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)