

TITLE 30: PROFESSIONS AND OCCUPATIONS
PART 3001: MISSISSIPPI PHARMACY PRACTICE REGULATIONS

ARTICLE XXXII PHARMACEUTICAL DRUG FACILITY PERMITS

1. For purposes of this Article the following definitions shall apply:

A. "Wholesale Distribution" means distribution of prescription drugs or devices, to include active pharmaceutical ingredients (API's), to a person other than a consumer or patient, but does not include:

- (1) The sale, purchase, or trade of a specified drug or device or an offer to sell, purchase, or trade a specified drug or device for an immediate emergency medical reason including a public health emergency declaration pursuant to section 319 of the Public Service Act. Routine or temporary shortages do not constitute an immediate emergency medical reason;
- (2) The sale, purchase, or trade of a drug or device, an offer to sell, purchase, or trade a drug or device, or the dispensing of a drug or a device pursuant to a patient specific prescription;
- (3) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives;
- (4) The sale, purchase, or trade of a drug or device or an offer to sell, purchase, or trade a drug or device among pharmacies 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. Common ownership transactions shall not include any upcharges or fees;
- (5) The sale, purchase, or trade of a drug or device or an offer to sell, purchase, or trade a drug or device 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;
- (6) The sale/purchase of a prescription drug or device by a pharmacy 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 sales. In office use is defined as occurring in locations that are not serviced by a pharmacy permit;
- (7) Medication transfer from facilities/businesses to meet an immediate need for a specific patient in a quantity no greater than the prescribed amount;
- (8) Distribution of drugs or devices for research purposes in humans under an IND to an investigator.

2. Every facility/business that engages in the wholesale distribution of prescription drugs, API's, or devices as defined in § 73-21-71, 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 via the licensing portal. Every facility/business that engages in the distribution of prescription drugs or devices into this state to an affiliated or related company under common

ownership and control must register annually with the Board. Pharmaceutical Facility Permits issued by the Board may include, but are not limited to, the following pharmaceutical facilities/businesses:

- A. Manufacturer
- B. Virtual Manufacturer
- C. Wholesaler
- D. Virtual Wholesaler
- E. Third Party Logistics (3PL)
- F. Repackager
- G. Outsourcer
- H. Reverse Distributor
- I. Private Label Distributor
- J. Veterinary Wholesaler

The Board may declare a pharmaceutical facility/business permit inactive due to the lack of legitimate business activity for sixty (60) consecutive days. Any permit declared inactive by the Board must petition the Board to be re-instated.

3. To obtain or renew a pharmaceutical facility/business permit, the applicant shall:
 - A. Complete an application via the licensing portal which shall include, but not be limited to the following:
 - (1) Name and address of the facility/business, including all trade or business names;
 - (2) Detailed photo(s) of physical location that clearly display related signage and conveys business activity when requested;
 - (3) Ownership information;
 - (a) If a corporation: the State of incorporation and the name, telephone number, and address of all officers and directors;
 - (b) If a partnership: the name, telephone number, and address of all partners;
 - (c) If a sole proprietorship: the name, telephone number, and address of the sole proprietor.
 - (4) Type of activities conducted by the facility/business;
 - (5) Name, address, telephone number and signature of a designated representative;
 - (6) Initial applications will be valid for up to 180 days from the date of filing within the application portal. A renewal application will remain active for no more than 120 days from the date of filing within the application portal. Renewal applications will be considered filed timely if they are received prior to 30 days of expiration of the permit and contain all of the requested documents necessary for permitting. If a renewal application is not approved prior to the expiration of the permit, the drug facility must cease all Mississippi focused operations until application approval is obtained
 - B. Provide evidence of a surety bond in the amount of \$100,000 (or \$25,000 for a facility/business 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. Complete a criminal background check for the designated representative, including fingerprinting.
 - D. Provide the most recent inspection report for the physical facilities including facilities maintaining oversight of product label codes. Inspection reports may be required for

contracted partners providing services for the permitted location. All facilities/businesses must provide a recent, detailed inspection (generally within the last 3 years) whether their home state licensing authority conducts inspections or not. The most recent FDA inspection is not subject to time limitations.

- E. Provide a copy of each state license/permit held by the applicant.
 - F. All Pharmaceutical Facility permit applicants including Third Party Logistics Providers and Virtual Entities must provide a list of all trading partners.
 - G. A permit granted by the Board to a pharmaceutical facility will be based on its stated and actual business activity(s). Such activity may take precedence over licensure type in home state. Each permitted business activity at that location (if multiple exist) must have separate operations and records.
 - H. A fee of five hundred dollars (\$500.00) will be required to be submitted by the applicant for the initial registration and each annual license renewal period as noted by the online system. 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 current registration period only.
 - I. Pharmaceutical facility permits shall not be issued for the same location occupied by a Pharmacy Permit.
4. Each pharmaceutical facility that maintains or distributes controlled substances in or into Mississippi 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 an application via the licensing portal.
 - B. Submit a fee of 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.

5. 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, API's, or devices:
- A. Any convictions of the applicant, principal owners, officers, directors and/or partners under any federal, state, or local laws relating to drug samples, wholesale or retail drug or device distribution, or distribution of controlled substances;
 - B. Any felony convictions of the applicant under federal, state or local laws;
 - C. The past experience of the applicant, principal owners, officers, directors and/or partners in the distribution of prescription drugs or devices, including controlled substances;
 - D. The furnishing by the applicant of false or fraudulent information in any application made in connection with drug or device 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 or devices, 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 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.

- 6. The Designated Representative shall attest to 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.
- 7. The Designated Representative shall be required to be physically onsite at the facility a minimum of twenty (20) hours per work week or fifty per cent (50%) of the hours of operation of the facility, whichever is less. A record of the onsite hours of the designated representative shall be produced upon request by the Board or an agent of the Board. Exceptions will be recognized for practical reasons, i.e., vacation, sick time, etc.
- 8. If the employment of a 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 notify the MS Board of Pharmacy via the online portal. Application for a new designated representative must be made by within fifteen (15) days.
- 9. Any facility/business licensed by the State of Mississippi shall notify the Board of Pharmacy within fifteen (15) days, via the license portal, of any changes that might affect permitting status. This includes a closing, change of name, location, ownership, or legal matters involving the facility/business or its leadership.
 - A. If a permitted facility has a change in ownership, a new online application must be made to the board within fifteen (15) days.
 - B. If a permitted facility has a change in name or location, a facility amendment must occur within 15 days of the change.
- 10. All pharmaceutical supply chain facilities 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, chemicals, or devices shall be stored at appropriate temperatures and under appropriate conditions 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/National 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 at least daily.

- (2) A separate storage section shall be provided for legend drugs or devices that are deteriorated, outdated, misbranded, or otherwise adulterated.
- (3) Controlled substances should be isolated from non-controlled substances and stored in a secure area in accordance with Drug Enforcement Administration security requirements and standards.

B. Labeling:

- (1) All Federal labeling requirements must be met to include but not limited to:
 - (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) Facilities/businesses shall have systems in place to verify product at the package level, including standard numerical identifiers and must be in full compliance with the Drug Supply Chain & Security Act (DSCSA).

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 or devices that are outdated, damaged, deteriorated, non-compliant with DSCSA requirements, misbranded, or adulterated, or that are in immediate or sealed outer or sealed secondary container that have been opened. All suspect products should be quarantined until investigation is complete.
- (3) A facility shall 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 and meets all applicable federal, state, and local standards. 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) All facilities 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) All facilities/businesses 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) All facilities/businesses shall establish and maintain inventories and other records of

all transactions regarding the receipt, distribution, and disposition of legend drugs or devices including the name and principal 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 and must be compliant with all aspects of DSCSA. These records shall be made available for inspection and copying by 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 written request by the Mississippi Board of Pharmacy or other authorized federal, state, or local law enforcement agency officials.
- (3) Upon request by the Board, facilities/businesses that are permitted by the Board and who distribute prescription drugs or devices shall make available to the Board the following:
 - (a) A complete Mississippi customer roster;
 - (b) Transaction records of all distribution and sales for any period during the past six (6) years listing all sales or distribution of prescription drugs or devices to authorized persons upon request by the Board. This request shall be made in writing by the Board. The transaction records shall be supplied to the Board within two (2) working days and shall consist of the following:
 - (i) Name and address of the purchaser;
 - (ii) Name and address of the distributor;
 - (iii) Drug name, strength and dosage form, and quantity, including number of containers distributed
 - (iv) The invoice number;
 - (v) The lot number of the product if required by DSCSA;
 - (vi) Date of transaction and shipment;
 - (vii) All records of returns or credits;
 - (viii) Must also include product identifiers at package level by applicable DSCSA deadline.
- (4) Transaction records must also accompany products whenever prescription drug or devices products change hands (unless the product is being returned to the manufacturer as unsalable).
 - (a) These records should be in a single electronic document as required by DSCSA.
 - (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 applicable DSCSA deadline).
- (6) Systems and processes should be in place for accepting salable returns by associating products with transaction records (compliance required by applicable DSCSA deadline).

F. Written Policies and Procedures:

Facilities/businesses shall establish, maintain, and adhere to written policies and procedures which allow and demonstrate oversight of legend product based on their scope of service. Specifically, wholesale drug or device 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 or devices, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Written policies and procedures shall include:

- (1) A procedure to assure that the facility/business 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 or device product is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.
- (3) A procedure to assure that any outdated stock, or any stock with an expiration date that does not allow sufficient time for 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 outdated prescription drugs. This documentation shall be maintained for a period of six (6) years after the disposition of the outdated drugs or devices.
- (4) A procedure to assure the facility/business exercises control over the shipping and receiving of all stock within the operation, including the following practices:
 - (a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or devices or prescription drugs or devices 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 or devices and to ensure that there is no delivery of prescription drugs or devices that have been damaged in storage or held under improper conditions.
 - (c) The recordkeeping requirements in paragraph (E.) of this section shall be followed for all incoming and outgoing prescription drugs or devices.

G. Returned, Damaged and Outdated Prescription Drugs:

- (1) Prescription drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs or devices until they are destroyed or returned to their supplier.
- (2) Any prescription drug or device 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 or device has been returned cast doubt on the safety, identity, strength, quality, or purity, then the drug or device shall be destroyed, or returned to the supplier, unless examination, testing or other investigation proves that appropriate standards of safety, identity, strength, quality, and purity are met. In determining whether the conditions under which a product has been returned cast doubt on the drug's or device's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug or device 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 E. of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs or devices. Written policies and procedures shall be maintained at the permitted facility to implement the above requirements.

H. Handling Recalls:

- (1) A facility/business shall provide support for manufacturer recalls and withdrawals of prescription drugs or devices.
- (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 or devices 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. Due Diligence To Identify Suspect/Illegitimate Products:

- (1) A facility/business in the drug supply chain shall cooperate in efforts to identify, isolate, investigate suspect products, and determine if such products are illegitimate.
- (2) A facility/business should establish processes for identifying trading partners and transactions that require heightened vigilance in preventing the receipt of suspect product. Heightened vigilance includes the examination of required records (ie. invoices, shipping documents, transaction history) for suspicious business practices and physical examination of product for factors that increase the risk of a product being suspect, such as:
 - (a) A trading partner that has been involved in business transactions where they sold or delivered illegitimate product;
 - (b) A trading partner that has a history of problematic or potentially false transaction histories or pedigrees, such as those that contain misspelled words or incomplete information;
 - (c) A Trading Partner that is reluctant to provide a Transaction History associated with the Product being purchased or does not do so in a timely manner;
 - (d) A Trading Partner that provides Transaction Information, a Transaction Statement, and/or Transaction History that appears to be incomplete or suspicious;
 - (e) The trading partner providing wholesale operations but is co-located with a pharmacy.

- (f) The product offered for sale was previously owned by a dispenser;
 - (g) The price of a product is suspicious;
 - (h) The product has been previously or is currently the subject of a drug shortage;
 - (i) A product that is in higher demand because of its potential or perceived relationship to a public health or other emergency;
 - (j) The appearance of the package is suspicious; or
 - (k) The package exhibits unusual or excessive adhesive residue.
- (3) Suspect products shall be quarantined, and an investigation opened into the product legitimacy. The FDA 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.
- (4) Products deemed illegitimate shall be disposed of after a sample is taken for physical exam/laboratory analysis.
- J. Due Diligence for Controlled Substance Ordering and Dispensing
- (1) Facility/business that perform customer visits as part of customer diligence reviews to resolve red flags regarding ordering or dispensing practices of controlled substances shall share with the Board all reports and determinations within three (3) business days of receiving reports from customer.
 - (2) Facility/business that make the determination to suspend controlled substance ordering ability for customers must notify and provide related detailed rationale to the Board within one business day of suspension of ordering abilities.
- K. Compliance with Local, State and Federal Law; Inspections, Violations and Penalties:
- (1) Each facility/business 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 from another regulatory or inspecting body which the Board determines to be comparable to that made by the Federal Food and Drug Administration or the Board. Upon request, the facility shall furnish to the Board a copy of any and all reports of inspections conducted by the Federal Food and Drug Administration or any other inspecting entity.
 - (3) Any facilities/businesses that possess, transport or store controlled substances in or into MS shall obtain a controlled substance registration from the MS Board of Pharmacy in addition to 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. Failure to allow an inspection is cause to deny a permit or result in disciplinary action upon a permit.
 - (5) The Board shall have the authority to suspend, revoke, or restrict any permit or registration issued under this Article upon discipline and/or conviction of violations of this Article or other federal, state, or local drug laws or regulations.
 - (6) Before any permit may be suspended, restricted, or revoked or monetary penalties imposed, the facility/business shall have the right to prior notice and a hearing pursuant to Section 73-21-99, Mississippi Code of 1972.
- L. Personnel
- (1) Each facility/business shall employ adequate personnel with the education and

experience necessary to safely and lawfully engage in the sale and wholesale distribution of prescription drugs or devices.

- (2) Each facility/business 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) Each facility/business 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.

M. Salvaging and Reprocessing:

- (1) All facilities/businesses 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 Title 21, Chapter 1, Subchapter C, Parts 207, 210 and 211 of the Code of Federal Regulations. Any reverse distributor that receives saleable product for reintroduction into the supply chain will also need to be permitted as a wholesale distributor.

N. Repackaging:

- (1) Every repackager shall register with the Federal Food and Drug Administration and shall be in compliance with all laws, rules, regulations, and FDA issued guidance 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) Repackagers shall maintain all products in the manufacturer's original container except as allowed by federal laws, rules, and regulations regarding prescription drug repackaging. Once distributed, repackaged products which are returned to the repackager shall be immediately quarantined and either destroyed or returned to the original manufacturer.

11. Prohibited Acts

- A. No facility/business may engage in wholesale distribution of a prescription drug, API's, or device in or into Mississippi unless the facility/business is licensed/permitted:
 - (1) By the state from which the drug, API, or device is distributed, or if the State from which the drug, API, or device is distributed has not established a licensure requirement, is licensed by the Federal Drug Administration; and
 - (2) By the state into which the drug, API, or device is distributed.
- B. No facility/business engaged in wholesale distribution is allowed to acquire prescription drugs, API's, or devices from a dispenser for resale within the State of Mississippi. The return by a dispenser of prescription drugs, API's, or devices originally purchased from that facility/business is exempt from this requirement.
- C. Any facility/business permitted by the Mississippi Board of Pharmacy shall not sell or distribute a prescription drug, API, or device to any individual or business unless the individual or business is licensed or permitted to prescribe, dispense, or possess prescription drugs, API's, or devices by an agency of the state in which the individual or business is located.
- D. Any facility/business permitted by the Board shall not distribute prescription drugs, API's, or devices 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 facility/business permitted by the Board. An optometrist licensed by the Mississippi State Board of Optometry, may purchase prescription drugs or devices as authorized by said Board of Optometry. An advanced practice registered nurse, licensed by the Mississippi Board of Nursing may purchase prescription drugs or devices as authorized by said Board of Nursing.