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SECRETARY OF STATE
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Transmittal Sheet

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Secretary of State
State Capitol
Little Rock, Arkansas 72201-1094

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Name of Agency ARKANSAS STATE BOARD OF PHARMACY

Department _____

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CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted In Compliance With Act 434 of 1967 As Amended.

Lester Hosto, P.D.
SIGNATURE

Executive Director
TITLE

7/5/91
DATE

070.00.91-001

CHANGES IN BOARD OF PHARMACY REGULATIONS

1. The Arkansas State Board of Pharmacy shall consist of six pharmacist members as provided by Arkansas Stats. 17-91-201 (a)(1) and 17-91-201(d) plus a consumer member and a senior Citizen consumer member as provided by Arkansas Stats. 17-91-201(a)(2). The qualifications, powers, and duties of the Board shall be those enumerated by the provisions of Arkansas Stats. 17-91-201 through 17-91-208. (10-9-80, Revised 6/20/91)

5. Any person, corporation or partnership operating a pharmacy in this state desiring to continue such operation must pay a fee for a permit as established by law and/or regulation. If said fee is not paid on or before February 1st of any year, a penalty of $20 shall be levied for each month the pharmacy permit fee is delinquent. If said permit fee is unpaid by April 1st of any 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)

6. No owner or owners of a drugstore, apothecary, pharmacy, etc., should 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)

9. A., F. 4. k. 3. add:
Each hospital pharmacy shall have available for personal and patient use a current copy of the U.S.P. DI 3 book set including "Drug Information for the Healthcare Professional" (2 volumes) and "Advice for the Patient" (1 volume), or the two volume set "Facts and Comparisons" (1 volume) and Patient Drug Facts" (1 volume).

12. A. Satisfactory proof of graduation and receipt of the first professional undergraduate degree from a college of pharmacy which has been approved by the Board of Pharmacy; or satisfactory proof of graduation from a foreign college of pharmacy, completion of a transcript verification program, successful completion of a college of pharmacy equivalency exam program equivalent to graduation from a Board of Pharmacy approved College of Pharmacy, and a minimum score of 550 on the Test of

English as a Foreign Language (TOEFL) within two years of the completion of the College of pharmacy equivalency exam.

B. Applicants will apply to the Board of Pharmacy for an application blank which must be completed and returned to the Board of Pharmacy office together with the fee of $25 plus cost of the exam as determined by the Board, not less than 30 days before the examination is scheduled.

D. Examination will be held at the time and place set by the Board of pharmacy, and each applicant will be notified in advance.

Upon the receipt of certification of the requirements as defined in section A. of this regulation, and receipt of an application for examination for licensure by the Board of Pharmacy, such applicant may practice pharmacy in the State of Arkansas temporarily until such time as the first meeting of the Board of Pharmacy for examination for licensure as a pharmacist.

The granting of the temporary permission to practice pharmacy upon such certification, shall in no way entitle the recipient thereof to any rights of tenure or permanent license and is purely discretionary and gratuity by the Board.

E. The test or tests shall be graded and reported, and a reported score of 75 or above is considered passing.

16. Remove

19. 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) disignation 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 therefrom 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 and Drug Administration, by telephone, that the particular drug or drugs involved do not have the required NDA or ANDA and that they are not exempt from this 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 and will also constitute good and sufficient cause for 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 Pharamcy. (10/14/81, revised 6/20/91)

20. All certificates of licensure issued by the Arkansas State Board of Pharmacy shall expire on the 31st day of December, following the date of issuance of the same. Every licensed pharmacist engaged in the active practice of pharmacy shall pay to the Board of Pharmacy annually, between January 1st and January 31st a minimum renewal fee of $50. If the renewal fee for any pharmacist certificate be unpaid by the first day of February of any year, the holder thereof must pay a penalty of $20 for each month thereafter, provided, that if the renewal be unpaid by April 1st of any year, such certificate shall be null and void, and the holder thereof must be reinstated as a licensed pharmacist by satisfying the State Board of Pharmacy that he 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 is competent and qualified to compound and fill prescriptions, and must pay a reinstatement fee of fifty dollars ($50) for each delinquent year up to a maximum of two hundred dollars ($200) plus the current year's renewal fee of fifty dollars ($50). (10/9/80, amended 10/14/81, Act of 1985, 6/20/91)

21. The Arkansas State Board of Pharmacy shall meet the second Tuesday in February, the Second Tuesday in June, and the second Tuesday 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, time, and place as determined by the Board of Pharmacy. (10/9/80, amended 6/20/91)

22. Every location holding a retail/wholesale prophylactic license issued by the Board including pharmacies shall cause periodic inspection and tests of prophylactics and contraceptives in order to determine their condition and shall report damaged or inferior merchandise to the Inspector of the Board of Pharmacy.

The Inspector of the Arkansas State Board of Pharmacy shall have free access to inspect and test all prophylactics and contraceptives. And any such merchandise considered to be out-dated, not properly labeled, or inferior in any way, must be disposed of and cannot be sold, in order to protect the health and welfare of the general public. (10/9/80, amended 6/20/91)

23. Every licensed pharmacist or intern who shall fill or refill a prescription, shall attest that he has personally filled said prescription by placing upon said prescription his signature with date thereof.

All drustores or pharmacies must have on duty an Arkansas Licensed Pharmacist a minimum of 40 hours per week. The said 40 hours per week must be served by a single person and cannot be met by a combination of weekly hours or two or more pharmacist with less than 40 hours each. (10/9/80, amended 10/14/81, 6/20/91)

27. A. (2). Graduate Intern--An intern who has graduated or completed requirements for examination as set forth in Regulation 12 A.

B. GRADUATION: 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 12 A.

E. 2. All students accepted by and enrolled as a student in the University of Arkansas College of Pharmacy shall be licensed as an intern.

All students enrolled in Colleges of Pharmacy outside Arkansas shall license as an intern in Arkansas prior to any participation in the practice of Pharmacy as defined in 17-91-101, 17-91-301, and 17-91-307.

Provided that any licensed intern shall not participate in the practice of Pharmacy as defined in 17-91-101, 17-901-301, and 17-91-307, until said intern has successfully completed the first pro-

fessional year on a 2-3 or 2-4 program of study or the second professional year on a 1-4 program of study in a school or college of pharmacy approved by the Arkansas Board of Pharmacy. The intern license remains valid as long as the intern maintains active student status in a Board-approved College of Pharmacy and for one year (12 calendar months) after graduation from a College of Pharmacy or completion of foreign pharmacist requirements as set forth in Regulation 12 A. At this time, the intern license becomes void. The graduate intern may not practice pharmacy until approval by the Board of Pharmacy has been granted and another license as an intern in Arkansas has been granted.

6. The Arkansas State Board of Pharmacy examination will be offered upon graduation and proof of participation in an approved extern clerkship program in a school curriculum, or proof of completion of foreign pharmacist requirements as set forth in Regulation 12 A.

7. After proving eligibility to sit for the Board Examination, the candidate may practice pharmacy in the State of Arkansas under limited supervision in a Class A pharmacy. Failure to make a passing grade on the examination will reduce the applicant to extern status for further training under the personal and physical supervision of an assigned Preceptor or Alternate Preceptor.

RULES APPLYING TO PRECEPTOR:
9. Remove last paragraph. (Leave rest of 9.)

28. A. Applications for pharmacy permits other than annual renewal of existing permits, will be considered by the Board at any meeting of the Board, and applications to be considered must be received in the Board of Pharmacy office at least 14 days prior to the next scheduled meeting. Provided that no store may open for business within thirty (30) days of submission of original application. Applications for a pharmacy permit for a new store must have the name and license number of the pharmacist in charge at the time of submission and cannot be altered within 14 days of the consideration meeting day. The pharmacist in charge of the new store application cannot be the pharmacist in charge of another store at the time of the meeting that the new store application is heard.

42. WHOLESALE DRUG DISTRIBUTORS REGULATION

A. DEFINITIONS. As used in this Regulation, unless the context otherwise requires.

1. 'Board' means the Arkansas State Board of Pharmacy;
2. 'Person" includes individual, partnership, corporation, business firm and association;
3. '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;
4. a. '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:
      i. Habit-forming;
      ii. Toxic or having potential for harm;
      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 the federal Food, Drug, and Cosmetic Act which shall be exempt if certain specified conditions are met.
5. 'Prescription drug" means controlled substances, legend drugs and veterinary legend drugs as defined herein.
6. 'Blood' means whole blood collected from a single donor and processed either for transfusion or further manufacturing.
7. 'Blood component' means that part of blood separated by physical or mechanical means.
8. 'Manufacturer' means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.
9. '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 or from other hospitals or health care entities that are members of such 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 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 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 regulation, 'emergency medical reasons' includes transfers of prescription drugs by a retail pharmacy or a hospital pharmacy to a hospital pharmacy or a retail pharmacy to alleviate a temporary shortage;

f. The sale, purchase, or trade of a drug; and 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.

10. 'Wholesale distributor' means any person engaged in wholesale distribution of prescription drugs, including but not limited to manufacturers; repackers' own-label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; prescription drug repackagers; physicians; dentists, veterinarians; birth control and other clinics; individuals; hospitals; nursing homes and their providers; health maintenance organizations and other 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.

11. '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.

12. '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."

B. 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.

C. WHOLESALE DISTRIBUTOR--PERMIT REQUIRED.

1. 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, and/or affiliate companies within this state when operations are conducted at more than one(1) location and there exists joint ownership and control among all the entities.

2. a. The permit may be renewed annually at a renewal permit fee of one hundred dollars ($100).
   b. All permits issued under this section shall expire on December 31 of each calendar year.
   c. Each application for the renewal of the permit must be made on or before December 31 of each year, a penalty of twenty dollars ($20) per month from February 1 of any year will by charged, provided that if the renewal is unpaid by April 1 of any year, the license shall be null and void.
3. Each permit issued hereunder shall be displayed by the holder thereof in a conspicuous place.

D. WHOLESALE DISTRIBUTORS--SHIPMENT TO CERTAIN LICENSED PROFESSIONALS.

1. 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.
2. 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.

E. MINIMUM REQUIRED INFORMATION FOR LICENSURE.

1. 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:

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 contact persons for the facility used by the license for the storage, handling, and distribution of prescription drugs;
d. The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship); and
e. The name(s) of the owner and/or operator of the licensee, including:
    i. If a person, the name of the person;
    ii. If a partnership, the name of each partner, and the name of the partnership;
    iii. 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;
    iv. 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 single wholesale distributor, each such location shall be licensed by the Arkansas Board of Pharmacy.
3. Changes in any information in this regulation shall be submitted to the Arkansas Board of Pharmacy within 30 days after such change.

F. MINIMUM QUALIFICATIONS.

1. 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 relating 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.

2. 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.

G. 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.

H. 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.

1. Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed or displayed shall:
   a. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
   b. have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
   c. 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;
   d. Be maintained in a clean and orderly condition; and
   e. Be free from infestation by insects, rodents, birds, or vermin of any kind.
2. Security.
   a. All facilities used for wholesale drug distribution shall be secure from unauthorized entry.
      i. Access from outside the premises shall be kept to a minimum and be well-controlled.
      ii. The outside perimeter of the premises shall be well-lighted.
      iii. Entry into areas where prescription drugs are

held shall be limited to authorized personnel.

b. All facilities shall be equipped with an alarm system to detect entry after hours.

c. 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.

3. 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 requirement in the current edition of an official compendium.

   a. 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.

   b. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.

   c. The recordkeeping requirements in paragraph 6 of this section shall be followed for all stored drugs.

4. Examination of materials.

   a. 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.

   b. 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.

   c. The recordkeeping requirements in paragraph 6 of this section shall be followed for all incoming and outgoing prescription drugs.

5. Returned, Damaged, and Outdated Prescription Drugs.

   a. 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.

   b. 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.

c. 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 of shipping.

d. The recordkeeping requirements in paragraph 6 of this section shall be followed for all outdate, damaged, deteriorated, misbranded, or adulterated prescription drugs.

6. Recordkeeping.

a. 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.

i. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

ii. The identity and quantity of the drugs received and distributed or disposed of, and

iii. The dates of receipt and distribution or other disposition of the drugs.

b. 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 years following disposition of the drugs.

c. 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 working days of a request by any official authorized by the Arkansas Board of Pharmacy.

I. 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 of 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 replacing 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 years after disposition of the outdated drugs.

J. 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.

K. 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.

L. 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.

M. APPLICABILITY.

Nothing in this regulation 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 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.

N. 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.

49. 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 NABPLEX Score Transfer Form either before the administration date of NABPLEX or within seven (7) days after the examination and fulfill other state requirements for licensure in the state to which the scores are transferred for licensure by examination in that state. Score Transfer Forms will be available, upon request, from the Board of Pharmacy office.

If a candidate takes NABPLEX in another participating state, properly transfers the score to Arkansas, and completes other requirements for licensure, Arkansas will license the applicant by the examination process.

The Arkansas Board will provide information related to states participating, NABP fees, and Arkasnas fees.

50. ARKANSAS PHARMACY SUPPORT GROUP

A. Definitions. As used in this

(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 alleged 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 pharmacists 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.

B. Administration.

(a) The Board 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 where 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 (3) year terms with the initial members appointed to staggered terms.

(c) The Board will consider recommendations from the Arkansas Pharmacy Support Group in making these appointments and any person appointed to the Committee shall continue appointment based on continued involvement in the Pharmacy Support Group.

C. 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 Board.

D. Board Referral.

(a) The Board 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 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.

E. 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 impairment program. The Board shall also resolve complaints voiced regarding the impaired pharmacists program.

F. Civil Liability.

(a) All persons acting on behalf of the Board in the impaired pharmacists program under this section shall be considere "committee" and behalf of the Board" and considered officers or employees of the state.

(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.

G. Funding. The Board is authorized to provide up to five thousand dollars ($5,000) per year to the committee for expenses incurred in management and operation of the program. Documentation of the use of these funds shall be provided to the Board of Pharmacy for review and comment.

Expenses considered for reimbursement by the Board shall be in the areas of travel as determined by the Board, phone or other necessary communication expenses, secretarial help, postage, food when traveling out of town of residence and acting on behalf of the Pharmacy Support Group other than meetings not to exceed $13.00 per day--unless specifically approved by the Board, limited meeting room costs and other expenses deemed appropriate by the "committee". Meal expense may be paid without an overnight stay.

It is recognized that the Board will also consider special and specific requests for expenses to cover costs related to education or ability enhancement of committee or intervenor members to improve the Group or better serve the Group.