character references; and

(G) Other evidence demonstrating that the applicant does not pose a threat to the public health, safety, or welfare.

(h)

(1) Any information received by the board from the Identification Bureau of the Department of Arkansas State Police under this section shall not be available for examination except by:

(A) The affected applicant or the applicant's authorized representative; or

(B) The person whose license or registration is subject to revocation or his or her authorized representative.

(2) No record, file, or document shall be removed from the custody of the Department of Arkansas State Police.

(i) Only information pertaining to the person making the request may be made available to the affected applicant or the person whose license or registration is subject to revocation.

(j) Rights of privilege and confidentiality established in this section shall not extend to any document created for purposes other than the criminal background check.

(k) The board shall adopt the necessary rules and regulations to fully implement the provisions of this section.

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

(a) A pharmacy operating outside the state that routinely ships, mails, or delivers in any manner a dispensed legend drug into Arkansas or otherwise practices pharmacy in Arkansas shall hold a pharmacy license issued by the Arkansas State Board of Pharmacy, and that part of the pharmacy operation dispensing the prescription for an Arkansas resident shall abide by Arkansas law and regulations of the board.

(b)

(1) Any pharmacy operating outside the state that routinely ships, mails, or delivers in any manner a dispensed legend drug into Arkansas shall be required to have on staff in the out-of-state pharmacy an Arkansas-licensed pharmacist, who shall be designated the pharmacist-in-charge for the Arkansas out-of-state pharmacy license.

(2) If the out-of-state pharmacy fails to have on staff an Arkansas-licensed pharmacist due to extended illness, death, resignation, or for any other reason, the pharmacy within ten (10) calendar days shall notify the board of the fact and must within thirty (30) calendar days or such additional time at the discretion of the board not to exceed thirty (30) calendar days, either:

(A) Secure the services of an Arkansas-licensed pharmacist; or

(B) Cease to operate as a pharmacy in the State of Arkansas.

(c) An out-of-state pharmacy that ships, mails, or delivers in any manner a dispensed legend drug into Arkansas shall designate an agent who is a resident of Arkansas for service of process and register the agent with the Secretary of State.

(d) If under investigation for violation of this chapter, an out-of-state pharmacy shall be required to appear before the board to respond to questions concerning the investigation.

(e) The board shall have all the powers to enforce this chapter as are granted to the board under § 17-92-101 et seq.

17-92-402. Licensed pharmacist required

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

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

(b) It shall be unlawful for the proprietor of a store or pharmacy or other facility subject to this chapter to allow any person other than a licensed pharmacist to compound or dispense the prescriptions of authorized practitioners except as an aid to and under the supervision of a licensed pharmacist as provided in this chapter.

(c) However, any person who is not a licensed pharmacist may own or conduct a pharmacy or other facility as identified in § 17-92-403 if the owner keeps constantly in the pharmacy or other facility a licensed pharmacist subject to § 17-92-607.

(d) Any person violating the provisions of this act shall be guilty of a violation and upon conviction shall be liable to a fine of not less than five dollars ($5.00) nor more than one hundred dollars ($100).

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

(a) No person shall operate a pharmacy or other facility dispensing prescriptions as identified in this section or be issued a pharmacy permit or other permit issued by the Arkansas State Board of Pharmacy to facilities dispensing prescriptions unless an Arkansas-licensed pharmacist-in-charge is on duty in the drugstore or pharmacy a minimum of forty (40) hours per week or as otherwise provided in this chapter or by board regulation.

(b) In the absence of a licensed pharmacist, no one shall fill a prescription except a student serving as a graduate intern.

(c) If the owner of any pharmacy or other facility dispensing prescriptions as identified in this section fails to have on duty a licensed pharmacist-in-charge forty (40) hours per week or as otherwise provided in this chapter due to illness, death, resignation, or for any other reason, the owner shall within five (5) days notify the board of the fact and shall within thirty (30) days or such additional time at the discretion of the board either secure the services of a licensed pharmacist-in-charge or remove all prescription legend drugs and drug signs from the pharmacy or facility as identified in this section and cease to operate as a pharmacy or facility as identified in this section.

(d)

(1) The board shall provide by regulation for the issuance of permits for specialty pharmacies to which § 17-92-607 shall apply.

(2) The owners of specialty pharmacies shall have on duty a licensed pharmacist-in-charge whose minimum number of hours on duty shall be determined by board regulations regarding the nature of the pharmacy service provided.

(3) Specialty pharmacies dispensing prescriptions to in-house patients that are cared for on a twenty-four-hour-per-day basis must have a pharmacist on duty no less than forty (40) hours per week.

(4) The owners of specialty pharmacies shall abide by all provisions established for the employment of pharmacists in this chapter and board regulations.

(5) If the owner of any specialty pharmacy fails to have on duty a licensed pharmacist-in-charge as provided in subdivision (d)(2) or subdivision (d) (3) of this section due to illness, death, resignation, or for any other reason, the owner shall within five (5) days notify the board of the fact and shall within thirty (30) days, or such additional time as the board in its discretion may allow, either secure the services of a licensed pharmacist-in-charge or remove all prescription legend drugs and drug signs from the pharmacy and cease to operate the pharmacy.

(e) The board may provide by regulation for the issuance of hospital pharmaceutical permits to pharmacists employed in hospitals under which the pharmacist-in-charge employed in a hospital may have a flexible schedule of attendance and to which the requirement of a licensed pharmacist-in-charge on duty for a minimum of forty (40) hours a week shall not apply.

(f) The board shall provide for the issuance of ambulatory care center pharmaceutical services permits to entities so licensed by the Department of Health and that shall employ a licensed pharmacist-in-charge as provided by board regulation.

(g) The board shall provide by regulation for the issuance of institutional pharmacy permits to governmentally funded institutions that provide inpatient pharmaceutical services to persons confined to such institutions or in which drugs are administered to inpatients on orders of practitioners authorized by law to prescribe or administer the drugs and to which the requirement that the licensed pharmacist-in-charge on duty for a minimum of forty (40) hours a week shall not apply.

(h) The board may provide by regulation for the issuance of charitable clinic pharmacy permits to clinics operated on a nonprofit basis to furnish medical and dental care to poor and underprivileged persons and in which drugs are dispensed or administered to such persons on orders or prescriptions of practitioners authorized by law to prescribe or administer the drugs and to which the requirement of a licensed pharmacist-in-charge on duty for a minimum of forty (40) hours a week shall not apply.

17-92-404. Pharmacy permit required

(a) No person shall conduct any pharmacy or other facility as identified in § 17-92-403 in which practitioners' prescriptions are compounded and drugs are retailed or dispensed and in which a licensed pharmacist-in-charge must be employed unless the pharmacy or other facility as identified in § 17-92-403 has obtained a permit issued by the Arkansas State Board of Pharmacy.

(b)

(1) Keeping a pharmacy or other facility as identified in § 17-92-403 where drugs and medicines or chemicals are dispensed or sold or displayed for sale at retail or where prescriptions are compounded or which has on it a sign using the words “pharmacist”, “pharmaceutical chemist”, “apothecary”, “pharmacy”, “druggist”, “drug store”, “drugs”, or their equivalent in any language, or advertising such a store or shop as a drugstore, apothecary shop, or pharmacy by any method or means shall be prima facie evidence of the sale and dispensing of drugs.

(2) Unless the place so conducted holds a permit issued by the board, it shall be unlawful for any person, firm, or corporation:

(A) To carry on, conduct, or transact a retail business under any name that contains as a part thereof the words “drugs”, “drugstore”, “pharmacy”, “medicine”, “apothecary”, or “chemist shop” or any abbreviation, translation, extension, or variation thereof; or

(B) In the operation of any pharmacy or other facility as identified in § 17-92-403 in any manner by advertisement, circular, poster, telephone directory listing, sign, or otherwise, to describe or refer to the place of business conducted by such a person, firm, or corporation by such a term, abbreviation, translation, extension, or variation.

(3) Any person, firm, or corporation violating this subsection shall be guilty of a violation and, if a corporation, any officer thereof who participates in such a violation also shall be guilty of a violation and shall be punished by a fine of not less than twenty-five dollars ($25.00) nor more than three hundred dollars ($300).

(c)

(1) The control of the dispensing of medicines being essential to the protection of the public health and general welfare of the people, any violation of subsection (b) of this section may be enjoined by action in any court of competent jurisdiction at the instance of the board or of the owner of any licensed pharmacy.

(2) Proceedings under this subsection shall be governed by rules applicable to circuit courts.

17-92-405. Pharmacy permit--Application

(a)

(1) Upon application, the Arkansas State Board of Pharmacy shall issue a permit to maintain a pharmacy or other facility as described in § 17-92-403 or § 17-92-404 for the sale at retail or otherwise dispensing of drugs and medicines to such persons, firms, or corporations as the board may deem to be qualified to conduct such a pharmacy or other facility.

(2)

(A) The permit, to be known as a “pharmacy permit”, “specialty permit”, “hospital pharmaceutical services permit”, or “ambulatory care center pharmacy permit”, is for the compounding of practitioners' prescriptions and for the manufacture, sale, and distribution of drugs, medicines, and poisons.

(B) The pharmacy, specialty pharmacy, hospital pharmacy, or ambulatory care center pharmacy is to be under the direct supervision of a licensed pharmacist.

(3) All permits shall expire on December 31.

(b) Application for a permit shall be made in such a manner and in such a form as the board may determine.

(c) The permits shall at all times be displayed in a conspicuous place in the pharmacy or other facility as identified in § 17-92-403 for which the permit is issued.

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

17-92-407. Revocation--Grounds

(a) The Arkansas State Board of Pharmacy may revoke any permit issued under this subchapter in the event the holder thereof allows any person other than an Arkansas-licensed pharmacist or those students or graduates of a college of pharmacy serving an internship to fill prescriptions, compound and dispense drugs or medicines, or otherwise perform the duties and functions of a licensed pharmacist.

(b) Whenever any person, firm, partnership, estate, or corporation holding any permit issued under this subchapter obtains a permit by false representations or knowingly violates any of the pharmacy laws or fails to comply with the rules and regulations of the board passed by authority of the pharmacy laws, the board shall revoke the holder's pharmacy permit.

(c) The board shall also revoke any permit issued under this subchapter when information in possession of the board shall disclose that the operations for which the permit was issued are not being conducted according to law or are being conducted so as to endanger the public health or safety.

17-92-408. Revocation--Procedure

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

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

17-92-409. Pharmacy library required

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

17-92-410. Records of poison sales

(a) The proprietor shall at all times keep in his or her place of business a record book in which shall be entered all sales of the following, other than sales to physicians, dentists, veterinarians, and sales made on prescriptions of a physician, dentist, or veterinarian: arsenious acid, hydrocyanic acid, potassium cyanide, cyanide mixture, mercury bichloride, and strychnine and its salts, except in proper dosage in pill and tablet form.

(b)

(1) The record shall show in parallel columns: date of sale, name of article sold, quantity of article sold, purpose for which sold, name or initial of dispenser, and the signature and address of the purchaser. The record shall at all times during business hours be open for inspection by any police officer, sheriff, city or town representative, or any representative of the Arkansas State Board of Pharmacy and shall be preserved for a period of not less than two (2) years from the date of the last entry in the record.

(2) If the purchaser is a person not known to the seller, the seller shall require necessary identification to determine the true name and address of the purchaser.

17-92-411. Prescription content and labels

(a) Labels on original packages shall bear the label of the distributor or manufacturer, with the proper medicinal dose, if a remedy used internally. In the case of poisons, the word “POISON” shall be displayed thereon in a conspicuous manner with the antidote for a poisonous dose.

(b) A doctor of medicine or other person authorized to issue prescriptions, upon the request of the patient, shall indicate briefly and concisely on the prescriptions the conditions for which the medication is prescribed. Every pharmacist filling any such prescription shall include on the label of the prescription container the labeling as stated on the prescription issued.

17-92-412. Nursing home consultant permit

(a)

(1) The Arkansas State Board of Pharmacy shall provide for the issuance of nursing home consultant permits by regulation.

(2) The consultant pharmacist-in-charge and the nursing home administrator shall be jointly responsible to ensure that a valid permit is posted at the facility at all times.

(b) The board shall set by regulation the standards by which the controlled and legend drugs and devices will be maintained in the nursing home or long-term care facility.

(c) The consultant pharmacist-in-charge, in conjunction with the nursing home administrator and director of nurses, shall ensure the proper control and accountability, storage, and proper utilization of drugs and other legend devices dispensed to patients residing in the facility according to board standards as well as those established by state and federal guidelines.

17-92-501. Violations of provisions

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

17-92-502. Rules and regulations

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

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

(a)

(1)

(A) Except as provided in subsection (b) of this section, when a pharmacist receives a prescription for a brand or trade name drug product or biological product, the pharmacist may dispense a generically equivalent drug product or interchangeable biological product only when there will be a cost savings for the patient.

(B) The pharmacist shall disclose the amount of the cost savings at the request of the patient.

(2) The total amount charged for the substituted generically equivalent drug product or interchangeable biological product or for dispensing the drug product shall not exceed the amount normally and regularly charged under comparable circumstances by the pharmacist for that drug product or biological product or for the dispensing of that drug product or biological product.

(3) A pharmacist may not dispense a drug product or interchangeable biological product with a total charge that exceeds the total charge of the drug product or biological product originally prescribed unless agreed to by the purchaser.

(b) The pharmacist shall not dispense a generically equivalent drug product under subsection (a) of this section if:

(1) The prescriber, in the case of a prescription in writing signed by the prescriber, indicates in his or her own handwriting by name or initial that no substitution shall be made;

(2) The prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates that the prescription is to be dispensed as communicated;

(3) The person for whom the drug product or biological product is prescribed indicates that the prescription is to be dispensed as written or communicated; or

(4) The Arkansas State Board of Pharmacy has determined that the drug product or biological product should not be substituted and has notified all pharmacists of that determination.

(c)

(1) The Arkansas State Board of Pharmacy shall determine which drugs are generically equivalent and which biological products are interchangeable biological products as defined in § 17-92-101, relying on standards scientifically supported and generally accepted in the field of pharmacy, and shall notify each licensed pharmacist and the Arkansas State Medical Board of this determination.

(2) In making this determination, the Arkansas State Board of Pharmacy may use a nationally recognized reference source that meets the requirements of this act, notifying each licensed pharmacist and the Arkansas State Medical Board of the reference source to be used and any additions or deletions the Arkansas State Board of Pharmacy may make in its discretion.

(d)

(1) Within five (5) business days after dispensing an interchangeable biological product that has been substituted for a biological product, the dispensing pharmacist or his or her designee shall record the specific interchangeable biological product provided to the patient, including without limitation the name of the interchangeable biological product and the manufacturer of the interchangeable biological product.

(2) The record shall be electronically accessible to the prescriber through:

(A) An interoperable electronic medical records system;

(B) An electronic prescribing technology;

(C) A pharmacy benefit management system; or

(D) A pharmacy record.

(3) If requested by a prescriber, a pharmacist shall communicate to the prescriber within five (5) business days using facsimile, telephone, electronic transmission, or other prevailing means that an interchangeable biological product has been dispensed.

(4) A communication is not required when:

(A) An interchangeable biological product does not exist for the prescribed biological product; or

(B) A refill prescription for a biological product is not substituted with an interchangeable biological product on a subsequent filling of the prescription.

(5) The pharmacist or pharmacy shall maintain a record of biological products dispensed for at least two (2) years.

(6) Under subdivision (d)(2) of this section, the dispensing pharmacist or prescriber is not:

(A) Required to show proof that a prescriber has access to the record in any type of payment audit conducted by a payer or pharmacy benefit manager; or

(B) Subject to disciplinary action or civil penalties for failure to ensure that the record is accessible or for failure to access the record.

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

17-92-505. Labeling requirements

(a)

(1) The pharmacist filling a prescription for dispensing to an ultimate patient may affix to the container a label showing:

(A) The pharmacy name, address, and telephone number;

(B) The date of dispensing;

(C) The serial number of the prescription;

(D) The name of the patient;

(E) The name of the prescribing practitioner;

(F) Either:

(i) The trade name of the drug product, if any, or the generic name and identity of the manufacturer of the dispensed drug product, if the drug product appears generically listed on the drug formulary list as established by this subchapter; or

(ii) In the case of a biological product, the trade name of the biological product, if any, or the proper name of the biological product and identity of the manufacturer of the dispensed biological product;

(G) The strength per unit dose of the medication;

(H) The quantity of the medication; and

(I) Directions for use.

(2) If a pharmacist dispenses a generically equivalent product or interchangeable biological product, the person for whom the medication is prescribed shall be informed before dispensing or the label should appropriately indicate the substitution.

(3) This subsection does not apply to the dispensing of medication to inpatients in hospitals.

(4) In the case of dispensing a drug product or biological product, the prescribing practitioner may indicate that the name, manufacturer, and strength of the medication dispensed shall be deleted from the label.

(b) An authorized person who fills a prescription for dispensing to an ultimate patient shall affix to the container a label showing:

(1) The trade name of the medication or the generic name of the medication unless directed to the contrary by the prescribing practitioner; or

(2) The trade name, if any, or the proper name of the biological product unless directed to the contrary by the prescribing practitioner.

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

(a)

(1) A pharmacist may display, within the confines of the pharmacy, lists of available drug products and biological products, other than controlled substances, and current charges for the drug products or biological products or for the dispensing of the drug products or biological products in specified quantities.

(2) Upon request, a pharmacy may make such lists available to its customers and other members of the public.

(b) The Arkansas State Board of Pharmacy shall maintain on the website of the board a link to the lists of all interchangeable biological products approved by the United States Food and Drug Administration.

17-92-507. Maximum Allowable Cost Lists

(a) As used in this section:

(1)

(A) "Maximum Allowable Cost List" means a listing of drugs or other methodology used by a pharmacy benefits manager, directly or indirectly, setting the maximum allowable payment to a pharmacy or pharmacist for a generic drug, brand-name drug, biologic product, or other prescription drug.

(B) "Maximum Allowable Cost List" includes without limitation:

(i) Average acquisition cost, including national average drug acquisition cost;
(ii) Average manufacturer price;
(iii) Average wholesale price;
(iv) Brand effective rate or generic effective rate;
(v) Discount indexing;
(vi) Federal upper limits;
(vii) Wholesale acquisition cost; and
(viii) Any other term that a pharmacy benefits manager or a healthcare insurer may use to establish reimbursement rates to a pharmacist or pharmacy for pharmacist services;

(2) "Pharmaceutical wholesaler" means a person or entity that sells and distributes prescription pharmaceutical products, including without limitation a full line of brand-name, generic, and over-the-counter pharmaceuticals, and that offers regular and private delivery to a pharmacy;

(3) "Pharmacist" means a licensed pharmacist as defined in § 17-92-101;

(4) "Pharmacist services" means products, goods, and any combination of products, goods, and services, provided as a part of the practice of pharmacy as defined in § 17-92-101;

(5) "Pharmacy" means the same as in § 17-92-101;

(6) "Pharmacy acquisition cost" means the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy's billing invoice;

(7) "Pharmacy benefits manager" means an entity that administers or manages a pharmacy benefits plan or program;

(8) "Pharmacy benefits manager affiliate" means a pharmacy or pharmacist that directly or indirectly, through one (1) or more intermediaries, owns or controls, is owned or controlled by, or is under common ownership or control with a pharmacy benefits manager; and

(9) "Pharmacy benefits plan or program" means a plan or program that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services to individuals who reside in or are employed in this state.

(b) Before a pharmacy benefits manager places or continues a particular drug on a Maximum Allowable Cost List, the drug:

(1) If the drug is a generically equivalent drug as defined in § 17-92-101, shall be listed as therapeutically equivalent and pharmaceutically equivalent "A" or "B" rated in the United States Food and Drug Administration's most recent version of the "Orange Book" or "Green Book" or have an NR or NA rating by Medi-Span, Gold Standard, or a similar rating by a nationally recognized reference;

(2) Shall be available for purchase by each pharmacy in the state from national or regional wholesalers operating in Arkansas; and

(3) Shall not be obsolete.

(c) A pharmacy benefits manager shall:

(1) Provide access to its Maximum Allowable Cost List to each pharmacy subject to the Maximum Allowable Cost List;

(2) Update its Maximum Allowable Cost List on a timely basis, but in no event longer than seven (7) calendar days from an increase of ten percent (10%) or more in the pharmacy acquisition cost from sixty percent (60%) or more of the pharmaceutical wholesalers doing business in the state or a change in the methodology on which the Maximum Allowable Cost List is based or in the value of a variable involved in the methodology;

(3) Provide a process for each pharmacy subject to the Maximum Allowable Cost List to receive prompt notification of an update to the Maximum Allowable Cost List; and

(4)

(A)

(i) Provide a reasonable administrative appeal procedure to allow pharmacies to challenge maximum allowable cost list and reimbursements made under a maximum allowable cost list for a specific drug or drugs as:

(a) Not meeting the requirements of this section; or

(b) Being below the pharmacy acquisition cost.

(ii) The reasonable administrative appeal procedure shall include the following:

(a) A dedicated telephone number, email address, and website for the purpose of submitting administrative appeals;

(b) The ability to submit an administrative appeal directly to the pharmacy benefits manager regarding the pharmacy benefits plan or program or through a pharmacy service administrative organization; and

(c) No less than thirty (30) business days to file an administrative appeal.

(B) The pharmacy benefits manager shall respond to the challenge under subdivision (c)(4)(A) of this section within thirty (30) business days after receipt of the challenge.

(C) If a challenge is under subdivision (c)(4)(A) of this section, the pharmacy benefits manager shall within thirty (30) business days after receipt of the challenge either:

(i) If the appeal is upheld:

(a) Make the change in the maximum allowable cost list payment to at least the pharmacy acquisition cost;

(b) Permit the challenging pharmacy or pharmacist to reverse and rebill the claim in question;

(c) Provide the National Drug Code number that the increase or change is based on to the pharmacy or pharmacist; and

(d) Make the change under subdivision (c)(4)(C)(i)(a) of this section effective for each similarly situated pharmacy as defined by the payor subject to the Maximum Allowable Cost List;

(ii) If the appeal is denied, provide the challenging pharmacy or pharmacist the National Drug Code number and the name of the national or regional pharmaceutical wholesalers operating in Arkansas that have the drug currently in stock at a price below the Maximum Allowable Cost List; or

(iii) If the National Drug Code number provided by the pharmacy benefits manager is not available below the pharmacy acquisition cost from the pharmaceutical wholesaler from whom the pharmacy or pharmacist purchases the majority of prescription drugs for resale, then the pharmacy benefits manager shall adjust the Maximum Allowable Cost List above the challenging pharmacy's pharmacy acquisition cost and permit the pharmacy to reverse and rebill each claim affected by the inability to procure the drug at a cost that is equal to or less than the previously challenged maximum allowable cost.

(d)

(1) A pharmacy benefits manager shall not reimburse a pharmacy or pharmacist in the state an amount less than the amount that the pharmacy benefits manager reimburses a pharmacy benefits manager affiliate for providing the same pharmacist services.

(2) The amount shall be calculated on a per unit basis based on the same generic product identifier or generic code number.

(e) A pharmacy or pharmacist may decline to provide the pharmacist services to a patient or pharmacy benefits manager if, as a result of a Maximum Allowable Cost List, a pharmacy or pharmacist is to be paid less than the pharmacy acquisition cost of the pharmacy providing pharmacist services.

(f)

(1) This section does not apply to a Maximum Allowable Cost List maintained by the Arkansas Medicaid Program or the Employee Benefits Division of the Department of Finance and Administration.

(2) This section shall apply to the pharmacy benefits manager employed by the Arkansas Medicaid Program or the Employee Benefits Division if, at any time, the Arkansas Medicaid Program or the Employee Benefits Division engages the services of a pharmacy benefits manager to maintain a Maximum Allowable Cost List.

(g)

(1) A violation of this section is a deceptive and unconscionable trade practice under the Deceptive Trade Practices Act, § 4-88-101 et seq., and a prohibited practice under the Arkansas Pharmacy Benefits Manager Licensure Act, § 23-92-501 et seq., and the Trade Practices Act, § 23-66-201 et seq.

(2) This section is not subject to § 4-88-113(f)(1)(B).

17-92-601. Citation

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

17-92-602. Definitions

As used in this subchapter:

(1) "Board" means the Arkansas State Board of Pharmacy;

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

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

(4) "Hospital pharmacy" means the place or places in which drugs, chemicals, medicines, prescriptions, or poisons are prepared for distribution and administration for the use or benefit of patients in a hospital. The "hospital pharmacy" may also provide pharmacy services to patients in a "swing bed" within the hospital that may periodically swing back and forth from being a short-term acute hospital bed to a longer-term nursing home bed. The "hospital pharmacy" shall also mean the place or places in which drugs, chemicals, medicines, prescriptions, or poisons are compounded for the dispensing to hospital employees, members of the immediate families of hospital employees, patients being discharged, and for other persons in emergency situations;

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

(6) "Licensed pharmacist" means any person licensed to practice pharmacy by the board.

17-92-604. Regulatory authority

(a) The Arkansas State Board of Pharmacy shall adopt, promulgate, and enforce rules and standards as may be necessary to the regulation of the operation of a hospital pharmacy and for the accomplishment of all other purposes of this subchapter.

(b) The board may modify, amend, or rescind the rules and standards, provided the modification, amendment, or rescission does not in any manner defeat the purposes of this subchapter.

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

(a) All hospital pharmacies shall be licensed by the Arkansas State Board of Pharmacy as provided for by this subchapter. The hospital pharmacy license shall be issued in the name of the hospital.

(b) Any hospital receiving a permit shall advise the board of the name of:

(1) The hospital administrator or other person assuming responsibility for the general administration of the hospital;

(2) The director of the pharmacy, or other person assuming responsibility for the general operation of the hospital pharmacy, who shall be a licensed pharmacist; and

(3) All other licensed pharmacists employed by the hospital in its hospital pharmacy.

(c) The hospital and the director of pharmacy shall be required to report to the board any change in licensed pharmacist personnel.

(d) Upon the receipt of a hospital pharmacy license, a hospital pharmacy may provide the following pharmaceutical services:

(1) Prepare for distribution and administration of drugs, chemicals, medicines, prescriptions, or poisons for

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

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

17-92-606. Hospital pharmaceutical permit

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

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

(a) It shall be unlawful for any nonprofit, tax exempt, or governmentally funded hospital to acquire direct or indirect interest in or otherwise hold directly or indirectly a licensed pharmacy permit pursuant to the provisions of § 17-92-405, for the sale at retail of drugs and medicines.

(b) However, nothing contained in this section shall be construed to prohibit any hospital having a direct or indirect interest in or otherwise holding either directly or indirectly a permit prior to March 28, 1975, from continuing to have an interest in or holding the permit. Nothing contained in this section shall be construed to prohibit any hospital so holding a permit prior to March 28, 1975, from receiving a renewal of the permit.

17-92-701. Definitions

As used in this subchapter:

(1) "Board" means the Arkansas State Board of Pharmacy;

(2) "Board-approved intervenors" means persons trained in intervention and designated by the board to implement the intervention process when necessary;

(3) "Committee" means a committee appointed by the board to formulate and administer the impaired pharmacists program;

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

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

(6) "Intervention" means a process whereby an allegedly impaired pharmacist is confronted by the board or board-approved intervenors who provide documentation that a problem exists and attempt to convince the pharmacist to seek evaluation and treatment;

(7) "Rehabilitation" means the process whereby an impaired pharmacist advances in an impaired pharmacist program to an optimal level of competence to practice pharmacy without endangering the public; and

(8) "Verification" means a process whereby alleged professional impairment is identified or established.

17-92-702. Administration

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

shall fulfill two (2) functions:

(1) The program shall serve as a diversion program to which the board may refer licensees when appropriate in lieu of or in addition to other disciplinary action; and

(2) The program shall also be a source of treatment or referral for pharmacists who, on a strictly voluntary basis, desire to avail themselves of its services.

(b) The board may appoint a committee of five (5) persons who are recovering pharmacists to serve three-year terms with the initial members appointed to staggered terms.

17-92-703. Functions

The functions of the committee shall include:

(1) Evaluation of pharmacists who request participation in the program;

(2) Review and designation of treatment facilities and services to which pharmacists in the program may be referred;

(3) Receipt and review of information relating to the participation of pharmacists in the program;

(4) Assisting the pharmacists' professional association in publicizing the program; and

(5) Preparation of reports for the Arkansas State Board of Pharmacy.

17-92-704. Board review

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

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

(a) The Arkansas State Board of Pharmacy shall inform each pharmacist referred to the program by board action of the procedures followed in the program, of the rights and responsibilities of the pharmacist in the program, and of the possible consequences of noncompliance with the program.

(b) The board shall be informed of the failure of a pharmacist to comply with any treatment provision of a program if the committee determines that the resumption of the practice of pharmacy would pose a threat to the health and safety of the public.

(c) Participation in a program under this section shall not be a defense to any disciplinary action which may be taken by the board. Further, no provision of this section shall preclude the board from commencing disciplinary action against a licensee who is terminated from a program pursuant to this section.

(d) The board shall be informed when pharmacists who enter the program resume professional practice.

17-92-706. Funding

(a)

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

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

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

17-92-707. Liability

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

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

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

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

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

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

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

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

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

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

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

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

17-92-901. Definitions

As used in this subchapter:

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

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

(3) "Legend device" means a device which, because of any potential for harmful effect or the method of its use, is not safe except under the supervision of a practitioner;

(4)

(A) "Medical equipment" means technologically sophisticated medical devices, including, but not limited to:

(i) Oxygen and oxygen delivery systems;

(ii) Ventilators;

(iii) Respiratory disease management devices;

(iv) Electronic and computer-driven wheelchairs and seating systems;

(v) Apnea monitors;

(vi) Transcutaneous electrical nerve stimulator units;

(vii) Low air loss cutaneous pressure management devices;

(viii) Sequential compression devices;

(ix) Neonatal home phototherapy devices;

(x) Feeding pumps;

(xi) Electrically powered hospital beds; and

(xii) Infusion pumps.

(B) "Medical equipment" does not include:

(i) Medical equipment used or dispensed in the normal course of treating patients by hospitals, hospices, nursing facilities, or home health agencies;

(ii) Medical equipment used or dispensed by health care professionals licensed in Arkansas, provided that the professional is practicing within the scope of that professional's practice act;

(iii) Upper and lower extremity prosthetics and related orthotics; or

(iv) Canes, crutches, walkers, bathtub grab bars, standard wheelchairs, commode chairs, and bath benches;

(5) "Medical gas" means those gases and liquid oxygen intended for human consumption; and

(6) "Order" means an order issued by a licensed medical practitioner legally authorized to order medical gases or legend devices, or both.

17-92-902. License required

(a)

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

(2) The licensure requirements of this subchapter will apply to all companies, agencies, and other business entities that are in the business of supplying medical equipment to patients in their residences and that bill the patient or the patient's insurance, Medicare, Medicaid, or other third-party payor for the rent or sale of that equipment.

(b)

(1) The application for a license shall be on a form furnished by the Arkansas State Board of Pharmacy and shall be accompanied by payment of the fee prescribed by § 17-92-108.

(2) The board shall require a separate license for each facility directly or indirectly owned or operated within this state by the same person or business entity within this state, or for a parent entity with divisions, subdivisions, subsidiaries, or affiliate companies, or any combination thereof, when operations are conducted at more than one (1) location and there exists joint ownership and control among all the entities.

(c)

(1) All licenses issued under this subchapter shall expire on December 31 of each calendar year.

(2)

(A) Each application for renewal of the license must be made on or before December 31 of each year.

(B) Penalties for late payment include:

(i) A twenty-dollar penalty if not paid by February 1 of each year; and

(ii) A forty-dollar penalty if not paid by March 1 of each year.

(C) The license shall be considered null and void if the fee is not paid by April 1 of each year.

(d) Wholesale distributors licensed under § 20-64-501 et seq. may exchange those licenses for licenses issued under this subchapter without payment of additional fees.

(e) Each license issued hereunder shall be displayed by the holder thereof in a conspicuous place.

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

(a) The licensure requirements of this subchapter and any retail pharmacy permit requirements that may apply to the distribution or provision of legend medical gases, medical equipment, legend devices, and medical supplies, except legend drugs, do not apply to the following unless the following have a separate company, corporation, division, or other business entity that is in the business of providing medical equipment for sale or rent to a patient at his or her home as covered by this subchapter:

(1) Home health agencies;

(2) Hospitals;

(3) Manufacturers and wholesale distributors when not selling directly to the patient;

(4) Health care practitioners legally eligible to prescribe or order home medical equipment, medical gases, and legend devices;

(5) Medical doctors, physical therapists, respiratory therapists, occupational therapists, speech pathologists, optometrists, chiropractors, and podiatrists who use home medical equipment or legend devices, or both,

to treat patients;

(6) Nurses who use but do not sell home medical equipment or legend devices, or both, to their patients;

(7) Pharmacies;

(8) Hospice programs;

(9) Nursing homes;

(10) Veterinarians;

(11) Dentists; and

(12) Emergency medical services.

(b) Although excluded from a separate licensure requirement for medical equipment, pharmacies shall be subject to the same rules and regulations for the sale or rental of medical equipment covered by this subchapter.

17-92-904. Supply order required

(a) Home medical equipment, legend device, and medical gas suppliers shall not supply medical gases or legend devices to a patient without an order.

(b)

(1) Orders may be issued for institutional, medical practitioner, and individual patient use.

(2) It is also recognized that oxygen, liquid oxygen, and legend devices may be used in emergencies by trained individuals.

(3) Nothing in this subchapter shall prohibit the prehospital emergency administration of oxygen by licensed health care providers, emergency medical technicians, first responders, firefighters, law enforcement officers, and other emergency personnel trained in the proper use of emergency oxygen.

17-92-905. Labeling

(a) Medical gases shall be labeled in compliance with existing federal and state laws.

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

17-92-906. Regulations

(a)

(1) The Arkansas State Board of Pharmacy shall adopt regulations for the distribution of home medical equipment, legend devices, and medical gases which promote the public health and welfare and which comply with, at least, the minimum standards, terms, and conditions of federal laws and federal regulations.

(2) The regulations shall include, without limitation:

(A) Minimum information from each home medical equipment, legend device, and medical gas supplier required for licensing and renewal of licenses;

(B) Minimum qualifications of persons who engage in the distribution of these products;

(C) Appropriate education or experience, or both, of persons employed in distribution of these products who assume responsibility for positions related to compliance with state licensing requirements;

(D) Minimum requirements for the storage and handling of these products;

(E) Minimum requirements for the establishment and maintenance of distribution records for these products; and

(F) Federal and state labeling requirements.

(b) State regulations shall not apply to the following:

(1) Home health agencies;

(2) Hospitals;

(3) Manufacturers and wholesale distributors when not selling directly to the patient;

(4) Health care practitioners legally eligible to prescribe or order home medical equipment, medical gases, and legend devices;

(5) Medical doctors, physical therapists, respiratory therapists, occupational therapists, speech pathologists, optometrists, chiropractors, and podiatrists who use home medical equipment or legend devices, or both, to treat patients;

(6) Nurses who use but do not sell home medical equipment or legend devices, or both, to their patients;

(7) Hospice programs;

(8) Nursing homes; and

(9) Veterinarians.

(c) No regulations promulgated to implement this subchapter shall be effective until they have been reviewed by the House Committee on Public Health, Welfare, and Labor and the Senate Committee on Public Health, Welfare, and Labor or appropriate subcommittees thereof.

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

(a) The manufacture within this state, shipment into this state, or sale or offer for sale within this state of medical gases shall not be subject to § 20-56-211(11)(C).

(b)

(1) Pursuant to this subchapter, the dispensing of medical gases does not require a retail pharmacy permit.

(2) The sale of medical gases directly to patients shall not be subject to § 20-56-211(11)(C) or § 20-64-504.

17-92-908. Revocation or suspension of license

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

(1) Violation of any federal, state, or local law or regulation relating to medical equipment, medical gases, and medical supplies, except legend drugs and legend devices;

(2) Violation of any provisions of this subchapter or any regulation promulgated hereunder; or

(3) Commission of an act or engaging in a course of conduct which constitutes a clear and present danger to the public health and safety.

17-92-1001. Title

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

17-92-1002. Purpose

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

(1) Make certain disclosures on their Internet sites;

(2) List the principals, pharmacists, and physicians associated with the Internet sites; and

(3) Include amending licensing requirements for pharmacists and physicians to address prescribing and dispensing medication via the Internet.

17-92-1003. Definitions

As used in this subchapter:

(1) "Deliver" means the actual, constructive, or attempted transfer from one (1) person to another of any drug whether or not an agency relationship exists;

(2) "Dispense" means to deliver prescription medication to the ultimate user or research subject pursuant to the lawful order of a practitioner or pursuant to the prescription of a mid-level practitioner;

(3) "Distribute" means to deliver, other than by administering or dispensing, any drug;

(4) "Electronic mail" means any message transmitted through the international network of interconnected government, educational, and commercial computer networks, including without limitation messages transmitted from or to any address affiliated with an Internet site;

(5) "Foreign entity" means any corporation, limited liability company, or other body corporate organized under the law of any jurisdiction other than the State of Arkansas;

(6) "Internet broker" means an entity that serves as an agent or intermediary or other capacity that causes the Internet to be used to bring together a buyer and seller to engage in the dispensing of prescription-only drugs;

(7) "Internet site" means a specific location on the international network of interconnected government, educational, and commercial computer networks that is determined by Internet protocol numbers, by a domain name, or by both, including without limitation domain names that use the designations ".com", ".edu", ".gov", ".org", and ".net";

(8) "Person" means any individual, corporation, partnership, limited liability company, limited liability partnership, limited partnership, association, joint venture, or any other legal or commercial entity, whether foreign or

domestic;

(9) "Pharmacist" means any natural person licensed under this subchapter to practice pharmacy;

(10) "Pharmacy", "drug store", or "apothecary" means premises, laboratory, area, or other place:

(A) Where drugs are offered for sale, where the profession of pharmacy is practiced, and where prescriptions are compounded and dispensed;

(B) Which has displayed upon it or within it the words "pharmacist", "pharmaceutical chemist", "pharmacy", "apothecary", "drugstore", "druggist", "drugs", "drug sundries", or any of these words or combination of these words; or

(C) Where the characteristic symbols of pharmacy or the characteristic prescription sign "Rx" may be exhibited;

(11) "Practitioner" means:

(A) A person licensed to practice medicine and surgery, dentistry, podiatry, veterinary medicine, or optometry licensed under the optometry law as a therapeutic licensee or diagnostic and therapeutic licensee; or

(B) A scientific investigator or other person authorized by law to use a prescription-only drug in teaching or chemical analysis or to conduct research with respect to a prescription-only drug;

(12) "Premises" means the portion of any building or structure leased, used, or controlled by the licensee in the conduct of the business registered by the Arkansas State Board of Pharmacy at the address for which the registration was issued;

(13)

(A) "Prescription-only drug" means any drug, whether intended for use by man or animal, required by federal or state law to be dispensed only pursuant to a written or oral prescription or order of a practitioner or that is restricted to use by practitioners only.

(B) "Prescription-only drug" does not mean contact lenses;

(14)

(A) "Prescription order" means:

(i) An order to be filled by a pharmacist for prescription medication issued and signed by a practitioner or a mid-level practitioner in the authorized course of professional practice; or

(ii) An order transmitted to a pharmacist through word of mouth, note, telephone, or other means of communication directed by the practitioner or mid-level practitioner.

(B) In the absence of a prior and proper patient-practitioner relationship, "prescription order" does not include an order for a prescription-only drug issued solely in response to:

(i) An Internet questionnaire;

(ii) An Internet consultation; or

(iii) A telephonic consultation; and

(15) "Proper practitioner-patient relationship" means that before the issuance of a prescription, a practitioner,

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

(A) The prescribing practitioner is consulting at the specific request of another practitioner who:

(i) Maintains an ongoing relationship with the patient;

(ii) Has performed an in-person physical examination of the patient; and

(iii) Has agreed to supervise the patient's ongoing care and use of prescribed medications; or

(B) The prescribing practitioner interacts with the patient through an on-call or cross-coverage situation; or

(C) The relationship is established through telemedicine pursuant to the Telemedicine Act, § 17-80-401 et seq.

17-92-1004. Requirements for Internet sales

(a) A pharmacy operating within or outside Arkansas shall not sell, dispense, distribute, deliver, or participate in the sale, dispensing, distribution, or delivery of a prescription-only drug to any consumer in this state through an Internet site or by electronic mail unless:

(1) All Internet sites and electronic mail used by the person for purposes of sales or delivery of a prescription-only drug are in compliance with all requirements of federal law applicable to the Internet site or electronic mail;

(2)

(A) The pharmacy that sells, dispenses, distributes, or delivers the prescription-only drug is in compliance with all requirements of relevant state law.

(B) The pharmacy shall be properly regulated by the Arkansas State Board of Pharmacy to engage in the practice of pharmacy pursuant to § 17-92-101 et seq.;

(3) The pharmacist who fills the prescription order is in compliance with subsection (c) of this section;

(4)

(A) Any pharmacy that participates in the sale of a prescription-only drug is in compliance with subsection (d) of this section.

(B) Any pharmacy that participates in the sale of a prescription-only drug is in compliance with an Arkansas prescription drug monitoring program, if an Arkansas prescription drug monitoring program exists;

(5)

(A) The pharmacy, if a foreign entity, is registered with the Secretary of State and is in compliance with all requirements for foreign corporations provided in any applicable state law.

(B) Nothing in this subdivision (a)(5) shall be construed to authorize any corporation to engage in the practice of medicine contrary to any applicable Arkansas law; and

(6) Any practitioner who sells, dispenses, distributes, or delivers the prescription-only drug is in compliance with all requirements of relevant state law.

(b) Any practitioner who writes a prescription order through an Internet site or electronic mail for a consumer

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

(c) A pharmacist practicing within or outside Arkansas may not fill a prescription order to dispense a prescription-only drug to a patient if the pharmacist knows or reasonably should have known under the circumstances that the prescription order was issued:

(1) On the basis of:

(A) An Internet questionnaire;

(B) An Internet consultation; or

(C) A telephonic consultation; and

(2) Without a valid prior patient-practitioner relationship.

(d)

(1) An Internet broker operating within or outside Arkansas may participate in the sale of a prescription-only drug in this state only if the Internet broker knows that the pharmacist who dispenses the drug has complied with the requirements of subsection (c) of this section.

(2) The board shall report to the Attorney General any violations of subdivision (d)(1) of this section.

17-92-1005. Requirements for Internet sites

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

(1) Name of each pharmacy that causes the sale, dispensing, or delivery of a prescription-only drug to any consumer in this state;

(2) Address of the principal place of business of each pharmacy that causes the sale, dispensing, or delivery of a prescription-only drug to any consumer in this state;

(3) Telephone number of each pharmacy that causes the sale, dispensing, or delivery of a prescription-only drug to any consumer or other person in this state; and

(4) Pharmacy's:

(A) Permit number assigned by the Arkansas State Board of Pharmacy; or

(B) Certification by the National Association of Boards of Pharmacy as a Verified Internet Pharmacy Practice Sites site and the Verified Internet Pharmacy Practice Sites seal with a link to the National Association of Boards of Pharmacy's verification site.

17-92-1006. Disclaimers or limitations of liabilities

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

(b) Any disclaimer, limitation, or waiver in violation of this section is void.

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

17-92-1007. Enforcement

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

17-92-1101. Purpose

It is the purpose of this subchapter to:

(1) Improve the health of needy Arkansans through a prescription drug redispensing program that authorizes charitable clinic pharmacies to redispense medicines that would otherwise be destroyed; and

(2) Reaffirm the existing broad latitude of the Arkansas State Board of Pharmacy to protect the safety of the prescription drug supply in this state.

17-92-1102. Definitions

As used in this subchapter:

(1) "Charitable clinic" means a charitable nonprofit corporation or a facility organized as a not-for-profit corporation under §§ 4-28-201--4-28-206 and 4-28-209--4-28-224 that:

(A) Holds a valid exemption from federal income taxation issued pursuant to section 501(a) of the Internal Revenue Code;

(B) Is listed as an exempt organization under section 501(c)(3) of the Internal Revenue Code;

(C) Provides advice, counseling, diagnosis, treatment, surgery, care, or services relating to the preservation or maintenance of health on an outpatient basis for a period of less than twenty-four (24) consecutive hours to persons not residing or confined at the facility;

(D) May charge an administrative fee or request a donation not to exceed ten dollars ($10.00) per visit; and

(E) Has a licensed outpatient pharmacy;

(2) "Charitable clinic pharmacy" means the practice of a pharmacy at a site where prescriptions are dispensed by a charitable clinic free of charge to appropriately screened and qualified indigent patients;

(3) "Controlled substances" means substances defined by the Uniform Controlled Substances Act, §§ 5-64-101--5-64-510;

(4) "Indigent" means a person with an income that is below two hundred percent (200%) of the federal poverty level;

(5) "Nursing facility" means the same as under § 20-10-1401;

(6)

(A)

(i) "Prescription drug" means a drug limited by section 503(b)(1) of the Federal Food, Drug, and

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

(a) Habit-forming;

(b) Toxic or having potential for harm; or

(c) Limited in its use to use under a practitioner's supervision by the new drug application for the drug.

(ii) The product label of a legend drug is required to contain the statement:

(a) "CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION"; or

(b) "Rx only".

(iii) The drug is subject to the requirement of section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act which shall be exempt from section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., if certain specified conditions are met.

(B) "Prescription drug" does not include controlled substances; and

(7) "Properly transferred" means the storage, handling, and distribution of the drug under this subchapter in:

(A) Accordance with the label; and

(B) Its dispensed, sealed, tamper-evident single-user unit.

17-92-1103. Prescription drug redispensing program

(a) The prescription drug redispensing program established by this subchapter shall be a pilot program to determine the efficacy of redispensing prescription drugs to indigent patients.

(b) In cooperation with the Department of Health and the Department of Human Services, the Arkansas State Board of Pharmacy shall develop and implement the program consistently with public health and safety through which unused prescription medications other than controlled substances may be transferred from a nursing facility to a charitable clinic pharmacy for the purpose of distributing the medication to Arkansas residents who are indigent.

(c) In cooperation with the Department of Health and the Department of Human Services, the board shall monitor the program and submit to the General Assembly two (2) reports along with any recommendations or findings, as follows:

(1) The first report shall be submitted on or before January 1, 2006; and

(2) The second report shall be submitted on or before October 1, 2006.

(d) Participation in the program by any entity, including individuals, pharmacies, charitable clinics, charitable clinic pharmacies, nursing facilities, and drug manufacturers, shall be voluntary.

17-92-1104. Donations of unused prescription drugs

(a)

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

clinic pharmacy for relabeling and dispensing free of charge and pursuant to a valid prescription order to an indigent patient.

(2) The donor patient shall be considered to be the owner of the prescription drug and entitled to donate the prescription drug for use by a charitable clinic.

(b)

(1)

(A)

(i) Any nursing home may enter into a contract with any charitable clinic for the transfer of prescription drugs under this section.

(ii) No prescription drugs may be transferred without a contract.

(B) A contract entered into under subdivision (b)(1)(A) of this section shall:

(i) Be approved by the Arkansas State Board of Pharmacy, in cooperation with the Department of Health and the Department of Human Services; and

(ii) Set out procedures for ensuring a safe chain of custody to protect the safety of all transferred drugs.

(C) The contract may specify that the charitable clinic will:

(i) Define a specified set of prescription drugs that will be transferred from the nursing home to the charitable clinic;

(ii) Request from time to time the transfer of particular prescription drugs;

(iii) Receive all the prescription drugs that the nursing home is authorized to transfer under this section; or

(iv) Make such other provisions as may be approved by the board.

(2) The pharmacist-in-charge at the charitable clinic shall be responsible for determining the description of the prescription drugs that will be included in the contract.

(c) Donations of prescription drugs to a charitable clinic pharmacy shall meet the following requirements:

(1)

(A) The charitable clinic pharmacy accepts the prescription drugs only in their original sealed and tamper-evident packaging.

(B) However, the charitable clinic pharmacy may accept prescription drugs packaged in single-unit doses or blister packs with the outside packaging opened if the single-unit dose packaging remains intact;

(2) A pharmacist of the charitable clinic pharmacy determines that the prescription drug is not adulterated or misbranded and is safe to dispense;

(3) No product of which the integrity cannot be assured is accepted for redispensing by the pharmacist of the charitable clinic pharmacy;

(4) The prescription drugs are physically transferred from the nursing facility to a charitable clinic pharmacy

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

(5)

(A) The donor executes a form stating that the donor is authorized to donate the prescription drugs and intends to voluntarily donate them to a charitable clinic pharmacy.

(B) The nursing facility retains the donor form along with other acquisition records;

(6) The donor patient's name, prescription number, and any other identifying marks are obliterated from the packaging before the nursing facility sends the prescription drug to the charitable clinic;

(7) The drug name, strength, and expiration date remain on the prescription drug package label;

(8) The redispensed prescription drug is assigned the same expiration date as on the original package;

(9) Expired prescription drugs accepted by a charitable clinic pharmacy are not redispensed and are destroyed according to the charitable clinic pharmacy's destruction procedures; and

(10) The charitable clinic pharmacy accepts no controlled substances.

(d)

(1) If a nursing facility that releases prescription drugs to a charitable clinic receives notice from a pharmacy that a prescription drug has been recalled, the nursing facility shall inform the clinic of the recall.

(2) If a charitable clinic receives a recall notification from a nursing facility, the clinic shall perform a uniform destruction of all of the recalled prescription drug in the facility.

(e) No prescription drug dispensed through a charitable clinic pharmacy shall be eligible for reimbursement from the state Medicaid program.

(f) Indigent patients receiving prescription drugs through the prescription drug redispensing program shall sign a waiver form releasing the nursing facility, the donor, and the donor's estate from liability.

(g) The board shall promulgate rules to develop:

(1) Forms and procedures for authorizations and certifications required under subdivision (c)(4) of this section;

(2) The donor consent form required under subdivision (c)(5) of this section;

(3) The waiver forms required under subsection (f) of this section; and

(4)

(A) Specific requirements for a charitable clinic pharmacy or other specialty pharmacy for the medically indigent as defined by rules of the board to qualify for participation in and to participate in the prescription drug redispensing program.

(B) On request, the board shall provide the information required under subdivision (g)(4)(A) of this section to charitable clinics.

(h)

(1) The following persons and entities that participate in the prescription drug redispensing program shall not be subject to any professional disciplinary action or criminal prosecution for actions taken under the prescription drug redispensing program:

(A) The donor and the donor's estate;

(B) A nursing facility;

(C) The prescribing physician, physician's assistant, registered nurse, advanced practice nurse, or nurse practitioner;

(D) Pharmacists and pharmacy technicians except when the board has promulgated regulations dealing specifically with the prescription drug redispensing program;

(E) The charitable clinic;

(F) The Department of Health;

(G) The Department of Human Services; or

(H) The board.

(2) Participation in the prescription drug redispensing program shall not be used as an independent basis for a claim of liability in tort or other civil action against any person or entity, including, but not limited to:

(A) The donor and the donor's estate;

(B) A nursing facility;

(C) The prescribing physician, physician's assistant, nurse practitioner, or nurse;

(D) The charitable clinic;

(E) The charitable clinic pharmacy acting in conformity with board regulations;

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

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

(H) The Department of Health;

(I) The Department of Human Services; or

(J) The board.

(3)

(A) In the absence of bad faith, a prescription drug manufacturer shall not be subject to criminal prosecution or liability in tort or other civil action for injury, death, or loss to person or property for matters related to the donation, acceptance, or dispensing of a prescription drug manufactured by the prescription drug manufacturer that is donated by any person under the prescription drug redispensing program, including, but not limited to, liability for failure to provide:

(i) Product or consumer package insert information; or

(ii) The expiration date of the donated prescription drug.

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

17-92-1105. Sample drug use not restricted

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

17-92-1106. Resale prohibited

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

17-92-1107. Applicability

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

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

(a) This subchapter shall be known and may be cited as the "Arkansas Pharmacy Audit Bill of Rights".

(b) Notwithstanding any other law, when an audit of the records of a pharmacy is conducted by a managed care company, an insurance company, a third-party payor, or any entity that represents responsible parties such as companies or groups, the audit shall be conducted in accordance with the following bill of rights:

(1) The entity conducting the initial on-site audit shall give the pharmacy notice at least one (1) week before conducting the initial on-site audit for each audit cycle;

(2) Any audit that involves clinical or professional judgment shall be conducted by or in consultation with a pharmacist;

(3)

(A)

(i) Any clerical or recordkeeping error, such as a typographical error, scrivener's error, or computer error, regarding a required document or record shall not in and of itself constitute fraud.

(ii) However, a claim arising under subdivision (b)(3)(A)(i) of this section may be subject to recoupment.

(B) A claim arising under subdivision (b)(3)(A)(i) of this section is not subject to criminal penalties without proof of intent to commit fraud;

(4) A pharmacy may use the records of a hospital, physician, or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug;

(5)

(A) A finding of an overpayment or underpayment may be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs.

(B) However, recoupment of claims under subdivision (b)(5)(A) of this section shall be based on the actual overpayment unless the projection for overpayment or underpayment is part of a settlement by the pharmacy;

(6)

(A) Where an audit is for a specifically identified problem that has been disclosed to the pharmacy, the audit shall be limited to claims that are identified by prescription number.

(B) For an audit other than described in subdivision (b)(6)(A) of this section, an audit shall be limited to
twenty-five (25) prescriptions that have been randomly selected.

(C) If an audit reveals the necessity for a review of additional claims, the audit shall be conducted on site.

(D) Except for audits initiated under subdivision (b)(6)(A) of this section, an entity shall not initiate an audit of a pharmacy more than two (2) times in a calendar year;

(7)

(A) A recoupment shall not be based on:

(i) Documentation requirements in addition to or exceeding requirements for creating or maintaining documentation prescribed by the Arkansas State Board of Pharmacy; or

(ii)

(a) A requirement that a pharmacy or pharmacist perform a professional duty in addition to or exceeding professional duties prescribed by the Arkansas State Board of Pharmacy.

(b) This subdivision (b)(7) applies only to audits of claims submitted for payment on or after January 1, 2012
.

(B) Subdivisions (b)(7)(A)(i) and (ii) do not apply in cases of Food and Drug Administration regulation or drug manufacturer safety programs;

(8) Recoupment shall only occur following the correction of a claim and shall be limited to amounts paid in excess of amounts payable under the corrected claim;

(9) Except for Medicare claims, approval of drug, prescriber, or patient eligibility upon adjudication of a claim shall not be reversed unless the pharmacy or pharmacist obtained the adjudication by fraud or misrepresentation of claim elements;

(10) Each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies audited by the entity;

(11) A pharmacy shall be allowed at least thirty (30) days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit;

(12) The period covered by an audit shall not exceed twenty-four (24) months from the date the claim was submitted to or adjudicated by a managed care company, an insurance company, a third-party payor, or any entity that represents such companies or groups;

(13) Unless otherwise consented to by the pharmacy, an audit shall not be initiated or scheduled during the first seven (7) calendar days of any month due to the high volume of prescriptions filled during that time;

(14)

(A) The preliminary audit report shall be delivered to the pharmacy within one hundred twenty (120) days after conclusion of the audit.

(B) A final audit report shall be delivered to the pharmacy within six (6) months after receipt of the

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

(15) Notwithstanding any other provision in this subsection, the agency conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits.

(c) Recoupments of any disputed funds shall only occur after final internal disposition of the audit, including the appeals process as set forth in subsection (d) of this section.

(d)

(1) Each entity conducting an audit shall establish an appeals process under which a pharmacy may appeal an unfavorable preliminary audit report to the entity.

(2) If, following the appeal, the entity finds that an unfavorable audit report or any portion of the unfavorable audit report is unsubstantiated, the entity shall dismiss the audit report or the unsubstantiated portion of the audit report without any further proceedings.

(e) Each entity conducting an audit shall provide a copy of the final audit report to the plan sponsor after completion of any review process.

(f)

(1) The full amount of any recoupment on an audit shall be refunded to the responsible party.

(2) Except as provided in subsection (f)(3) of this section, a charge or assessment for an audit shall not be based, directly or indirectly, on amounts recouped.

(3) Subsection (f)(2) does not prevent the entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if both the following conditions are met:

(A) The responsible party and the entity have a contract that explicitly states the percentage charge or assessment to the responsible party; and

(B) A commission or other payment to an agent or employee of the entity conducting the audit is not based, directly or indirectly on amounts recouped.

(g) This section does not apply to any audit, review, or investigation that involves alleged fraud, willful misrepresentation, or abuse, including without limitation:

(1) Medicaid fraud as defined in § 5-55-111;

(2) Abuse or fraud as defined in § 20-77-1702; or

(3) Insurance fraud.

Miscellaneous Statutes Related to Pharmacy

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

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

(b) Subject to the provisions of subsection (c) of this section, in determining eligibility under this section, the board, commission, department, or agency may take into consideration conviction of certain crimes which have not been annulled, expunged, or pardoned. However, such convictions shall not operate as an automatic bar to registration, certification, or licensing for any trade, profession, or occupation.

(c) The following criminal records shall not be used, distributed, or disseminated in connection with an application for a registration, license, or certificate:
   (1) Records of arrest not followed by a valid felony conviction by the courts;
   (2) Convictions which have been annulled or expunged or pardoned by the Governor; and
   (3) Misdemeanor convictions, except misdemeanor sex offenses and misdemeanors involving violence.

(d) The board, commission, department, or agency shall state explicitly in writing the reasons for a decision which 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.

(e) For the purposes of this section, completion of the following shall be deemed prima facie evidence of sufficient rehabilitation:
   (1) Probation or parole 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.

(f) 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.

(g) 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.

(h) 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.

(i) This section shall not apply to teacher licensure or certification, as these areas of licensure or certification are specifically governed by § 6-17-410.

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 tat 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.
No 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 shall be liable in damages to any person for slander, libel, defamation of character, breech 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 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 regulations requiring the continuing education of the persons licensed by the board.
(b) All regulations 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 and regulations.

(c) The regulatory boards shall establish by regulation 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 regulations requiring continuing education.

Uniform Controlled Substances Act

5-64-101. Definitions.
As used in subchapters 1-6 of this chapter.

(a) "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:
   (1) A practitioner; or
   (2) The patient or research subject at the direction and in the presence of the practitioner;

(b) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman;

(c) "Bureau" means the Drug Enforcement Agency of the United States Department of Justice, or its successor agency;

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

(e) The term "counterfeit substance" means a noncontrolled substance, which 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;

   In determining whether a substance is counterfeit, the following factors shall be utilized. A finding of any two (2) of these factors constitutes prima facie evidence that a substance is a "counterfeit substance:"
   (1) Statements made by an owner or by anyone else in control of the substance concerning the nature of the substance, or its use or effect;
   (2) The physical appearance of the finished product containing the noncontrolled substance is substantially the same as that of a specific controlled substance;
   (3) The noncontrolled substance is unpackaged or is packaged in a manner normally used for the illegal delivery of a controlled substance;
   (4) The noncontrolled substance is not labeled in accordance with 21 U.S.C. § 352 or § 353;
   (5) 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;
   (6) Evasive tactics or actions utilized by the owner or person in control of the substance to avoid detection by law enforcement authorities;
   (7) Prior convictions, if any, of an owner, or anyone in control of the object under state or federal laws related to controlled substances or fraud;

(f) "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;

(g) "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 substance for that delivery;

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

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

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

(k) "Drug" means (1) Substances recognized as drugs in the official *United States Pharmacopoeia*, official *Homeopathic Pharmacopoeia of the United States*, or official *National Formulary*, or any supplement to any of them; (2) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (3) Substances (other than food) intended to affect the structure or any function of the body of man or animals; and (4) Substances intended for use as a component of any article specified in clause (1), (2), or (3) of this subsection. It does not include devices or their components, parts, or accessories;

(l) "Immediate precursor" means a substance which the director has found to be and by rule designates as being the principal compound commonly used or produced primarily for use, and which 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;

(m) "Manufacture" means the production, preparation, propagation, compounding, conversion, or processing of a controlled substance, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a controlled substance by an individual for his own use or the preparation, compounding, packaging, or labeling of a controlled substance:

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

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

(n) "Marijuana" means all parts and any variety and/or species of the plant Cannabis that contains THC (Tetrahydrocannabinol) whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination;

(o)

(1) "Narcotic drug" means any drug which is defined as a narcotic drug by order of the Director of the Department of Health. In the formulation of definitions of narcotic drugs, the Director of the Department of Health is directed to include all drugs which he finds are narcotic in character and by reason thereof are dangerous to the public health or are promotive of addiction-forming or addiction-sustaining results upon the user which threaten harm to the public health, safety, or morals. In formulating these definitions, the Director of the Department of Health shall 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 herein and under the policy of this section.

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

(A) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation. This term does not include the isoquinoline alkaloids of opium;

(B) Poppy straw and concentrate of poppy straw;

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

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

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

(F) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subdivisions (o)(2)(A)-(E).

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

(q) "Practitioner" means:

(1) 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;

(2) 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;

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

(s) "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;

(t) "Ultimate user" means a person who lawfully possesses a controlled substance for his own use or for the use of a member of his household or for administering to an animal owned by him or by a member of his household;

(u) "Director" shall mean the Director of the Arkansas Department of Health or his duly authorized agent;

(v) The term "drug paraphernalia" means all equipment, products, and materials of any kind which 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 subchapters 1-6 of this chapter (meaning the Controlled Substances Act of this state). It includes, but is not limited to:

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

(2) Kits used, intended for use, or designed for use in manufacturing, compounding, converting, producing, processing, or preparing controlled substances;

(3) Isomerization devices used, intended for use, or designed for use in increasing the potency of any species of plant which is a controlled substance;

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

(5) Scales and balances used, intended for use, or designed for use in weighing or measuring controlled substances;

(6) Diluents and adulterants, such as quinine hydrochloride, mannitol, mannite, dextrose, and lactose, used, intended for use, or designed for use in cutting controlled substance;

(7) Separation gins and sifters used, intended for use, or designed for use in removing twigs and seeds from, or in otherwise cleaning or refining, marijuana;

(8) Blenders, bowls, containers, spoons, mixing devices used, intended for use, or designed for use in packaging small quantities of controlled substances;

(9) Capsules, balloons, envelopes and other containers used, intended for use, or designed for use in packaging small quantities of controlled substances;

(10) Containers and other objects used, intended for use, or designed for use in storing or concealing controlled substances;

(11) Hypodermic syringes, needles, and other objects used, intended for use, or designed for use in parenterally injecting controlled substances into the human body; and

(12) Objects used, intended for use, or designed for use in ingesting, inhaling, or otherwise introducing marijuana, cocaine, hashish, or hashish oil into the human body, such as:
- (A) Metal, wooden, acrylic, glass, stone, plastic, or ceramic pipes with or without screens, permanent screens, hashish heads, or punctured metal bowls;
- (B) Water pipes;
- (C) Carburetion tubes and devices;
- (D) Smoking and carburetion masks;
- (E) Roach clips: meaning objects 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) Miniature cocaine spoons and cocaine vials;
- (G) Chamber pipes;
- (H) Carburetor pipes;
- (I) Electric pipes;
- (J) Air-driven pipes;
- (K) Chillums;
- (L) Bongs; and
- (M) Ice pipes or chillers.

In determining whether an object is drug paraphernalia, a court or other authority should consider, in addition to all other logically relevant factors, the following:

(1) Statements by an owner or by anyone in control of the object concerning its use;

(2) Prior convictions, if any, of an owner, or of anyone in control of the object, under any state or federal law relating to any controlled substance;

(3) The proximity of the object, in time and space, to a direct violation of subchapters 1-6 of this chapter;

(4) The proximity of the object to controlled substances;

(5) The existence of any residue of controlled substances on the object;

(6) Direct or circumstantial evidence of the intent of an owner, or of anyone in control of the object, to deliver it to persons whom he knows, or should reasonably know, intend to use the object to facilitate a violation of subchapters 1-6 of this chapter; the innocence of an owner, or of anyone in control of the object, as to a direct violation of subchapters 1-6 of this chapter shall not prevent a finding that the object is intended for use, or designed for use, as drug paraphernalia;

(7) Instructions, oral or written, provided with the object concerning its use;

(8) Descriptive materials accompanying the object which explain or depict its use;

(9) National and local advertising concerning its use;

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

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

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

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

(14) Expert testimony concerning its use.

(w) "Noncontrolled substance" means any liquid, substance, or material not listed in Schedules I through VI of the Schedules of Controlled Substances promulgated by the Director of the Arkansas Department of Health;

(x) The term "anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestin, and corticosteroid, that promotes muscle growth. Except that such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Director of the Department of Health for such administration. If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this subdivision.

5-64-201. Director's duties.

(a) The director shall administer subchapters 1-6 of this chapter and may add substances to or delete or reschedule all substances enumerated in the schedules, pursuant to the procedures of the Administrative Procedure Act, as amended § 25-15-201 et seq. Provided, the director shall not delete any substance from the Schedules in effect on July 20, 1979, without prior approval by the Legislative Council. In making a determination regarding a substance, the director shall consider the following:

(1) The actual or relative potential for abuse;

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

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

(4) The history and current pattern of abuse;

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

(6) The risk to public health;

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

(8) 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 director shall make findings with respect thereto and issue a rule controlling the substance if he finds the substance has a potential for abuse.

(c) If the director designates a substance as an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

(d) If any substance is designated as a controlled substance under federal law and notice thereof is given to the director, the director shall similarly control the substance under subchapters 1-6 of 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 director objects to inclusion. In that case, the director shall publish the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the director shall publish his decision. Any person aggrieved by a decision of the director shall be entitled to judicial review in the Circuit Court of Pulaski County. Upon publication of objection to inclusion under subchapters 1-6 of this chapter by the director, control under subchapters 1-6 of this chapter is stayed until the director publishes his decision or, if judicial review is sought, such inclusion is stayed until such adjudication.

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

(f) The director 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.
The controlled substances listed or to be listed in the schedules shall be included by whatever official, common, usual chemical, or trade name designated.

5-64-203. Criteria for Schedule I.
The director shall place a substance in Schedule I if he finds that the substance:

(a) Has high potential for abuse; and

(b) Has no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision.

5-64-204. [Reserved.]

5-64-205. Criteria for Schedule II.
The director shall place a substance in Schedule II if he finds that:

(a) The substance has high potential for abuse;

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

(c) 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 director shall place a substance in Schedule III if he finds that:

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

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

(c) 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 director shall place a substance in Schedule IV if he finds that:
(a) The substance has a low potential for abuse relative to substances in Schedule III;
(b) The substance has currently accepted medical use in treatment in the United States; and
(c) Abuse of the substance may lead to limited physical dependence or psychological dependence relative to the substances in Schedule III.

5-64-210. [Reserved.]

5-64-211. Criteria for Schedule V.
The director shall place a substance in Schedule V if he finds that:
(a) The substance has low potential for abuse relative to the controlled substances listed in Schedule IV;
(b) The substance has currently accepted medical use in treatment in the United States; and
(c) The substance has limited physical dependence or psychological dependence liability relative to the controlled substances listed in Schedule IV.

5-64-212. [Reserved.]

5-64-213. Schedule VI established.
There is established a Schedule VI for the classification of those substances which are determined to be inappropriately classified by placing them in Schedules I through V. Schedule VI includes controlled substances 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 director shall place a substance in Schedule VI if he finds that:
(a) The substance is not currently accepted for medical use in treatment in the United States;
(b) That there is lack of accepted safety for use of the drug or other substance even under direct medical supervision;
(c) That the substance has relatively high psychological and/or physiological dependence liability; and
(d) That use of the substance presents a definite risk to public health.

5-64-215. Substances in Schedule VI.
(a) Any material, compound, mixture, or preparation, whether produced directly or indirectly from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, which contains any quantity of the following substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation are included in Schedule VI:
    1. Marijuana

2. Tetrahydrocannabinols

Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of cannabis, sp. And/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:

[ ] 1 cis or trans tetrahydrocannabinol, and their optical isomers

[ ] 6 cis or trans tetrahydrocannabinol, and their optical isomers

[ ] 3.4 cis or trans tetrahydrocannabinol and their optical isomers.

(b) Provided, that the director shall not delete the controlled substances listed in this section from Schedule VI.

5-64-216. Schedule revisions.

The director shall revise and republish the schedule annually.

5-64-301 – 5-64-306. [Reserved.]

5-64-307. Order forms.

Controlled substances in Schedules I and II shall be distributed by a practitioner to another practitioner only pursuant to an order form. Compliance with the provisions of federal law respecting order forms shall be deemed compliance with this section.

5-64-308. Written prescriptions.

(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.

(b) In emergency situations, as defined by rule of the director, Schedule II drugs may be dispensed upon oral prescription of a practitioner, reduced promptly to writing, and filed by the pharmacy. Prescriptions shall be retained in conformity with the requirements of section 6 of this subchapter. No prescription for a Schedule II substance may be refilled.

(c) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, no controlled substance included in Schedules III or IV, which is a prescription drug, shall not be dispensed without a written or oral prescription of a practitioner. The prescription shall not be filled or refilled more than six (6) months after the date thereof or be refilled more than five (5) times, unless renewed by the practitioner.

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

5-64-1005. Exemptions.

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

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

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

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

(d) Any sale, transfer, furnishing, or receipt by a retail distributor of any drug which contains any ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and which is sold, transferred, or furnished over the counter without a prescription pursuant to the Federal Food, Drug, and Cosmetic Act or regulations adopted thereunder, provided that:

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

(2) If the use of a blister pack is technically unfeasible, the drug is packaged in unit dose packets or pouches;

(3) In the case of liquids, the drug is sold in package sizes of not more than three (3) grams of ephedrine, pseudoephedrine, or phenylpropanolamine base; and

(4) The total quantity of the sale is not greater than three (3) packages or nine (9) grams, whichever is smaller.

5-64-1006. Suspicious order reports.

(a) Any manufacturer, wholesaler, or retail distributor who is required to keep records under this subchapter and who 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) For the purposes of 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 the Uniform Controlled Substances Act, § 5-64-101 et seq., based on such factors as the amount involved, the method of payment, the method of delivery, and past dealings with the person acquiring the substance; or

(2) The transaction involves a 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 suspicious, taking into consideration the recommendations in Appendix A, Report to the United States Attorney General by the Suspicious Orders

Task Force, under the federal Comprehensive Methamphetamine Control Act of 1996, Pub.L. 104-237.

(2) In addition to any other penalties 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.

5-64-1101. Possession – Penalty.

(a) It shall be unlawful for any person to possess more than five (5) grams of ephedrine or nine (9) grams 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, or veterinarian; or

(2) Without a prescription, pursuant to the Federal Food, Drug, and Cosmetic Act or regulations adopted under the act, provided that the person possesses a sales and use tax permit issued by the Department of Finance and Administration; or

(3) Any physician, dentist, podiatrist, or veterinarian who administers or furnishes ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, optical isomers, and salts of optical isomers to his or her patients; or

(4)

(A) Any manufacturer, wholesaler, or distributor licensed by the Arkansas State Board of Pharmacy who 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 a licensed pharmacy, physician, dentist, podiatrist, veterinarian, or any person who possesses a sales and use tax permit issued by the department.

(B)

(i) The manufacturer, wholesaler, or distributor must hold or store the substances in facilities that meet the packaging requirements of § 5-64-1005(d)(1)-(3).

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

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

(c) Any person who violates the provisions of this section shall be guilty of a Class D felony.

History. Acts 1997, No. 565, § 1; 2001, No. 1209, § 3; No 1782, § 1; 2003, No. 867, § 2.

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

(a)

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

(2) Any person who violates the provisions of subdivision (a)(1) of this section shall be guilty of a Class D felony.

(b)

(1) It shall be unlawful for a person to sell, transfer, distribute, or dispense any product containing ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, optical isomers, and salts of optical isomers if the person knows that the purchaser will use the product as a precursor to manufacture methamphetamine or another controlled substance, or if the person sells, transfers, distributes, or dispenses the product with reckless disregard as to how the product will be used.

(2) Any person who violates the provisions of subdivision (b)(1) of this section shall be guilty of a Class D felony.

5-64-1103. Retail sales limits.

(a) It shall be unlawful for a retail distributor or an employee of a retail distributor to knowingly sell, transfer, or otherwise furnish in a single transaction:

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

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

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

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

(B) Where the use of blister packs is technically infeasible, that is packaged in unit dose packets or pouches; or

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

(4)

(A) Any product containing ephedrine, pseudoephedrine, or phenylpropanolamine to any person under the age of eighteen (18)

years, unless the person is purchasing a pediatric product intended for a child.

(B) The person making the sale shall require proof of age from the purchaser, unless from the purchaser's outward appearance the person would reasonably presume the purchaser to be twenty-five (25) years of age or older.

(C) "Proof of age" means any document issued by a governmental agency which:

(i) Contains a description of the person or a photograph of the person, or both, and gives the persons' date of birth; and

(ii) Includes, without being limited to, a passport, military identification card, or driver's license.

(b)

(1) Any retail distributor or employee of the retail distributor who violates subsection (a) of this section shall be guilty of a Class A misdemeanor and may also be subject to a civil fine not to exceed five thousand dollars ($5,000).

(2)

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

(B) In making a 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.

(c)

(1) It shall be unlawful for any person, other than a person or entity described in § 5-64-1101(a)(1)-(4) of this section, to knowingly purchase, acquire, or otherwise receive in a single transaction:

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

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

(2) Any person who violates the provisions of subdivision (c)(1) of this section shall be guilty of a Class A misdemeanor.

(d) This section shall not apply to:

(1) Pediatric products primarily intended for administration to children under twelve (12) years of age, according to label instructions, either:

(A) In solid dosage form whose individual dosage units to not exceed recommended dosage, according to label instructions, does not exceed fifteen (15) milligrams of ephedrine, pseudoephedrine, or phenylpropanolamine; or

(B) In liquid form whose recommended dosage, according to label instruction, does not exceed fifteen milligrams (15 mg) of ephedrine, pseudoephedrine, or phenylpropanolamine per five milliliters (5 ml) of liquid product;

(2) Pediatric liquid products primarily intended for administration to children under two (2) years of age for which the recommended dosage does not exceed two milliliters (2 ml) and the total package content does not exceed one fluid ounce (1 fl. oz.); or

(3) Products that the 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.

(1) For the purposes of this subchapter:

(1) The terms "ephedrine," "pseudoephedrine," and "phenylpropanolamine" mean any drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine or any of their salts, isomers, or salts of isomers, alone or in a mixture;

(2) "Retail distributor" means a grocery store, general merchandise store, drugstore, convenience stroe, or other related entity, the activities of which, as a distributor of ephedrine, pseudoephedrine, or phenylpropanolamine products, are limited exclusively to the sale of ephedrine, pseudoephedrine, or phenylpropanolamine products for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales and includes any person or entity that makes a direct sale or has knowledge of the sale, but does not include any manager, supervisor, or owner not present and not otherwise aware of the sale, nor shall it include the parent company of that entity if the company is not involved in direct sales regulated by this subchapter; and

(3) "Sale for personal use" means the sale in a single transaction to an individual customer for a legitimate medical use of a product containing ephedrine, pseudoephedrine, or phenylpropanolamine in quantities at or below that specified in subsection (a) of this section, and includes the sale of those products to employers to be dispensed to employees from first-aid kits or medicine chests.

(f) Nothing in this section shall prohibit a person under the age of eighteen (18) years from possessing and selling ephedrine, pseudoephedrine, or phenylpropanolamine as an agent of the minor's employer acting within the scope of the minor's employment.

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 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 § 23-60-101 et seq.

(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, § 23-60-101 et seq.

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 program as developed by the American Diabetes Association;

(2) "Health care 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, § 23-60-101 et seq.;
(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 the following laws:

(A) The Arkansas Insurance Code, § 23-60-101 et seq.;
(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 one (1) 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 health care professional upon certification by the health

care professional providing the training that the insured patient has successfully completed the training.

(b) Every health care insurer shall offer, in addition to the one (1) 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 health care 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 Program as developed by the American Diabetes Association.

(d) Diabetes self-management training shall be provided only upon prescription by a physician licensed under § 17-95-201 et seq.

(e) Nothing in this subchapter shall be construed to prohibit health care 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, Type II, 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, Type II, 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 regulations.

23-79-605. Regulations.

The State Insurance Department shall develop and promulgate regulations 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 policy shall be deemed to be delivered in this state within the meaning of this subchapter, regardless of whether the health care insurer or other entity that provides the coverage is located within or outside of Arkansas.

23-79-607. Applicability – Exceptions.

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.

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) The term "board" means the State Board of Health;
(2) The term "person" includes an individual, partnership, corporation, or association;
(3) The term "food" means:
  (A) Articles used for food or drink for man or other animals;
  (B) Chewing gum; and
  (C) Articles used for components of any such article;
(4) The term "drug" means:
  (A) Articles recognized in the official *United State 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 man or other animals;
  (C) Articles other than food intended to affect the structure or any function of the body of man or other animals; and
  (D) Articles intended for use as a component of any article specified in subdivisions (4)(A)-(C) of this section; but does not include devices or their components, parts, or accessories;
(5) The term "device," except when used in subdivision (10)(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 man or other animals; or
  (B) To affect the structure of any function of the body of man or other animals;
(6) The term "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) The term "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;
(8) The term "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;

(9) The term "immediate container" does not include package liner;

(10)

(A) The term "labeling" means all labels and other written, printed, or graphic matter upon an article or any of its container 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;

(11) The term "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;

(12) 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;

(13) The term "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;

(14) The term "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;

(15) The term "federal act" means the federal Food, Drug, and Cosmetic Act;

(16) The term "human growth hormone" means somatrem, somatropin, or an analogue of either of them;

(17) The term "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;

(18) The term "human growth hormone" includes both cadaver source and biosynthetic human growth hormones;

(19) "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 and 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 federal 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 federal 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.

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 ($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 (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 (2) of this subsection, 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 of any person of more than two hundred (200) capsules or tablets or more than sixteen cubic centimeters (16cc.) of human growth hormones 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. Provided, 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. Injunction 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 it bears or contains any poisonous or deleterious substance which may render it injurious to health. However, if the substance is not an added substance, the food shall not be considered adulterated under this subdivision if the quantity of the substance in the food does not ordinarily render it injurious to health;

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

(C) If it consists in whole or in part of a diseased, contaminated, filthy, putrid, or decomposed substance, or it is otherwise unfit for food;

(D) 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 diseased, unwholesale, or injurious to health;

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

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

(2)

(A) If any valuable constituent has been in whole or in part omitted or abstracted therefrom;

(B) If any substance has been substituted wholly or in part therefore;

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

(D) If any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, to reduce its quality or strength, or to make it appear better or of greater value than it is;

(3) If it is confectionery and it 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. However, this subdivision shall not apply to any confectionery by reason of its containing less than one-half of one percent (1/2 of 1%) by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances; or

(4) If 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.

20-56-209. 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;

(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 regulations 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 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 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 regulations as provided in § 20-56-219 or by the federal Food, Drug, and Cosmetic Act and its quality falls below the standard, unless it label bears, in such manner and form as the regulations specify, a statement that it falls below the standard; or

(B) A food for which a standard of fill or container has been prescribed by 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 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) 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.
(C) However, to the extent that compliance with the requirements of subdivision (9)(B) of this section is impractical or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the State Board of Health;

(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 regulations 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 is impracticable, exemptions shall be established by regulations 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 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) It is 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 test 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 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 State 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 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 regulations 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 theron 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 man 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, acetanilide, 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 is impracticable, exemptions shall be established by regulations 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 regulations 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 State 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 be regulations require as necessary for the protection of public health. No such regulations 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; or
(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 man 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) Upon the oral prescription of a physician, dentist, or veterinarian which is reduced promptly to writing by the pharmacist; or
(iii) By refilling any written or oral prescription if the refilling is authorized by the prescriber either in the original prescription or by oral order which is promptly reduced to writing by the pharmacist. However, any drug dispensed by filling or refilling a written or oral prescription of a physician, dentist, or veterinarian shall be exempt from the requirements of this section except subdivisions (1) and (9) of this section if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or its filling, the name of the prescriber and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in the prescription. This exemption shall not apply to any 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 purpose of this subdivision 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 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 regulations 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.

(b)

(1) For the purpose of this subchapter, the advertisement of a drug or device representing it to have any effect in albuminuria, appendicitis, arteriosclerosis, blood poison, bone disease, Bright's disease, cancer, carbuncles, cholecystitis, diabetes, diphtheria, dropsy, erysipelas, gallstones, heart and vascular diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis media, parlysis, pneumonia, poliomyelitis or infantile paralysis, prostate gland disorders, pyelitis, scarlet fever, sexual impotence, sinus infection, smallpox, tuberculosis,

tumors, typhoid, uremia, or venereal disease shall also be deemed to be false, except that no advertisement not in violation of subsection (a) of this section shall be deemed to be false under this subsection if it is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices.

(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 above, the board shall by regulation authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the board may deem necessary in the interest 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 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 regulations 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 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 regulations 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 regulations 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 regulations.

(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 – Regulation 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(1)(B), but when the substance is so required or cannot be so avoided, the State Board of Health shall promulgate regulations 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(1)(B).

(b) While such a regulation 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 regulation, be considered to be adulterated within the meaning of § 20-56-208(1)(A).

(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 regulations for the efficient enforcement of this subchapter is vested in the State Board of Health.

(2) The board is authorized to make the regulations promulgated under this subchapter conform, insofar as practicable, with those promulgated under the federal Food, Drug, and Cosmetic Act.

(b)

(1) Before promulgating any regulations contemplated by §§20-56-209(10), 20-56-211(4) and (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 regulation so promulgated shall become effective on a date fixed by the board which shall not be prior to thirty (30) days after its promulgation.

(3) The regulation may be amended or repealed in the same manner as is provided for its adoption, except that, in the case of a regulation amending or repealing a regulation, 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 regulations 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 – Inspection.

(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 Food and Drug Division of the State Board of Health.
(b) The board 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 federal Food and Drug Administration in the enforcement of the national Food, Drug, and Cosmetic Act as it may apply to food, liquor, drugs, and cosmetic productions 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) "Board" means the Arkansas State Board of Pharmacy;
(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 coordinator 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 § 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 § 503(b)(1) of the federal Food, Drug, and Cosmetic Act which shall be exempt from § 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 health care 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 health care 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 federal 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 hospital or other health care 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 physicians; dentists; veterinarians; birth control and other clinics; individuals; hospitals; nursing homes and their providers; health maintenance organizations and other health care 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 a 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. Regulations.

(a) The Arkansas State Board of Pharmacy shall adopt regulations for the wholesale distribution of prescription drugs which promote the public health and welfare and which comply with the minimum standard, terms, and conditions of the federal 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 regulations 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 regulations 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 and regulations 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 or regulation relating to drugs;
    (2) Violation of any provisions of this subchapter or any regulation promulgated hereunder; or
    (3) Commission of an act or engaging in a course of conduct which constitutes a clear and present danger to the public health and safety.

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 Procedures 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, unless the context otherwise requires:

(1) "Adjudication" means agency process for the formulation of an order;

(2)

(A) "Agency" means each board, commission, department, officer, or other authority of the government of the State of Arkansas, whether or not within, or subject to review by, another agency, except the General Assembly, the courts, and Governor.

(B) The word "agency" shall include the Division of Child Care and Early Childhood Education of the Department of Human Services and the Child Care Appeal Review Panel for purposes of administrative appeal.

(C) The word "agency" shall not include the Arkansas Public Service Commission, the Arkansas Pollution Control and Ecology Commission, the Workers' Compensation Commission, and the Arkansas Employment Security Department, it being determined by the General Assembly that the existing laws governing those agencies provide adequate administrative procedures for those agencies.

(D) Nothing in this subchapter shall be construed to repeal delegations of authority as provided by law;

(3) "License" includes any agency permit, certificate, approval, registration, charter, or similar form of permission required by law;

(4) "Licensing" means any agency process respecting the grant, denial, renewal, revocation, suspension, annulment, withdrawal, limitation, or amendment of a license;

(5) "Order" means the final disposition of an agency in any matter other than rule making, including licensing and rate making, in which the agency is required by law to make its determination after notice and hearing;

(6) "Party" means any person or agency named or admitted as a party, or properly seeking and entitled as of right to be admitted as a party, in any agency proceeding;

(7) "Person" means any individual, partnership, corporation, association, or public or private organization of any character;

(8)

(A) "Rule" means any agency statement of general applicability and future effect that implements, interprets, or prescribes law or policy, or describes the organization, procedure, or practice of any agency and includes, but is not limited to, the amendment or repeal of a prior rule.

(B) "Rule" does not mean:

(i) Statements concerning the internal management of an agency and which do not affect the private rights or procedures available to the public;
(ii) Declaratory rulings issued pursuant to § 25-15-206; or
(iii) Intra-agency memoranda; and

(9) "Rule making" means agency process for the formulation, amendment, or repeal of a rule.

25-15-203. Rules – Required rules – Public inspection.

(a) In addition to other rule making 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;
(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.

25-15-204. Rules – Procedure for adoption.

(a) Prior to the adoption, amendment, or repeal of any rule, the agency shall:
(1)
(A) Give at least thirty (30) days' notice of its intended action. The thirty-day period shall begin on the first day of the publication of notice.
(B) The notice shall include a statement of the terms or substance of the intended action or a description of the subjects and issues involved, and the time, the place where, and the manner in which interested persons may present their views thereon.
(C) The notice shall be mailed to any person specified by law and to all persons who shall have requested advance notice of rule making proceedings.
(D) Unless otherwise provided by law, the notice shall be published in a newspaper of general daily circulation for seven (7) consecutive days and, where appropriate, in those trade, industry, or professional publications which the agency may select; and
(2)
(A) Afford all interested persons reasonable opportunity to submit written data, views, or arguments, orally or in writing.

(B) Opportunity for oral hearing must be granted if requested by twenty-five (25) persons, by a government subdivision or agency, or by an association having no fewer than 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 (d) of this section.

(D) Upon adoption of a rule, the agency, if requested to do so by an interested person either prior to adoption or within thirty (30) days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, incorporating therein its reasons for overruling the considerations urged against its adoption.

(E) Where 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).

(b) In an agency finds that imminent peril to the public health, safety, or welfare 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. The rule may be effective for no longer than one hundred twenty (120) days.

(c) Every agency shall accord any person the right to petition for the issuance, amendment, or repeal of any rule. Within thirty (30) days after submission of a petition, the agency shall either deny the petition, stating in writing its reasons for the denial, or shall initiate rule-making proceedings.

(d)

(1) Every agency, including those exempted under § 25-15-202, shall file with the Secretary of State, the Arkansas State Library, and the Bureau of Legislative Research a copy of each rule and regulation adopted by it and a statement of financial impact for the rule or regulation.

(2) The Secretary of State shall keep a register of the rules open to public inspection, and it shall be a permanent register.

(3) Each agency shall provide its regulations to the Bureau of Legislative Research in an electronic format acceptable to the bureau. The bureau shall place the agency regulations in the General Assembly's Internet Web site.

(4)

(A) The scope of the financial impact statement shall be determined by the agency, but shall include, at a minimum, the estimated cost of complying with the rule and the estimated cost for the agency to implement the rule.

(B) If the agency has reason to believe that the development of a financial impact statement will be so speculative as to be cost prohibitive, the agency shall submit a statement and explanation to that effect.

(C) If the purpose of a state agency rule or regulation is to implement a federal rule or regulation, the financial impact statement shall be

limited to any incremental additional cost of the state rule or regulation as opposed to the federal rule or regulation.

(e)

(1) Each rule adopted by an agency shall be effective ten (10) days after filing unless a later date is specified by law or in the rule itself.

(2)

(A) However, an emergency rule may become effective immediately upon filing, or at a stated time less than then (10) days thereafter, if the agency finds that this effective date is necessary because of imminent peril to the public health, safety, or welfare. The agency's finding and a brief statement of the reasons therefore 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 them.

(f) No rule adopted after June 30, 1967, shall be valid unless adopted and filed in substantial compliance with this section.

(g) In any proceeding brought which questions the existence of imminent peril to the public health, safety, or welfare, a written finding by the agency that adoption of any emergency rule was necessary to avoid the loss of federal funding or certification shall establish a prima facie case of the existence of imminent peril to the public health, safety, or welfare and the burden of proof shall shift to the challenger to rebut the existence of the condition by a preponderance of the evidence.

25-15-205. Rules – "The Arkansas Register."

(a) The Secretary of State shall compile, index, and publish a publication to be known as "The Arkansas Register." This publication shall contain all adopted rules of any agency.

(b) The Secretary of State shall publish "The Arkansas Register" at least monthly, setting forth a synopsis of rules filed by agencies. A cumulative index shall be published annually.

(c)

(1) "The Arkansas 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 Arkansas Register" shall be deposited in 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.

(e)

(1) The Secretary of State shall publish the rules contained in "The Arkansas Register" on its Internet Web site.

(2) The Secretary of State may omit from publication on its Internet Web site any rules:

(A) That are published on an agency, board, or commission Internet Web site and are accessible at no cost to the public; or

(B) In which publication would be unduly cumbersome, expensive, or otherwise, so long as its Internet Web site indicates where and how a copy of the omitted materials may be obtained.

(3) The Secretary of State may adopt regulations implementing the provisions of this section, including, but not limited to, requiring the submission of rules in an acceptable electronic format.

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 adjunction.

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 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;

(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 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) 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) 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 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) Parties shall be served either personally or by mail with a copy of any decision or order.

25-15-211. Administrative adjudication – Licenses.

(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 Department of Correction grievance procedure.

(2) For the purposes of this section, “offender” means any person sentenced to the Department of Correction or sentenced to the Department of Correction for judicial transfer to the Department of Community Punishment or any person confined in a community punishment 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 Department 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 of 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 disposition 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 the 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 preformed by agencies.

(b)
(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) As soon as is practicable after each regular session of the General Assembly, each agency shall review any newly enacted laws to determine whether:
(1) Any existing rule should be repealed or amended; or
(2) Any new rule should be adopted.

(b) At the conclusion of each review, the agency shall adopt a written report of the result of the review.

(c) A copy of each report shall be maintained as a public record by the agency.

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.

Table of Contents

Regulation 1: General Operations

01-00 ***General Operations***

01-00-0001 Description of the Board..... 1-1
01-00-0002 Location of the Board..... 1-1
01-00-0003 Requests for Information..... 1-1
01-00-0004 Licensees Governed by the Pharmacy Practice Act..... 1-1
01-00-0005 Certificates of Licensure - Expiration..... 1-1
01-00-0006 Board of Pharmacy Meeting Requirements..... 1-3
01-00-0007 Fees Charged by the Board of Pharmacy..... 1-3
01-00-0008 Declaratory Order..... 1-6
01-00-0009 Inspector's Warning Notice……..…..……..... 1-8

Regulation 2: Pharmacists

02-00 ***General Requirements for Pharmacists***

02-00-0001 Changes in Employment..... 2-1
02-00-0002 Replacement of Pharmacist's Certificate..... 2-1
02-00-0003 Practice After Inactivity When Reciprocating or Reinstating a License..... 2-1
02-00-0004 Armed Forces Certificates..... 2-1

02-01 ***Internship/Clerkship***

02-01-0001 Internship Required..... 2-2
02-01-0002 Board of Pharmacy Regulates Internship Program..... 2-2
02-01-0003 Definitions..... 2-2
02-01-0004 Requirements for Internship Training..... 2-3
02-01-0005 Rules Applying to Preceptors Who Train Interns..... 2-5
02-01-0006 Penalty for Violation..... 2-6
02-01-0007 Accredited Pharmacy Degree Program..... 2-6

02-02 ***Examination***

02-02-0001 Requisites for Examination..... 2-6
02-02-0002 Score Transfer..... 2-7

02-03 ***Reciprocity***

02-03-0001 Requirements for Reciprocity..... 2-7

02-04 ***Defining Unprofessional or Dishonorable Conduct***

02-04-0001 Preamble..... 2-8
02-04-0002 Definition..... 2-8

02-05 ***Board Action***

02-05-0001 Emergency Suspension..... 2-9

02-06 ***Continuing Education for Pharmacists***

02-06-0001 Establishing an Arkansas Tripartite Committee on Continuing Pharmacy Education..... 2-10
02-06-0002 Accreditation Guidelines..... 2-10
02-06-0003 Implementation of Pharmacy Continuing Education..... 2-12

Regulation 3: Pharmacy Technicians

03-00 ***Pharmacy Technicians - Registration/Permit Required***

03-00-0001 Definitions..... 3-1
03-00-0002 Registration Required..... 3-1
03-00-0003 A Pharmacy Technician Shall..... 3-2

03-00-0004 Qualifications..... 3-2
03-00-0005 Tasks, Responsibilities, and Duties of the Pharmacy Technician..... 3-2
03-00-0006 Duties of the Pharmacist in the Use of Pharmacy Technicians. 3-4
03-00-0007 Pharmacist to Pharmacy Technician Ratio..... 3-5

Regulation 4: Pharmacy

04-00 ***General Regulations Regarding Pharmacies***
04-00-0001 Equipment Specifications..... 4-1
04-00-0002 Time Requirements for Pharmacist on Duty and Pharmacist in Charge..... 4-1
04-00-0003 Vending Machines..... 4-2
04-00-0004 Re-Use of Drugs Prohibited..... 4-2
04-00-0005 Pick Up Stations..... 4-2
04-00-0006 Emergency Pharmacy Services..... 4-3
04-00-0007 Applications for Pharmacy Permits..... 4-3
04-00-0008 Requirements for a New Pharmacy Permit..... 4-3
04-00-0009 Responsibility of Pharmacist, Intern, or Pharmacy Technician..... 4-3
04-00-0010 Pharmacist in Charge..... 4-4
04-00-0011 Permit Required..... 4-4
04-00-0012 Change of Ownership..... 4-5
04-00-0013 Inventory Required..... 4-5
04-00-0014 Owners Responsibility – Pharmacist is Licensed..... 4-6

04-01 ***Pharmacy Permit Fees***
04-01-0001 Permit Fees..... 4-6

04-02 ***Regulations Regarding Retail Pharmacies***
04-02-0001 Applications for Pharmacy Permits..... 4-6
04-02-0002 Requirements for a New Pharmacy Permit..... 4-7
04-02-0003 Leased Operations - Pharmacy is a Department of Another Business..... 4-7
04-02-0004 Necessary Equipment Required..... 4-7
04-02-0010 Regulating the Use of Electronic Data Processing in Lieu Of Present Record Keeping Systems in Pharmacies Holding Pharmacy Permits..... 4-7
04-02-0011 Central Fill Pharmacy..... 4-10
04-02-0012 Retail Pharmacy Off-Site Order Entry..... 4-13
04-02-0100 Nuclear Pharmacy..... 4-16

04-03 ***Regulations Regarding Retail Specialty Pharmacies***
04-03-0001 Specialty Pharmacy Permits..... 4-19
04-03-0002 Methadone Clinic Specialty Pharmacy Permit..... 4-20
04-03-0003 Student Health Clinic Pharmacy Permit..... 4-20
04-03-0004 Permit for Pilot Program for Donated Prescription Medications Pursuant To ACA § 17-92-1101 Et Seq..... 4-21

04-04 ***Out of State Pharmacies***
04-04-0001 Out of State Pharmacy Regulation..... 4-23

04-05 ***Regulations Regarding Hospital Pharmacies***
04-05-0001 Hospital Pharmaceutical Services Permit..... 4-25
04-05-0002 Mechanical Storage and Delivery..... 4-32

04-05-0003 Regulating the Use of Electronic Data Processing in Lieu of Present Record Keeping Systems in Hospital Pharmacies Holding Hospital Pharmacy Permits..... 4-33
04-05-0004 Off-Site Order Entry..... 4-34
04-06 *Institutional Pharmaceutical Services Permit*
04-06-0001 Class #1 Institutional Permit..... 4-35
04-06-0002 Class #2 Institutional Pharmaceutical Services Permit..... 4-37
04-06-0003 Class #3 Institutional Pharmaceutical Services Permit – Correctional Facilities..... 4-37
04-07 *Charitable Clinic Permit*
04-07-0001 Issuance of Charitable Clinic Permit..... 4-41
04-07-0002 Prescriptions..... 4-41
04-07-0003 Policies and Procedures for Clinics..... 4-41
04-07-0004 Categories for permits..... 4-41
04-07-0005 Pharmacist Present When Medication Provided..... 4-41
04-07-0006 Regulation Regarding Charitable Clinic Pharmacies Procuring And Dispensing Donated Prescription Medications 4-42
Regulation 5: Long-Term-Care Facilities
05-00 *Nursing Home Consultants*
05-00-0001 Definitions..... 5-1
05-00-0002 General Requirements..... 5-1
05-00-0003 Responsibilities..... 5-2
05-00-0004 Emergency Kits for Long-Term-Care Facilities..... 5-4
05-00-0005 Drug Categories for Emergency Kits in Long-Term-Care Facilities..... 5-5
Regulation 6: Disciplinary Procedures
06-00-000 I Procedures for Disciplinary Action..... 6-1
Regulation 7: Drug Products/Prescriptions
07-00 *General Regulations Regarding Drugs/Prescriptions*
07-00-0001 Facsimile (Fax) Prescription Drug Order..... 7-1
07-00-0002 Prescription Transfers..... 7-2
07-00-0003 Signing Prescriptions..... 7-3
07-00-0004 Secret Codes Prohibited..... 7-3
07-00-0005 Maintenance and Retention of Drug Records..... 7-3
07-00-0006 Generic Substitution..... 7-3
07-00-0007 A Pharmacist Shall not Dispense a Generically Equivalent Drug Product Under ACA § 17-92-503(a) and (b) of the Generic Substitution Act if:..... 7-4
07-00-0008 Electronic Prescription Processing and Patient Confidentiality.... 7-4
07-00-0009 Proper Practitioner-Patient Relationship..... 7-6
07-01 *F.D.A. Approval of Drugs*
07-01-0001 Controlled Substances Approved by F.D.A..... 7-6
07-01-0002 Drug Products Must Have a New Drug Application or an Abbreviated New Drug Application..... 7-6
07-02 *Compounding*
07-02-0001 Standards for Compounding and Dispensing Sterile Products..... 7-7
07-02-0002 Good Compounding Practices..... 7-12

07-03 ***Samples***
07-03-0001 Drug Samples..... 7-17
07-04 ***Controlled Substances***
07-04-0001 Schedule II Prescription Drugs..... 7-18
07-04-0002 Partial Filling of a Schedule II Prescription..... 7-18
07-04-0003 Computer Records for Partial Filling..... 7-19
07-04-0004 Time Limit on a New Schedule II Prescription..... 7-20
07-04-0005 Theft or Loss of Controlled Drugs..... 7-20
07-04-0006 Schedule V- Exempt Narcotics..... 7-20
Regulation 8: Wholesale Distribution
08-00 ***Wholesale Drug Distributors of Legend/Controlled Substances***
08-00-0001 Definitions..... 8-1
08-00-0002 Sales Permit Required..... 8-2
08-00-0003 Wholesale Distributor - Permit Required..... 8-2
08-00-0004 Shipment to Certain Licensed Professionals 8-3
08-00-0005 Minimum Required Information for Licensure..... 8-3
08-00-0006 Minimum Qualifications..... 8-4
08-00-0007 Personnel..... 8-4
08-00-0008 Minimum Requirements for the Storage and Handling of Prescription Drugs and for the Establishment and Maintenance of Prescription Drug Distribution Records..... 8-5
08-00-0009 Written Policies and Procedures..... 8-7
08-00-0010 Responsible Persons..... 8-7
08-00-0011 Compliance with Federal, State, and Local Laws..... 8-7
08-00-0012 Salvaging and Reprocessing..... 8-8
08-00-0013 Applicability..... 8-8
08-00-0014 Inspection of Premises and Records..... 8-8
08-01 ***Medical Equipment, Legend Devices, and/or Medical Gas***
08-01-0001 Definitions..... 8-8
08-01-0002 Licensure Required..... 8-9
08-01-0003 Standards of Practice..... 8-11
08-02 ***Wholesale Distributor of List I Chemicals***
08-02-0001 Definitions..... 8-13
08-02-0002 Wholesale Distributor of List I Chemicals - Permit Required..... 8-14
08-02-0003 Minimum Required Information for Obtaining a Permit..... 8-15
08-02-0004 Minimum Qualifications..... 8-15
08-02-0005 Personnel..... 8-16
08-02-0006 Minimum Requirements for the Storage and Handling of List I Chemicals..... 8-16
08-02-0007 Inspection of Premises and Records..... 8-17
08-02-0008 Suspicious Orders for List I Chemicals..... 8-18
Regulation 9: Pharmaceutical Care/Patient Counseling
09-00 ***Patient Counseling***
09-00-0001 Patient Information, Drug Use Evaluation, and Patient Counseling..... 9-1
09-00-0002 Prescription Orders to Administer Medication and/or Immunizations..... 9-3

09-01 ***Disease State Management***
09-01-0001 Disease State Management..... 9-6
09-01-0002 Areas of Practice in Disease State Management..... 9-8
09-01-0003 Qualifications, Resources, and Record Keeping Required for Practicing in a Disease State Management Area in Arkansas..... 9-8
09-01-0004 Minimum Competencies and Standards to be Met by the Competency Examinations for Disease State Management..... 9-9
09-01-0005 Notification of Credential In Disease State Management Required..... 9-9
09-01-0006 Continued Competence..... 9-9
Regulation 10: Arkansas Pharmacy Support Group
10-01-0001 Support Group..... 10-1
Regulation 11: Criminal Background Checks
11-00-0001 Definitions..... 11-1
11-00-0002 Background Check Required..... 11-1
11-00-0003 Application Procedure..... 11-1
11-00-0004 Eligibility for License/Registration..... 11-2
11-00-0005 Board Waiver of Conviction..... 11-5
11-00-0006 Provisional License and Registration..... 11-5
11-00-0007 Applicant Confidentiality..... 11-6
11-00-0008 Challenges to the Accuracy of the Report..... 11-7
Regulation 12: Automation
12-00-0001 Automated and Robotic Pharmacy Systems..... 12-1

ARKANSAS STATE BOARD OF PHARMACY REGULATIONS

REGULATION 1 —GENERAL OPERATIONS

01-00-0001—DESCRIPTION OF THE BOARD

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

01-00-0002—LOCATION OF BOARD OFFICES

The office of the Arkansas State Board of Pharmacy shall be located at 322 South Main Street, Suite 600, Little Rock, Arkansas. All communications thereto may be addressed to Arkansas State Board of Pharmacy, 322 South Main Street, Suite 600, Little Rock, AR 72201. (10/9/89, Amended 5/31/2014)

01-00-0003—REQUESTS FOR INFORMATION

Any person or persons seeking information respecting the Arkansas State Board of Pharmacy or desiring to submit complaints or charges thereto or make request thereof shall do so by filing with the Board an instrument in writing, signed by the writer and containing a return address. Communications need not be typed but should be legible. (10/9/80)

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

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

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

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

(b) All preceptor permits shall expire on December 31 of the first odd-numbered year following the date of their issuance.

(c)
  (1) An intern license issued to a student intern shall expire six (6) months following graduation or when the intern is issued a pharmacist license, whichever occurs first.
  (2) Intern licenses issued to foreign graduates shall expire on December 31 of the second calendar year following the date of issuance or when the intern is issued a pharmacist license, whichever occurs first.

(d) Non-renewable provisional licenses and provisional registrations shall expire six months after the date of issuance or upon issuance of a pharmacist, intern or technician license, whichever comes first.

(e) All pharmacy technician permits, hospital pharmacy permits, ambulatory care center pharmaceutical services permits, wholesale distributors of legend or controlled substance

permits, wholesale distributors of medical equipment, legend devices, and medical gases permits, institutional pharmaceutical services permits, List I chemical permits and charitable clinic permits shall expire on December 31 of the first even-numbered year following the date of the issuance of the permit, license, registration, or certificate.

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

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

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

(2) Every registered pharmacy technician shall pay to the Board of Pharmacy a renewal fee as defined in regulation 01-00-0007. If the renewal fee for any pharmacy technician registration is unpaid by the first day of February following the date of expiration, the holder thereof must pay a penalty as defined in regulation 01-00-0007 for each month thereafter, provided that if the renewal is unpaid by the first day of April following the date of expiration, such registration shall be null and void. The pharmacy technician may be reinstated as a pharmacy technician upon payment of a reinstatement fee as defined in regulation 01-00-0007 plus the renewal fee.

(3) Every nursing home consultant shall pay to the Board of Pharmacy a renewal fee as defined in regulation 01-00-0007. If the renewal fee for the nursing home consultant is unpaid by the first day of February following the date of expiration, the holder thereof must pay a penalty as defined in regulation 01-00-0007 for each month thereafter, provided that if the renewal is unpaid by the first day of April following the date of expiration, such registration shall be null and void.

(4) Every preceptor shall pay to the Board of Pharmacy a renewal fee as defined in regulation 01-00-0007. If the renewal fee for the preceptor license is unpaid by the first day of July following the date of expiration, the holder thereof must pay a penalty as defined in regulation 01-00-0007 for each month thereafter, provided that if the renewal is unpaid by the first day of September following the date of expiration, such registration shall be null and void.

(5) Every licensed pharmacy, hospital, ambulatory care center, wholesale distributor, List I chemical or supplier of medical equipment, legend device or medical gas shall pay to the Board of Pharmacy a renewal fee as defined in regulation 01-00-0007. If the renewal fee for any pharmacy or business license is unpaid by the first day of February following the date of expiration, the holder thereof must pay a penalty as defined in regulation 01-00-0007 for

each month thereafter, provided that if the renewal is unpaid by the first day of April following the date of expiration, such license shall be null and void.

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

01-00-0006—BOARD OF PHARMACY MEETING REQUIREMENTS

The Arkansas State Board of Pharmacy shall meet the second Tuesday and Wednesday in February, the second Tuesday and Wednesday in June or at the time of the Annual Meeting of the Arkansas Pharmacists Association in June, and the second Tuesday and Wednesday in October of each year--unless changed and announced in advance by the Board of Pharmacy. Examination of candidates for licensure to practice pharmacy shall be on dates, and at times and places as determined by the Board of Pharmacy. (10/09/80 Revised 6/20/91, and 11/13/2006)

01-00-0007—FEES CHARGED BY THE BOARD OF PHARMACY

(a) The fees charged by the Arkansas State Board of Pharmacy for the various examinations, permits, licenses, certificates, and books issued by the board shall be as follows:

(1) The fee for examination to become a licensed pharmacist upon examination shall be twenty-five dollars ($25.00) plus the actual cost of the examination;

(2) The fee for a license as a licensed pharmacist from another state by reciprocity (license transfer) shall be two hundred dollars ($200);

(3)

(A) The fee for the initial issuance of a license as a licensed pharmacist shall be seventy-five dollars ($75.00);

(B) The fee for the renewal of a license as a licensed pharmacist shall be seventy-five dollars ($75.00) per year;

(4)

(A)

(i) The fee for issuance of a permit for the first time to operate an in-state pharmacy shall be three hundred dollars ($300);

(ii) The fee for renewal of a permit to operate an in-state pharmacy shall be one hundred fifty dollars ($150) per year;

(iii) When there is a change of ownership of an in-state pharmacy, a new permit must be obtained, and the fee shall be one hundred fifty dollars ($150);

(B)

(i) The fee for issuance of a permit for the first time to operate a specialty pharmacy shall be three hundred dollars ($300);

(ii) The fee for renewal of a permit to operate a specialty pharmacy shall be one hundred fifty ($150) per year;

(iii) When there is a change in ownership in a specialty pharmacy, a new permit must be obtained and the fee shall be one hundred fifty dollars ($150);

(C)

(i) The fee for issuance of a permit for the first time to operate an out-of-state pharmacy shall be three hundred dollars ($300);

(ii) The fee for renewal of a permit to operate an out-of-state pharmacy shall be one hundred fifty dollars ($150) per year;

(iii) When there is a change in ownership in an out-of-state pharmacy or drug store, a new permit must be obtained, and the fee shall be one hundred fifty dollars ($150);

(5) The fee for a certificate as a licensed pharmacist shall be ten dollars ($10.00);

(6) The fee for certifying grades in connection with an application for reciprocity (license transfer) shall be ten dollars ($10.00);

(7)

(A) The fee for issuance of a hospital pharmaceutical service permit shall be three hundred dollars ($300), and the fee for the renewal of a hospital pharmaceutical service permit shall be one hundred fifty dollars ($150) per year.

(B) When there is a change of ownership of a hospital pharmacy, a new permit must be obtained and the fee shall be one hundred fifty dollars ($150);

(C)

(i) The fee for issuance of an ambulatory care center pharmaceutical service permit shall be three hundred dollars ($300), and the fee for the renewal of an ambulatory care center pharmaceutical service permit shall be one-hundred fifty dollars ($150) per year.

(ii) When there is a change in ownership of an ambulatory care center pharmacy, a new permit must be obtained and the fee shall be one hundred fifty dollars ($150);

(8)

(A) The fee for issuance of an institutional pharmaceutical services permit shall be thirty-five dollars ($35.00);

(B) The fee for the renewal of an institutional pharmaceutical services permit shall be thirty-five dollars ($35.00) per year;

(9)

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

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

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

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

(12) The fee for reinstatement of a pharmacist license shall be seventy-five dollars ($75.00) for each delinquent year up to a maximum of three hundred dollars ($300);

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

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

(15) The penalty for late payment of renewal of any permit, license, registration or certificate, unless specifically stated in this regulation, shall be twenty dollars ($20.00) per month beginning the first day of the second month after expiration, provided that if the renewal is not paid by the first day of the fourth month after expiration, the license shall be null and void;

(16)

(A) The fee for issuance of a wholesale distributor of legend drugs and/or controlled substances permit shall be three-hundred dollars ($300), and renewal shall be one-hundred fifty dollars ($150) per year;
(B) When there is a change in ownership of a wholesale distributor of legend drugs and/or controlled substances, a new permit must be obtained and the fee shall be one hundred fifty dollars ($150);

(17)
(A) The fee for the original issuance of a pharmacy technician's permit shall not exceed thirty-five ($35.00);
(B) The fee for the renewal of a pharmacy technician's permit shall not exceed thirty-five dollars ($35.00) per year;
(C) There shall be no fee for the original issuance and renewal of a restricted charitable clinic pharmacy technician's permit issued pursuant to Board Regulation 04-03-0004 (f).

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

(19)
(A) The application fee for a license to sell, rent, offer to sell, or rent directly to patients in this state any home medical equipment, legend devices, or medical gases shall not exceed two-hundred fifty dollars ($250);
(B) The license renewal fee shall not exceed one hundred twenty-five dollars ($125);
(C) The change of ownership fee shall not exceed one hundred twenty-five dollars ($125).

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

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

(22)
(A) The fee for a permit for wholesale distributors of List I chemicals shall not exceed three hundred dollars ($300), and the renewal shall not exceed one hundred fifty dollars ($150) per year.
(B) When there is a change of ownership of a wholesale distributor of List I chemicals, a new permit must be obtained and the fee shall not exceed one hundred fifty dollars ($150).

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

(c) Should any license, certificate, or registration not be renewed within ninety (90) days after expiration thereof, it may be reinstated by the board as authorized in this section upon payment of the renewal fee and reinstatement fee. However, the following are not subject to reinstatement if not renewed within ninety (90) days after expiration:
(1) pharmacy permits,
(2) out of state pharmacy permits,
(3) specialty pharmacy permits,
(4) hospital permits,

(5) ambulatory care center pharmacy permits,
(6) wholesale distributors of legend drugs and/or controlled substance permits, or both; and
(7) suppliers of medical equipment, legend devices, and/or medical gas licenses,
(8) institutional pharmacy permits
(9) List I chemical permits
(10) charitable clinic permits.

(d)
(1) All retail pharmacy permits, out of state pharmacy permits, specialty pharmacy permits, and pharmacist licenses expiring in odd-numbered years shall be renewed every two (2) years.
(2) All pharmacy technician permits, hospital pharmaceutical service permits, ambulatory care center pharmaceutical services permits, wholesale distributors of legend or controlled substance permits, wholesale distributors of medical equipment, legend devices, and medical gases permits, wholesale distributors of List I chemicals, institutional pharmaceutical services permits, nursing home consultant pharmacists permits, charitable clinic permits and any other permit, license, registration, or certificate issued by the board expiring in even-numbered years and not covered in subdivision (d) (1) of this section shall be renewed every two (2) years.
(3) The fee for any biennial renewal term will be the amount of two (2) annual renewal fees for the applicable license, permit, registration, or certification as provided in subsection (a) of this section.
(4) If the initial licensure, permit, certificate, or registration occurs in the first year of a biennial renewal term, the applicant shall pay the appropriate initial fee and the applicable annual fee for the license, permit, certificate, or registration for the second year in the renewal term, as provided in subsection (a) of this section.
(5) If the initial licensure, permit, certificate, or registration occurs in the second year of the biennial renewal term, the applicant will only pay the original fee and will not be responsible for the renewal fee until the biennial renewal period for the license, permit, certificate, or registration. 8/23/96 (Revised 6/19/97 8/19/99, 6/2001, 11/13/2006, and 7/5/2007)

01-00-0008—DECLARATORY ORDER

(a) Scope-When a regulation, statute or order enforced by the Board of Pharmacy or its application will injure or threatens to injure a person in his person, business, or property, that person may file a petition for a declaratory order as to the applicability of that regulation, statute or order pursuant to this regulation.
(b) Petition-Contents-The petition for a declaratory order shall contain the following:
(1) The venue, a heading specifying the subject matter and name of the petitioner and the name of the pleading;
(2) The name, address, and telephone number of the petitioner and whether petitioner is licensed by the Board under A.C.A. §17-92-101 *et seq.*;
(3) The name, address, and telephone number of petitioner's attorney, if any;
(4) A statement of the injury to result from the regulation, statute or order or the application thereof to the petitioner;
(5) The declaratory ruling that the petitioner seeks;
(6) The regulation, statute or order which is the subject of the petition;

(7) The facts relevant to the order which petitioner seeks; said statement of facts shall be complete, specific and particularized to the issue presented;
(8) Memorandum of law and legal authorities in support of the order the petitioner seeks;
(9) The name, address and telephone number of each person known to the petitioner who may have a specific personal interest in the application of the regulation, statute or order or who may be adversely affected by the declaratory order sought by the petitioner;
(10) The signature of petitioner or petitioner's attorney, if any; and
(11) All documents pertinent to the petition shall be attached thereto.

(c) Filing of the Petition.
(1) The original and three copies of each petition shall be in writing and shall be delivered in person or by mail to the Executive Director of the Board during regular business hours at the Board's offices. The Executive Director shall mark said petition as having been received by the Board and return a file-marked copy to petitioner.
(2) In order to determine whether to issue a declaratory order, the Board will consider any pertinent issues including, without limitation, the following:
(A) whether the petition substantially conforms to section (b) above or is not supported by a memorandum of law in support of the petition;
(B) whether the petition is frivolous;
(C) whether the matter is within the jurisdiction of the Board;
(D) whether there is a genuine controversy of material fact, the resolution of which is necessary before any declaratory order may issue;
(E) whether the order will terminate a controversy or remove uncertainties as to the applicability to petitioner of any regulation, statute or order by the Board;
(F) whether the petition involves any subject, question or issue which the subject of a formal or informal matter or investigation currently pending before the Board, a court or other agency of this state or the federal government;
(G) whether the petition seeks a ruling on a moot or hypothetical question, speculative facts or will result in an advisory ruling or opinion;
(H) whether the issue presented is of such complexity that the Board has had insufficient opportunity or resources to develop a fully matured opinion;
(I) whether a declaratory order would provide a broad interpretation of a regulation, statute or order applicable to an entire class of persons;
(J) whether the promulgation of a regulation or an adjudication would be more appropriate to resolve the question; and
(K) any other pertinent matter.

(e) Parties
(1) Petitioner, persons identified in section b (9) and the Board shall be parties to a proceeding for a declaratory order.
(2) Any other person may seek leave of the Board to intervene in such proceeding and leave to intervene will be granted at the sole discretion of the Board.
(3) A petition to intervene shall be filed in the manner as set forth the same matters as required by section b herein. Any reference to "petitioner" herein also refers to any person who has been granted leave to intervene, unless the context clearly indicates to the contrary.

(f) Disposition of Petition. The Board may:
(1) Decide the issue solely upon the facts presented in the petition; in such case the decision will apply only to the extent of the facts presented in the petition and amended to the petition;

(2) Require that additional information be submitted before the petition will be considered; in such event the additional facts will be considered as an amendment to the petition;
(3) Require the petitioner to provide notice of the pendency of the proceeding to persons who may be necessary parties as well as other persons;
(4) Schedule a time, date and place at which the Board will conduct a hearing on the petition for the purpose of obtaining additional facts or inquiring into any facts set forth in the petition; notice of the hearing and purpose therefore shall be provided to the petitioner.
(5) Schedule a date, time and place at which the petitioner and other persons may make an oral presentation on the petition;
(6) Consider the petition and any attachments without oral presentation; and/or

(g) Order
(1) The Board shall state its decision in writing signed by the President or other person designated by the Board.
(2) The Board's decision deciding the issue presented by the petition shall include findings of fact and conclusions of law supporting the declaratory order; the decision may be in the form of a letter or pleading.
(3) The Board's decision shall be rendered and entered as promptly as reasonably practicable considering the facts, circumstances, complexity and other factors pertinent to the proceeding.
(4) The order shall be served upon the petitioner and any other parties to the proceeding by certified mail, return receipt requested. (Adopted 8/19/99)

01-00-0009—INSPECTOR'S WARNING NOTICE

(a) Purpose. An inspector's warning notice protects public health by allowing registrants to expeditiously correct violations of laws and rules, and report these corrections to the Board in writing.
(b) Recipient. A warning notice may be issued to any person or facility holding a permit, license, registration, certificate, or credential issued by the Arkansas State Board of Pharmacy that is found to be violating any Arkansas Code pertaining to the practice of pharmacy or any regulation of the Arkansas State Board of Pharmacy as well as any other applicable state or federal law, rule, or regulation.
(c) Issuance. An inspector may issue a warning notice at the time a violation is found.
(d) Filing. The warning notice shall become an integral part of a file.
(e) Failure to respond. A recipient's failure to satisfactorily respond to a warning notice may be referred by the Executive Director of the Board for review and hearing.
(f) Board review of two warning notices. Any registrant receiving two or more warning notices within a twelve-month period may be referred to the Board for review and hearing. (Adopted 2/2001)

REGULATION 2 —PHARMACISTS

02-00: GENERAL REQUIREMENTS FOR PHARMACISTS

02-00-0001 CHANGES IN EMPLOYMENT

Whenever any licensed pharmacist shall change his place of employment for any reason, it shall be the duty of the former and current employer and said licensed pharmacist to notify the Arkansas State Board of Pharmacy in writing of such change within five days after such change of employment. Notification must be made by letter, fax, email or through the Board website and must contain the new place of employment of the licensed pharmacist and their license number. (10/9/80, amended 10/14/81, 11/13/2006, and 8/31/2011).

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

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

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

(a) To be reinstated and immediately practice without supervision, the pharmacist's license shall not have lapsed more than two calendar years.
(b) To be reciprocated and immediately practice without supervision, the pharmacist shall have practiced the profession of pharmacy, as defined by law, at least forty (40) hours per year in the previous two calendar years or be granted a waiver by the Board.
(c) If the pharmacist must practice under supervision, the pharmacist must:
    (1) Prior to resuming the unsupervised practice of pharmacy, practice 40 hours under direct pharmacist supervision of an Arkansas licensed pharmacist for each year or part of year out of practice. This time under supervision shall not exceed 240 hours.
    (2) Cause the supervising pharmacist to document in writing to the Board, that the pharmacist has completed the designated number of hours of supervised practice.
    (3) Meet with a Board representative in a practice situation so that the Board representative can, by observation, questioning, and other methods, ensure that the pharmacist is able to competently practice pharmacy. (10/12/93, Revised 11/30/2010)

02-00-0004—ARMED FORCES CERTIFICATES

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

02-01: INTERNSHIP/CLERKSHIP

02-01-0001—INTERNSHIP REQUIRED

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

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

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

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

Hereafter, every applicant for licensure by examination in Arkansas must have 2,000 hours of acceptable internship training obtained after beginning the professional college curriculum. Required hours may be obtained in a training program as part of school curriculum under Arkansas Board of Pharmacy approved conditions. (Amended 5/31/14)

02-01-0003—DEFINITIONS

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

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

(c) "Supervision" means a licensed pharmacist and/or certified preceptor supervises the practical experience of a licensed intern with both personal and physical supervision, and actually gives instruction to the intern obtaining the experience during the entire period of such experience.
(d) "Class A pharmacy" means a pharmacy which has a pharmacy permit with a pharmacist on duty at least forty (40) hours per week, and no unsatisfactory deficiency and no more than three non-compliant deficiencies noted on its last Board inspection. (Amended 10/00, 11/13/2006, 7/5/2007, 11/1/2007, and 8/31/2011.)

02-01-0004—REQUIREMENTS FOR INTERNSHIP TRAINING

(a) Any extern or intern receiving internship training practice or experience in the State of Arkansas must be licensed as an intern with the Arkansas State Board of Pharmacy. No credit for internship training will be allowed prior to licensure as an intern. The intern license application can be obtained from the office of the Board of Pharmacy. The intern license fee is specified in regulation 01-00-0007(a)10.
(b) An applicant for an intern license shall submit an application on a form provided by the Board and shall have the following qualifications:
   (1) Be of good moral character and temperate habits, and
   (2) Be enrolled as a student in a college of pharmacy accredited by ACPE and approved by the Board, or be a graduate of a foreign college of pharmacy who has obtained Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification from NABP.
(c) All students enrolled in any college of pharmacy shall be licensed as interns by the Board prior to any participation in the practice of Pharmacy as defined in §17-92-101, §17-92-301, and §17-92-307 in Arkansas.
(d) The intern license remains valid as long as the intern maintains active student status in a Board-approved College of Pharmacy, and for six (6) months after graduation from a College of Pharmacy, or completion of foreign pharmacist requirements as set forth in regulation 02-02-0001 (a). At this time, the intern license becomes void.
(e) An intern may not practice pharmacy as a graduate intern until they have met all criteria for graduate intern status.
(f) The licensed intern's certificate must be displayed in the drugstore or pharmacy in which the intern is being trained. Licensed interns shall not be left in sole charge of the prescription department at any time. Violation of this regulation may result in a cancellation of any and all internship hours toward licensure that may be accrued by the pharmacy intern, and suspension, revocation or other penalties of the Pharmacist in Charge, the supervising pharmacist and/or the pharmacy permit.
(g) For graduates of a foreign college of pharmacy, the first 500 hours of pharmacy practice as a pharmacy intern, for each pharmacy setting where an intern practices pharmacy, the intern shall complete and file with the Board of Pharmacy office, prior to any practice, a "Training Plan" that is signed by the pharmacist in charge for that particular work situation. Prior to completion of the first 500 hours of practical experience, the pharmacy intern may only work under the direct supervision of a certified preceptor. Hours of practical experience include only those hours worked under the direct supervision of a preceptor and may not exceed 40 hours per week. The pharmacist in charge must approve and verify, by signing the affidavit of experience, that the intern has earned their hours of practical experience under the direct supervision of a certified preceptor. Training plans shall expire on May 31 of each year. At no time may a preceptor supervise more than one licensed intern. Interns must file affidavits of

experience prior to the expiration date of their training plan to get credit for these hours with the Board of Pharmacy.

(h) An intern may practice pharmacy in any Class A pharmacy under the supervision of a licensed pharmacist provided:
   1. The intern notifies the Board of Pharmacy in writing of his or her employment as a pharmacy intern within five days of starting to work in any pharmacy, and
   2. The intern notifies the Board of any change in his or her employment for any reason within five days of the change.
   3. Notification is made in writing by letter, fax, email or through the Board website and must contain the name of the intern, the name and address of the pharmacy, and the date of hire or date of change in employment. It is the intern's responsibility to verify that the notification has been received and processed by the Arkansas Board of Pharmacy.
   4. At no time may a supervising pharmacist or preceptor supervise more than one intern outside of an assigned educational rotation sponsored by a college of pharmacy.

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

(j) The Arkansas State Board of Pharmacy will not approve applicants for the NAPLEX until the applicant has provided proof of graduation from a college of pharmacy approved by the Board or proof of completion of foreign pharmacist requirements as set forth in regulation 02-01-0004(b)(3).

(k) A graduate intern may practice pharmacy in the State of Arkansas under the supervision of a pharmacist in a Class A pharmacy and will not count in the pharmacist or preceptor to intern ratio. A graduate intern must sit for the NAPLEX within 6 months of the date of graduation. If a graduate intern sits for the NAPLEX and does not make a passing grade, the graduate intern will be reduced to intern status and will once again count in the pharmacist to intern ratio.

(l) After presenting satisfactory proof of either
   (1) graduation and receipt of the first professional undergraduate degree from an ACPE accredited college of pharmacy approved by the Arkansas State Board of Pharmacy; or
   (2) Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification from NABP and submitting an affidavit of 2,000 hours of practical experience or training under Arkansas Board of Pharmacy approved conditions, the intern may be designated as a candidate suitable for full licensure if other conditions have been met.

(m) If the pharmacy intern is suspected to have, or evidence exists that a pharmacy intern may have violated any law or regulation regarding the practice of pharmacy, legend drugs or controlled substances, the preceptor shall notify the Board in writing, within ten days or immediately, if any danger to the public health or safety may exist. Any other pharmacist, whether or not practicing in the same pharmacy, who has such knowledge or suspicion, shall notify the Board in a like manner.

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

disciplinary proceedings against pharmacists shall be applicable to any proceeding against an intern in this subsection.

(Revised 6/22/84, 4/07/89, 6/20/91, 4/10/92, 10/2004, 11/13/2006, 11/1/2007, 7/10/2009, and 8/31/2011)

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

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

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

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

02-01-0006—PENALTY FOR VIOLATION

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

02-01-0007—ACCREDITED PHARMACY DEGREE PROGRAM

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

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

02-02: EXAMINATION

02-02-0001—REQUISITES FOR EXAMINATION

Before being approved to take the NAPLEX examination for licensure in Arkansas, each applicant must meet the following requirements:

(a) Satisfactory proof of graduation and receipt of the first professional undergraduate degree from a college of pharmacy approved by the Arkansas State Board of Pharmacy; or Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification from NABP with 2,000 hours of practical experience or training under Arkansas Board of Pharmacy approved conditions.

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

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

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

(e)

(1) The examination will be held at a site and at a time or during a time period designated by NABP or their contracted testing vendor.

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

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

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

(C)

i. the expiration of 6 calendar months following the applicant's graduation date from a college of pharmacy approved by the Arkansas State Board of Pharmacy; or

ii. reaching the intern license expiration date on December 31 of the second calendar year following issuance for foreign pharmacy graduates. Foreign pharmacy graduates may request an extension for the expiration of their intern permit while making progress towards the 2000 practice hours required for examination. Foreign pharmacy graduates must attain 500 initial practice hours in order to practice as a graduate intern.

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

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

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

(g) The applicant must make a score of 70% or more on the jurisprudence exam prior to making application for licensure as a pharmacist in the state of Arkansas. (10/09/80, Revised 1/14/81, 6/22/84, 6/13/85, 6/20/91, 2/11/97, 11/15/2003, 03/01/2004, 11/13/2006,11/1/2007, and 8/31/2011)

02-02-0002—SCORE TRANSFER

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

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

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

02-03: RECIPROCITY

02-03-0001—REQUIREMENTS FOR RECIPROCITY

No temporary license shall be granted to a reciprocity applicant until the preliminary application has been received and approved by the National Association of Boards of Pharmacy and the applicant has submitted the application to the Arkansas State Board of Pharmacy office, paid the reciprocity fee, undergone a criminal background check pursuant to Regulation 11, supplied a copy of the applicant's birth certificate, submitted proof of required continuing education, and supplied a current photograph of the applicant. The temporary license shall expire at the next meeting of the Board of Pharmacy after the issuance of the temporary license, or when the results of the criminal background check have been received, whichever is later. However, the temporary license will automatically expire 180 days from the date of issue and the holder of the temporary license must cease practicing pharmacy in the State of Arkansas until reciprocity has been granted by the Arkansas State Board of Pharmacy.

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

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

02-04: DEFINING UNPROFESSIONAL OR DISHONORABLE CONDUCT:

02-04-0001—Preamble

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

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

02-04-0002—Definition

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

(a) Violation of any provision of the pharmacy act.
(b) Violation of the Board of Pharmacy regulations.
(c) Violation of the Food, Drug and Cosmetic act.
(d) Violation of the Uniform Controlled Substances Act.
(e) Failure of a pharmacist to conduct himself or herself professionally in conformity with all applicable federal, state, and municipal laws and regulations in his or her relationship with the public, other health care professions, and fellow pharmacists.
(f) Failure to keep his or her pharmacy and/or area of professional practice clean, orderly, maintained and secured for the proper performance of his professional duties.
(g) Acquiring prescription stock from unlicensed sources or buying or selling legend drugs in violation of local, state, or federal law.
(h) Personal participation in the sale of alcoholic beverages while "on duty" as a pharmacist. (Exempts pharmacies selling alcoholic beverages before 6/85.)
(i) Failure to hold to the strictest confidences all knowledge concerning patrons, their prescriptions, and other confidence entrusted or acquired by him; divulging in the interest of the patron, only by proper release forms, or where required for proper compliance with legal authority.
(j) Participation in a plan or agreement, which compromises the quality or extent of professional services or facilities, at the expense of the public health and welfare.

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

02-05: BOARD ACTIONS

02-05-0001—EMERGENCY SUSPENSION

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

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

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

The Executive Director of the Board of Pharmacy shall introduce evidence why he/she thinks an emergency exists and that a violation of the Pharmacy licensing law or regulation has occurred. The Board shall determine whether the license should be summarily suspended. A hearing shall be scheduled promptly for which notice shall be given pursuant to § 17-92-313. If immediate action is requested, this hearing shall be within 14 days from the final Board decision. (10/12/88)

02-06: CONTINUING EDUCATION FOR PHARMACISTS

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

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

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

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

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

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

02-06-0002—ACCREDITATION GUIDELINES

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

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

(2) In the temporary absence of a designated Committee member, a designated representative may review and offer recommendations for establishing and reviewing the criteria for the accreditation of continuing education offerings.
(3) The Executive Director of the Board of Pharmacy shall review all programs within seven (7) days of receipt of request for accreditation.
(4) All requests for accreditation must be received, in writing, in the Board of Pharmacy office at least seven (7) days before the offering is to occur.

(c) Requirements for Accreditation
(1) The organization shall have completed the appropriate program requirements specified in section (d).
(2) The organization shall have the proper personnel to plan and produce educational programs.
(3) The organization and personnel presenting the offering shall be qualified in the area of the presentation.
(4) The organization shall provide the proper administrative facilities, provide the proper physical facilities, and have the financial resources for the production of educational programs.

(d) Program Criteria for Accreditation
(1) The program criteria shall be appropriate to meet the needs of the pharmacist.
(2) Beginning and ending times for each section of "live" programs must be indicated.
(3) A description of the program content shall accompany the request for accreditation and must be evaluated prior to its presentation.
(4) The program description, which is presented for accreditation, shall have a statement of objectives and goals.
(5) The program outline shall indicate how performance and effectiveness by the pharmacist will be measured.
(A) Live programs in themselves shall be acceptable for accreditation.
(B) Audiovisual and correspondence programs shall require a live moderator or testing procedure.
(6) The program shall allow the pharmacist a method to evaluate the presentation.
(7) The program shall demonstrate a quality educational process.
(A) Appropriate handout materials will be used with live presentations and correspondence courses.
(B) Appropriate audiovisual materials will be used with audiovisual presentations and correspondence courses when necessary.
(8) The program administrator shall present accreditation certificates to pharmacists, who satisfy requirements of the program. The application for approval shall specifically state how the accreditation certificates will be presented to participants.
(9) The Executive Director of the Board of Pharmacy must approve changes in the date, starting time, or duration, of the program being presented, if said changes are made after initial accreditation.
(10) Changes in speakers are acceptable if the quality of the program being presented is not diminished.
(11) The Executive Director of the Board of Pharmacy must receive any changes in topics to be presented at least seven (7) days before the program is to be presented.

(12) The organization presenting a continuing education program must provide reasonable notification to potential participants of any changes in date, time, or duration of the program; changes in speakers; or changes in topics to be presented.
(13) The program administrator shall require all participating pharmacists to sign in and out to show attendance during the entire CE session unit in order to be eligible for credit.
(14) The program administrator must keep a record of all attendees receiving credit for four (4) years for verification by the Board.

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

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

(Revised 11/30/2010)

02-06-0003—IMPLEMENTATION OF PHARMACY CONTINUING EDUCATION

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

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

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

(d) The Arkansas State Board of Pharmacy will accept continuing education credits, approved by State Boards of Pharmacy in other states, toward licensure as a pharmacist in Arkansas provided that there is a reciprocal arrangement and that the requirements of this section are met.

(e) Pharmacists are required to retain certificates of participation in continuing education for a period of four years and to certify completion of the required continuing education on a form furnished by the Board of Pharmacy with the license renewal forms. The pharmacist must

present certificates of participation to any representative of the Board of Pharmacy if requested to do so.

(f) Pharmacists who wish to retain their license, but do not want to meet the continuing education requirements, may go on inactive pharmacist status for an indefinite period. To reestablish active status and return to practice in Arkansas, a pharmacist must acquire half of the continuing education hours missed plus the continuing education hours for the current licensure period up to 60 hours. If the pharmacist has been on inactive status with regard to continuing education for two (2) calendar years or more and has not been actively practicing pharmacy in another state, said pharmacist shall also comply with all requirements in regulation 02-00-0003.

(g) Certifications awarded by the Board of Pharmaceutical Specialties during any biennium, will satisfy continuing education requirements for that biennium, subject to approval by the Arkansas Tripartite Committee on Continuing Pharmacy Education.

(h) Completion of post-graduate health professional course work may satisfy continuing education requirements subject to approval by the Arkansas Tripartite Committee on Continuing Pharmacy Education.

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

REGULATION 3 —PHARMACY TECHNICIANS

03-00—PHARMACY TECHNICIANS—REGISTRATION/PERMIT REQUIRED

03-00-0001—DEFINITIONS

(a) "Pharmacy technician" means those individuals, exclusive of pharmacy interns, who assist the pharmacist in pharmaceutical services.

(b) "Supervision" means that the responsible pharmacist must be physically present to observe, direct, and supervise the pharmacy technician at all times when the pharmacy technician performs acts specified in this regulation. The supervising pharmacist is totally and absolutely responsible for the actions of the pharmacy technician. (Revised 11/15/2003)

03-00-0002—REGISTRATION REQUIRED

(a) A pharmacy technician shall register with the Board of Pharmacy on a form provided by the Board and undergo a criminal background check pursuant to Board Regulation 11;

(b) The registration shall expire on December 31 biennially as provided in Board Regulation 01-00-0007

(c) The registration fee for a pharmacy technician shall be defined in regulation 01-00-0007.

(d) No person shall work as a pharmacy technician prior to the Board issuing a certificate of registration and a permit. The permit shall be prominently displayed for public perusal in any pharmacy where the technician is working. The pharmacist-in-charge shall determine that the person is registered as a pharmacy technician and that the Board has issued a permit for the technician before the technician performs any tasks identified in regulation 03-00-0005 or 03-00-0006.

(e) If there is a change of mailing address for the pharmacy technician, the pharmacy technician shall immediately notify the Board of Pharmacy, in writing, of the new address.

(f) When a pharmacy technician leaves the employment of a pharmacy, the pharmacist in charge shall notify the Board, in writing, within fourteen (14) days.

(g) Any concurrent or subsequent employment at any pharmacy shall be reported to the Board of Pharmacy by both the pharmacy technician and the pharmacist in charge of the pharmacy where the pharmacy technician will be working. The pharmacist in charge must notify the Board of Pharmacy, in writing, of the exact date when the pharmacy technician will begin working. The pharmacy technician shall not work at that location until the Board of Pharmacy has received said notification.

(h) A pharmacy technician shall identify himself/herself as such in any telephone conversation regarding the functions of a pharmacy technician while on duty in the pharmacy.

(i) If the pharmacy technician is suspected to have, or evidence exists that a pharmacy technician may have violated any law or regulation regarding the practice of pharmacy, legend drugs or controlled substances, the pharmacist in charge shall notify the Board, in writing, within ten days or immediately if any danger to the public health or safety may exist. Any other pharmacist, whether or not practicing in the same pharmacy, who has such knowledge or suspicion, shall notify the Board in a like manner.

(j)

(1) The Board may, after notice and hearing, suspend or revoke the permit of a pharmacy technician upon a finding of the following:

(A) Violation of this regulation.

(B) Violation of any law or regulation regarding the practice of pharmacy.
(C) Violation of any law or regulation related to legend drugs or controlled substances.

(2) The Board shall follow the same procedures for hearings for pharmacy technicians as applicable to hearings for pharmacists as set forth in §17-92-101 et seq. and Board regulations. (Revised 11/15/2003 and 7/22/2015)

03-00-0003—A PHARMACY TECHNICIAN SHALL

(a) Conduct himself/herself professionally in conformity with all applicable federal, state, and municipal laws and regulations in his relationship with the public, health care professions, and pharmacists.
(b) Hold to the strictest confidences all knowledge concerning patrons, their prescriptions, and other confidence entrusted or acquired by him/her; divulging in the interest of the patron, only by proper release forms, or where required for proper compliance with legal authority.
(c) Provide valid and sufficient checks in payment for licenses or renewals.

03-00-0004—QUALIFICATIONS

(a) A high school graduate or a recognized graduate equivalency degree (G.E.D.).
(b) Of good moral character and temperate habits.
(c) The applicant must complete a criminal background check pursuant to Board regulation 11. If the pharmacy technician has a past record of alcohol or drug addiction or past record of violation of any law related to controlled substances, registration must be prior approved by the Board of Pharmacy. (Revised 11/15/2003)

03-00-0005—TASKS, RESPONSIBILITIES, AND DUTIES OF THE PHARMACY TECHNICIAN

(a) A pharmacy technician may assist the pharmacist in performing the following specific tasks in accordance with specific written policy and procedures established by the pharmacist-in-charge covering the areas described in this section. The supervising pharmacist is responsible for all tasks performed by the pharmacy technician. All tasks performed by the pharmacy technician must be supervised, checked, and approved by the supervising pharmacist. If the pharmacy technician performs any other task that is defined as the practice of pharmacy, it will be considered a violation.
(b) Approved tasks:

(1) Placing, packing, pouring, or putting in a container for dispensing, sale, distribution, transfer possession of, vending, or barter any drug, medicine, poison, or chemical which, 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. This shall also include the adding of water for reconstitution of oral antibiotic liquids.
(2) Placing in or affixing upon any container described in this regulation, 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.
(3) Selecting, taking from, and replacing upon shelves in the prescription department of a pharmacy or apothecary drugs, medicines, chemicals, or poisons which are required by

the law 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.

(4)

(A) In a manual system -- preparing, typing, or writing labels to be placed or affixed on any container described in §17-92-101 on which a 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.

(B) In a computer system -- a pharmacy technician may enter information into the pharmacy computer. The pharmacy technician shall not make any judgment decisions that could affect patient care. The final verification of prescription-information, entered into the computer shall be made by the supervising pharmacist– prior to dispensing – who is then totally responsible for all aspects of the data and data entry.

(5) A pharmacy technician may obtain prescriber authorization for prescription refills provided that nothing about the prescription is changed; a pharmacy technician shall not receive prescriber authorization for a new prescription by telephone or by other verbal communication.

(6) Prepackaging and labeling of multi-dose and unit-dose packages of medication. The pharmacist must establish the procedures, including selection of containers, labels and lot numbers, and must check the finished task.

(7) Dose-picking for unit dose cart fill for a hospital or for a nursing home patient.

(8) Nursing unit checks in a hospital or nursing home. Pharmacy technicians may check nursing units for proper medication storage and other related floor stock medication issues. Any related medication storage problems or concerns shall be documented and initialed by a pharmacist.

(9) Patient and medication records. The recording of patient or medication information in manual or electronic system for later validation by the pharmacist may be performed by pharmacy technicians.

(10) The pharmacy technician shall not make any judgment decisions that could affect patient care.

(c)

(1) A pharmacy technician may assist in the following tasks when the pharmacist-in-charge has established a specific written policy and procedure for reconstitution of prefabricated non-injectable medication, bulk compounding, and/or preparation of parenteral products that establishes the order of addition of ingredients, the point at which the ingredients will be checked by the pharmacist, and the point at which the final product will be checked for integrity, correctness, and pharmaceutical elegance.

(2)

(A) Prior to any of these tasks being carried out by a pharmacy technician:

(i) the technician shall successfully complete an initial training, assessment of skills program, and test pursuant to a written training and assessment procedure established by the pharmacist-in-charge as provided in Regulation 03-00-0006; and

(ii) the pharmacist supervising a technician who engages in the above-referenced reconstitution, bulk compounding, and/or preparation of parental product shall

perform all calculations of ingredients and provide written directions for measurement of ingredients by the technician;

(B) Prior to dispensing any of said products for administration, the supervising pharmacist shall verify and approve in written form all ingredients as well as the final product.

(d)

(1) Bulk reconstitution of prefabricated non-injectable medication may include addition of multiple additives.

(2) Bulk compounding may include such items as sterile bulk solutions for small-volume injectables, sterile irrigating solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other products for the pharmacy or other departments of the facility.

(3) Preparation of parenteral products.

(A) Pharmacy technicians may:

(i) reconstitute and withdraw any amount (i.e. partial or entire amount) of an injectable medication to be administered to a patient; and

(ii) reconstitute, withdraw, and add any amount (i.e. partial or entire amount) of one or more injectable products to an IV solution to be administered to a patient. (Revised 10/12/99, 11/152003)

03-00-0006—DUTIES OF THE PHARMACIST IN THE USE OF PHARMACY TECHNICIANS

(a) A pharmacist-in-charge who utilizes a pharmacy technician to enter information into the pharmacy computer must develop and keep on file at the pharmacy, written policies and procedures which describe the process by which the supervising pharmacist verifies the accuracy, validity, and appropriateness of the filled prescription or medication order.

(b)

(1) A pharmacist-in-charge who utilizes a pharmacy technician for (1) bulk reconstitution of prefabricated non-injectable medication, (2) bulk compounding, and/or (3) preparation of parental products shall develop written policies and procedures for training, testing, and competency assessment of any pharmacy technicians performing these tasks.

(2) These policies and procedures shall incorporate those standards developed in the American Society of Health-Systems Pharmacists (ASHP) Guidelines on Quality Assurance for Pharmacy-Prepared Sterile Products (Copyright 2002) or a Board approved equivalent.

(c) The pharmacist-in-charge shall include, in the policy and procedure manual, the specific scope of responsibilities for pharmacy technicians or procedures delegated to pharmacy technicians.

(d) In each instance in which a pharmacy technician prepares or processes any medication identified in Regulation 03-00-0005, the supervising pharmacist

(1) Shall supervise the technician participating in those tasks as provided in Regulation 03-00-0001 (b);

(2) Shall personally determine all medication dose calculations and drug compatibilities, maintain proper storage conditions, and verify the proper labeling of all finished products, to include:

(A) For bulk products, the product name, name and strength of each drug, the name and volume of each vehicle, the preparation and expiration dates, and lot or equivalent numbers; and

(B) For individual products, the information required by law for individual prescriptions;

(3) Determine all medication dose calculations, drug compatibilities, maintain proper storage conditions, and verify the proper labeling of all finished products including appropriate expiration dates; and

(4) Shall record in written form his or her verification of the amount of each ingredient by volume, weight, or measure and of the final product by lot or equivalent number.

(e) The supervising pharmacist shall ensure that the pharmacy technician maintains confidentiality of all patient records.

(f) The pharmacist-in-charge shall maintain records of each drug product resulting from the procedures identified in paragraph (b) above for a period of two years and make said records available for inspection by the Board to include:

(1) A copy of all individual training, testing, and competency assessments;

(2) The record of verification of ingredients and final drug product described in paragraph (d) (4) above; and

(3) Policies and procedures applicable to producing said drug products.

(Revised 11/15/2003)

03-00-0007—PHARMACIST TO PHARMACY TECHNICIAN RATIO

(a) Retail or Specialty Pharmacy Settings

(1) Each pharmacist on duty in a retail or specialty pharmacy may utilize three pharmacy technicians to assist the pharmacist.

(2) In addition to the technician(s) described in this section, a pharmacist shall not also supervise more than one student intern unless the student(s) are working as part of an experiential learning experience as assigned by an ACPE accredited, Board approved College of Pharmacy. A graduate intern will not affect the ratio.

(b) Hospital or Ambulatory Care Facility Settings

(1) Pharmacy technicians used in assisting the pharmacist in pharmaceutical services for inpatients of the hospital, or patients of an ambulatory care facility shall be permitted to perform under direct supervision of a licensed pharmacist within the following conditions:

(A) The number of pharmacy technicians utilized in a hospital pharmacy or ambulatory care facility shall not exceed a ratio of three pharmacy technicians to each pharmacist on duty.

(B) This ratio shall not include pharmacy interns counted as either supportive personnel or pharmacists. Also excluded from the count of supportive personnel are those persons whose functions are not related to the preparation or distribution of medication. Such persons include clerks, secretaries, messengers, and delivery personnel. (8/23/96, Revised 10/2000, 8/2001 and 7/22/2015).

REGULATION 4 —PHARMACY

04-00: GENERAL REGULATIONS REGARDING PHARMACIES

04-00-0001—EQUIPMENT SPECIFICATIONS

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

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

Each pharmacy shall maintain a pharmacy library:

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

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

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

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

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

04-00-0003—VENDING MACHINES

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

04-00-0004—RE-USE OF DRUGS PROHIBITED

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

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

(b) to allow return of oral medications packaged in unit dose or blister packs, oral liquids in sealed unit dose packaging, and injectables in sealed unit dose vials or sealed multi-dose vials that have been sent to a long term care facility or correctional facility but have not been opened or partially used by that facility. The aforementioned medications may be returned to the dispensing pharmacy for reuse to another nursing home or correctional facility patient by relabeling the medication if the medication is returned to the pharmacy within 72 hours of delivery to the facility provided that:

(1) The drugs were originally dispensed by that pharmacy to the facility,
(2) Under the pharmacist's professional judgment the drugs are appropriate for return and reuse,
(3) Any pharmacist or pharmacy accepting eligible drugs for return or reuse must adopt written policies and procedures governing such drugs to assure compliance with section (b) of this regulation,
(4) Medications meet all federal and state standards for product integrity to the satisfaction of the dispensing pharmacist,
(5) The pharmacist has the assurance from a healthcare professional responsible for the drugs at the facility that the drugs have been stored in accordance with the manufacturer's recommendations,
(6) Medications requiring refrigeration can not be returned for re-use, and
(7) Controlled substances can not be returned for re-use.

(10/9/80, Revised 6/23/05, and 6/30/2007)

04-00-0005—PICK UP STATIONS

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

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

04-00-0006—EMERGENCY PHARMACY SERVICES

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

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

04-00-0007—APPLICATIONS FOR PHARMACY PERMITS

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

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

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

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

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

04-00-0010—PHARMACIST IN CHARGE

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

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

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

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

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

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

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

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

04-00-0011—PERMIT REQUIRED

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

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

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

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

04-00-0012—CHANGE OF OWNERSHIP

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

04-00-0013 —INVENTORY REQUIRED

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

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

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

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

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

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

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

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

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

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

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

(d) Pharmacists, pharmacy interns and pharmacy technicians shall implement the tools provided by the permit holder and follow the pharmacy's policies and procedures as instructed by the pharmacist in charge.
(Adopted 11/30/2010)

04-01: PHARMACY PERMIT FEES

04-01-0001—PERMIT FEES

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

04-02: REGULATIONS REGARDING RETAIL PHARMACIES

04-02-0001—APPLICATIONS FOR PHARMACY PERMITS

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

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

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

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

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

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

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

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

04-02-0004—NECESSARY EQUIPMENT REQUIRED

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

04-02-0005—RETAIL VETERINARY PHARMACY

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

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

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

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

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

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

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

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

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

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

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

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

(B) Date refilled.

(C) Number of authorized refills remaining.

(3) Daily Prescription Record

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

(i) Date of record.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

04-02-0011—CENTRAL FILL PHARMACY

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

(a) Definitions

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

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

(b) Record keeping

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(e) Carriers to transport filled prescriptions

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

(2) Retail pharmacies must comply with all federal and state laws when using private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy. When retail pharmacies contract with private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy, the retail pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a DEA Form 106.

(f) Labeling

The central fill pharmacy shall:

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

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

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

(g) Policies and Procedures

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

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

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

(3) Include policies and procedures for:

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

(B) Protecting the confidentiality and integrity of patient information

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

(D) Complying with federal and state laws and regulations

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

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

(11/15/2003, Revised 3/14/2006, Amended 5/31/2014)

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

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

(a) Definitions

(1) "Off-site order entry pharmacy" means a retail pharmacy which is licensed by the Board to process legend and controlled substance prescriptions that remotely accesses another pharmacy's electronic data base from outside the pharmacy in order to process prescription

drug orders, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

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

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

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

(C) performing drug regimen review;

(D) reconciling third party insurance claims;

(E) obtaining refill and substitution authorizations;

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

(G) performing therapeutic interventions; and

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

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

(A) known allergies;

(B) rational therapy-contraindications;

(C) reasonable dose and route of administration;

(D) reasonable directions for use;

(E) duplication of therapy;

(F) drug-drug interactions;

(G) drug-food interactions;

(H) adverse drug reactions; and

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

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

for safety and efficacy prior to the administration of the medication to the patient. Off-site order entry shall be prohibited out of state for prescriptions dispensed in the state of Arkansas.

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

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

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

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

(C) include policies and procedures for:

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

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

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

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

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

(d) General requirements.

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

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

(B) the same owner; or

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

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

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

(B) supervision requirements for pharmacy technicians.

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

(e) Notifications to patients.

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

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

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

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

(1) separately by each pharmacy and pharmacist; or

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

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

04-02-0100—NUCLEAR PHARMACY

The practice of nuclear pharmacy is hereby recognized as a specialty of pharmacy practice regulated by the Arkansas State Board of Pharmacy. As such, the following rules are included to address those areas specific, or unique to, this specialty practice. These regulations are intended to supplement the regulations of other state and federal agencies.

(a) Definitions:

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

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

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

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

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

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

(i) Radiation physics and instrumentation

(ii) Radiation protection

(iii) Mathematics pertaining to the use and measurement of radioactivity

(iv) Radiation biology

(v) Radiopharmaceutical chemistry

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

(i) Procuring radioactive materials

(ii) Compounding radiopharmaceuticals

(iii) Performing routine quality control procedures

(iv) Dispensing radiopharmaceuticals

(v) Distributing radiopharmaceuticals

(vi) Implementing basic radiation protection procedures

(vii) Consulting and educating the nuclear medicine community, pharmacists, other health professionals, and the general public.

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

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

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

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

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

(b) General requirements for pharmacies providing radiopharmaceutical services

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

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

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

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

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

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

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

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

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

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

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

(10) The immediate inner container label of a radiopharmaceutical to be dispensed shall be

labeled with:
(A) the standard radiation symbol;
(B) the words “Caution Radioactive Material”;
(C) the identity of the radionuclide;
(D) the chemical form;
(E) the name of the procedure; and
(F) serial number of the radiopharmaceutical.

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

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

(c) Minimum equipment

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

(1) Radionuclide Dose Calibrator;
(2) Refrigerator;
(3) Single or multiple channel scintillation counter with well-type Nal(TI) or Ge(Li) detector;
(4) Radiochemical fume hood and filter system with suitable air sampling equipment;
(5) At least two GM survey meters (including one high-range meter);
(6) Microscope and hemacytometer;
(7) Supplies to perform quality assurance testing;
(8) Syringe and vial radiation shields;
(9) Lead-shielded drawing station;
(10) Decontamination supplies;
(11) Supplies to perform quality assurance testing;
(12) Lead transport shields for syringes and vials; and
(13) D.O.T. approved USA Type A, 7A approved transport containers and other labels and supplies for shipping radioactive materials. (10/14/98 and 11/1/2007, Amended 5/31/2014)

04-03 REGULATIONS REGARDING RETAIL SPECIALTY PHARMACIES

04-03-0001—SPECIALTY PHARMACY PERMITS

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

04-03-0002 METHADONE CLINIC SPECIALTY PHARMACY PERMIT

(a) Definitions:

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

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

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

(b) Permit

(1) Applications for methadone clinic permits shall be submitted pursuant to regulation 04-02-0001.

(2) Any pharmacist shall notify the Board of Pharmacy in writing and ascertain that a methadone clinic pharmacy permit has been issued to the clinic before beginning practice in that clinic.

(c) Pharmacy operations

(1) The pharmacist in charge shall provide written policies, procedures, and protocols for the operation of the pharmacy and shall obtain the approval of same by the Executive Director of the Pharmacy Board prior to operation of said pharmacy.

(2) A methadone clinic pharmacy shall stock and dispense methadone or buprenorphine only unless permission is obtained from the Board of Pharmacy to utilize other medications for research purposes.

(d) Physical Facilities

(1) The pharmacy shall be a controlled area for the storage, safeguarding, preparation, and dispensing of methadone, a Schedule II narcotic, buprenorphine, a Schedule III controlled substance, and any other medications approved by the Board for research purposes, and shall have adequate facilities for pharmaceutical services including the procurement, storage, distribution, security and control of said drug consistent with all federal and state laws and regulations.

(2) The pharmacy shall have all equipment necessary to carry out the functions of the methadone clinic pharmacy and is otherwise exempt from regulation 04-02-0004; the equipment must be identified in the policies and procedures of each methadone clinic specialty pharmacy.

(e) Licensed pharmacist personnel requirements

(1) A methadone pharmacy shall be open to serve its patients, with a pharmacist or pharmacists on duty, a minimum of ten (10) hours per week or, if necessary, a greater period of time in order to perform pharmacy duties necessary to ensure patient safety.

(2) The pharmacy's operating hours must be approved by the Executive Director of the Arkansas State Board of Pharmacy. (Revised 11/15/2003, Amended 5/31/2014)

04-03-0003 – STUDENT HEALTH CLINIC PHARMACY PERMIT

(a) Definitions:
(1) "Student Health Clinic Pharmacy" means a pharmacy located on a university or college campus for the purpose of filling prescriptions for students or employees or their spouses or dependents.
(2) "Board" means the Arkansas State Board of Pharmacy.
(b) Permit
(1) Applications for student health clinic pharmacy permits shall be submitted pursuant to regulation 04-02-0001.
(2) Any pharmacist shall notify the Board of Pharmacy in writing and ascertain that a student health clinic pharmacy permit has been issued to the clinic before beginning practice in that clinic.
(c) Pharmacy operations
(1) The pharmacist in charge shall provide written policies, procedures, and protocols for the operation of the pharmacy and shall obtain the approval of same by the Board prior to operation of said pharmacy.
(2) A student health clinic pharmacy may stock and dispense legend and controlled substances
(d) Physical Facilities
(1) The pharmacy shall be a controlled area for the storage, safeguarding, preparation, and dispensing of legend and controlled substances, and shall have adequate facilities for pharmaceutical services including the procurement, storage, distribution, security and control of said drugs consistent with all federal and state laws and regulations.
(2) The pharmacy shall have all equipment specified in regulation 04-00-0001.
(e) Licensed pharmacist personnel requirements
(1) The pharmacy's minimum operating hours must be approved by the Board prior to operation of said pharmacy.
(2) A pharmacist or pharmacists must be on duty during all hours of operation.
(3) The pharmacist in charge must work fifty-percent (50%) of the hours of operation. (07/15/2004)

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

(a) The definitions in Ark. Code Ann. § 17-92-1102 are applicable in the regulation unless the context otherwise requires.
(b) Permit
(1) (A) Application for a pilot program permit for the reuse of donated prescription medications authorized by Ark. Code Ann. § 17-92-1101 *et seq*. shall be on a form provided by the Board, signed by the pharmacist in charge, and shall be submitted pursuant to Board regulation, but the fee for the application will be waived. The application and documentation identified in the following subparagraph shall be delivered to the Board's office 30 days prior to the meeting at which the applicant desires to appear for consideration of its application.
(B) The application shall be accompanied by appropriate documentation including:
(i) that necessary to qualify the applicant as a charitable clinic as defined in Ark. Code Ann. § 17-92-1102(1),

(ii) written policies and procedures for the operation of the charitable clinic pharmacy,

(iii) protocols to include the procedure for screening and determining that the patient qualifies on the basis of income below two hundred percent (200%) of the federal poverty level,

(iv) a depiction of the physical facilities for the pharmacy and a description of provisions for security for and access to the pharmacy,

(v) a statement of any fees charged to patients,

(vi) a list stating the pharmacy's hours of operation, equipment and library materials, and

(vii) the proposed contract with nursing home(s) for donation of unused prescription mediations, and

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

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

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

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

(c) Pharmacy operations

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

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

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

(d) Physical Facilities

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

(e) Changes in pharmacy operations

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

(f) Limited Use Technician Permit

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

04-04: OUT OF STATE PHARMACIES

04-04-0001—OUT OF STATE PHARMACY REGULATION

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

(a)

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

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

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

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

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

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

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

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

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

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

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

(5) Medical necessity.
(6) The effect on the health and welfare of persons in Arkansas.
(7) Any other relevant matters.

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

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

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

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

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

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

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

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

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

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

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

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

(A) The pharmacy is sold and the sale becomes final or the new owner assumes control of the pharmacy--whichever occurs first.
(B) The proprietor enters into a partnership with another individual or business entity.

(2) A change of ownership of a pharmacy, owned by a PARTNERSHIP, is deemed to have occurred when:
(A) There is an addition or deletion of one or more partners in a partnership to which a pharmacy license has been issued.
(B) The pharmacy is sold and the sale becomes final or the new owner assumes control of the pharmacy--whichever occurs first.

(3) A change of ownership of a pharmacy, owned by a CORPORATION, is deemed to have occurred when:
(A) An individual or business acquires or disposes of twenty percent (20%) or more of the corporation's outstanding shares of voting stock. (This shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over the counter market); or
(B) The corporation merges with another business or corporation. (The corporation owning the pharmacy is required to notify the Arkansas State Board of Pharmacy if a change of ownership or merger occurs within the parent corporation of the corporation which owns the pharmacy); or
(C) The corporation's charter expires or is forfeited; or
(D) The pharmacy is sold and the sale becomes final or the new owner assumes control of the pharmacy-whichever occurs first.

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

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

04-05: REGULATIONS REGARDING HOSPITAL PHARMACIES

04-05-0001—HOSPITAL PHARMACEUTICAL SERVICES PERMIT

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

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

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

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

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

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

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

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

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

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

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

(2) Compounding, dispensing and distributing

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

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

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

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

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

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

(3) Administering

An act, restricted to nursing personnel as defined in Nurses Practice Act 43 of 1971, in which a single dose of a prescribed drug or biological is given a patient. This activity includes the removal of the dose from a previously dispensed, properly labeled container,

verifying it with the prescriber's orders, giving the individual dose to the proper patient and recording the time and dose given.

(4) Pharmacy and therapeutics committee

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

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

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

(C) The committee performs the following specific functions:

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

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

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

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

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

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

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

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

(5) Pharmacy operations

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

(A) Pharmacy supervision

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

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

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

(iii) All licensed pharmacists who provide pharmaceutical services as defined by the Pharmacy Practice Act shall practice under policies, procedures, and protocols

approved by the director of pharmacy. These policies, procedures, and protocols shall be subject to review and approval by the Board of Pharmacy.

(6) Physical facilities

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

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

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

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

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

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

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

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

(i.) available for use by the pharmacist and the patient, including either current drug information manuals, or computers capable of printing current drug information for the pharmacist and patient drug information and monographs for patients.

(ii.) other pharmacy reference books and periodicals necessary for effective pharmacy practice.

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

(7) Personnel

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

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

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

(i) Chief pharmacist (director of pharmacy)

(ii) One or more assistant chief pharmacists (assistant director of pharmacy).

(iii) Staff pharmacists.

(iv) Pharmacy residents (where program has been activated).

(v) Trained non-professional pharmacy helpers (qualified hospital personnel).

(vi) Clerical help.

(8) Emergency pharmaceutical services

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

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

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

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

(9) Pharmacy records and labeling

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

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

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

(ii) Charging patients for drugs and pharmaceutical supplies.

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

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

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

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

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

(10) Control of toxic or dangerous drugs

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

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

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

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

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

(11) Drugs to be dispensed

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

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

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

(12) Policy and procedure manual

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

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

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

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

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

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

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

(13) Employee prescription medication

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

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

(14) Patient discharge medication

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

(15) Licensed pharmacist personnel requirements

The minimum requirements for licensed pharmacists in hospitals are:

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

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

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

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

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

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

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

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

(16) Responsibility of a pharmacist in a hospital pharmacy

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

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

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

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

a. Accuracy and appropriateness of dose and dosage schedule.

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

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

(C) Final certification of the prepared medication.

(17) Operation of pharmacy department without a pharmacist

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

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

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

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

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

04-05-0002—MECHANICAL STORAGE AND DELIVERY

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(D) The pharmacist in charge of the hospital pharmacy will maintain a bound log book in which each individual pharmacist and intern involved in the dispensing of medications will sign the log book each day, attesting to the fact that the prescription information entered into the computer that day has been reviewed by him and is correct as shown. The log shall identify the time of day at which the pharmacist started filling and stopped filling prescriptions. The log book shall be maintained by the pharmacist in charge or his successor, in the hospital pharmacy employing such a system for a period of two (2) years after the date of dispensing the appropriately authorized prescription.

(3) Assure strict confidentiality of all patient records.

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

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

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

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

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

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

04-05-0004 - OFF SITE ORDER ENTRY

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

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

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

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

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

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

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

(ii) competent to enter faxed or scanned order for patients in that facility, including, but not limited to the ability to accurately:

(iii) receive, interpret, and accurately enter medication orders from any physician on staff at that facility;

(iv) access and interpret clinical data as it pertains to that patient's drug regimen;

(v) perform therapeutic interventions;

(vi) perform cross checks for known drug allergies, adverse drug reactions, and contraindications;

(vii) perform drug-drug interaction as well as drug-food interaction review;

(viii) identify any over-utilization or under-utilization.

(ix) available via telephone for any questions or issues from nursing staff as well as from staff physicians; this number shall be posted in a visible place at each nursing station, in all dictation rooms, and all other areas within the facility that physician might write order or nurse might fax or scan order.

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

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

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

(i) software,

(ii) hardware, and

(iii) connectivity

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

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

04-06: INSTITUTIONAL PHARMACEUTICAL SERVICES PERMIT

04-06-0001—CLASS #1 INSTITUTIONAL PERMIT

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

(b) A licensed pharmacist employed or otherwise engaged to provide pharmaceutical service may have a flexible schedule of attendance in the institution, provided, however, the pharmacist must be physically present in the institution for a sufficient number of hours weekly to maintain adequate supply of medications at the service area from which medications are administered, to maintain all records, to perform other pharmaceutical services authorized by law and provide adequate control and accountability of all drugs under his responsibility.

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

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

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

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

(g) With recognition of DEA's statement of policy regarding emergency kits for long-term care facilities, and recognizing DEA's definition of long term care facilities, the following requirements must be met for facilities with institutional pharmaceutical services permits to store emergency kits, containing controlled substances and/or other legend drugs, in these facilities in Arkansas.
   (1) All contents of the emergency kit will be provided by one pharmacy designated by the facility.
   (2) The facility holding an institutional permit with the Board of Pharmacy must have resident patients to which the facility provides extended health care.
   (3) The controlled and legend drugs must remain the property of and under the responsibility of the pharmacy, which must have an Arkansas permit.

(4) All medications must be administered only on the order of a practitioner and medications administered from the nurse's supply must be recorded as a prescription by the pharmacy prior to the pharmacy's replacement of the drug in the emergency supply.
(5) All medication records must be maintained as required by law, and out of date drugs must be properly destroyed by the pharmacy.
(6) Careful patient planning should be a cooperative effort between the pharmacy and the nursing department at the facility to make all medications available, and the emergency supply should only be used for emergency or unanticipated needs and shall not become a routine source or supply.
(7) The pharmacy is responsible to assure compliance with this regulation, and any abuse or misuse of the intent of this regulation shall be immediately reported to the Board of Pharmacy.
(8) Storage conditions for the emergency kit shall meet all state and federal requirements. The storage conditions shall be set out in the policy and procedures of the facility.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(e) Institutional pharmaceutical services permits may be issued to correctional infirmaries and dispensaries.
  (1) Correctional infirmaries
    (A.) All policies and procedures related to the institutional pharmaceutical services permit must first be approved by the Board staff before a permit will be issued to ensure compliance with all existing laws and regulations. Any changes to the policies and procedures related to the procurement, administration, distribution or storage of prescription medications shall be reported to the Board of Pharmacy within 30 days.
    (B.) Policies and procedures for obtaining, dispensing, and administering drugs and biologicals shall be developed with the consultation of an Arkansas licensed pharmacist and the approval of medical staff.
    (C.) Special floor stock or back up medications to meet the emergency needs of the patients in the correctional facility will be permitted only when specifically outlined in the policies and procedures manual. The policy and procedures manual shall at a minimum include:

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

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

(2) Correctional Dispensaries

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) Patient Drug Regimen Review

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

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

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

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

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

(iii) Review patient compliance with drug regimen.

(iv) Review drug allergies or sensitivities.

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

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

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

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

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

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

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

(4) Labeling of drugs and biologicals and proper storage

(A.) It is the duty of the pharmacist consultant(s) to ascertain during each visit to the correctional facility, that medications are properly labeled, properly stored, refrigerated when needed, expiration dates routinely checked, and that appropriate accessory and cautionary instructions are on all medications when required. (11/1/2007)

04-07: CHARITABLE CLINIC PERMIT

04-07-0001—ISSUANCE OF CHARITABLE CLINIC PERMIT

The Arkansas State Board of Pharmacy may provide for the issuance of a charitable clinic pharmacy permit to clinics and facilities furnishing medical care and dental care to poor and underprivileged persons, in which drugs are dispensed without charge to such persons on orders or prescriptions of practitioners authorized by law to prescribe or administer said drugs and to which the requirements of a licensed pharmacist on duty for a minimum of forty (40) hours shall not apply.

04-07-0002—PRESCRIPTIONS

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

04-07-0003—POLICIES AND PROCEDURES FOR CLINICS

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

04-07-0004—CATEGORIES FOR PERMITS

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

(a) Clinics of the Arkansas Department of Health

(1) recognizing that medications are provided to patients in the absence of a pharmacist and that the medications dispensed in these clinics are limited to birth control medications, drugs to treat tuberculosis, and drugs to treat sexually transmitted disease treatment program.

(2) Packaged and labeled prescription drugs shall be initialed by the pharmacist to assure accuracy and appropriateness. The prescribing practitioner or a licensed nurse may issue these pre-dispensed prescription drugs, by placing the patients name, date of issue and prescription number on the label at the time of issue to patients on order of the prescriber.

(3) The prescription number, as placed on the label of the dispensed prescription drug, is to be placed with the prescribing practitioner's order in the patients medical record. The pharmacist shall monitor patients’ medical records to assure that medication profiles and prescription orders are maintained and utilized.

(4) Since the pharmacist is not present when the patient receives the medication, the pharmacist shall develop protocol to assure that the patient is monitored and counseled by the prescribing practitioner or nurse consistent with the requirements of Board of Pharmacy regulation 09-00-0001.

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

04-07-0005—PHARMACIST PRESENT WHEN MEDICATION PROVIDED

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

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

(a) Purpose

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

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

(b) Definitions

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

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

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

(c) Donation of prescription drugs

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

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

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

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

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

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

(B) The drugs can be identified.
(C) The drugs are not adulterated or mutilated.
(D) The expiration dates are more than 30 days after the date the drugs are to be delivered to the charitable clinic pharmacy.

(2) A manifest has been properly completed to include the following;
(A) Names of Consultant Pharmacist and Director of Nursing or designee, the nursing home and the name of the receiving pharmacy;
(B) Name, strength, expiration date and quantity of each prescription drug to be donated;

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

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

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

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

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

(e) Eligible prescription drugs.

(1) A charitable clinic pharmacy shall accept from a nursing facility only those unused prescription medications identified in the contract identified in paragraph c(2) of this regulation; the charitable clinic pharmacy shall not accept any unused prescription medication identified in said contract for which the charitable clinic pharmacy does not have or reasonably anticipate a patient need.

(2) Eligible prescription drugs are those packaged in single-unit doses or blister packs provided that the outside packaging can be opened if the single-unit dose packaging remains intact, or the manufacturer's original sealed or tamper evident packaging.

(3) The expiration date placed on the medication by the original pharmacy dispensing to the nursing home patient, consistent with USP standards, shall become the actual expiration date for the eligible medication;

(4) No lost identity or unknown drugs shall be accepted by a charitable clinic pharmacy;

(5) No adulterated or misbranded drugs shall be accepted by a charitable clinic pharmacy; and

(6) Only those drugs that have physically been in the nursing facility at all times since being dispensed by the originating pharmacy shall be accepted by a charitable clinic pharmacy.

(7) Compounded drugs shall not be accepted by a charitable clinic pharmacy.

(f) Patients eligible for donated prescription drugs

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

(g) Pharmacies eligible to accept and dispense unused prescription medications from nursing homes.

(1) A pharmacy shall hold a permit in good standing under Board regulation 04-03-0004.

(2) Prescription medications donated under this Section shall not be sold, resold, offered for sale, traded or transferred to another charitable clinic pharmacy.

(h) Procedures for charitable clinic pharmacies to dispense donated prescription drugs.

(1) (A) A pharmacist on staff at the charitable clinic pharmacy shall verify, utilizing an appropriate reference resource, that the drug name and strength noted on the label of each unit of the packaged donated medication is correct.

(B) The pharmacist verifying the drug shall place his/her initials on the medication label.

(C) If the identity of the drug cannot be verified, the pharmacist shall segregate the unidentified drug for destruction and shall not dispense the medication.

(D) Medications shall not be removed from the donor's original packaging until after verification by the charitable clinic pharmacist; a pharmacist shall then re-label the medication with the name and strength of the medication and the expiration date from the donor's original drug package.

(2) Pharmacists shall dispense unused prescription drugs only upon the valid prescription of an Arkansas licensed health care practitioner.

(3) (A) Pharmacists shall label each medication to be dispensed according to Ark. Code Ann. § 17-92-505.

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

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

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

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

(4) Storage.

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

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

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

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

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

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

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

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

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

(7) Destruction of drugs.

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

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

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

REGULATION 5 - LONG-TERM-CARE FACILITIES

05-00—NURSING HOME CONSULTANTS

05-00-0001—DEFINITIONS

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

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

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

05-00-0002— GENERAL REQUIREMENTS

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

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

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

05-00-0003—RESPONSIBILITIES

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

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

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

(b) Control and accountability of all legend drugs (including controlled substance)
(1) The consultant pharmacist develops written procedures for control and accountability of all drugs and biologicals throughout the facility and supervises the implementation of these procedures.
(2) Only approved drugs and biologicals are used in the facility and shall be dispensed in compliance with federal and state laws. Records of receipt and disposition of all controlled drugs shall be maintained in sufficient detail to enable an accurate reconciliation. The consultant pharmacist shall determine that drug records are in order and that an account of all controlled drugs is maintained and reconciled.
(3) The consultant pharmacist(s) shall establish procedures to ensure that:
(A) All legend drugs and controlled substances must be stored in a secured location and appropriately locked.
(B) Proper records of receipt and administration of controlled drugs must be maintained for review by the consultant pharmacist.
(C) Non-controlled legend drugs.
(i) Drugs to be destroyed shall be handled in accordance with state and federal requirements.
(ii) Drugs to be donated. The consultant pharmacist shall cause all drugs that are designated for donation to charitable clinics licensed by the Board under Regulation 04-03-0004 and ACA § 17-92-1101 et seq., to be processed in accordance with Board Regulation 04-07-0006.
(D) Controlled drugs shall be handled in accordance with state and federal requirements

(c) Patient Drug Regimen Review
(1) The primary duty of the consultant pharmacist(s) to the patients' concerns is to apply his or her expertise on drugs to the patient's specific situation.
(2) State and federal regulations shall be the minimum standards for an adequate drug regimen review.
(3) Additionally, the consultant pharmacist shall routinely review each patient's chart and:
(A) Ascertain that patient history and drug utilization is being properly recorded.
(B) Review drug usage (including O.T.C. and prescriptions).
(C) Review patient compliance with drug regimen.
(D) Review drug allergies or sensitivities.
(E) Determine whether the patient is predisposed to side effects due to disease, illness, or age.

(F) Determine whether potential exists for significant drug interaction.
(G) Develop procedures to monitor patients' records for signs that indicate abuse or misuse of drugs by the patient or individuals.
(H) Make recommendations regarding drug therapy to the physician, nurse or other persons involved in the patient's care.
(I) Communicate to the facility, procedures that ensure adequate pharmacy services are available for emergencies that might develop in the nursing home for a specific patient.
(J) Promote pharmacists' ability and knowledge to all persons involved in patient care and to offer assistance in solving specific problems relating to patient drug regimen.

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

(d) Labeling of drugs and biologicals and proper storage

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

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

(e) Quality assurance and patient assessment committee

(1) A consultant pharmacist(s) shall be a member of the quality assurance and patient assessment committee (or its equivalent) and make official reports to this committee as often as needed to ensure quality pharmaceutical care.

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

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

(A) Stop order policies or other methods to ensure appropriateness of continued drug therapy.
(B) Maintaining the contents of the emergency kit in compliance with Board regulation 05-00-0005.
(C) Policies for the safe procurement, storage, distribution, and use of drugs and biologicals. (10/9/80, Reg. Revised 2/17/82, 6/25/83, 10/12/93, 02/11/2003, 6/23/05, 7/10/2009 and 8/1/2018)

05-00-0004—EMERGENCY KITS FOR LONG-TERM-CARE AND OTHER APPROVED INSTITUTIONAL FACILITIES

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

Requirements

(1) All contents of the emergency kit will be provided by one pharmacy designated by the long-term-care facility. This pharmacy must be properly registered with D.E.A.

(2) The emergency kit shall be properly sealed, stored, and accessible only to authorized personnel.
(3) The emergency kit contents shall only be administered by authorized personnel acting on order of a physician in compliance with 21 CFR 1306.11 and 21 CFR 1306.21.
(4) The categories of drugs that may be contained in an emergency kit are identified in Board regulation 05-00-0005. The contents of the kit shall be determined by the medical director, director of nurses and consultant pharmacist at the long-term-care facility. Any exceptions to the established standard categories must be approved by the Board of Pharmacy. A list of contents shall be kept in the kit.
(5) The facility's licensed consultant pharmacist shall be responsible for maintaining the nursing home's emergency kit contents in compliance with Board regulation 05-00-0005 and the facility's licensed consultant pharmacist shall check the kit monthly for outdated drugs, etc.
(6) All drugs administered from the kit will be replaced within 72 hours by the designated provider pharmacy based on a prescription for the patient to whom the drugs were administered.
(7) Violation of this regulation 05-00-0001 through 05-00-0005 shall be just cause for the Board to impose appropriate disciplinary action.
(8) Emergency kit drugs shall be of such a nature that the absence of such drugs would detrimentally affect the health of the patient.
(9) Before an out of state pharmacy may supply an emergency kit to an Arkansas long-term care facility, it must provide an affidavit on a form supplied by the Board that it will comply with Arkansas law regarding emergency kits. If applicable, an out of state pharmacy will also be subject to reciprocal restrictions as are imposed by its home state on out of state pharmacies. (10/14/1981 and 7/27/2011)

(b) Recognizing the emergency and or unanticipated need for certain legend (non-controlled) drugs to be available to nurses employed by Arkansas licensed home health agencies, an Arkansas licensed pharmacy may provide certain medications under the following conditions:
(1) A written contract must exist between the Arkansas licensed home health agency and the Arkansas licensed pharmacy, and this must be available for review by the Board of Pharmacy upon request.
(2) The legend drugs remain the property of, and under the responsibility of, the Arkansas licensed pharmacy.
(3) All medications shall be administered only on physician's orders and any medication administered from the nurse's supply must be recorded as a prescription by the pharmacy prior to the pharmacy's replacement of the drug in the emergency supply.
(4) All medication records must be maintained as required by law, and out of date drugs must be properly destroyed by the pharmacy.
(5) The emergency supply may be carried by each nurse or an emergency kit may be provided for each patient's home.
(6) Careful patient planning shall be a cooperative effort between the pharmacy and the nursing agency to make all medications available and this emergency supply shall only be used for emergency or unanticipated needs and shall not become a routine source or supply.
(7) Only the following medications can be supplied for emergency use by licensed home health agencies under this paragraph by the pharmacy in sufficient but limited quantities:
(A) Heparin flush: pediatric (one strength)
(B) Heparin flush: adult (one strength)

(C) Sterile water for injection: small volume
(D) Sodium chloride for injection: small volume
(E) Adrenalin (epinephrine) injection: single dose only
(F) Benadryl (diphenhydramine) injection : single dose only
Note: For heparin, adrenaline and benadryl, all patients shall have a precalculated dose.
(G) If a container is opened and partially used, the unused portion shall be immediately discarded.

(8) The pharmacy is responsible to ensure compliance with this regulation, and any abuse or misuse of the intent of this regulation shall be immediately reported to the Board of Pharmacy.

(9) The pharmacy and the agency shall develop policy and procedures to address storage conditions for medications. (Revised 10/12/93, 10/14/97, 02/11/2003, 6/23/05, 7/10/2009 and 8/1/2018)

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

The following is a list of categories of drugs which are acceptable in emergency kits in long-term-care facilities in accordance with this regulation of the Arkansas State Board of Pharmacy. The Board shall set guidelines for specific quantities of approved medications which will be reviewed biennially or periodically as needed. The provision or presence of an emergency kit in long-term care facilities does not waive the requirements of board regulation 04-00-0006 which requires any pharmacy providing prescription drugs to one or more patients in a nursing home or other institution to provide emergency prescription services for those patients and to provide information to the nursing home or institution indicating how the pharmacists can be reached after pharmacy hours. In every instance where injectables are indicated, only single-dose injectables are acceptable**.**

(a) Analgesics, controlled drugs
(b) Anti-Infectives
(c) Anticholinergics
(d) Anticoagulant
(e) Antidiarrheals
(f) Antihistamine Injectables
(g) Antinauseants
(h) Antipsychotic injectables
(i) Anti-hyperglycemics
(j) Anxiolytics
(k) Cardiac life support medications
(l) Coagulants
(m) Corticosteroids
(n) Hypoglycemics
(o) Seizure control medications
(p) Large volume parenterals
(q) Poison control
(r) Respiratory medications
(s) GI Medications
(t) Other medications as approved by the Board

(Revised 02/11/2003, 11/1/2007, 7/10/2009, 7/22/2015 and 8/1/2018)

05-00-0006—DRUG CATEGORIES FOR EMERGENCY KITS IN HOSPICE CARE FACILITIES.

The following is a list of categories of drugs which are acceptable in emergency kits in licensed in-patient hospice facilities in accordance with this regulation of the Arkansas State Board of Pharmacy. The Board shall set guidelines for specific quantities of approved medications which will be reviewed periodically. The provision or presence of an emergency kit in an in-patient hospice facility does not waive the requirements of board regulation 04-00-0006 which requires any pharmacy providing prescription drugs to one or more patients in a nursing home or other institution to provide emergency prescription services for those patients and to provide information to the nursing home or institution indicating how the pharmacists can be reached after pharmacy hours.

(a) Analgesics, controlled drugs
(b) Antihistamine Injectables
(c) Antinauseants
(d) Antipsychotic Medications
(e) Anxiolytics
(f) Seizure control medications
(g) Corticosteroids
(h) Anticholinergic medications
(i) Opioid antagonist
(j) Other medications as approved by the Board

(5/31/2014, Revised 7/22/2015)

05-00-0007—DRUG CATEGORIES FOR EMERGENCY KITS IN CRISIS STABILIZATION UNITS.

The following is a list of categories of drugs which are acceptable in emergency kits for facilities that are certified by the Arkansas Department of Human Services as a Crisis Stabilization Unit (CSU). The Board shall set guidelines for specific quantities of approved medications which will be reviewed periodically. The provision or presence of an emergency kit in a Crisis Stabilization Unit does not waive the requirements of board regulation 04-00-0006 which requires any pharmacy providing prescription drugs to one or more patients in a nursing home or other institution to provide emergency prescription services for those patients and to provide information to the nursing home or institution indicating how the pharmacists can be reached after pharmacy hours.

(a) Analgesics, controlled drugs
(b) Antihistamine Injectables
(c) Antinauseants
(d) Antipsychotic Medications
(e) Anxiolytics
(f) Cardiac life support medications
(g) Injectable seizure control medications

(h) Anticholinergic medications
(i) Opioid antagonist
(j) Other medications as approved by the Board
(Adopted 8/1/2018)

REGULATION 6 —DISCIPLINARY PROCEDURES

06-00-0001—PROCEDURES FOR DISCIPLINARY ACTION

Before revoking the certificate of licensure of any licensed pharmacist or licensed pharmacy permit, the Board of Pharmacy shall give the licensee proper notice in writing to appear before the Board, at such time and place as the Board may direct, to show cause if any, why the certificate or permit should not be revoked. Said notice shall be signed by the Executive Director of the State Board of Pharmacy and shall set forth in clear concise language the nature of the charge against the licensee. Mailing a copy of such notice by registered mail, addressed to the licensee at the address appearing upon the records of the State Board of Pharmacy concerning the issuance of the certificate or permit or the last renewal thereof, shall be sufficient service to such notice. At such hearing, the Board shall have power to subpoena witnesses and the President or Chairman of the Board shall have the power to administer oaths and the Board shall hear evidence. If the Board finds, after such hearing, that the certificate of licensure or permit of the licensee should be revoked, the same shall be done forthwith.

REGULATION 7—DRUG PRODUCTS/PRESCRIPTIONS

07-00: GENERAL REGULATIONS REGARDING DRUGS/PRESCRIPTIONS

Definitions:

“Prescription” means an order for medicine or medicines usually written as a formula by a physician, optometrist, dentist, veterinarian, or other licensed medicinal practitioner. It contains the names and quantities of the desired substance, with instructions to the pharmacist for its preparation and to the patient for the use of the medicine at a particular time and may authorize the pharmacist to substitute a therapeutically equivalent drug that is at a lower cost to the patient and communicate that authorization by any generally accepted means of communication of a prescription from a prescriber to a pharmacist.

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

"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;

"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

"Written prescription" means a prescription that is presented to an apothecary, pharmacy or pharmacist in compliance with federal law and regulations, including a written, oral, faxed, or electronic prescription. (5/31/2014, Amended 11/30/2014)

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

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

(a) Faxing Schedule II prescriptions
   (1) Faxing a Schedule II prescription for a home infusion, or intravenous pain therapy patient or both - a prescription, written for a Schedule II narcotic substance to be compounded for direct administration to a home infusion patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, may be transmitted directly from the prescribing practitioner, by the practitioner or the practitioner's agent, to the pharmacy by facsimile. The facsimile serves as the original written prescription. This exception does not apply to oral dose medications. (Also see Regulation #07-04-0001)
   (2) Faxing a Schedule II prescription for a long-term-care patient – a prescription written for a Schedule II substance, for a resident of a long-term-care facility may be transmitted directly from the prescribing individual practitioner, or the practitioner's agent, to the provider pharmacy by facsimile. The facsimile serves as the original written prescription. (See also regulation 07-04-0001)

(3) A prescription written for a Schedule II substance, for a home hospice patient may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. It must be noted on the prescription that this is a hospice patient. The facsimile serves as the original written prescription. (see regulation 07-04-0001)

(b) Faxing from a long-term-care facility to a pharmacy – a pharmacist may accept a fax prescription from a long-term-care facility provided:

(1) For Schedule II drugs, all requirements of a written prescription are met, including the prescriber's signature on the faxed order and it is faxed by the nurse/person the physician and the long-term-care facility has designated as his/her "agent" to transmit the order, and must contain the nurse/person's signature.

(2) For drugs other than Schedule II, the order is faxed by the nurse/person the physician and the long-term-care facility has designated as his/her "agent" to transmit the order, and must contain the nurse/person's signature.

(3) The pharmacist verifies the fax is from the machine in the long-term-care facility.

(c) Faxed prescriptions

(1) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V which is a prescription drug, or any legend drug, only pursuant to either a written prescription signed by a prescribing individual practitioner or a facsimile of a written signed prescription transmitted directly by the prescribing practitioner, or the practitioner's agent, to the pharmacy or pursuant to an oral prescription made by a prescribing individual practitioner, or the practitioner's agent, and either entered into the pharmacy’s electronic prescription system or promptly reduced to writing by the pharmacist.

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

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

(4) A pharmacist may dispense new prescription orders transmitted by fax only when signed by the prescribing practitioner and transmitted from the practitioner's office or a long-term-care facility in compliance with all sections of this document. Any faxed new prescription order that is not signed must be treated as a verbal order and verified to the pharmacist’s satisfaction that it is legitimate.

(5) The original fax shall be assigned the number of the prescription dispensed, and maintained in pharmacy records for at least two years.

(6) The receiving fax machine must be in the prescription department of the pharmacy to protect patient/pharmacist authorized prescribing practitioner confidentiality and security.

(7) Refill authorizations for prescriptions, other than Schedule II, may be transmitted using a facsimile device. Any faxed authorization to renew or refill a prescription that is not signed must be treated as a verbal order and verified to the pharmacist’s satisfaction that it is legitimate.

(d) Patient/prescriber consideration

(1) No pharmacist shall enter into any agreement with a practitioner or health care facility concerning the provision of facsimile machine services or equipment which adversely

affects any person's freedom to choose the pharmacy at which a prescription will be filled.

(2) A pharmacy/pharmacist shall not provide a fax machine to a prescriber, a long-term-care facility, or any healthcare facility free of charge or for less than the pharmacy/pharmacist cost.

(3) No agreement between a prescriber and a pharmacy shall require that prescription orders be transmitted by facsimile machine from the prescriber to only that pharmacy.

(4) A pharmacy/pharmacist shall not enter into any agreement whereby the pharmacy/pharmacist pays to obtain the prescription order by fax or any electronic data transfer. (10/12/93 Amended 2/15/95, 10/14/1997, 7/10/2009, and 5/31/2014)

07-00-0002—PRESCRIPTION TRANSFERS

(a) The transfer of original prescription information for a legend drug or a controlled substance for the purpose of dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization. Transfers are subject to the following requirements:

(1) The transfer is communicated directly between two licensed or registered individuals where one of the two must be a pharmacist and the transferring individual records the following information:

(A) Void the transferred prescription.

(B) Record the name, address, and DEA registration number of the pharmacy to which it was transferred and the name of the individual receiving the prescription information.

(C) Record the date of the transfer and the name of the individual transferring the information.

(b) The individual receiving the transferred prescription information shall electronically record or reduce to writing the following:

(1) Record that the prescription is a transferred prescription.

(2) Provide all information required to be on a prescription pursuant to 21 CFR 1306.05 and include:

(A) date of issuance of original prescription;

(B) original number of refills authorized on original prescription;

(C) date of original dispensing;

(D) number of valid refills remaining and date(s) and locations of previous refill(s);

(E) pharmacy's name, address, DEA registration number and prescription number from which the prescription information was transferred;

(F) name of individual who transferred the prescription.

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

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

(e) Pharmacies transferring prescriptions may utilize facsimile or other electronic means to communicate information for transfers.

(f) Transfers of controlled substances must follow federal law and regulations.
(Amended 5/31/2014 and 1/1/19)

07-00-0003—SIGNING PRESCRIPTIONS

Every licensed pharmacist or intern who shall fill or refill a prescription, shall attest that he or she has personally filled said prescription by placing upon said prescription his or her signature with date thereof unless the pharmacy is electronically processing prescriptions. If the pharmacy uses an electronic prescription processing system, they must fill prescriptions in accordance with regulation 07-00-0008. (10/09/80, Revised 10/14/81, 6/20/91, and 8/19/99)

07-00-0004—SECRET CODES PROHIBITED

The treatment of disease, injury or deformity by secret means or secret drugs being contrary to both the spirit and the letter of the Arkansas Medical Practices Act, and dispensing of secret medicines or drugs being contrary to both the spirit and the letter of the Arkansas Pharmacy Act and the Arkansas Food, Drug, and Cosmetic Act, hereafter no licensed pharmacist or intern shall enter into any agreement or arrangement with a physician, or other practitioner authorized by law to prescribe medicine or drugs, for the compounding and/or dispensing of secret formula or coded prescription. (10/09/80)

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

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

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

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

07-00-0006—GENERIC SUBSTITUTION

The Arkansas State Board of Pharmacy recognizes the Federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (The Orange Book or The Green Book) as the basis for the determination of generic equivalency within the limitations stipulated in that publication. If the Federal Food and Drug Administration approves a drug product as bioequivalent and publishes that product with an "A" (AA, AB, AN, AO, AP, and AT) rating in the Approved Drug Products with Therapeutic Equivalence Evaluations (The Orange Book or The Green Book), an Arkansas pharmacist, or any pharmacist dispensing drugs to patients in Arkansas, may substitute that product consistent with law. Conversely, if the drug product is "B" rated, is changed from an "A" rating to a "B" rating, or is not rated, the pharmacist may not substitute without the consent of the prescribing practitioner. When a pharmacist substitutes a bioequivalent drug product for the drug prescribed, the patient shall be notified of the substitution by a pharmacist involved in the dispensing process. (6/21/2001, Amended 5/31/2014)

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

(a) In the case of a written prescription, on the prescription the prescriber writes in his or her own handwriting words that specify that no substitution shall be made and then also signs the prescription.

(b) The prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly states at the time the prescription is given, that it is to be dispensed as communicated, and same is either entered into the pharmacy's electronic prescription system or reduced to writing on the prescription by the pharmacist, or

(c) The person for whom the drug product is prescribed indicates the prescription is to be dispensed as written or communicated. (4/07/89, Amended 5/31/2014)

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

(a) Definitions

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

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

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

(b) Patient confidentiality requirements:

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

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

(3) The pharmacist in charge shall:

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

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

(c) Manner of issuance of a prescription drug order

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

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

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

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

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

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

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

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

(d) Patient records:

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

(e) Discipline:

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

(e) Security:

To maintain the confidentiality of patient and prescriber records, the computer system shall have adequate security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. Once the drug has been dispensed,

any alterations in prescription drug order data shall be documented -- including the identification of the pharmacist responsible for the alteration.

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

07-00-0009—PROPER PRACTITIONER-PATIENT RELATIONSHIP

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

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

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

07-00-0010– THERAPEUTIC SUBSTITUTION

A pharmacist may substitute a therapeutically equivalent drug that is at a lower cost to the patient only after the prescriber grants such authorization for each prescription. A prescriber may authorize a pharmacist to dispense a therapeutically equivalent drug product as part of a written prescription as defined to include a written, oral, faxed, or electronic prescription by indicating Therapeutic Substitution Allowed or May Therapeutically Substitute or abbreviating "TSA" or "MTS" as part of the prescription verbally, in writing or by utilizing a separate signature line to show such authorization.

(a) Therapeutic equivalence may be established with clinical publications comparing dosages of drugs in a therapeutic class.

(b)
  (1) 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. This discussion 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.

(c) 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.

(d) This section does not apply to specific acts of drug therapy management or disease state management delegated to a pharmacist based upon a written protocol or patient care plan approved by a physician under § 17-92-101(16)(A)(ix); (Adopted 12/29/2014)

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

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

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

(b) Violation of this regulation shall be grounds for suspension or revocation of the license of the wholesale drug or drug manufacturer's license to do business in the State of Arkansas. 10/14/81

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

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

In order to protect the public health and safety, drug products offered for sale by, or stored at the premises of, a manufacturer, wholesaler, distributor, or pharmacy location in Arkansas, which do not have the required NDA or ANDA, or exemption there from referenced in the above paragraph, are hereby declared to be contraband and subject to surrender to and destruction by the Arkansas State Health Department.

(b) Whenever it is made to appear to the Board that any licensee of the Arkansas State Board of Pharmacy is in possession of a stock of drugs which are contraband as defined above, a representative of the Board shall confirm with the Federal Food Drug Administration, by telephone, that the particular drug or drugs involved do not have the requirement. Upon receipt of this confirmation, the Board shall inform the owner, or person in charge, of the contraband status of the drugs in question.

(c) Retention, dispensing, promotion, or advertisement of drug products by a licensee of the Board of Pharmacy, either at their business premises or at any separate storage facility after notification of their contraband status, shall constitute a direct and immediate danger to the public health and safety and will be good and sufficient cause for the suspension or revocation

of any license issued by the Board of Pharmacy for knowingly retaining, dispensing, promoting, or advertising any drug products which are contraband under this regulation.

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

07-02: COMPOUNDING

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

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

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

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

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

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

solid frozen state at negative twenty (–20) degrees centigrade or colder, while properly stored.

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

(A) Multiple individual or small doses of sterile products are combined or pooled to prepare a sterile product that will be administered either to multiple patients or to one patient on multiple occasions.

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

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

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

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

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

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

(B) Sterile ingredients, components, devices, and mixtures are exposed to air quality inferior to a Class 100 environment. This includes storage in environments inferior to a Class 100 environment of opened or partially used packages of manufactured sterile products that lack antimicrobial preservatives.

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

(D) It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients.

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

(b) Pharmacist requirements:

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

(1) Have available written policies and procedures for all steps in the compounding of sterile preparations. In addition, said policies and procedures shall address personnel education and training and evaluation, storage and handling, clothing, personal hygiene, hand washing, aseptic technique, quality assurance, expiration dating, and other procedures as needed.

(2) Certify that all participating pharmacists and pharmacy technicians have completed a Board approved training and testing program in sterile product preparation. Documentation of training and testing shall be available for review, by February 30, 2002.
(3) Develop policies and procedures to annually test and review the techniques of participating pharmacists and pharmacy technicians to assure adherence to aseptic procedures.

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

(d) Work area and equipment:
Any pharmacy dispensing sterile parenteral solutions shall meet or exceed the following requirements:
(1) A separate controlled limited access area (also called a buffer area or buffer room) for compounding sterile solutions, which shall be of adequate space for compounding, labeling, dispensing, and sterile preparation of the medication. This area shall have controlled temperature and humidity. Cleanliness of the area is of critical importance. Drugs and other materials, taken into the limited access area, shall be removed from cardboard and other particle generating materials before being taken into the area.
(2) The controlled limited access area shall have a certified and inspected Class100 environment. Such an environment exists inside a certified laminar airflow hood (clean room, biological safety cabinet or other barrier isolator meeting Class 100 requirements) used for the preparation of all sterile products. The Class 100 environment device or area is to be inspected and certified yearly. Barrier isolator workstations are closed systems and are not as sensitive to their external environment as laminar airflow equipment. It is recommended to place them in a limited access area with cleaning and sanitizing in the surrounding area on a routine basis.
(3) Hazardous drugs shall be prepared within a certified Class 11, Type A (exhaust may be discharged to the outdoors) or Class 11, Type B (exhaust may be discharged to the outdoors) laminar flow biological safety cabinet. The Class 11, Type B can be obtained with a “bag in-bag out” filter to protect the personnel servicing the cabinet and facilitate disposal. When preparing cytotoxic agents, gowns and gloves shall be worn. All new construction, and those undergoing renovation requiring the moving of existing hoods used in the preparation of cytotoxic drugs, shall exhaust the hood to the outdoors, unless the Board of Pharmacy grants an exception. The cabinet of choice is a Class 11, Type B. For the purpose of this regulation, hazardous drugs shall be defined as agents that exhibit characteristics of genotoxicity, carcinogenicity, teratogenicity, or evidence of serious organ or other toxicity at low doses.
(4) The area shall be designed to avoid excessive traffic and airflow disturbances.
(5) The area shall be ventilated in a manner not interfering with laminar flow hood conditions.
(6) Daily procedures must be established for cleaning the compounding area.

(e) Storage:
All pharmacies preparing and dispensing sterile products must provide:
(4) Adequate controlled room temperature storage space for all raw materials.
(5) Adequate storage space for all equipment. All drugs and supplies shall be stocked on shelving above the floor.

(6) Adequate refrigerator storage space for compounded solutions, with routinely documented temperatures. Temperature ranges required are 36-46° F or 2-8° C.
(7) Adequate freezer storage space if finished products are to be frozen (e.g. reconstituted antibiotics.) There shall be a procedure to routinely document temperatures.

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

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

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

(i) Destruction of cytotoxic drugs:
Any pharmacy providing cytotoxic drugs shall establish procedures assuring the return and proper destruction of any unused radioactive or cytotoxic drugs or other hazardous material (destruction containers for needles).
In every instance, the pharmacist in charge shall monitor the delivery, storage, and administration records of medications dispensed from his/her pharmacy.

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

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

(2) Use total aseptic techniques, including gowning, mask, and hair net. Scrubs may be worn, instead of gowning, if not worn or covered outside of the controlled limited access area.

(3) Provide a system for tracking each compounded product including:
   (A) Personnel involved in each stage of compounding;
   (B) Raw materials used including quantities, manufacturer, lot number, and expiration date;
   (C) Labeling;
   (D) Compounding records shall be kept for 2 years.

(4) Establishment of procedures for sterilization of all products prepared with any non-sterile ingredients by filtration with 0.22 micron or other means appropriate for the product components.

(5)
   (A) All high-risk level compounded sterile products for administration by injection into the vascular and central nervous systems that are prepared in groups of more than twenty-five (25) identical individual single-dose packages (such as ampules, bags, syringes, and vials), or in multiple dose vials for administration to multiple patients, or are exposed longer than twelve (12) hours at a two (2) to eight (8) degrees centigrade and longer than six (6) hours at warmer than eight (8) degrees centigrade before they are sterilized shall be tested to ensure they are sterile, do not contain excessive bacterial endotoxins, and are of labeled potency before they are dispensed or administered as provided below.
   (B) Sterility Testing (Bacterial and Fungal) – The USP Membrane Filtration Method is the method of choice where feasible (e.g. components are compatible with the membrane). The USP Direct Transfer Method is preferred when the membrane filtration is not feasible. An alternative method may be used if verification results demonstrate that the alternative is at least as effective and reliable as the USP Membrane Filtration Method or the USP Direct Transfer Method. The pharmacist in charge shall establish written procedures requiring daily observation of the media and requiring an immediate recall if there is any evidence of microbial growth and said procedures must be available to Board inspectors.
   (C) Bacterial Endotoxin (Pyrogen) Testing – The USP Bacterial Endotoxin Test, or verified equivalent, shall be used to ensure compounded sterile products do not contain excessive endotoxins.
   (D) Potency Testing – The potency of all compounded products meeting the criteria described in Board regulation 07-02-0001 (j) (5) above must be tested to verify the potency stated on the label. Products for which there is no known or commercially available potency test standard require Board approval prior to compounding.
   (E) The USP Membrane Filtration Method and the USP Direct Transfer Method are the membrane filtration and direct transfer methods described in Chapter 71,United States Pharmacopeia ("USP"), 2001 Edition. The USP Bacterial Endotoxin Test is the bacterial filtration test described in Chapter 85, USP, 2001 Edition. Should there be any amendment or change in any of the above methods or test by USP subsequent

to the effective date of this paragraph, said change or amendment to USP shall be effective under this regulation after the expiration of thirty (30) days from the effective date of said change or amendment, unless within said time period, the Executive Director objects to said change or amendment. In that case, the Executive Director shall publish the reasons for objection and afford all interested parties an opportunity to present commentary; said notice and commentary shall be pursuant to A.C.A. § 25-15-204, as amended, and the resulting decision by the Board shall be reflected by an amendment to this regulation.

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

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

07-02-0002—GOOD COMPOUNDING PRACTICES

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

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

(b) Definitions:

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

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

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

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

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

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

(3) "Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substance(s) or labeling or re-labeling of its container, and the promotion and marketing of such drugs or devices. Manufacturing also includes any preparation of a drug or device that is given or sold for resale by pharmacies, practitioners, or other persons. The distribution of inordinate amounts of compounded products, without a practitioner/patient/pharmacist relationship is considered manufacturing.

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

(c) Pharmacist responsibilities:

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

(2) The pharmacist has the responsibility to:

(A) Assure the validity of all prescriptions;

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

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

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

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

(d) Drug compounding facilities:

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

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

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

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

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

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

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

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

(e) Compounding equipment

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

(2) Compounding equipment shall be of suitable composition so the surfaces that contact

components shall not be reactive, additive, or absorptive so as to alter the purity of the product compounded.

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

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

(5) Automated, mechanical, electronic, limited commercial scale manufacturing or testing equipment, and other types of equipment may be used in the compounding of drug products. If such equipment is used, it shall be routinely inspected, calibrated (if necessary), or checked to ensure proper performance.

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

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

(f) Component selection requirements:

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

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

(g) Control of drug products:

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

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

(h) Drug compounding controls:

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

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

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

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

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

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

capsules) to ensure reasonable uniformity and integrity of compounded drug products.

(A) Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product.

(B) Such control procedures shall include, but are not limited to, the following (where appropriate):

(i) capsule weight variation;

(ii) adequacy of mixing to assure uniformity and homogeneity; and

(iii) clarity, completeness or pH of solutions.

(7) Appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile shall be established and followed. Such procedures shall follow accepted standards of practice and/or include validation of any sterilization process.

(8) Beyond use dates and storage requirements (e.g. refrigeration) should be established. The USP-NF guidelines should be used.

(i) Labeling:

(1) If a component is transferred from the original container to another (e.g. a powder is taken from the original container, weighed, placed in a container) and stored in another container, the new container shall be identified with the:

(A) component name;

(B) lot and expiration date if available;

(C) strength and concentration;

(D) weight or measure; and

(E) route of administration

(2) Products prepared in anticipation of a prescription prior to receiving a valid prescription should not be an inordinate amount.

(A) A regularly used amount should be prepared based on a history of prescriptions filled by the pharmacy.

(B) These products shall be labeled or documentation referenced with the:

(i) complete list of ingredients or preparation name and reference;

(ii) federal expiration date—up to one (1) year;

(iii) assigned beyond –use date:

(a) based on published data, or;

(b) appropriate testing, or;

(c) USP-NF standards.

(iv) storage under conditions dictated by its composition and stability (e.g., in a clean, dry place or in the refrigerator); and

(v) batch or lot number.

(3) Upon the completion of the drug preparation operation, the pharmacist shall examine the product for correct labeling.

(4) The prescription label shall contain the following:

(A) patient name;

(B) prescriber’s name;

(C) name and address of pharmacy;

(D) directions for use;

(E) date filled;
(F) beyond use date and storage (may be auxiliary labels); and
(G) an appropriate designation that this is a compounded prescription, with reference to active ingredients.

(j) Records and Reports:
(1) Any procedures or other records required to comply with good compounding practices shall be retained for the same period of time as required for retention of prescription records.
(2) All records required to be retained under good compounding practices, or copies of such records, shall be readily available for authorized inspection.
(3) Computer information and the hard copy of the prescription should indicate that the prescription is to be compounded.
(4) Adequate records must be kept of controlled substances (Scheduled drugs) used in compounding.

(k) Pharmacy generated product requirements:
(1) A pharmacy generated product (PGP) may be prepared from legend drugs, not to exceed recommended strengths and doses.
(2) PGP will be labeled properly and will be sold with the public's health and welfare in mind.
(3) PGP cannot be bulk compounded to sell to a second entity for resale. This would require a manufacturer's permit.

(l) Compounding for a prescriber's office use:
(1) Pharmacies may prepare compounded drug products for a duly authorized prescriber's office use.
(2) An order by the duly authorized prescriber, indicating the formula and quantity ordered, will be filed in the pharmacy.
(3) The product is to be administered in the office and not dispensed to the patient. The product shall be labeled "For Office Use Only—Not for Resale".
(4) A record of the compounded drug product may be kept as a prescription record in the pharmacy computer.
(5) A label may be generated and a number assigned by the pharmacy computer for the compounded drug product.
(6) Patient specific prescriptions for controlled substances cannot be filled "for office or medical bag use".
(7) A retail pharmacy is not precluded from making more than five percent (5%) of its annual sales to licensed practitioners. The pharmacy must, however, obtain a State Wholesale Legend Drug and/or Controlled Substance Distributor Permit.

(m) Compounding veterinarian products:
(1) Prescriptions for animals may be compounded based on an order or prescription from a duly authorized prescriber.
(2) These prescriptions are to be handled and filled the same as the human prescriptions.
(3) Patient specific prescriptions for controlled substances cannot be filled "for office or medical bag use".

(Adopted 2/2001, Revised emergency 6/2003 & 10/26/2003, Revised 11/30/2010)

07-03: SAMPLES

07-03-0001—DRUG SAMPLES

(a) Definitions

(1) "Drug sample" means a unit of a legend drug which is distributed to a practitioner by a manufacturer or a manufacturer's representative at no charge, is not intended to be sold, and is intended to promote the sale of the drug. "Drug sample" shall not mean a drug under clinical investigations approved by the federal Food and Drug Administration.

(2) "Coupon" means a form which may be redeemed as part of, or all of, the cost of a prescription for a legend drug after it has been dispensed.

(3) "Legend Drug" means a drug limited by Section 503 (b)(1) of the Federal Food, Drug, and Cosmetic Act to being dispensed by or upon a medical practitioner's prescription because the drug is (a) habit forming, (b) toxic or having potential for harm, or (c) the new drug application for the drug limits its use to use under a practitioner's supervision. The product label of which is required to contain the statement "CAUTION, FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION."

Provided, however, a legend drug includes prescription drugs subject to the requirement of Section 503 (b)(1) of the federal Food, Drug, and Cosmetic Act which shall be exempt from Section 502 (f)(1) if certain specified conditions are met.

(b) Unprofessional conduct pursuant to regulation 02-04-0001 shall include the following:

(1) It shall be unprofessional conduct for a licensed pharmacy, pharmacist, or pharmacy intern licensed in the state of Arkansas to sell, purchase, or trade or offer to sell, purchase, or trade any drug sample.

(2) It shall be considered unprofessional conduct for any licensed pharmacy, pharmacist, or pharmacy intern licensed in the state of Arkansas to sell, purchase, trade, or counterfeit, or offer to sell, purchase, trade, or counterfeit any "coupon."

(3)

(A) The possession of a drug sample by a pharmacy, pharmacist or licensed intern shall be considered unprofessional conduct unless prior approval has been obtained from the Board of Pharmacy or unless the sample was provided for personal use by the pharmacist, intern, or his or her family.

(B) If a licensed pharmacy, pharmacist, or pharmacy intern believes that he or she has a valid reason to possess and/or distribute a drug sample free of charge, the involved pharmacist shall make a written request to the Board of Pharmacy so that the Board may review the request to assure that there is not a violation of federal or state law or Board of Pharmacy regulation.

Upon written request stating the purpose or use of drug sample and quantity to be possessed, the Board shall approve possession of sample drugs when reasonably necessary to serve a public purpose when consistent with federal and state law. The Board may impose any conditions upon possession as determined appropriate.

The pharmacist in charge of the pharmacy where the drug samples will be located shall maintain same separated from other stock and in original sample packages.

No compensation shall be charged for sample drugs. (10/12/86)

07-04: CONTROLLED SUBSTANCES

07-04-0001—SCHEDULE II PRESCRIPTION DRUGS

(a) Emergency Prescriptions -- In the case of an emergency situation, as defined by this regulation, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner -- provided that the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (never more than 72 hours). Dispensing, beyond the emergency period, must be pursuant to a written prescription signed by the prescribing individual practitioner. For the purposes of authorizing an oral prescription for a controlled substance listed in Schedule II of the Arkansas Controlled Substance List, the term "emergency situation" means those situations in which the prescribing practitioner determines that:

(1) Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user;

(2) No appropriate alternative treatment is available (which includes the administration of a drug which is not a Schedule II), and

(3) It is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the pharmacist dispensing the drug prior to the dispensing.

The prescription shall be immediately reduced to writing by the pharmacist. Within seven (7) days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. The statement "Authorization for Emergency Dispensing," and the date of the oral order, must be on the face of the prescription. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription, which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the DEA if the prescribing practitioner fails to deliver a written prescription--failure of the pharmacist to do so shall void the authority conferred by this regulation to dispense without a written prescription of a prescribing practitioner.

(b) Licensees of the Arkansas State Board of Pharmacy may not dispense a quantity of a Schedule II Narcotic that exceeds the prescriber’s authority to prescribe.

(Amended 1/1/19)

07-04-0002—PARTIAL FILLING OF A SCHEDULE II PRESCRIPTION

The partial filling of a prescription for a controlled substance listed in Schedule II is permissible. If the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription), the remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

A prescription, for a Schedule II controlled substance written for a patient in a long-term-care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness, may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist may contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record, on the prescription, whether the patient is "terminally ill" or an "LTCF patient".

For each partial filling, the dispensing pharmacist shall record, on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable), the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.

Prior to any subsequent partial filling, the pharmacist is to determine that the additional partial filling is necessary. The total quantity of Schedule II controlled substances dispensed, in all partial filling, must not exceed the total quantity prescribed. A Schedule II prescription for a patient in a LTCF or a patient with a medical diagnosis documenting a terminal illness, if partially filled, shall be totally dispensed within sixty (60) days and dispensing cannot occur after sixty (60) days or after the medication has been discontinued by the prescriber.
(Amended 1/1/19)

07-04-0003—COMPUTER RECORDS FOR PARTIAL FILLING

Information, pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness, may be maintained in a computerized system -- if the system has the capability to permit:

(a) Output (display or print) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of the LTCF or address of the hospital or residence of the patient, identification of medication authorized (to include dosage, form, strength and quantity) and listing of the partial fillings that have been dispensed under each prescription.
(b) Immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted.
(c) Retrieval of partially filled Schedule II prescription information is the same as required for Schedule III and IV prescription refill information.

The authority to dispense Schedule II prescriptions for partial quantities does not apply to other classes of patients -- such as a patient with severe intractable pain who is not diagnosed as terminal.

07-04-0004--TIME LIMIT ON A NEW SCHEDULE II PRESCRIPTION

Prescriptions written for Schedule II controlled substances may be dispensed up to six (6) months from the date written if the pharmacist is certain of the validity of the prescription. An exception to this would be prescriptions written for a patient classified as terminally ill or a long-

term-care facility patient and these prescriptions are valid for 60 days from date of issue and may be partially filled. (2/15/95, Amended 10/14/97)

07-04-0005—THEFT OR LOSS OF CONTROLLED DRUGS

In the event a holder of a pharmacy permit issued by the Arkansas State Board of Pharmacy under ACA §17-92-405 and Board Regulation 04-05-0001 has suffered a theft or loss of controlled substances. Said permit holder shall:

i. Notify Arkansas Department of Health Division of Pharmacy Services and Drug Control, the nearest Drug Enforcement Administration Diversion Field Office, and the Arkansas State Board of Pharmacy immediately upon discovery by phone or fax, and

ii. Deliver a completed DEA Form-106 to each of the agencies listed in (a) within 7 days of the occurrence of said loss or the discovery of said loss.

(10/09/83 Revised 6/26/03 and 7/27/2011)

07-04-0006—SCHEDULE V--EXEMPT PRODUCTS & PHARMACIST-AUTHORIZED DRUGS

(a) A Pharmacist-Authorized Drug is a nonprescription drug that is subject to the same restrictions as are imposed for ephedrine, pseudoephedrine, or phenylpropanolamine under Ark. Code Ann. § 5-64-1103(c) and (d)(4) and § 5-64-1104.

(b) A pharmacist may dispense a Schedule V exempt product or a Pharmacist Authorized Drug only after making a professional determination that there is a legitimate medical and pharmaceutical need for the product. A pharmacist must base the decision to dispense on factors relevant to the patient's medical need and the appropriateness of the requested product, including, without limitation:

1. the patient's medication filling history as maintained in the pharmacy's system;
2. the pharmacist's personal knowledge of the patient; and/or
3. the pharmacist's screening of the patient's existing medical conditions and physical symptoms as appropriate for the treatment being considered. The screening may include a review of the patient's medical history, disease history, prescription history, physical symptoms, and relevant vital signs, such as blood pressure. All screening performed by the pharmacist must be documented and maintained in the patient's pharmacy record.

(c) A pharmacist should not dispense a Schedule V exempt product or Pharmacist Authorized Drug if the pharmacist is aware of information indicating that the patient is inappropriately self-medicating. If the patient does not provide a satisfactory explanation regarding inappropriate self-medicating, the pharmacist must decline to dispense the product and refer the patient to a physician.

1. For ephedrine, pseudoephedrine, or phenylpropanolamine products, a pharmacist should question a patient regarding inappropriate self-medicating when records indicate that the patient may be exceeding the maximum recommended daily dose.
2. For Schedule V exempt narcotics, a pharmacist should question a patient regarding inappropriate self-medicating when records indicate that the patient has been dispensed a Schedule V exempt product:
   A. more than ten (10) days;
   B. more than twice in a thirty (30) day period;

C. more than four (4) times in two (2) consecutive months; or
D. every month.

(d) The Arkansas State Board of Pharmacy may revoke or suspend a certificate of licensure, license, registration or permit or may refuse to issue a certificate of licensure, license, registration or permit to any person or entity that dispenses or sells a Schedule V exempt product or Pharmacist Authorized Drug in violation of a state or federal pharmacy law or regulation.

(e) A pharmacist is immune from civil liability for refusing to dispense, sell, transfer or otherwise furnish a Schedule V exempt product or Pharmacist Authorized Drug based on a professional determination or a determination of age or identity.

(f) Nothing in this regulation shall be interpreted to require that a Schedule V exempt product or Pharmacist Authorized Drug must be sold upon request. There shall be no penalty or other disciplinary action taken against a pharmacist who chooses not to sell these products to a patient or individual. (Adopted 7/27/2011)

07-04-0007—SCHEDULE V--EXEMPT NARCOTICS

A controlled substance listed in Schedule V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

(a) Such dispensing is made only by a pharmacist and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a nonpharmacist);

(b) Not more than 240 cc. (8 ounces) of any such controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other such controlled substance nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given 48-hour period;

(c) The purchaser is at least eighteen (18) years of age;

(d) The pharmacist requires every purchaser of a controlled substance under this section not known to him to furnish suitable identification (including proof of age where appropriate);

(e) A bound record book for dispensing of controlled substances under this section is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of §21 CFR 1304.04); and

(f) A prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State or local law. (6/07/90 Revised 7/27/2011)

07-04-0008—SCHEDULE V—EPHEDRINE, PSEUDOEPHEDRINE OR PHENYLPROPRANOLAMINE

(a) As provided in Ark. Code Ann. § 5-64-1101, et seq., unless dispensed under a valid prescription, all sales or transfers of ephedrine, pseudoephedrine or phenylpropanolamine are subject to the following quantity limits and restrictions:

(1) In a single transaction, no more than three (3) packages of one (1) or more products that contain ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers;

(2) In a single transaction, no more than a single package of any product that contains ephedrine, pseudoephedrine, or phenylpropanolamine, that contains more than ninety-six (96) pills, tablets, gelcaps, capsules, or other individual units or more than three grams (3g) of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, or a combination of any of these substances, whichever is smaller;

(3) In a single transaction, any product containing ephedrine, pseudoephedrine, or phenylpropanolamine, unless:

(A) The product is sold in a package size of not more than three grams (3g) of ephedrine, pseudoephedrine, or phenylpropanolamine base and is packaged in a blister pack, each blister containing not more than two (2) dosage units;

(B) When the use of a blister pack is technically infeasible, that is packaged in a unit dose packet or pouch; or

(C) In the case of a liquid, the drug is sold in a package size of not more than three grams (3 g) of ephedrine, pseudoephedrine, or phenylpropanolamine base; or

(4) No product containing ephedrine, pseudoephedrine, or phenylpropanolamine may be sold or transferred to any person under eighteen (18) years of age, unless the person is purchasing an exempt product under Ark. Code Ann. § 5-64-1103 (b).

(5) No more than 5 grams of any product containing ephedrine or 9 grams of any product containing pseudoephedrine or phenylpropanolamine to a single patient in any 30 day period.

(b) A pharmacist may not dispense and a pharmacy technician or intern may not sell or transfer ephedrine, pseudoephedrine, or phenylpropanolamine unless the patient has provided either:

(1) a driver's license or non-driver’s identification card issued by the Arkansas Department of Finance and Administration that contains a photograph of the person, the person's date of birth, and a functioning magnetic stripe or bar code; or

(2) An identification card issued by the United States Department of Defense to active duty military personnel and their dependents that contains a photograph of the person and the person’s date of birth.

(c) In addition to documenting the professional determination required by Regulation 07-04-0006(a), a sale of ephedrine, pseudoephedrine, or phenylpropanolamine must also be approved by scanning the license or identification card into the real-time electronic logbook using the magnetic stripe or bar code except and unless using a military ID as described in regulation 07-04-0008 (b)(2) in which case the identification may be manually entered into the real-time electronic logbook.

(d) A pharmacist, pharmacy or pharmacy employee must also comply with Federal law prohibiting the sale of more than 3.6 grams of ephedrine, pseudoephedrine, or

phenylpropanolamine to a patient in any 24 hour period. (Adopted 7/27/2011, Amended 5/31/2014)

REGULATION 8 —WHOLESALE DISTRIBUTION

08-00: WHOLESALE DRUG DISTRIBUTORS OF LEGEND/CONTROLLED SUBSTANCES

08-00-0001—DEFINITIONS

As used in this regulation, unless the context otherwise requires.

(a) "Board" means the Arkansas State Board of Pharmacy;

(b) "Person" includes individual, partnership, corporation, business firm and association;

(c) "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 coordinator pursuant to his authority under § 5-64-214 - § 5-64-216;

(d) "Legend drug" means a drug limited by the federal Food, Drug, and Cosmetic Act to being dispensed by or upon a medical practitioner's prescription because the drug is:

(1) Habit-forming;

(2) Toxic or having potential for harm;

(3) Limited in its use to use under a practitioner's supervision by the new drug application for the drug.

(i) The product label of a legend drug is required to contain the statement "CAUTION; FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION."

(ii) A legend drug includes prescription drugs subject to the requirement of the Federal Food, Drug, and Cosmetic Act, which shall be exempt if certain specified conditions are met.

(e) "Prescription drug" means controlled substances, legend drugs and veterinary legend drugs as defined herein.

(f) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(g) "Blood component" means that part of blood separated by physical or mechanical means.

(h) "Manufacturers" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

(i) "Wholesale distribution" means the distribution of prescription drugs to persons other than consumers or patients and reverse distribution of such drugs, but does not include:

(1) Intra-company sales;

(2) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(3) 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 federal Internal Revenue Code to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for the purposes of this regulation "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 or stock or voting rights, by contract or otherwise;

(5) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug; or the dispensing of a drug pursuant to a prescription;

(6) The distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(7) The sale, purchase or trade of blood components intended for transfusion.

(j) "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; hospital; nursing homes and their providers; health maintenance organizations and other health care 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.

(k) "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.

(l) "Veterinary legend drugs" means drugs defined in 21 CFR 201.105 and bearing a label required to bear the cautionary statement, "CAUTION: FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON THE ORDER OF A LICENSED VETERINARIAN."

(m) "Reverse distribution" means the receipt of prescription drugs including controlled substances, whether received from Arkansas locations or shipped to Arkansas locations, for the purpose of destroying the drugs or returning the drugs to their original manufacturers or distributors.

(n) "Outsourcing Facility" means a facility at one geographic location or address that:

(1) Is engaged in the Compounding of sterile drugs for human use;

(2) Is registered as an Outsourcing Facility with the FDA; and

(3) Complies with all of the requirements of Section 503B of the Federal FD&C Act.

(4) Shall be a licensed under the Wholesale Distribution regulations as a 503B Outsourcer,

(5) Shall have an Arkansas licensed Pharmacist in Charge on staff a minimum of 32 hours per week,

(6) All Compounding shall be done under the supervision of a licensed Pharmacist and comply with Federal requirements applicable to Outsourcing Facilities,

(7) Does not provide patient specific prescription products unless also licensed as a pharmacy and does not provide any products that are prohibited under the FDA guidelines of a 503B

(Amended 8/1/2018)

08-00-0002—SALES PERMIT REQUIRED.

It shall be unlawful for any person to sell or offer for sale by advertisement, circular, letter, sign, or oral solicitation or any other means any prescription drug unless the person holds and possesses a permit authorizing such sale as provided by this regulation.

08-00-0003—WHOLESALE DISTRIBUTORS THIRD-PARTY LOGISTICS PROVIDERS, MANUFACTURERS AND OUTSOURCING FACILITIES--PERMIT REQUIRED.

(a) Every wholesale distributor, third-party logistics provider, manufacturer and outsourcing facility who shall engage in the 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 with the Arkansas State Board of Pharmacy by application for a permit on a form furnished by the Board and accompanied by a fee as defined in regulation 01-00-0007. 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, and/or affiliate companies within this state when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

(b)

(1) The permit may be renewed biennially at a renewal permit fee as defined in regulation 01-00-0007.

(2) All permits issued under this section shall expire on December 31 of each year. A penalty, as defined in regulation 01-00-0007, will be charged, provided that if the renewal is unpaid by April 1, of any year, the license shall be null and void.

(c)

(1) Upon a change of ownership of a wholesale distributor, as set out herein, a new permit shall be secured by the new owner(s). The new owner(s) can continue operation of the wholesale distributor for fourteen (14) days after the effective date of the change of ownership; after said fourteen (14) day period the permit issued to the prior owner shall be void and the operation of the wholesale distributor in Arkansas shall cease.

(2) A change of ownership of a wholesale distributor occurs under, but is not limited to, the following circumstances:

(A) A change of ownership of a wholesale distributor owned by a SOLE PROPRIETOR, is deemed to have occurred when:

(i) The business is sold and the sale becomes final or the new owner assumes control of the wholesale distributor -- which ever occurs first.

(ii) The proprietor enters into a partnership with another individual or business entity.

(B) A change of ownership of a wholesale distributor, owned by PARTNERSHIP, is deemed to have occurred when:

(i) There is an addition or deletion of one or more partners in a partnership to which a wholesale distributor's license has been issued.

(ii) The business is sold and the sale becomes final or the new owner assumes control of the wholesale distributor -- which ever occurs first.

(C) A change of ownership of a wholesale distributor, owned by a CORPORATION, is deemed to have occurred when:

(i) An individual or business acquires or disposes of twenty percent (20%) of the corporation's outstanding shares of voting stock. (This shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over the counter market); or

(ii) The corporation merges with another business or corporation. (The corporation owning the wholesale distributor is required to notify the Arkansas State Board of Pharmacy if a change of ownership or merger occurs within the parent corporation of the corporation which owns the wholesale distributor); or

(iii) The corporation's charter expires or is forfeited.

(iv) The business is sold and the sale becomes final or the new owner assumes control of the wholesale distributor -- which ever occurs first.

(D) The board may issue a limited-use wholesale distributor license to entities that do not engage in the wholesale distribution of prescription drugs except medical gases and may waive certain requirements of regulation based on the limited nature of such distribution.

(E) Each permit issued hereunder shall be displayed by the holder thereof in a conspicuous place. (Amended 03/14/2007 and 8/1/2018)

08-00-0004—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 regulation, ascertain that the person to whom shipment is made is either a licensed physician licensed by the Arkansas State Medical Board, a licensed Doctor of Dentistry, a licensed Doctor of Veterinary Medicine, a licensed Doctor of Podiatry Medicine, a hospital licensed by the State Board of Health, a licensed wholesale distributor as defined in this regulation, a licensed 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 board or other state or federal agency that the person no longer holds a registered pharmacy permit or is not a licensed physician, dentist, veterinarian or hospital.

08-00-0005—MINIMUM REQUIRED INFORMATION FOR LICENSURE

(a) The Arkansas Board of Pharmacy requires the following from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license:
   (1) The name, full business address, and telephone number of the licensee;
   (2) All trade or business names used by the licensee;
   (3) Addresses, telephone numbers, and the names of contact persons for the facility used by the licensee for the storage, handling, and distribution of prescription drugs;
   (4) The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship); and
   (5) The name(s) of the owner and/or operator of the licensee, including:
      (A) If a person, the name of the person;
      (B) If a partnership, the name of each partner, and the name of the partnership;
      (C) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent company, if any;
      (D) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(b) Where operations are conducted at more than one location by a single wholesale distributor, each such location shall be licensed by the Arkansas Board of Pharmacy.

(c) Changes in any information on the application for licensure shall be submitted to the Arkansas Board of Pharmacy within thirty (30) days after such change.

08-00-0006—MINIMUM QUALIFICATIONS

The Arkansas Board of Pharmacy will consider the following factors in determining eligibility for licensure of persons who engage in the wholesale distribution of prescription drugs.

(a) Any convictions of the applicant under any federal, state or local laws related to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(b) Any felony convictions of the applicant under federal, state, or local laws;

(c) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(d) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(e) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(f) Compliance with licensing requirements under previously granted licenses, if any;
(g) Compliance with the requirements to maintain and/or make available to the state licensing authority or to federal, state, or local law enforcement officials those records required to be maintained by wholesale drug distributors;
(h) Any other factors or qualifications the Arkansas Board of Pharmacy considers relevant to and consistent with the public health and safety.

The Arkansas Board of Pharmacy reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

08-00-0007—PERSONNEL

The licensed wholesale distributor shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs.

08-00-0008—MINIMUM REQUIREMENTS FOR THE STORAGE AND HANDLING OF PRESCRIPTION DRUGS AND FOR THE ESTABLISHMENT AND MAINTENANCE OF PRESCRIPTION DRUG DISTRIBUTION RECORDS

The following are required for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees.

(a) Facilities.
All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed or displayed shall:
(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operation;
(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
(3) Have a designated and clearly identified area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened;
(4) Be maintained in a clean and orderly condition; and
(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) Security.
(1) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.
(A) Access from outside the premises shall be kept to a minimum and well controlled.
(B) The outside perimeter of the premises shall be well lighted.
(C) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
(2) All facilities shall be equipped with an alarm system to detect entry after hours. This requirement shall not apply to those wholesale drug distributors of legend/controlled substances that carry only medical gas.
(3) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) Storage.

All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs with requirements in the current edition of an official compendium.

(1) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.
(3) The record keeping requirements in section (f) of this regulation shall be followed for all stored drugs.
(4) The requirements of this subsection do not apply to reverse distributors.

(d) Examination of materials.

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
(2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
(3) The record keeping requirements in section (f) of this regulation shall be followed for all incoming and outgoing prescription drugs.

(e) Returned, damaged, and outdated prescription drugs.

(1) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.
(2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.
(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.
(4) The record keeping requirements in section (f) of this regulation shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(f) Record keeping.

(1) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

(A) The source of the drugs, including the name and principal address of the seller or transferer, and the address of the location from which the drugs were shipped;
(B) The identity and quantity of the drugs received and distributed or disposed of, and
(C) The dates of receipt and distribution or other disposition of the drugs.

(2) Inventories and records shall be made available for inspection and photocopying by any official authorized by the Arkansas Board of Pharmacy for a period of two (2) years following disposition of the drugs.

(3) Records described in this regulation that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by any official authorized by the Arkansas Board of Pharmacy. (Revised 6/23/05)

08-00-0009—WRITTEN POLICIES AND PROCEDURES

Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(a) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

(b) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(1) Any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the Arkansas Board of Pharmacy;

(2) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(3) Any action undertaken to promote public health and safety by replacement of existing merchandise with an improved product or new package design.

(c) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(d) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two (2) years after disposition of the outdated drug.

08-00-0010—RESPONSIBLE PERSONS

Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

08-00-0011—COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAWS

Wholesale drug distributors shall operate in compliance with applicable federal, state and local laws and regulations.

Wholesale drug distributors that deal in controlled substances shall register with the appropriate state-controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local, and DEA regulations.

In the event a holder of a wholesaler permit issued by the Arkansas State Board of Pharmacy under ACA §17-92-108, §20-64-505, et. seq. and Board Regulation 08-00-0001 and 08-00-0003 has suffered a theft or loss of controlled substances, said permit holder shall:

(a) Notify the Arkansas State Board of Pharmacy, the Arkansas Department of Health Pharmacy Services and Drug Control, and the Drug Enforcement Administration (DEA) immediately upon discovery by telephone or FAX, and

Deliver a completed DEA Form 106 to each of the agencies listed in (a) within seven (7) days of the occurrence of the loss or the discovery of the loss. (Revised 11/6/2008)

08-00-0012—SALVAGING AND REPROCESSING

Wholesale drug distributors shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including Chapter 21, parts 207, 210d, 211 of the Code of Federal Regulations.

08-00-0013—APPLICABILITY

Nothing in this regulation shall apply to the sale of chemicals or poisons for use for non medical purposes or for uses as insecticides or biologics or medicine used for the cure, mitigation, or prevention of disease of animals or fowl or for agricultural uses 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 REGULATION.

08-00-0014—INSPECTION OF PREMISES AND RECORDS

The Board may conduct inspections upon all premises, including delivery vehicles, purporting or appearing to be used by a person licensed under this regulation. The Board, in its discretion, may accept a satisfactory inspection by the United States Food and Drug Administration (USFDA) or a state agency of another state which the Board determines to be comparable to that made by USFDA or the Arkansas Board of Pharmacy. (6/22/84, Revised 6/20/91, 6/23/96, and 8/23/96)

08-01: MEDICAL EQUIPMENT, LEGEND DEVICES, AND/OR MEDICAL GAS

08-01-0001—DEFINITIONS

(a) "Home medical equipment, legend device and medical gas supplier" means a person, business, corporation, agency, company, etc., licensed to supply home medical equipment, medical gases and/or legend devices to patients on an order from medical practitioners licensed to order, use, or administer these products and to other persons, businesses, corporations, agencies, companies, etc., licensed to supply home medical equipment, medical gases, and/or legend devices.

(b) “Home medical equipment services” means the delivery, installation, maintenance, replacement, and/or instruction in the use of medical equipment, used by a sick or disabled individual, to allow the individual to be maintained in a noninstitutional environment.

(c) “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. These devices, as approved by the Food and Drug Administration, may be labeled "Caution: Federal (USA) law restricts this device to sale by or on the order of a physician."

(d)

(1) “Medical equipment” means technologically sophisticated medical devices including but not limited to:

(A) Oxygen and oxygen delivery systems;
(B) Ventilators;
(C) Respiratory disease management devices;
(D) Electronic and computer driven wheelchairs and seating systems;
(E) Apnea monitors;
(F) Transcutaneous electrical nerve stimulator (T.E.N.S.) units;
(G) Low air loss cutaneous pressure management devices;
(H) Sequential compression devices;
(I) Neonatal home phototherapy devices;
(J) Feeding pumps;
(K) Electrically-powered hospital beds;
(L) Infusion pumps; and
(M) Patient lifts.

(2) The term "medical equipment" does not include:

(A) medical equipment used or dispensed in the normal course of treating patients by hospitals, hospices, nursing facilities, or home health agencies;
(B) medical equipment used or dispensed by health care professionals, licensed in Arkansas -- provided the professional is practicing within the scope of that professional's practice act;
(C) upper and lower extremity prosthetics and related orthotics; or canes, crutches, walkers, bathtub grab bars, standard wheelchairs, commode chairs, and bath benches.

(e) “Medical gas” means those gases and liquid oxygen intended for human consumption.

(f) “Order” means an order issued by a licensed medical practitioner legally authorized to order medical gases and/or legend devices.

08-01-0002—LICENSURE REQUIRED

(a) 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, and/or medical gases, unless the person or entity is licensed as required by Act 1101.

The licensure requirements of this act will apply to all companies, agencies, and other business entities that are in the business of supplying medical equipment to patients in their home and which bill the patient or the patient's insurance, Medicare, Medicaid, or other third-party payer for the rent or sale of that equipment. The application for a license shall be on a form, furnished by the Board, and shall be accompanied by payment of fee as defined in regulation 01-00-0007. 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, and/or affiliate companies when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

(b) Minimum Required Information for Licensure:

(1) Applicants may apply for a Supplier of Medical Equipment, Legend Devices, and/or Medical Gas permit using forms provided by the Board. Entities who complete the application process and otherwise meet the qualifications for a permit will be granted a license. Licenses will not be granted to those who are exempt from licensure requirements and Board regulation as provided for in ACA 17-92-903. The Arkansas Board of Pharmacy requires the following from each applicant for a permit as a Supplier of Medical Equipment, Legend Devices, and/or Medical Gas as part of the initial licensing procedure and as part of any renewal of such license:

a. The name, full business address, and telephone number of the licensee;

b. All trade or business names used by the licensee;

c. Addresses, telephone numbers, and the names of responsible on-site manager for the facility used by the licensee for the storage, handling, and distribution of medical equipment, legend devices, and/or medical gas;

d. Full disclosure of the type of ownership or operation (i.e. partnership, corporation, LLC, LLP or sole proprietorship); and

e. The name(s) of the owner and/or operator of the entity, including:

a. If a person, the name of the person;

b. If a partnership, the name of each partner, and the name of the partnership;

c. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, the employer identification number and the name of the parent company, if any;

d. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(2) Where operations are conducted at more than one location by a Supplier of Medical Equipment, Legend Devices, and/or Medical Gas each such location shall be licensed by the Arkansas Board of Pharmacy.

(3) If the entity is located outside of Arkansas, the name and address of the Arkansas resident agent.

(4) Copies of other licenses and permits issued to the entity.

(5) Changes in any information on the application for licensure shall be submitted to the Arkansas Board of Pharmacy within thirty (30) days after such change.

(6) Copy of liability insurance for products and services provided in the amount of $500,000 or more.

(7) A written description of the proposed operation.

(c) Minimum Qualifications for licensure:

The Arkansas Board of Pharmacy will consider the following factors in determining eligibility for licensure of entities who engage in supplying 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.

(1) Any convictions of the applicant under any federal, state or local laws related to the distribution of medical equipment, legend devices, and/or medical gas.

(2) Any felony convictions of the applicant under federal, state, or local laws;
(3) The furnishing by the applicant of false or fraudulent material in the application;
(4) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant;
(5) Compliance with licensing requirements under previously granted licenses, if any;
(6) Compliance with the requirements to maintain and/or make available to the Arkansas Board of Pharmacy or to federal, state, or local law enforcement officials those records required to be maintained by suppliers of medical equipment, legend devices, and/or medical gas;
(7) Any other factors or qualifications the Arkansas Board of Pharmacy considers relevant to and consistent with the public health and safety.

(d)
(1) The biennial license renewal fee is defined in regulation 01-00-0007.
(2) All licenses issued under this act shall expire on December 31, of each calendar year.
(3) Each application for renewal of the license must be made on or before December 31 of each year. Penalties for late payment are defined in regulation 01-00-0007. The license shall be considered null and void if the fee is not paid by April 1 of each year.

(e) Each license issued hereunder shall be displayed by the holder thereof in a conspicuous place.

The Arkansas Board of Pharmacy reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.
(Revised 11/13/2006)

08-01-0003—STANDARDS OF PRACTICE

(a) Written policies and procedures must be available for review and designed to meet all the following standards. Documentation of all staff training must be kept in each employee's personnel file. All local, state, and federal regulatory agency policies concerning home medical equipment and oxygen must be followed.
(1) Order intake: A home medical equipment provider shall recognize the importance of order intake. The provider is responsible for assuring that order intake personnel are appropriately trained in the following:
(A) Identifying equipment;
(B) Determining patient/caregiver needs;
(C) Determining referral sources needs;
(D) Knowing equipment coverage criteria based on diagnosis;
(E) Responding appropriately during a medical equipment emergency;
(F) Explaining service procedures;
(G) Billing third party; and
(H) Verifying insurance.
The provider must assure that only trained order intake personnel receive referrals.
(2) Selection of appropriate equipment:
(A) When providing equipment services for a patient, a provider shall consider: physician orders, equipment needs of the patient, economic situation of the patient and caregiver, and requirement of any third party payer source.
(B) A provider shall recognize those items, which require special fitting and evaluation. Fitting of custom items shall be performed within a reasonable time frame by specially trained personnel.
(3) Delivery and set up - patient and caregiver education.

(A) A provider shall maintain trained personnel to coordinate order fulfillment and to schedule equipment services with timely delivery. Documentation of training will be maintained.

(B) A provider shall assure delivery personnel are appropriately trained to:

(i) Conduct an environment/equipment compatibility assessment.

(ii) Appropriately and safely set up the equipment.

(iii) Instruct patient and caregivers in the safe operation and client maintenance of the equipment.

(iv) Recognize when additional education and/or follow-up patient compliance monitoring is appropriate.

(C) Written instructions must be provided to the patient/caregiver upon delivery, and documentation of receipt of written instruction must be maintained in the patient record.

(4) Services during use:

(A) A provider shall document that patients are advised of service hours and emergency service procedures. If equipment malfunction may threaten the customer's health, access to 24-hours-per-day, 365-days-per-year emergency service must be available for equipment maintenance or replacement.

(B) A provider shall establish a schedule at the time of the initial delivery for any appropriate follow-up home medical equipment services such as periodic maintenance, supply delivery and other related activities.

(5) Retrieval, disinfection, and maintenance of home medical equipment

(A) A provider shall assure that state/federal requirements for equipment disinfection are followed including red-tagging for bio-hazards, maintaining dirty equipment isolation, equipment cleaning and disinfection areas and procedures, and appropriate staff training on hazard prevention.

(B) Cleaning and disinfection solutions must be bactericidal, tuberculocidal, and viricidal.

(C) Centers for Disease Control universal precautions and Occupational Health Safety Administration regulations concerning equipment handling must be followed.

(D) Create and implement a preventative maintenance program based on manufacturers' guidelines, which include appropriate record keeping. Trained staff must be utilized.

(6) Patient record:

(A) A supplier must maintain a record for each customer when required by state or federal law or when a physician's order is required.

(B) The patient record must include an intake form and applicable physician's orders.

(C) Records should be safeguarded from loss and kept confidential.

(D) Documentation of proper patient/caregiver instruction must be maintained in the patient record.

(7) Patient rights:

(A) The patient has the right to considerate and respectful service.

(B) The patient has the right to obtain service without regard to race, creed, national origin, sex, age, disability, diagnosis or religious affiliation.

(C) Subject to applicable law, the patient has the right to confidentiality of all information pertaining to his/her medical equipment and service. Individuals or organizations not involved in the patient's care may not have access to the information without the patient's written consent.

(D) The patient has the right to a timely response to his/her request for home medical equipment services.
(E) The patient has the right to select the home medical equipment supplier of his/her choice.
(F) The patient has the right to voice grievances without fear of termination of service or other reprisals.
(G) The patient has the right to expect reasonable continuity of service.
(H) The patient has the right to an explanation of charges for equipment and supplies.

(8) Quality assurance:
(A) There is an ongoing continuous quality improvement program designed to monitor and evaluate the quality of patient care, improvement of patient services, if applicable, and resolution of identified problems.
(B) Continuous quality improvement activities are defined in a written plan.
(C) Issues monitored should be determined by evaluating all complaints or incidents and items that are high volume, high risk or problem prone.

(1) Liability insurance coverage for products provided and operations of each licensed entity is required in the amount of at least $500,000.

(b) Prohibited Practices -- The following practices are prohibited:

(1) Patient freedom of choice:
Participation in any plan, agreement, or arrangement which eliminates the patient's right to select a provider, licensed under this act, of their choice shall be considered a violation of this regulation.

(2) Bribes, kickbacks and rebates:
It shall be considered a violation of this regulation for anyone to knowingly and willfully offer, pay, solicit or receive any payment in return for referring an individual to another person for the furnishing, or arranging for the furnishing, of any item or service covered by this regulation.

(3) The solicitation of DME business by providing prescribers with prescription blanks, patient order forms, or patient order invoices with the name of any home medical equipment, legend device, and/or medical gas provider printed thereon.

(4) A provider of home medical equipment and/or medical gas may provide more than five percent (5%) of its annual sales to licensed practitioners or facilities. The provider must, however, obtain a State Wholesale Legend Drug and/or Controlled Substance Distributor Permit.

(10/13/95, amended 8/23/96, and 11/13/2006)

08-02—WHOLESALE DISTRIBUTOR OF LIST I CHEMICALS

08-02-0001—DEFINITIONS

As used in this regulation unless the context otherwise requires

(a) “Board” means the Arkansas State Board of Pharmacy;

(b) “Person” includes an individual, general or limited partnership, corporation, business firm, limited liability company, and association;

(c) “List I chemical” means ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, optical isomers and salts of optical isomers, alone or in a mixture.

(d) "Manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a List I chemical;
(e) "Wholesale distribution" means the distribution of List I chemicals to persons other than consumers or patients, but does not include entities exempt by Arkansas Code Annotated §5-64-1006 as amended by Act 1209 of 2001.
(f) "Wholesale distributor" means any person engaged in wholesale distribution of List I chemicals; 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; List I chemical repackagers; physicians; dentists, veterinarians; clinics; individuals; hospitals; nursing homes and their providers; and retail and hospital pharmacies that conduct wholesale distributions. A wholesale distributor shall not include any for-hire carrier or person or entity hired solely to transport List I chemicals.

08-02-0002—WHOLESALE DISTRIBUTOR OF LIST I CHEMICALS—PERMIT REQUIRED

(a) Every wholesale distributor who shall engage in the wholesale distribution of List I chemicals to include without limitation, manufacturing in this state, shipping in or into this state, or selling or offering to sell in this state, if not exempt by Act 1209 of 2001, shall register with the Arkansas State Board of Pharmacy by application for a permit on a form furnished by the Board and accompanied by a fee as defined in regulation 01-00-0007. The Board may require a separate permit for each facility directly or indirectly owned or operated by the same business entity or for a parent entity with divisions, subdivision, subsidiaries, and/or affiliate companies when operations are conducted at more than one location and there exists joint ownership and control among all the entities.
(b) The permit shall be renewed as defined in regulation 01-00-0007.
(c) All permits issued under this section shall expire as defined in regulation 01-00-0007.
(d) A change of ownership of a wholesale distributor of List I chemicals occurs under, but is not limited to, the following circumstances:
  (1) A change of ownership of a wholesale distributor of List I chemicals owned by a *sole proprietor* is deemed to have occurred when:
    (A) The business is sold and the sale becomes final or the new owner assumes control of the wholesale distributor -- which ever occurs first.
    (B) The proprietor enters into a partnership with another individual or business entity.
  (2) A change of ownership of a wholesale distributor of List I chemicals, owned by *partnership*, is deemed to have occurred when:
    (A) There is an addition or deletion of one or more partners in a partnership to which a List I chemical wholesale distributor's permit has been issued.
    (B) The business is sold and the sale becomes final or the new owner assumes control of the wholesale distributor of List I chemicals -- which ever occurs first.
  (3) A change of ownership of a wholesale distributor, owned by a *corporation*, is deemed to have occurred when:
    (A) An individual or business acquires or disposes of twenty percent (20%) of the corporation's outstanding shares of voting stock. (This shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over the counter market); or

(B) The corporation merges with another business or corporation. (The corporation owning the wholesale distributor is required to notify the Arkansas State Board of Pharmacy if a change of ownership or merger occurs within the parent corporation of the corporation which owns the wholesale distributor); or

(C) The corporation's charter expires or is forfeited.

(D) The business is sold and the sale becomes final or the new owner assumes control of the wholesale distributor -- which ever occurs first.

(4) A change of ownership of a wholesale distributor of List I chemicals, owned by a *limited liability company*, is deemed to have occurred when:

(A) There is an addition or deletion of one or more members of the limited liability company to which a List I chemical wholesale distributor's permit has been issued;

(B) The assets of the limited liability company devoted to or utilized in the wholesale distribution of List I chemicals are sold and the sale becomes final or new owner assumes control of the wholesale distribution of List I chemicals;

(C) There is dissolution of the limited liability company.

(e)

(1) The Board may, after notice and hearing suspend or revoke the registration of a List I wholesale distributor, or impose other disciplinary action pursuant to A.C.A § 17-92-315, upon a finding of any of the following:

(A) Violation of or failure to maintain qualification under Regulation 08-02-0001 et seq.

(B) Violation of any federal, state, or local law or regulation regarding List I chemicals.

(C) Revocation, suspension, or surrender of a license or other authority issued by the Drug Enforcement Administration as a List I wholesale distributor or to otherwise possess, distribute or sell or offer to distribute or sell List I chemicals

(2) The Board shall follow the same procedures for hearings for a List I chemical wholesale distributor as applicable to hearings for pharmacists as set forth in § 17-92-101 et seq. and Board regulations. (Revised 11/15/2003)

08-02-0003—MINIMUM REQUIRED INFORMATION FOR OBTAINING A PERMIT

(a) The Arkansas Board of Pharmacy requires the following from each wholesale drug distributor of List I chemicals as part of the initial registration procedure and as part of any renewal of such permit:

(1) The name, full business address, and telephone number of the permit holder;

(2) All trade or business names used by the permit holder;

(3) Addresses, telephone numbers, and the names of contact persons for the facility used by the permit for the storage, handling, and distribution of List I chemicals;

(4) The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship); and

(5) The name(s) of the owner and/or operator of the permit holder, including:

(A) If a person, the name of the person;

(B) If a partnership, the name of each partner, and the name of the partnership;

(C) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent company, if any;

(D) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(E) If a limited liability company, the name and state of organization of the limited liability company, the name of each member and manager of the limited liability company.

(b) Where operations are conducted at more than one location, by a single wholesale distributor of List I chemicals, each such location shall obtain a permit issued by the Arkansas State Board of Pharmacy.

(c) Changes in any information on the application for licensure shall be submitted to the Arkansas State Board of Pharmacy within thirty (30) days after such a change.

08-02-0004—MINIMUM QUALIFICATIONS

(a) The Arkansas State Board of Pharmacy will consider the following factors in determining eligibility for obtaining a permit as a Wholesale Distributor of List I chemicals.

(1) Any convictions of the applicant under any federal, state or local laws or regulations pertaining to wholesale or retail drug distribution of List I chemicals, distribution of controlled substances, or distribution of prescription drugs;

(2) Any felony convictions of the applicant under federal, state or local laws;

(3) The applicant's past experience in the manufacture or distribution of List I chemicals, prescription drugs, or controlled substances;

(4) The furnishing, by the applicant, of false or fraudulent material in any application made in connection with manufacturing or distribution of List I chemicals, prescription drugs, or controlled substances;

(5) Suspension or revocation by federal, state or local government of any permit currently or previously held by the applicant for the manufacture or distribution of any drugs or List I chemicals, prescription drugs, or controlled substances;

(6) Compliance with registration requirements under previously granted permits, if any;

(7) Compliance with the requirements to maintain and/or make available to the State Board of Pharmacy or to federal, state or local law enforcement officials those records required to be maintained by wholesale drug distributors of List I chemicals;

(8) Any other factors or qualifications the Arkansas Board of Pharmacy considers relevant to and consistent with the public health and safety.

(b) The applicant shall be registered with the Drug Enforcement Administration (DEA) as a retail distributor of List I Chemicals and said registration shall be in good standing.

(c) The Arkansas Board of Pharmacy reserves the right to deny a permit to an applicant if it determines that the granting of such a permit would not be in the public interest. (Revised 11/15/2003)

08-02-0005—PERSONNEL

The wholesale distributor of List I chemicals that is issued a permit by the Board of Pharmacy shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of List I chemicals.

08-02-0006—MINIMUM REQUIREMENTS FOR THE STORAGE AND HANDLING OF LIST I CHEMICALS

The following are required for the storage and handling of List chemicals, by wholesale drug distributors and their officers, agents, representatives, and employees.

(a) Facilities.

All facilities at which List I chemicals are stored, warehoused, handled, held, offered, marketed or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operation;
(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
(3) Have a designated and clearly identified area for storage of List I chemicals that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened;
(4) Be maintained in a clean and orderly condition; and
(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) Security.

(1) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.
    (A) Access from outside the premises shall be kept to a minimum and well controlled.
    (B) The outside perimeter of the premises shall be well lighted.
    (C) Entry into areas where List I chemicals are held shall be limited to authorized personnel.
(2) All facilities shall be equipped with an alarm system to detect entry after hours.
(3) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) Storage.

All List I chemicals shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such List I chemicals with requirement in the current edition of an official compendium.

(1) If no storage requirements are established for the List I chemical, the chemical may be held at "controlled" temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of List I chemicals.

(d) Examination of materials.

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated List I chemicals that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
(2) Each outgoing shipment shall be carefully inspected for identity of the List I chemical products and to ensure that there is no delivery of List I chemicals that have been damaged in storage or held under improper conditions.

(e) Returned, damaged, and out-dated List I chemicals.

(1) List I chemicals that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other List I chemicals until they are destroyed or returned to their supplier.
(2) Any List I chemicals whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically

separated from other List I chemicals until they are either destroyed or returned to the supplier.

(3) If the conditions under which a List I chemical has been returned cast doubt on the product's safety, identity, strength, quality, or purity, then the product shall be destroyed, or returned to the supplier, unless examination, testing or other investigation proves that the product meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a List I chemical has been returned cast doubt on the product's safety, identity, strength, quality, or purity, the wholesale distributor of List I chemicals shall consider, among other things, the conditions under which the List I chemical has been held, stored, or shipped before or during its return and the condition of the product and its container, carton, or labeling, as a result of storage or shipping.

08-02-0007—INSPECTION OF PREMISES AND RECORDS

The Board may conduct inspections upon all premises, including delivery vehicles, purporting or appearing to be used by a person maintaining a permit under this regulation. The Board, in its discretion, may accept a satisfactory inspection by a state agency of another state which the Board determines to be comparable to that made by the Arkansas State Board of Pharmacy.

08-02-0008—SUSPICIOUS ORDERS FOR LIST I CHEMICALS

Wholesale Distributors of List 1 chemicals should use their best judgment in identifying suspicious orders. The wholesalers should use the following criteria in order to identify suspicious orders:

(a) All Levels/All Chemicals

(1) New customer or unfamiliar representative or established customer who begins ordering List 1 chemicals.
(2) Customers who don’t seem to know industry practice or who fail to provide reasons for an order at variance with accepted legitimate industry practice.
(3) Customer whose communications are not prepared or conducted in a professional business manner.
(4) Customer who provides evasive responses to any questions or is unable to supply information as to whether chemicals are for domestic use or for export.
(5) Customer who has difficulty pronouncing chemical names.
(6) New customers who don’t seem to know federal or state government regulations.
(7) Customer whose stated use of List 1 chemicals is incompatible with destination country’s commercial activities or consignee’s line of business.
(8) Customers who want predominantly or only regulated chemicals.
(9) Customers who want multiple regulated or surveillance list products, particularly if in contrast to customary use and practice.
(10) Customer who is vague or resists providing information about the firm’s address, telephone number, and reason for seeking that chemical.
(11) Customer who provides false or suspicious addresses, telephone numbers, or references.
(12) Customer who is vague or will not furnish references for credit purposes.
(13) Customer who refuses or is reluctant to establish a credit account or provide purchase order information.
(14) Customer who prefers to pay by cashiers check, postal money order, etc.

(15) Customer who desires to pay cash.
(16) Customer who wants to pick up the chemicals outside of normal practice in the suppliers experience.
(17) Customer with little or no business background available.
(18) An established customer who deviates from previous orders or ordering methods.
(19) Customers who want airfreight or express delivery.
(20) Customers who want chemicals shipped to post office boxes or an address other than their usual business address. (i.e. residence address)
(21) Customer using a freight forwarder as ultimate consignee.
(22) Customer who requests unusual methods of delivery or routes of shipment.
(23) Customer who provides unusual shipping, labeling, or packaging instructions.
(24) Customer who requests the use of intermediate consignees whose location or business is incompatible with the purported end users nature of business or location.
(25) Above threshold hydrochloride gas or iodine sales to a non-commercial customer.

(b) Distributor (non-retail) of regulated over-the-counter products
(1) Customers who don't want to tell you what area they will resell into.
(2) Customers who don't want to tell you in what volumes they will resell.
(3) Customers who refuse to tell you who their customers are.
(4) Customers who don't have limits on resales.
(5) Customers who push to buy more than your sales limit.
(6) Customers who repeatedly buy your sales limit at the shortest interval you set.
(7) Customers who don't know what his or her customers' limits are on individual resales.
(8) Customers who resell to non-traditional outlets for regulated over-the-counter products. (i.e. hair salons, head shops, drug paraphernalia stores, liquor stores, record stores, video shops.)
(9) Customers who resell large volumes into "independent convenience store" market.
(10) Any customer who asks for large bottle sizes, 60 count or higher.
(11) Customers who buy only the largest size available.
(12) Customers that don't sell other pharmaceutical products or appear to sell those other products in token amounts.
(13) Any customer that resells multiple cases that flow through to individual retail outlets.
(14) New customers who want to sell regulated over-the-counter products into California, Arizona, Nevada, Oregon, Utah, Washington, New Mexico, Texas, Kansas, Missouri, or Arkansas.
(15) Any customer who wants to sell to an outlet relocated from California, Missouri, or Kansas to any of the states identified in the prior sentence.
(16) Any customer who wants to export, particularly to Mexico, Canada, or Southeast Asia.
(17) Customers who will not provide you with evidence of registration with the Drug Enforcement Administration (DEA)(Or have applied by Nov. 13, 1995 for single entity ephedrine; pseudoephedrine, and phenylpropanolamine products.)
(18) Customers who will not provide you with evidence of applicable state registrations/licenses.
(19) Customers who sell mail order and who don't report sales to the DEA monthly. (Note they must also be registered.)
(20) Nominal retail customers who sell above the federal, "retail" 24 gram individual sale limits.

(c) Wholesale drug distribution indicators
   (1) Individual pharmacies that intend to export.
   (2) Individual pharmacies or chains that won't set a voluntary limit for individual sales at some fraction of the Federal limit to qualify as retail outlet.
   (3) Pharmacies that stock large shelf volumes in stores that have repeated thefts or other sales problems. (6/21/2001)

REGULATION 9 —PHARMACEUTICAL CARE/PATIENT COUNSELING

09-00: PATIENT COUNSELING

09-00-0001--PATIENT INFORMATION, DRUG USE EVALUATION, AND PATIENT COUNSELING

The intent of this regulation is to improve pharmaceutical care by defining basic standards of care. Pharmacy care/pharmaceutical care is defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes are: (1) cure of disease, (2) elimination or reduction of a patient's symptomatology, (3) arresting or slowing a disease process, or (4) preventing a disease or symptomatology.

Pharmaceutical care (clinical pharmacy) involves four major functions on behalf of the patient: (1) identifying potential and actual drug-related problems, (2) resolving actual drug related problems, (3) preventing potential drug-related problems, and (4) optimizing patient therapy outcomes. It is recognized that the patient might be best served if medication is not provided.

(a) Patient information (profile)
In order to effectively counsel patients, the pharmacist must, through communication with the patient or caregiver, make a reasonable effort to obtain, record, and maintain the following information for each patient. It is recognized that most of this can be obtained using pharmacy technicians and designed forms, etc.
(1) Name, address, telephone number;
(2) Date of birth (age);
(3) Gender;
(4) Medical history
(A) Significant patient health problems known to the pharmacist;
(B) Prescription drug reactions/prescription drug allergies;
(C) List of prescription medications and legend drug administration devices known to the pharmacist.
(5) Transitory patients or situations where the pharmacy will only provide medication one time
In obtaining patient information, if the pharmacist knows or is informed by the patient that this is a one-time situation, the pharmacist may forego the above requirement to record and maintain the information.
(6) Pharmacist comments

(b) Drug use evaluation for new and refill prescriptions
Drug use evaluation or drug utilization review includes the following activities:
(1) The pharmacist shall evaluate the prescription or medication order for:
(A) Reasonable dose and route of administration;
(B) Reasonable directions for use.
(2) The pharmacist shall evaluate medication orders and patient information for:
(A) Duplication of therapy - is the patient taking the same or similar medication(s)?;

(B) Prescription drug-prescription drug interactions;
(C) Proper utilization (over or underutilization);
(D) Known drug allergies.

(3) Drug-drug contraindications as defined by the Board. (Is this medication contraindicated with another medication the patient is taking?)
(4) It is recognized that the ultimate decision to use the medication or not use the medication rests with the physician who has more complete patient information. It is the pharmacist's responsibility to monitor the patient's medication therapy in the areas addressed in this regulation and inform the physician of the suspected problem.
(5) If a problem is suspected and the physician is informed, the pharmacist shall document the process.

(c) Patient counseling.
(1) A pharmacist shall counsel the patient or caregiver "face to face" if the patient or caregiver is in the pharmacy. If not, a pharmacist shall make a reasonable effort to counsel the patient or caregiver;
(2) Alternative forms of patient information may be used to supplement, but not replace face-to-face patient counseling;
(3) Patient counseling, as described herein, shall also be required for outpatients of hospitals and institutions when medications are dispensed on discharge from the hospital or institution.
(4) Patient counseling as described in this regulation shall not be required for inpatients of a hospital or institution where a nurse or other licensed health care professional is authorized to administer the medication. However, the pharmacist shall provide drug therapy counseling it is when professionally deemed to be appropriate and when medications are provided by the pharmacy, and when a pharmacist is on duty and a patient is discharged from the hospital or institution.
(5) The pharmacist shall maintain and make available to all patients appropriate patient-oriented reference materials USP-DI or *Facts and Comparisons Patient Drug Facts* or an equivalent or better publication as determined by the Board.
(6) It is recognized that the ultimate decision to not provide patient counseling rests with the physician. If the physician in specific instances (blanket requests not accepted) requests that information NOT be provided to the patient and gives reason, the pharmacist should honor that request in almost all instances.

(d) "Patient counseling" shall mean the effective communication by the pharmacist of information, as defined in this act to the patient or caregiver, in order to improve therapeutic outcome by encouraging proper use of prescription medications and drug delivery devices.
(1) For original prescription medication orders, (excluding renewed or updated prescriptions the patient has been recently taking) and orders for legend devices, specific areas of counseling shall include:
(A) Name and general description of the medication dispensed, i.e. antibiotic, antihistamine, blood pressure medicine, etc.
(B) Name, general description and directions for use of drug delivery devices, i.e., insulin syringes, morphine pump, etc.

(C) Explanation of route of administration, dosage, times of administration, and continuity of therapy;
(D) Special directions for storage as deemed necessary by the pharmacist;
(E) If the drug has been determined to have a significant side effect by the Board of Pharmacy, the patient shall be properly counseled to the extent deemed necessary by the pharmacist.
(F) When the prescription drug dispensed has a significant side effect, if taken with over-the-counter drugs, the pharmacist should counsel the patient about that interaction. (Example: coumadin with aspirin)
(G) If the prescription medication is significantly affected by food or diet, the pharmacist should so advise the patient. (Example: tetracycline with milk or food)
(H) The pharmacist shall inform the patient or caregiver that he/she is available to answer questions about medications or general health information.

(2) Refills--On refills the pharmacist shall present the opportunity for the patient or caregiver to ask questions. However, counseling on refills is not required except when needed in the professional judgment of the pharmacist.

(d) Drug interactions – significant side effects
Recognizing that a pharmacist cannot be expected to recognize all possible drug interactions and also recognizing that the pharmacist and the patient do not have time to explain the numerous side effects of drugs, the pharmacy shall maintain a computer program which will identify significant drug interactions. (These are drugs with side effects which may be managed most effectively if the patient is aware of the specific side effect and what to do if it occurs.) The pharmacist in charge will be responsible for assuring that the computer system adequately flags and warns the pharmacist of any occurrence of significant drug interactions or significant side effects. (If a pharmacy was in business before September 1, 1997, and at that time, did not have a computer system, said pharmacy may substitute *Patient Drug Facts* or other drug interaction manuals to reference drug interactions and side effects for effective patient counseling. This method should only be used until such time as the pharmacy acquires an adequate computer program as described in this section.)
The pharmacist will be responsible for counseling the patient on these interactions with verbal and, where appropriate, written information. (2/12/91, 2/10/98, 07/15/2004)

09-00-0002—PRESCRIPTION ORDERS TO ADMINISTER MEDICATION AND/OR IMMUNIZATIONS

(a) Except as limited by these rules, an Arkansas licensed pharmacist has the ability to administer medications.
(b) Authority to administer medications/immunizations:
(1) An Authority to Administer is a written protocol, as defined in ACA § 17-92-101, from a practitioner for administration by a pharmacist of an approved medication or immunization.
(2) Pharmacists may provide pharmaceutical care to patients seven (7) years of age and older by administering medications or immunizations to an eligible patient upon receiving an Authority to Administer or a valid prescription order by a practitioner so authorized to prescribe such medications or immunizations as provided in ACA § 17-92-101(16)(A)(i). After completing the course of study described in (b)(5)(B) – (E)

of this section, licensed interns, as defined by Regulation 02-01-0003 (a), may provide pharmaceutical care to patients seven (7) years of age and older by administering medications or immunizations to an eligible patient, under the supervision of an appropriately licensed pharmacist with an Authority to Administer and in accordance with Regulations 02-01-004 and 02-01-0005(h).

(2) An Authority to Administer, once granted, is valid for a time period not to exceed one (1) year--unless such an order is invalidated by the practitioner granting the authority.

(3) An Authority to Administer is valid only for the pharmacist meeting the requirements set forth by the Arkansas State Board of Pharmacy and is not transferable.

(4) Unless otherwise specifically authorized by the Board, a person must possess a Certification for the Authority to Administer Medications/Immunizations issued by the Board to be qualified to accept an Authority to Administer. Certification for the credential (Authority to Administer Medications/Immunizations) will be issued to pharmacists who:

(A) obtain and maintain a license to practice pharmacy issued by the Arkansas State Board of Pharmacy;

(B) successfully complete a Board approved course of study, examination, and certification consisting of a training program that includes the current guidelines and recommendations of the Centers of Disease Control and Prevention. The course of study should include, at a minimum:

(i) basic immunology, including the human immune response;

(ii) the mechanism of immunity, adverse effects, dose, and administration schedule of available vaccines and approved medication/immunization;

(iii) how to handle an emergency situation in the event one should arise as a result of the administration of the medication /immunization;

(iv) how to persuade patients to be immunized and options for record keeping for patients that do get immunized;

(v) how to administer subcutaneous, intradermal, and intramuscular injection; and

(vi) record keeping requirements for these medications as required by law or regulation.

(C) obtain supervised instructions on the physical administration of vaccines during such course of study and certification;

(D) obtain and maintain current certification in Cardiopulmonary Resuscitation (CPR) or Basic Cardiac Life Support (BCLS), these certification courses must contain a live component where proficiency is tested; and

(E) successful completion of the above described course of study may be accomplished by:

(i) successfully completing the Board-approved course of study in a College of Pharmacy curriculum; or

(ii) successfully completing an American Council of Pharmaceutical Education (ACPE) Certificate Program of not less than twelve (12) hours on the course of study described in paragraph (b)(5)(B) above.

(F) The College of Pharmacy or the provider of said course of study shall provide participants a certificate of completion. A copy of said certificate shall be mailed to the Board of Pharmacy offices and placed in the pharmacist's permanent file.

(5) Pharmacists who complete items (A) through (E) of section (5) above may apply to the Board for a Certification for the Authority to Administer Medications/Immunizations. The certificate is valid until the pharmacist's license expires. The certificate shall be displayed in the pharmacy at which the pharmacist is working, and may be renewed when the pharmacist renews his or her license biennially after demonstrating continuing competency for certification.

(6) Continuing competency for certification for Authority to Administer must be maintained. A minimum of two (2) of the thirty (30) hour requirement for continuing education, each biennium, must be dedicated to this area of practice. In addition, the pharmacist must maintain a current certificate in cardiopulmonary resuscitation (CPR) or basic cardiac life support (BCLS).

(7) An Authority to Administer order shall meet the following requirements:
   (A) must properly identify the practitioner issuing the order;
   (B) must identify the medication or vaccine covered in any such order;
   (C) must identify the medication or vaccine administered, site of the administration, dose administered, identity of pharmacist administering the dose; and
   (D) must bear the date of the original order.

(c) Record keeping: Pharmacists shall maintain the following information for a minimum of two years:

(1) Authority to Administer

(2) Signed Patient Consent Form containing at least the following information
   (a) Name of Patient
   (b) Description of the medication or vaccine
   (c) Description of the risks and possible side effects of the medication or vaccine
   (d) Lot number of the medication or vaccine
   (e) Expiration date of the medication or vaccine
   (f) Date of administration

(Revised 07/15/2004, 03/14/2006, 7/5/2007, 7/27/2011 and 12/1/2017)

09-01: DISEASE STATE MANAGEMENT

09-01-0001 DISEASE STATE MANAGEMENT

The purpose of this regulation is to provide standards for the maintenance of records of a pharmacist engaged in the provision of disease state management as authorized in §17-92-101 (16) and §17-92-205 (a).

(a) Definitions. The following words and terms, when used in this regulation, shall have the following meanings, unless the context clearly indicates otherwise:

(1) "Act" means the Arkansas Pharmacy Practice Act

(2) "Board" means the Arkansas State Board of Pharmacy

(3) "Confidential record" means any health-related record maintained by a pharmacy or pharmacist--such as a patient medication record, prescription drug order, or medication order.

(4) "Disease state management" means the performance of specific acts of disease state management delegated to a pharmacist for an individual patient by an authorized practitioner through written protocol. (Disease state management shall not include the

selection of drug products not prescribed by the practitioner, unless the drug product is named in the practitioner initiated protocol.)

(5) "Written protocol" means a practitioner's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Arkansas State Medical Board under the Medical Practice Act.

(A) A written protocol must contain at a minimum the following:

(i) A statement identifying the individual practitioner authorized to prescribe drugs and responsible for the delegation of disease state management;

(ii) A statement identifying the individual pharmacist authorized to dispense drugs and to engage in disease state management delegated by the practitioner;

(iii) A statement identifying the types of disease state management decisions that the pharmacist is authorized to make which shall include:

(a) A statement of the ailments or diseases involved, drugs, and types of drug therapy management authorized; and

(b) A specific statement of the procedures, decision criteria, or plan the pharmacist shall follow when exercising disease state management authority

(iv) A statement of the activities the pharmacist shall follow in the course of exercising disease state management authority, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made. Documentation shall be recorded within a reasonable time of each intervention and may be performed on the patient medication record, patient medical chart, or in a separate log book; and

(v) A statement that describes appropriate mechanisms and time schedule for the pharmacist to report to the physician monitoring the pharmacist's exercise of delegated disease state management and the results of the disease state management.

(B) A standard protocol may be used, or the attending practitioner may develop a disease state management protocol for the individual patient. If a standard protocol is used, the practitioner shall record, what deviations if any, from the standard protocol are ordered for that patient;

(C) Maintenance of records:

(i) Every patient record required to be kept under this regulation shall be kept by the pharmacist and be available, for at least two (2) years from the date of such record, for inspecting and copying by the Board or its representative and to other authorized local, state, or federal law enforcement or regulatory agencies.

(ii) Patient records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

(a) The records maintained in the alternative system contain all of the information required on a manual record; and

(b) The data processing system is capable of producing a hard copy of the record upon the request of the Board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(D) Written protocol:
  (i) A copy of the written protocol and any patient-specific deviations from the protocol shall be maintained by the pharmacist and available for inspection by a Board Inspector upon request.
  (ii) Written protocols, including standard protocols, any patient specific deviations from a standard protocol, and any individual patient protocol, shall be reviewed by the practitioner and pharmacist at least annually and revised, if necessary. Such review shall be documented in the pharmacist's records. Documentation of all services provided to the patient, by the pharmacist, shall be reviewed by the physician on the schedule established in the protocol.
  (iii) Any protocol from a practitioner shall be maintained in the pharmacy and available for inspection by a Board Inspector upon request.
(E) Confidentiality:
  (i) A pharmacist shall provide adequate security to prevent indiscriminate or unauthorized access to confidential records. If confidential health information is not transmitted directly between a pharmacy and a practitioner, but is transmitted through a data communication device, the confidential health information may not be accessed or maintained by the operator of the data communication device unless specifically authorized to obtain the confidential information by this regulation.
  (ii) Confidential records are privileged and may be released only to:
    (a) the patient or the patient's agent;
    (b) practitioners and other pharmacists when, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well-being;
    (c) other persons, the Board, or other state or federal agencies authorized by law to receive such information;
    (d) a law enforcement agency engaged in investigation of suspected violations of the Controlled Substances Act; or
    (e) a person employed by any state agency which licenses a practitioner as defined in the Act if such person is engaged in the performance of the person's official duties.
  (iii) This regulation shall not affect or alter the provisions relating to the confidentiality of the physician-patient communication as specified in the Medical Practice Act.
  (Adopted 8/19/99)

09-01-0003 —QUALIFICATIONS, RESOURCES, AND RECORD KEEPING REQUIRED FOR PRACTICING DISEASE STATE MANAGEMENT IN ARKANSAS.

(a) To practice disease state management a pharmacist must:
  (1) be a licensed pharmacist in the State of Arkansas
  (2) complete requirements for a credential as established by a Board of Pharmacy approved organization.
(b) Resource requirements for the provision of disease state management services shall include—but are not limited to the following:

(1) Maintain a distinct area that provides privacy for the provision of disease state management services;
(2) Maintain references that include a current copy/edition of applicable national practice guidelines and such other resources as may be necessary for the provision of optimal care;
(3) Maintain devices, supplies, furniture, and equipment as may be needed for the provision of optimal care.

(c) Record keeping requirements for disease state management.
The pharmacist shall record, maintain, and transfer data essential to the continuity of care and consistent with all applicable state and federal laws and regulations; and these records and all related files shall be available to the Arkansas State Board of Pharmacy inspectors and professional staff upon request. Additionally, a transferable pharmaceutical care record is to be maintained and is to include:
(1) The written request for consultation from the patient or physician;
(2) The physician approved protocol and/or patient care plan, which is to recognize all concomitant diseases and the patient's complete medication history/profile;
(3) Pharmacy progress notes; and,
(4) Laboratory data.
(Adopted 8/19/99, Revised 11/12/2009)

09-01-0004 —MINIMUM COMPETENCIES AND STANDARDS

(a) Minimum competencies for pharmaceutical care in all disease state management areas:
(1) The pharmacist shall be capable of identifying and accessing the patient's current health status, health-related needs and problems, and desired therapeutic outcomes.
(2) The pharmacist shall be capable of implementing, and evaluating a pharmaceutical care plan that assures the appropriateness of the patient's medication(s), dosing regimens, dosage forms, routes of administration, and delivery systems.
(3) The pharmacist shall be capable of communicating appropriate information to the patient and/or caregiver and other health care professionals regarding prescription or non-prescription medications and/or medical devices, disease states, or medical conditions, and the maintenance of health and wellness.
(4) The pharmacist shall be capable of monitoring and documenting the patient's progress toward identified endpoints and outcomes of the pharmaceutical care plan and shall intervene when appropriate.
(Adopted 8/19/99, Revised 11/12/2009)

09-01-0005 —NOTIFICATION OF CREDENTIAL IN DISEASE STATE MANAGEMENT REQUIRED:

Every pharmacist who receives a credential in disease state management from a Board approved organization must provide a copy of the credential to the Board of Pharmacy office. The Board of Pharmacy will notify any party requesting notification that the pharmacist is so qualified.

(Adopted 8/19/99, Revised 8/2001, 07/2004, 11/12/2009)

REGULATION 10 —ARKANSAS PHARMACY SUPPORT GROUP

10-00-0001—SUPPORT GROUP

(a) Definitions. As used in this regulation:

(1) "Board" means the Arkansas State Board of Pharmacy;

(2) "Board-approved interveners" means persons trained in intervention and designated by the Board to implement the intervention process when necessary;

(3) "Committee" means a committee appointed by the Board to formulate and administer the impaired pharmacists program, to be known as the Arkansas Pharmacy Support Group ("ARPSG");

(4) "Impaired pharmacist" or "impaired pharmacy technician" means a pharmacist or pharmacy technician who is unable to practice pharmacy with reasonable skill, competency, or safety to the public because of substance abuse;

(5) "Impaired pharmacist program" means a plan approved by the Board for intervention, treatment, and rehabilitation of an impaired pharmacist or pharmacy technician. The program for each impaired pharmacist/pharmacy technician will be embodied by a contract with the ARPSG and the impaired pharmacist/ pharmacy technician will be required to comply with the contractual terms;

(6) "Intervention" means a process whereby an alleged impaired pharmacist/pharmacy technician is confronted by the Board or Board-approved interveners who provide documentation that a problem exists and attempt to convince the pharmacist to seek evaluation and treatment;

(7) "Rehabilitation" means the process whereby an impaired pharmacist/pharmacy technician advances in an impaired pharmacist program with progressive advocacy from the ARPSG to an optimal level of competence to practice pharmacy without endangering the public; and

(8) "Verification" means a process whereby alleged professional impairment is identified or established.

(b) Administration.

(1) The impaired pharmacist program authorized by Ark. Code Ann. § 17-92-701, et seq shall be administered by the ARPSG in accordance with guidelines set by the Board. The ARPSG shall serve as a diversion program to which the Board may refer licensees where appropriate in lieu of or in addition to other disciplinary action and also be a source of treatment, referral and monitoring for pharmacists who desire to avail themselves of its services on a strictly voluntary basis.

(2) The Board shall appoint an Executive Committee of five (5) persons who are recovering pharmacists and members of the ARPSG. The Committee members shall serve three year terms. The Committee is authorized to appoint subcommittees to assist in operations as needed, but all subcommittee actions are subject to review and approval of the Executive Committee.

(3) The Board shall also appoint an Executive Secretary who shall be a non-voting member of the Executive Committee and who shall serve at the pleasure of the Board. The Executive Secretary shall be responsible for administrative duties of the ARPSG and for supervision of

ARPSG contracts and monitoring functions. The Executive Secretary shall be compensated as may be determined by the Board.

(4) ARPSG Executive Committee Responsibilities

Subject to guidance and direction by the Board, the ARPSG Executive Committee shall be responsible for:

(a) Formulating and administering a program to monitor compliance by impaired pharmacists/pharmacy technicians with the recovery guidelines established by the ARPSG contract with the impaired pharmacist /pharmacy technician and approved by the Board;

(b) Appointing a member of the ARPSG as a monitor for impaired pharmacists/pharmacy technicians who are under contract with the ARPSG to supervise compliance with the recovery guidelines established in the contract and approved by the Board;

(c) Recommending to the Board that an impaired pharmacist/pharmacy technician has progressed in recovery and can return to the practice of pharmacy on terms determined by the Board without posing a threat to himself or herself or to the public;

(d) Approving addiction professionals, addiction centers and medical providers to perform evaluations of pharmacists/pharmacy technicians who are ordered to participate in the ARPSG or who voluntarily request participation in the program;

(e) Develop and administer requirements for personal drug testing of participants in the ARPSG;

(f) Reviewing and monitoring information relating to the compliance of pharmacists/pharmacy technicians in the ARPSG;

(g) Assisting the pharmacists' professional association in publicizing the program; and

(h) Preparing of reports for the Board as requested.

(c) Board referral

(1) The Board shall inform each pharmacist/pharmacy technician referred to the program by Board action of the procedures followed in the program, of the rights and responsibilities of the pharmacist/pharmacy technician in the program and of the possible consequences of noncompliance with the program.

(2) The Executive Director of the Board shall be immediately informed when a pharmacist/pharmacy technician has failed to comply with any contractual term of the treatment program or if the ARPSG Executive Committee determines that the pharmacist/pharmacy technician poses a threat to the health and safety of the public.

(3) Participation in a program under this regulation 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.

(4) The Board shall be informed when, in the opinion of the ARPSG Executive Committee, a pharmacist/pharmacy technician who enters the program is eligible to resume professional practice without posing a threat to himself or herself or the public.

(d) Review activities

The Board shall review the activities of the Committee. As part of this evaluation, the Board may review files of all participants in the ARPSG program. The Board shall also resolve complaints received regarding the impaired pharmacists program.

(e) Civil liability

(1) All persons acting on behalf of the Board in the impaired pharmacists program under this section shall be considered to be acting on behalf of the Board and considered officers or employees of the state.

(2) 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.

(f) Funding

The Board is authorized to provide up to $50,000 per year to the ARPSG Executive Committee for expenses incurred in management and operation of the program. The Committee shall prepare a budget for a July 1 to June 31 fiscal year outlining planned expenses of the ARPSG and submit the budget for review and approval prior to the Board's June meeting.

(6/20/91, Revised 7/10/2009)

REGULATION 11- CRIMINAL BACKGROUND CHECKS

11-00-0001 – DEFINITIONS

(a) "Board" means the Arkansas State Board of Pharmacy;

(b) "Criminal background check" means both a state criminal records check conducted by the Arkansas State Police ("state background check") and a nationwide criminal records check conducted by the Federal Bureau of Investigation ("federal background check"), including the taking of fingerprints;

(c) "Provisional license or registration" means a non-renewable, provisional license or registration that shall expire when the results of the nationwide criminal background check are received by the Board or 180 days after issue, whichever comes first. (11/15/2003, Revised 7/10/2009)

11-00-0002-BACKGROUND CHECK REQUIRED

(a) The Board shall not issue an initial license/registration, or reinstate a license/registration until the state and federal criminal background checks have been completed.

(b) The Board may issue a provisional license or registration to applicants for a new pharmacist or intern license, or for a new or reinstated pharmacy technician registration as provided in this Regulation. (11/15/2003, Revised 7/10/2009)

11-00-0003-APPLICATION PROCEDURE

(a)

(1) Effective March 1, 2004, prior to or contemporaneously with filing an application form for the applicable license or registration, each applicant for a new intern or pharmacist license, or a new or reinstated registration as a pharmacy technician, shall apply for state and national criminal background checks, using forms furnished by and pursuant to instructions provided by the Board.

(2)

(A) Before performing any practice of pharmacy while physically present within the State of Arkansas, a pharmacist shall:

(i) apply for state and federal criminal background checks described herein; and

(ii) obtain documentation from the Board of its approval of the pharmacist's practice of pharmacy while physically present in Arkansas.

(b) Each applicant shall authorize the release of criminal background check reports to the Board and shall pay any applicable fees~~,~~ associated with the state and federal criminal background checks, pursuant to written instructions provided by the Board.

(c) The state and federal criminal background checks may be used for an initial license/registration issued by the Arkansas State Board of Pharmacy for twelve (12) months after each check is completed.

(d) Background checks used to obtain an initial license or registration issued by the Board may be used for subsequent applications for a different license or registration issued by the Board for a period of up to four years after the date of the original license or registration. (11/15/2003, Revised 7/10/2009 and 7/22/2015)

11-00-0004-ELIGIBILITY FOR LICENSE/REGISTRATION

(a) No person shall be eligible to receive or hold an intern or pharmacist license or a 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 (collectively "conviction"):

(1) Any felony;

(2) Any of the following:

Title	**Ark. Code Number**
Theft	5-36-103(b)(5), 104(c)(3) & (4), 105(b)(2)& (3), 106(e)(3), & 202
Forgery and Fraudulent Practices	5-37-101 – 525
Fraud Against Government	5-55-101 – 401
Fraudulent Issuance of Warrants	6-20-407
Employer, Employee liens	18-42-106
Obtaining Information by Fraudulent Representation	20-13-705
Insurance Holding Companies	23-63-522
False Reports, Motor Fuel Taxes	26-56-107
Fraudulent Applications	27-14-303
Uniform Controlled Substances Act	5-64-101 – 1303
Pharmacy Licensing Law	17-92-101 – 1007
Food, Drug & Cosmetics Act	20-56-205, 210, 211, 215, & 216
Uniform Narcotic Drug Act	20-64-201 et seq.
Controlled Substances & Legend Drugs	20-64-501 et seq.

(b)

(1) If an applicant who has such a conviction wishes to request a waiver of the conviction from the Board, he or she must submit a request for waiver form, along with the following documentation:

(A) Copies of court documents pertinent to each conviction, including complete copy of the court file, certified by the court clerk;

(B) Documents from probation/parole officers, court clerk or other officials proving that any probation, parole, restitution, rehabilitation, community service or other court-ordered sentence has been successfully completed or, if still ongoing, with information regarding the history of compliance and current status;

(C) A notarized statement by the applicant explaining the circumstances of each conviction and explaining why he or she should be granted a waiver;

(D) An applicant may submit any additional evidence of rehabilitation, including

(i) Letters of reference from past and/or current employers.

(ii) Letters of reference from pharmacy instructors concerning attendance, participation and performance in pharmacy programs.

(iii) Letters from treatment/recovery program attesting to current sobriety and length of time of sobriety, if appropriate.

(iv) Letters of reference from other knowledgeable professionals, such as probation or parole officers.

(v) Fitness to practice release letter from appropriate health care professional.

(vi) Any other pertinent information may be considered.

(c) The application and request for waiver shall not be considered until the application, all fees, all the documentation identified in paragraph (b) of this section, and both federal and state criminal background check reports are received by the Board.

(d) The Board's Informal Review Committee or its designee shall determine whether the applicant is rehabilitated, the conviction has served the intended disciplinary purpose and the applicant can practice or work in the capacity that is the subject of the application without undue risk to the public health, safety or welfare because of the subject conviction. The Committee or its designee, shall consider all relevant data, including without limitation:

(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, including without limitation:

(i) Whether the applicant is on probation, parole, or probation as a result of suspended imposition of sentencing or similar deferral of judgment or sentencing, is in compliance with the terms and conditions of any such parole or probation, has complied with any terms and conditions of the judgment of conviction including

payment of restitution and any fines, costs or other monetary payments.

(ii) Whether the applicant has a currently suspended or revoked pharmacist or intern license, or pharmacy technician license or registration in any jurisdiction;

(iii) The applicant's activities, employment, relationships and other facts since the conviction;

(iv) Whether the applicant has provided information requested by the Board;

(v) Whether the applicant has falsified or misrepresented facts to the Board in the application or related procedure;

(vi) Whether the applicant has a conviction that relates to the practice of pharmacy or other conduct regulated by the Board;

(vii) Any Evidence of Rehabilitation as described above;

(viii) Whether the applicant has more than one criminal conviction; or

(ix) Whether the applicant has been pardoned or granted clemency by the governor, or the criminal conviction was expunged.

(e) Each applicant with a disqualifying conviction who requests a waiver may appear before the Informal Review Committee or its designee or may choose to allow the Committee to make a determination on the request upon the file documentation obtained by the Board and that submitted by the applicant.

(f) No application with a disqualifying conviction will be processed until all required documentation has been received and the applicant's request has been submitted to the Informal Review Committee or its designee. (11/15/2003, Revised 03/01/2004 and 7/10/2009)

11-00-0005–BOARD WAIVER OF CONVICTION

(a)

In the event that the Informal Review Committee or its designee determines not to waive a conviction, an applicant can request a full Board hearing on the request for a waiver of the conviction.

The applicant's written request for a full Board hearing on the waiver must be received by the Board office no later than thirty (30) days after the Informal Review Committee's denial of the initial waiver request. The applicant will be scheduled to appear before the Board as soon as is practicable. The applicant may, if desired, submit additional documentation described in Regulation 11-00-0004(b), for the Board's consideration.

(c) The Board shall consider the matters as identified in section 11-00-0004 above in determining whether to waive a conviction. (11/15/2003, Revised 7/10/2009)

11-00-0006-PROVISIONAL LICENSE AND REGISTRATION

(a)

(1) The Board may issue a provisional license or registration, limited to six months duration only to applicants who:

(A) certify on their Arkansas State Board of Pharmacy application that they have no criminal conviction; and

(B) meet all other qualifications for licensure or registration established by the Arkansas State Board of Pharmacy, and;

(C)

i. certify that they have submitted an Arkansas State Police and FBI Criminal Background Check form and associated fees pursuant to written instructions provided by the Board.

ii. Or, at the Board's discretion, when state criminal background check reports are available within a reasonable time after application, and the Board has received a state criminal background check report on the applicant acceptable to the Board and pursuant to this regulation, and the applicant certifies that he/she has submitted an Arkansas State Police and FBI Criminal Background Check form and associated fees for the FBI check pursuant to written instructions provided by the Board.

(2) The provisional license or registration shall permit the subject thereof to temporarily perform, pending the Board's receipt of the criminal background check report(s), the activities authorized by the license, permit or registration that is the subject of the application.

(3) An applicant who discloses any conviction identified in Section 11-00-0004 on the application form shall not be eligible to receive a provisional license or registration and will be considered for the applicable license or registration upon the Board's receipt of the criminal background check reports.

(b)

(1) Upon receipt of both the federal and state criminal background check reports containing no conviction of any offense identified in Section 11-00-0004, and upon the applicant meeting all other qualifications for the subject license/registration, the Board shall issue the appropriate license/registration to the applicant.

(2)

(A) Upon receipt of either criminal background check report that contains a conviction of an offense identified in Section 11-00-0004, the Executive Director shall cause to be served upon the applicant notice of the reported conviction, the applicant's failure to disclose the conviction in the application, any other relevant facts or law, and the immediate revocation of the provisional license/registration pursuant to A.C.A. § 17-92-317, and the opportunity for a hearing.

(B) In order to obtain a hearing on the subject issues, an applicant shall serve a written request for a hearing upon the Executive Director within ten (10) days of service upon the applicant of the notice described in the preceding paragraph. The hearing shall be conducted in accordance with the Administrative Procedures Act.

(c) Failure of an applicant to disclose any conviction of an offense identified in Regulation 11-00-0004 shall constitute grounds for the suspension, revocation, or denial of a license or registration.

(d) Fees and applications.
   (1) The license/registration fee shall be submitted with the application.
   (2) The fee is not refundable. (11/15/2003, Revised 03/01/2004 and 7/10/2009)

11-00-0007-APPLICANT CONFIDENTIALITY

(a) All reports obtained under these regulations are confidential and are restricted to the exclusive use of the Board. The information contained in reports shall not be released or otherwise disclosed to any other person or agency except by court order and are specifically exempt from disclosure under the Arkansas Freedom of Information Act (A.C.A. 25-19-101, et seq.)

(b) Criminal conviction reports may be reviewed by or provided to the subject, the subject's attorney or other designee at the request of the subject as follows:
   (1) To the subject, in person, upon his producing positive verification acceptable to the Board of his/her identity, or by mail upon receipt of an acknowledged authorization in a form acceptable to the Board; the Board will mail a copy of the report by certified mail, return receipt requested, delivery restricted to the subject or his authorized agent at the address stated in the request.
   (2) To the subject's attorney or other designated individual, in person, upon presentation of an acknowledged authorization by the subject and presentation of positive verification of the attorney's or designated individual's identity, both of which are acceptable to the Board. (11/15/2003)

11-00-0008-CHALLENGES TO THE ACCURACY OF THE REPORT

(a) The Board shall make determinations based on the information obtained from the Bureau and shall not be responsible for allegations regarding the disposition, expungement or accuracy of the information.

(b) A person may challenge the completeness or accuracy of a report of criminal conviction information issued by the State Police Identification Bureau or the Federal Bureau of Investigation as provided in A.C.A. § 12-12-1013, as amended.

(c) Upon receipt of a corrected criminal conviction report, the Board shall conduct a new evaluation of the report and the applicant's qualifications for the applicable license or registration. (11/15/2003)

REGULATION 12 —AUTOMATION

12-00-0001—AUTOMATED AND ROBOTIC PHARMACY SYSTEMS

(a) Purpose and Scope:

The purpose of this regulation is to recognize the use of automated pharmacy systems and or robotic pharmacy systems in community or institutional pharmacy settings.

(b) Definitions:

(1) "Automated pharmacy systems" include, but are not limited to, mechanical systems that perform operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of medications—and which collects, controls, and maintains all transaction information.

(2) "Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, labeling, and dispensing—and collects, controls, and maintains all transaction information.

(c) General requirements for automated pharmacy systems and robotic pharmacy systems:

(1) Duties and responsibilities of the permit holder

(A) Providing the Board prior written notice of the installation, removal, or substantive change of the automated or robotic pharmacy system. Such notice must include, but is not limited to:

(i) the name, address, and permit number of the pharmacy,

(ii) the identification of the responsible pharmacist,

(iii) the manufacturer's name and model of the system, and

(iv) the policies and procedures for the system operation (for initial installations)

(B) Obtaining written approval and authorization from the Board of Pharmacy prior to implementation.

(C) Developing and implementing an ongoing quality assurance program that monitors performance of the system, which is evidenced by written policies and procedures developed by the pharmacy and include the following:

(i) Method of ensuring accurate packaging and loading of the system,

(ii) Procedures for conducting quality control checks of final dispensing for accuracy,

(iii) Manufacturer's schedules and recommendations for maintenance of the device, and

(iv) Plan for maintenance of all related documentation for a minimum of two years.

(D) Assuring that the system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate record keeping and security safeguards.

(2) Pharmacy Practice

(A) The automated/robotic pharmacy system can be utilized in licensed pharmacies and licensed health care facilities where legally permissible and shall comply with the following provisions:

(i) documentation, as to type of equipment, serial numbers, content, policies and procedures, and location, shall be maintained on-site in the pharmacy for review by an agent of the Board of Pharmacy, and

(ii) the system shall be used only in settings where there is an established program of pharmaceutical care that ensures medication orders or prescriptions are reviewed by

a pharmacist in accordance with established policies and procedures and good pharmacy practice.

(3) The system shall have adequate security systems and procedures, evidenced by written policies and procedures, to:
   (A) prevent unauthorized access;
   (B) comply with federal and state regulations, and;
   (C) maintain patient confidentiality.

(4) The filling/stocking of all medications in the system, shall be accomplished by qualified personnel under the supervision of a licensed pharmacist. An electronic or hard copy record of medications filled into the system shall be maintained and include identification of the person filling the device.

(5) Access to and limits on access to the automated pharmacy system must be defined by policy and procedures and must comply with state and federal regulations. Proper identification and access control, including electronic passwords, biometric identification, or other coded identification, must be limited and authorized by the pharmacist-in-charge. The pharmacist in charge must:
   (A) be able to stop or change access at any time, and
   (B) maintain a current and retrievable list of all persons who have access and the limits of that access.

(6) The pharmacist in charge shall have the sole responsibility to:
   (A) assign, discontinue, or change access system;
   (B) ensure that access to the medications comply with state and federal regulations and;
   (C) ensure that the system is filled/stocked accurately and in accordance with established, written policies and procedures. (10/2001)