

ARTICLE XXXII PHARMACEUTICAL DRUG FACILITY PERMITS

1. Every facility/business that shall engage in the wholesale distribution of prescription drugs, to include without limitation, manufacturing in this state, distribution into this state, or selling or offering to sell in this state, or distribution from or within this state, shall register annually with the Mississippi Board of Pharmacy by applying for a permit on a form supplied by the Board and accompanied by a fee not to exceed five-hundred dollars (\$500.00) annually and the documentation listed below. Every facility/business that shall engage in distribution of prescription drugs into this state to an affiliated or related company under common ownership and control of a corporate entity must register annually with the Board. The Board shall determine criteria and classification of permits as required.

Permits issued to any drug supply chain entity become null and void sixty (60) days from the date of issuance if inspection reveals a lack of legitimate business activity.

2. To obtain a permit or renew a pharmaceutical drug facility permit, the applicant shall:
 - A. Submit a written application on a form prescribed by the Board which provides at a minimum the following information for each facility:
 - (1) Name of the business, including all trade or business names used by the business;
 - (2) Address of the business;
 - (3) Ownership of the business;
 - (4) Information identifying the type of activities to be conducted by the business;
 - (5) Signature, telephone number, and complete address of the individual applying for the permit;
 - (6) Complete name, telephone number, and address of all officers and directors and the name of the state of incorporation, if a corporation;
 - (7) Complete name, telephone number, and address of all partners if a partnership;
 - (8) If a sole proprietorship, the complete name, telephone number, and address of the sole proprietor and the business entity.
 - B. Provide evidence of a surety bond in the amount of \$100,000 (or \$25,000 for an entity whose annual gross receipts total \$10,000,000 or less for the previous tax year) or other equivalent means of security acceptable to the State.
 - C. Submit background checks for designated representatives, including fingerprinting.
 - D. Provide most recent inspection reports for physical facilities.
 - E. Provide list of all states in which licenses are held, license numbers, expiration date and license status.
 - F. Third Party Logistics Providers and Virtual Entities must also provide a list of all trading partners they provide service for.
 - G. Submit the required fees as follows:

A fee not to exceed five hundred dollars (\$500.00) for each registration period and each annual registration period thereafter will be collected.

- H. Pharmaceutical drug facility permits shall not be issued for the same location occupied by a Pharmacy Permit.
 - I. Any entity licensed by the State of Mississippi shall promptly notify the Board of Pharmacy of any changes that might affect licensing status (such as change of name, location, ownership, or legal matters involving the entity or its leadership).
3. Each Mississippi business that maintains or distributes controlled substances shall apply for and obtain a controlled substance registration issued by the Board. To obtain a controlled substance registration or renew a controlled substance registration the applicant shall:
- A. Submit a written application on a form prescribed by the Board;
 - B. Submit the required fees as follows:
Fifty dollars (\$50.00) for each registration period and each annual registration period thereafter.

Any loss or suspected loss of controlled substances shall be reported directly to the Mississippi Board of Pharmacy immediately upon discovery and a written report made to the Mississippi Board of Pharmacy within fifteen (15) days.

4. The Mississippi Board of Pharmacy will consider the following factors in determining eligibility for issuing or renewing a permit for 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 distribution of prescription drugs, including controlled substances;
 - D. The furnishing by the applicant of false or fraudulent information in any application made in connection with drug distribution;
 - E. Suspension or revocation by federal, state, or local government of any permit currently or previously held by the applicant for the distribution of any drugs, including controlled substances;
 - F. Compliance with requirements under previously granted permits or registrations, if any;
 - G. Compliance with the requirements to maintain and/or make available to state and federal regulatory authorities those records required to be maintained by wholesale drug distributors; and
 - H. Any other factors or qualifications the Mississippi Board of Pharmacy considers relevant to and consistent with the public health and safety.

The Mississippi Board of Pharmacy reserves the right to deny a permit or a registration to an applicant if it determines that the granting of such a permit or registration would not be in the public interest.

5. Every business issued a Pharmaceutical Drug Facility Permit by the Board shall renew this permit annually. Newly issued permits which do not coincide with the normal annual registration period shall be valid from the date issued until the end of the year only.
6. The Designated Representative shall sign the permit application or the permit renewal and shall be the operations manager for that facility and shall be responsible for all activities in the permitted facility which are subject to regulation by the Board. Once issued, a permit cannot be amended, transferred, or assigned to another person. Failure to comply with this paragraph invalidates the permit.
7. If the employment of a permit holder or designated representative is terminated, or if for any other reason he/she wishes to be relieved of the responsibilities of the permit holder, he/she must return the permit to the Mississippi Board of Pharmacy with written notice that he/she is no longer the permit holder for that facility. When a permit is thus returned, application for a new permit for that facility must be made to the board within 30 days and must have new permit within 60 days.
8. If a permitted facility is permanently closed or has a change of ownership, the permit holder for that facility shall give notice to the Board immediately of the effective date of closure or change in ownership. If change of ownership, a new application must be made to the board within 30 days and must have new permit within 60 days.
9. If a permitted facility has a change in name or location, a new permit must be obtained. The board must be notified and a new application for this permit must be made to the board within 30 days and must have new permit within 60 days.
10. All drug supply chain entities permitted by the Mississippi Board of Pharmacy shall comply with the following:
 - A. Storage Conditions;
 - (1) Each facility where legend drugs or devices are repackaged, wholesaled, manufactured, distributed, stored, held, sold, or offered for sale, shall provide storage areas that assure proper lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions. All legend drugs or chemicals shall be stored at appropriate temperatures and under appropriate condition per label requirements or official compendium requirements to assure that the identity, strength, quality, and purity of the products are not affected. If no storage requirements are established for a prescription drug, they may be stored at controlled room temperature as defined in an official compendium such as the United States Pharmacopeia/Nation Formulary. Appropriate manual, electro-mechanical, or electronic temperature and

humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs. This data shall be recorded daily.

- (2) A separate storage section shall be provided for legend drugs that are deteriorated, outdated, misbranded, or otherwise adulterated.

B. Labeling:

- (1) Beginning November 27, 2017, all Federal labeling requirements must be met as follows:
 - (a) Changes to product labeling must be submitted to the FDA annually.
 - (b) Labels must include product identifiers in a 2-dimensional data matrix barcode both on the package and homogeneous case, unless it is a product required to have a standardized numerical id.
 - (c) Distributors and 3PLs shall only accept products with proper labeling.
- (2) By November 27, 2019, entities shall have systems in place to verify product at the package level, including standard numerical identifiers.

C. Facilities:

- (1) All buildings in which legend drugs or devices are wholesaled, repackaged, manufactured, distributed, stored, held, sold, or offered for sale, shall be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations. Buildings shall meet all applicable federal, state, and local standards and shall be maintained in a clean and orderly condition and be free from infestation by insects, rodents, birds, or vermin of any kind.
- (2) Each facility shall have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed outer or sealed secondary container that have been opened.
- (3) A facility may not be located in a residence.

D. Security:

- (1) All facilities shall be equipped with an electronic 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.
- (2) Entities shall ensure that access from outside their premises is reduced to a minimum and be well controlled. This includes, but is not limited to, the installation of adequate lighting at the outside perimeter of the premises. Entry into areas where prescription drugs are stored or held shall be limited to authorized personnel.
- (3) Entities shall maintain written internal security policies which provide protection against theft and diversion by personnel. These policies shall

provide protection against computer theft and crimes.

E. Recordkeeping:

- (1) Entities shall establish and maintain inventories and other records of all transactions regarding the receipt, distribution, and disposition of legend drugs including the name and principle address of the seller or transferor and the address of the location from which the drugs were shipped. These records shall be maintained for a period of six (6) years following disposition of the drugs. These records shall be made available for inspection and copying by agents of the Mississippi Board of Pharmacy or other authorized federal, state, or local law enforcement agency officials. These records shall contain source of supply (items received, quantity, and date) and distribution (items distributed, quantity, and date).
- (2) Records described in this section 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 an agent of the Mississippi Board of Pharmacy or other authorized federal, state, or local law enforcement agency officials. (Note: all transaction records must be electronic by November 27, 2017).
- (3) Upon request by the Board, entities that are permitted by the Board and who distribute prescription drugs to persons or entities within this state shall make available to the Board the following:
 - (a) A complete Mississippi customer roster;
 - (b) Distribution and sales records for any period during the past six (6) years listing all sales or distribution of prescription drugs to authorized persons located in this state upon request by the Board. This request shall be made in writing and may be signed by a compliance agent of the Board. This data shall be supplied to the Board within two (2) working days and shall consist of the following:
 - (i) Identity of the purchaser;
 - (ii) Identity of the distributor;
 - (iii) Drug name, strength, dosage form, and quantity distributed;
 - (iv) The invoice number;
 - (v) Date distributed;
 - (vi) All records of returns or credits;
 - (vii) By November 27, 2023, must also include product identifiers at package level.
- (4) Transaction records must also accompany products whenever prescription drug products change hands (unless the product is being returned to the manufacturer as unsalable).
 - (a) As of November 27, 2017, these records (transaction history, transaction information and a transaction statement) should be in a single electronic document.

- (b) Products should be verified by their identifiers upon sale/return. Any product that does not correspond with transaction records shall be treated as suspect.
 - (c) Product shall not be accepted without transaction records, except when returned to the manufacturer as unsalable.
 - (d) Transaction records are considered confidential and may only be provided to appropriate government officials and authorized trading partners with whom a written agreement is established.
- (5) Transaction records shall be exchanged in a secure, interoperable, electronic manner, adhering to all regulations (compliance required by November 27, 2023).
 - (6) Systems and processes should be in place for accepting salable returns by associating products with transaction records (compliance required by November 27, 2023).

F. 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.

- (1) There shall be written policies and procedures to assure that the entity prepares for, protects against, and handles crisis situations that affect the security or operation of the facility. Such crises may include fires, floods, or other natural disasters, and situations of local, state, or national emergency.
- (2) 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.
- (3) There shall be written policies and procedures to assure that any outdated stock, or any stock with an expiration date that does not allow sufficient time for repacking or resale shall be segregated from other stock and shall be prepared for return to the manufacturer or otherwise appropriately destroyed. This procedure shall provide for written documentation of the disposition of out dated prescription drugs. This documentation shall be maintained for a period of six (6) years after the disposition of the outdated drugs.
- (4) There shall be written policies and procedures by which the entity exercises control over the shipping and receiving of all stock within the operation.
 - (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 (D.) of this section shall be followed for all incoming and outgoing prescription drugs.

G. 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 drug 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 recordkeeping requirements in paragraph D. of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs. Written policies and procedures shall be maintained at the permitted facility to implement the above requirements.

H. Handling Recalls:

- (1) All entities shall provide support for manufacturer recalls.
- (2) A wholesale operation must maintain and follow written policies and procedures for handling recalls and withdrawals of products. Such a policy should cover all recalls and withdrawals of drug products due to:
 - (a) Any voluntary action on the part of the manufacturer.
 - (b) The direction of the Food and Drug Administration, or any other federal, state, or local government agency.
 - (c) Replacement of existing merchandise with an improved product or new package design.

I. Suspect/Illegitimate Products:

- (1) All entities in the drug supply chain shall cooperate in efforts to identify, isolate, investigate, and, if necessary, eliminate any suspect/illegitimate products.
- (2) Suspect products shall be quarantined and an investigation opened into the product legitimacy. The Secretary and all trading partners shall be notified of any suspect product within 24 hours, and subsequently of the results of any investigation. Records of investigations shall be kept for a minimum of

6 years regardless of the outcome.

- (3) Products deemed illegitimate shall be disposed of after a sample is taken for physical exam/laboratory analysis.

J. Compliance with Local, State and Federal Law; Inspections, Violations and Penalties:

- (1) Each entity shall comply with all applicable local, state and federal laws and regulations.
- (2) The Board may conduct inspections upon all premises purporting or appearing to be used by persons permitted under this ARTICLE. The Board in its discretion may accept a satisfactory inspection by the Federal Food and Drug Administration or a state agency of another state which the Board determines to be comparable to that made by the Federal Food and Drug Administration or the Board. The permit holder of the permitted location, upon request, shall furnish to the Board a copy of any and all reports of inspections conducted by the Federal Food and Drug Administration or the state agency of another state.
- (3) Mississippi entities that deal in controlled substances shall obtain a controlled substance registration from the MS Board of Pharmacy and a registration number from the Federal Drug Enforcement Administration and shall comply with all applicable state and federal DEA regulations.
- (4) The Board or its representatives may enter to inspect, during reasonable hours, a facility which has obtained or applied for a permit with the Board relative to the following:
 - (a) Drug storage and security;
 - (b) Equipment;
 - (c) Sanitary conditions;
 - (d) Records, reports, or other documents required to be kept by the Board.
- (5) The Board shall have the authority to suspend, revoke, or restrict any permit or registration issued under this ARTICLE upon conviction of violations of this ARTICLE or other federal, state, or local drug laws or regulations.
- (6) The Board may impose monetary penalties of not less than (\$100.00) and not more than (\$25,000.00) for each violation.
- (7) Before any permit may be suspended, restricted, or revoked or monetary penalties imposed, the entity shall have the right to prior notice and a hearing pursuant to Section 73-21-99, Mississippi Code of 1972.

K. Personnel

- (1) Each entity shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the sale and wholesale distribution of prescription drugs.
- (2) Each entity shall maintain a list of all personnel who have access to controlled substances and shall make available to the Board proof of background searches on any such employee. No person who has access to controlled substances shall have been convicted in any federal or state court of any drug

related crime.

- (3) Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

L. Salvaging and Reprocessing:

- (1) 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. Repackaging:

- (1) Every entity permitted by the Board that repackages prescription drugs for distribution shall register with the Federal Food and Drug Administration and shall be in compliance with all laws, rules, and regulations regarding such registration. Written notification furnished by the Federal Food and Drug Administration citing violations of federal laws, rules, and regulations shall be prima facie evidence of violation of this ARTICLE.
- (2) In facilities permitted by the Board where prescription drugs are repackaged for distribution, all drug products shall be maintained in the manufacturer's original container except as allowed by federal laws, rules, and regulations regarding prescription drug repackaging. Once distributed, repackaged prescription drug products which are returned to the repackager shall be immediately quarantined and either destroyed or returned to the original manufacturer.
- (3) In addition every entity that repackages prescription drugs shall comply with the following:
 - (a) Maintain and provide documentation showing that solid oral dosage form drug products are repackaged into a container/closure system that is equivalent to the manufacturer's container closure system if the manufacturer's expiration date is placed on the repackaged container. In the absence of stability testing, the repackager shall obtain and maintain certification from the container/closure manufacturer, supporting the expiration date placed on the label of the repackaged drug product;
 - (b) Maintain and provide documentation of stability testing to support any expiration date placed on containers wherein liquid oral dosage forms have been repackaged;
 - (c) Maintain written specifications for labeling repackaged products and written procedures that assure only correct labels are used. Documentation should be maintained showing that labeling placed on the repackaged containers is examined for correctness before and after the drug is repackaged;
 - (d) The label placed on a repackaged product shall indicate at a minimum:

- (i) All active ingredients, dosage form, and strength;
 - (ii) Name and address of the repackager;
 - (iii) Name and address of the manufacturer;
 - (iv) Storage requirements;
 - (v) Control lot number and expiration date.
- (e) Assures that penicillin drug products or penicillin synthetics shall not be repackaged in the same room, on the same equipment, and using the same air handling system, where other drug products are repackaged;
 - (f) Maintain documentation that cleaning procedures are followed when equipment and other surfaces are cleaned to assure that no drug residue remains on or near repackaging equipment;
 - (g) Assures that drug products that are known to have stability problems such as, but not limited to, nitroglycerin sublingual tablets or other drug products that interact with packaging materials not be repackaged in the absence of specific test data demonstrating the stability of the repackaged drug product and the actual container/closure system used.
11. An entity permitted by the Mississippi Board of Pharmacy shall not sell or distribute a prescription drug to any individual or business unless the individual or business is licensed or permitted to prescribe, dispense, or possess prescription drugs by an agency of the state in which the individual or business is located.

An entity permitted by the Board shall not distribute prescription drugs to persons in this state unless such person is either a licensed physician, osteopath, podiatrist, or physician's assistant licensed by the Mississippi Board of Medical Licensure; a licensed dentist, licensed by the Mississippi Board of Dental Examiners; a licensed veterinarian, licensed by the Mississippi Board of Veterinary Medicine; or a drug supply chain entity permitted by the Board. An optometrist licensed by the Mississippi State Board of Optometry, may purchase prescription drugs as authorized by said Board of Optometry. An advanced practice registered nurse, licensed by the Mississippi Board of Nursing may purchase prescription drugs as authorized by said Board of Nursing.

12. For purposes of these regulations the following definitions shall apply:
- A. "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.
 - B. "Blood Component" means that part of blood separated by physical or mechanical means.
 - C. "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.
 - D. "Manufacturer" means a person engaged in the manufacturing preparing, propagating, compounding, processing, packaging, repackaging, distributing, or

- labeling of a prescription drug.
- E. "Prescription Drug" means any human drug including, but not limited to medical oxygen, which is required by federal law or regulation to be dispensed only by a prescription, and drugs which are required under federal law to be labeled with either of the following statements prior to being dispensed or delivered:
- (1) "Caution: Federal law prohibits dispensing without prescription," or
 - (2) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; or a drug which is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.
- F. "Wholesale Distribution" means distribution of prescription drugs to a person other than a consumer or patient, but does not include:
- (1) 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 these regulations "emergency medical reasons" includes transfers of prescription drugs from one permitted facility to another permitted facility to alleviate a temporary shortage;
 - (2) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;
 - (3) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives;
 - (4) The sale, purchase, or trade of blood and blood components intended for transfusion;
 - (5) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;
 - (6) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals that are under common control; for purposes of these regulations, "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, voting rights, by contract or otherwise;
 - (7) 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 U.S. Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
 - (8) Any entity that distributes prescription drugs or controlled substances into the state must hold a permit issued by the Mississippi Board of pharmacy.
 - (9) The sale/purchase of a prescription drug by a retail pharmacy to other retail pharmacies or to a licensed practitioner for office use, if the total annual dollar volume of these sales/purchases does not exceed five percent (5%) of that pharmacy's total annual prescription drug sales.
- G. "Wholesaler" means a person who buys or otherwise acquires prescription drugs or prescription devices for resale or distribution or for repackaging for resale or distribution to persons other than consumers.
- H. "Wholesale Distributor" means any person engaged in wholesale distribution of

prescription drugs or prescription devices, including but not limited to, manufacturers; repackagers; 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; and retail pharmacies that conduct wholesale distributions.

- I. "Deliver" or "Delivery" means the actual constructive or attempted transfer of a drug or device from one person to another, whether or not for a consideration.
- J. "Distribute" means the delivery of a drug or device other than by administering or dispensing to persons other than the ultimate consumer.
- K. "Repackager" means a person registered by the Federal Food and Drug Administration as a repackager who removes a prescription drug product from its marketed container and places it into another, usually of smaller size, to be distributed to persons other than the consumer.
- L. "Board of Pharmacy", "Pharmacy Board", "Board", or "MSBP" shall mean the Mississippi Board of Pharmacy.
- M. "Person" shall mean an individual, corporation, partnership, association, or any other legal entity.
- N. "Third Party Logistics Provider (3PL)" shall mean any person that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.
- O. "Virtual Entity" shall mean any person holding ownership of products but which never physically takes possession of said products (i.e., all manufacturing, warehousing, distribution, etc. is outsourced to other entities).