MISSISSIPPI BOARD OF PHARMACY
MINUTES
March 23, 2023

The Mississippi Board of Pharmacy (Board) met at 9:00 a.m. on Thursday, March 23, 2023 at the Board offices, 6360 I-55 N. Suite 400, Jackson, MS 39211. The following members were present: Todd Barrett – President, Ronnie Bagwell – Vice-President, Ryan Harper – Secretary, Jillian Foster, Guy Phillips, Tony Waits and Craig Sartin.

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CONSENT AGENDA

The following items were reviewed by Board members and approved without objection.

- The Agenda for this meeting and the Website Declaration of this meeting shall be placed in the minutes. See attached.

- Minutes for the January 19, 2023, of the Mississippi Board of Pharmacy.

- Requests for approval of the following pharmacy continuing education programs:

  - PROGRAM NUMBER 001-023-023-001, **"MPHA Midwinter Meeting"**, as requested by MPHA for 4 clock hours of LIVE pharmacist continuing education credit.
  - PROGRAM NUMBER 001-024-023-001, **"Vancomycin Plus Pepevacillin/Tazobactam: AKI vs. Pseudo nephrotoxicity"**, as requested by Brian Hairston for 1 clock hour of LIVE pharmacist continuing education credit.
  - PROGRAM NUMBER 001-025-023-001, **"MPHA Spring Journal: Understanding Appropriate Irritable Bowel Syndrome (IBS) Treatment"**, as requested by MPHA for 2 clock hours of pharmacist continuing education credit.
  - PROGRAM NUMBER 002-010-023-001, **"Keep Breathing: Treatment of Pulminary Embolism"**, as requested by McCall Cannon for 0.5 clock hours of LIVE pharmacist continuing education credit.
  - PROGRAM NUMBER 002-010-023-002, **"Alternative Treatment Durations"**, as requested by Brian Hairston for 0.5 clock hours of LIVE pharmacist continuing education credit.
  - PROGRAM NUMBER 002-010-023-003, **"Adrenal Insufficiency"**, as requested by Erica Claire Loden for 0.5 clock hours of LIVE pharmacist continuing education credit.
  - PROGRAM NUMBER 002-021-023-001, **"The Clot Thickens: IV Thrombolysis in Patients with Ischemic Stroke in the Presence of DOACs""**, as requested by Kaylee Hall for 0.5 clock hours of LIVE pharmacist continuing education credit.
  - PROGRAM NUMBER 002-021-023-002, **"To Inhibit or Not to Inhibit: Optimizing RAS Inhibitor Use in Chronic Kidney Disease"**, as requested by Alyssa Hooter for 0.5 clock hours of LIVE pharmacist continuing education credit.

- PROGRAM NUMBER 003-008-023-001, **"2022 FDA Drug Approvals"**, as requested by Jon Arnold for 0.5 clock hours of LIVE pharmacist continuing education credit.
- PROGRAM NUMBER 003-008-023-002, **"Stress and Burnouts"**, as requested by Jon Arnold for 0.5 clock hours of LIVE pharmacist continuing education credit.
- PROGRAM NUMBER 003-014-023-001, **"Thyroid Disorders"**, as requested by Katrianna Saltarelli for 0.5 clock hours of LIVE pharmacist continuing education credit.
- PROGRAM NUMBER 003-014-023-002, **"Rapid Diagnostic Testing in Critically Ill Patients"**, as requested by Lauren Yielding for 1 clock hour of LIVE pharmacist continuing education credit.
- PROGRAM NUMBER 003-014-023-003, **"AWSnap! Alternative treatment options in Alcohol Withdrawal Syndrome"**, as requested by Lydia Kneemueller for 0.5 clock hours of LIVE pharmacist continuing education credit.
- PROGRAM NUMBER 003-014-023-004, **"Dosin' Zosyn? Current Utility of Beta-Lactam Therapeutic Drug Monitoring"**, as requested by Blake Mangum for 0.5 clock hours of LIVE pharmacist continuing education credit.
- PROGRAM NUMBER 003-014-023-005, **"Stress Ulcer Prophylaxis (SUP)"**, as requested by Elizabeth Holley for 0.5 clock hours of LIVE pharmacist continuing education credit.
- PROGRAM NUMBER 003-014-023-006, **"Diabetes Management in the Hospital: Insulin Drip Protocols"**, as requested by Elizabeth Holley for 0.5 clock hours of LIVE pharmacist continuing education credit.

❖ Consultant Waiver Requests

- Bhakti Patel, Crystal Holmes-Carter, Diane Morris, Tiffany Flippin, Charlesteine Boyle

❖ Medical Equipment Advisory Committee Minutes

❖ Travel Requests

- Council on Licensure, Enforcement and Regulation (CLEAR), March 28-30, Raleigh, NC; May 15-17 Austin, TX – Compliance Agents

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EXECUTIVE DIRECTOR REPORT

Susan McCoy reported all voluntary surrenders submitted to the Board since its last meeting:

- Jacob Brewer – Technician
- Kalilah Burchfield – Technician
- Arlaychja Clay – Technician
- Darrien Hardnett – Technician

- Tatyana Johnson – Technician
- Jamaya Rand – Technician
- Taylor Spence – Technician
- Andrew Hendon – Pharmacist
- Kayla Massey - Pharmacist

Susan McCoy, Executive Director, reported to the Board concerning day-to-day activities of the agency.

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REGULATION WORKING GROUP

Todd Dear, Associate Director, presented the following regulations:

- Article XXII – Pharmaceutical Drug Facility Permits: Adopt as a final rule
- Definitions: Adopt as a final rule
- Article L – Surgery Center Clinic: Adopt as a proposed rule
- Article LI – Clinic Consultant Pharmacist: Adopt as a proposed rule
- USP 795, 797 and 800

Upon a motion by Board member Ryan Harper and a 2nd by Tony Waits, the Board adopted the final and proposed regulations as recommended by staff without objection.

Upon a motion by Board member Ryan Harper and a 2nd by Tony Waits, the Board unanimously voted to table the regulation regarding USP 795, 797 and 800 and refer to the Regulation Working Group and to present a proposed regulation at a later Board meeting.

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GENERAL BUSINESS

The Mississippi State Department of Health (MSDH) requested approval of an MOU authorizing deidentified data to be shared from the Mississippi Board of Pharmacy Prescription Monitoring Program with the MSDH.

Upon a motion by Board member Ronnie Bagwell and a 2nd by Jillian Foster, the Board voted unanimously to approve the MOU.

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RESPONDENTS

Journey Medical Corporation
Upon a motion by Board member Craig Sartin and a 2nd by Jillian Foster, the Board voted unanimously to approve the proposed agreed settlement order with Journey Medical Corporation. See the attached Settlement Order.

JG Pharma
Upon a motion by Board member Craig Sartin and a 2nd by Jillian Foster, the Board voted unanimously to approve the proposed agreed settlement order with JG Pharma. See the attached Settlement Order

Walgreens #10694, Permit to Operate as a Pharmacy, Permit Number 10694/1.2.
After an administrative hearing on this matter, the Board issued the attached Order.

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PETITIONERS

Jordan B. Rodenbaugh
After an administrative hearing on this matter, the Board issued the attached Order.

Austin Onyia, Intern/Extern Registration IE-8723
After an administrative hearing on this matter, the Board issued the attached Order.

Kenith Turner, Intern/Extern Registration IE-8912
After an administrative hearing on this matter, the Board issued the attached Order.

McGowen Enterprises dba Acute Care Pharmaceuticals
Upon a motion by Board member Ryan Harper and a 2nd by Craig Sartin, the Board voted unanimously to go into executive session pursuant to Section 25-41-7(4)(b) for the purposes of discussing potential litigation from an appeal of a Board order. On a motion by Board member Ryan Harper and a 2nd by Board member Guy Phillips, the Board voted unanimously to rise from executive session and enter open session.
Board member Ronnie Bagwell recused himself from all deliberation in executive session.
After an administrative hearing on this matter, the Board issued the attached Order.

Petitioner, Tip Allen Williams, License to Practice Pharmacy, Certificate of Registration Number D-07671
A motion by Board member Guy Phillips and a 2nd by Tony Waits, to reinstate the License to Practice Pharmacy, Certificate of Registration Number D-07671 with the condition that Petitioner enter into a ten year MARP contract and a prohibition from serving as a Pharmacist in Charge and authorizing the Petitioner to pay his previous penalty over twelve (12) monthly payments failed.
Board members voting against motion: Todd Barrett, Ronnie Bagwell, Ryan Harper, Craig Sartin
Board members voting for motion: Guy Phillips, Tony Waits, Jillian Foster
After an administrative hearing on this matter, the Board issued the attached Order.

Petitioner, Sanjani Barot, License to Practice Pharmacy, Certificate of Registration Number T-12769
After an administrative hearing on this matter, the Board issued the attached Order.

Petitioner, Nicole Gricreria,

After an administrative hearing on this matter, the Board issued the attached Order.

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The Board adjourned at 1:15 p.m.

These March 23, 2023, MINUTES of the Board are hereby approved this the 18th day of May, 2023.

J. Todd Barrett, President

Ronnie Bagwell, Vice-President

Ryan Harper, Secretary

Tony Waits

Guy Phillips

Jillian Foster

Craig Sartin

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

ARTICLE LI CONSULTING PHARMACISTS TO AMBULATORY SURGERY CENTERS AND MULTI-PROVIDER CLINICS

1. For purposes of this article, a consultant pharmacist for an ambulatory surgery center (ASC) or multi-provider clinic (MPC) shall mean any Mississippi licensed pharmacist who is listed on an ASC/MPC permit (pharmacist-in-charge). The consultant pharmacist is on site at least monthly to conduct a review of medication related processes and to ensure appropriate reconciliation of controlled substances. The consultant pharmacist for an ASC/MPC would not need a nursing home consultant certificate. The consultant pharmacist is responsible for providing recommendations only to the ASC/MPC.

2. Responsibilities of the ASC/MPC Consultant Pharmacist
   A. The ASC/MPC Consultant Pharmacist shall be responsible for advising the ASC/MPC on all matters related to safe and efficient administration, control, and accountability for drugs and proper licensing. The responsibilities of the consultant pharmacist shall include developing policies and procedures and implementation for the following:
      (1) All medications shall be purchased from facilities registered with the Mississippi Board of Pharmacy
      (2) Preparation of sterile medications prepared within the ASC/MPC
      (3) Admixture of parenteral products
      (4) Compounding of drugs, solutions, ointments, lotions, etc.
      (5) To assure that no legend medication shall be stored in patient care areas except upon the approval of the Consultant Pharmacist
      (6) Establishment of specifications for procurement of all materials, including drugs, chemicals and biologicals, subject to approval of the appropriate committee of the ASC/MPC and compliance with DSCSA requirements
      (7) Participation in the development of a formulary for the ASC/MPC where applicable
      (8) Proper filling and labeling of all containers from which drugs are to be administered
      (9) Maintenance of records of all transactions of the ASC/MPC as may be required by applicable law, state and federal, and as may be necessary to maintain accurate control and accountability for all pharmaceutical materials
      (10) Assure that all drugs shall be stored in areas within the ASC/MPC and satellite storage areas to provide proper sanitation, temperature, light, ventilation, moisture control, segregation and security; that disinfectants and drugs for external use are stored separately and apart from drugs for internal use or ingestion; that outdated or other unusable drugs are identified and stored in a manner that will prevent their administration prior to disposition; that emergency drugs are in adequate and proper supply at designated locations
      (11) Assure that all areas occupied by the ASC/MPC shall be capable of being locked to prevent unauthorized access, and that all areas where drugs are stored or administered shall be locked

(12) Ensure that discontinued and outdated drugs are returned to a MS Board of Pharmacy registered reverse distributor or destroyed onsite following DEA rules for onsite destruction and use of DEA Form 41.

(13) Drugs shall be administered only upon receipt of a written or oral order. There shall be no "take home" medications dispensed under this permit. Samples are exempt from this Article.

(14) All requirements of the Controlled Substances Act of 1970 and the requirements set forth in the regulations of the Mississippi Board of Pharmacy in the purchasing, storing, administration, record keeping, and disposal of controlled substances are met. There shall be policies and procedures to ensure the control of these drugs at all times, including those instances when drugs are stored in the surgery departments, nursing stations, clinics, diagnostic laboratories, etc. Periodic (at least monthly) inspections by the consultant pharmacist of the proper storage of these drugs is required and deficiencies must be corrected.

(15) At least monthly consultant audits of records of acquisition and disposition. Monthly audits of controlled substance inventory.

(16) Assisting the medical director as applicable in developing inventory listings of drugs to be included in these areas and assure that:

(a) Such drugs are available therein, properly stored and labeled

(b) Only pre-packaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements

(c) Each drug stored in these areas shall be assigned a "par value" and each addition or withdrawal by authorized persons shall be properly documented. The consultant pharmacist shall audit these areas on a regular basis but no less than once per month.

(17) The consultant pharmacist shall provide a monthly report to the ASC/MPC outlining any findings from their review. This document shall be signed by the medical director or designee and dated.

(18) A consultant pharmacist for an ASC/MPC shall report to the appropriate regulatory or licensing agency any serious deficiency or violation noted on his/her consultant report if such deficiency is not corrected or addressed by the permit holder by the date of the next monthly visit by the consultant pharmacist at the permit site.

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

ARTICLE L AMBULATORY SURGERY CENTERS AND MULTI-PROVIDER CLINICS

1. For purposes of this Article, an ambulatory surgery center (ASC) or multi-provider clinic (MPC) shall mean a facility where medical procedures or services are performed or provided by multiple practitioners for outpatients. Examples would include but would not be limited to an ambulatory surgery center, a medical doctor's office/clinic, or a dental office. An ASC/MPC consultant refers to any Mississippi licensed pharmacist who reviews processes and ensures appropriate reconciliation of controlled substances at least monthly on site in an ASC or MPC. The ASC/MPC is responsible for complying with all applicable regulations of the Mississippi Board of Pharmacy as well as other state and federal regulatory agency requirements.

2. Every ASC/MPC shall obtain an ASC/MPC permit from the Mississippi Board of Pharmacy for every location where controlled substances are administered by multiple providers/practitioners under one DEA number. This permit along with a DEA registration allows the ASC/MPC to order controlled substances for the facility to be used by multiple providers/practitioners under one clinic DEA number. Such a permit shall be obtained by applying for a permit on a form supplied by the Mississippi Board of Pharmacy and accompanied by a fee. This requirement does not apply to ASC's or clinics with only a single provider where the provider's registration is based at that location. All ASC/MPC permits will expire on December 31 of each year and shall be renewed annually by submitting a renewal application and renewal fee. Any renewal application received after December 31st of the renewal period will be assessed a $50.00 late fee prior to renewal. ASC/MPC permits are not transferable or assignable. There are two subcategories for ASC/MPC permits: outpatient surgery center/clinic pharmacy and outpatient surgery center/clinic consultant.
   A. Ambulatory Surgery Center/Multi-Provider Clinic Pharmacy Services (fee $300)
      (1) This permit should be used when a pharmacist is integrated into the daily workflows of the facility including ordering and stocking of medications and clinical support but is not an actual dispensing pharmacy. Additionally, a controlled substance permit is required.
      (2) See Institutional Pharmacy Regulations
   B. Ambulatory Surgery Center/Multi-Provider Clinic Consultant (fee $100)
      (1) Requires there to be at least a monthly arrangement with a pharmacist onsite to review processes and ensure appropriate reconciliation of controlled substances. The pharmacist reviews appropriate records for ordering, storage, and other record keeping requirements and documentation of administration, wastage, and disposal of medications in accordance with documented policies and procedures of the ASC/MPC.
      (2) This permit will serve as the controlled substance permit required by statute.

3. Consultant Pharmacist Requirement.
   A. A permit for an ASC/MPC shall not be issued or renewed unless the consultant pharmacist is licensed in this state.

B. If the license of the consultant pharmacist becomes void or inactive due to surrender, revocation, suspension, restriction or for any other reason, or if the license of the consultant pharmacist is removed from the permit of the ASC/MPC for any reason, application must be made for a new permit with another consultant pharmacist within fifteen (15) days.
C. Failure to submit an application with the new consultant pharmacist within fifteen (15) days shall render the permit inactive and the ASC/MPC shall not conduct any activities using the controlled substances that were obtained pursuant to the permit and the corresponding DEA registration until a new permit is issued to the ASC/MPC with a new consultant pharmacist on the permit.
D. The failure to obtain a new consultant pharmacist within the required fifteen (15) day time period shall be reported to DEA by the Mississippi Board of Pharmacy.

4. Record Keeping
   A. Every ASC/MPC permit issued by the Board of Pharmacy shall keep complete and accurate records of acquisition and disposition of all controlled substances. These records shall include:
      (1) Complete and accurate records of receipt of all controlled substances
      (2) Complete and accurate records of disposition of all controlled substances
   B. Records of acquisition and disposition must be maintained for a period of at least 2 years. These records shall be kept in such a manner that an audit will show the beginning inventory and record of acquisition of controlled substances to balance with controlled substances on hand and record of disposition of controlled substances.
   C. Unless authorized by the Federal Drug Enforcement Administration to maintain records of controlled substances at a location other than the location permitted by the Mississippi Board of Pharmacy, these records shall be maintained at the permitted location. All records pertaining to controlled substances shall be made available for inspection and copying by agents of the Mississippi Board of Pharmacy.
   D. The ASC/MPC consultant pharmacist shall provide a monthly report outlining any findings from their review. This document shall be signed by the medical director or designee and dated. The facility must maintain these reports for a period of two (2) years, and a copy must be available for inspection upon request.

5. Storage
   A. All drug products shall be maintained and stored in such a manner that maintains the integrity of the product.
   B. All containers from which drugs are administered must be properly labeled.
   C. Outdated drugs shall be removed from general stock and returned to a reverse distributor licensed with the Mississippi Board of Pharmacy or destroyed onsite following DEA rules for onsite destruction and use of DEA Form 41.

6. Security
   A. In all places where controlled substances are maintained, they shall be maintained in a manner to deter loss by theft or burglary. A securely locked, substantially constructed area shall be provided for storage of all controlled substances. Controlled substances for return to a MS licensed reverse distributor or for onsite destruction as described above shall be maintained in the drug storage area of the clinic and segregated from general stock until

proper disposition of such controlled substances is made. Controlled substances, thus maintained in the drug storage area, shall be kept in a locked cabinet, drawer, or other suitable locked container and only authorized personnel shall have access to the drug storage area.

7. Inventory
   A. A perpetual inventory shall be maintained on all Controlled Substances, Schedule II-V.
   B. The medical director shall develop inventory listings of drugs to be included in specified areas and assure that:
      a. Such drugs are available therein, properly stored and labeled
      b. Only pre-packaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements
      c. Each drug stored in these areas shall be assigned a "par value" and each addition or withdrawal by authorized persons shall be properly documented.
   C. If a facility has a loss of controlled substances, a complete inventory of all remaining controlled substances shall be made within forty-eight (48) hours of discovery of the loss of controlled substances. This inventory shall be dated and signed by the ASC/MPC staff conducting the inventory.
   D. The consultant pharmacist shall be notified within twenty-four (24) hours of discovery of any discrepancy in counts or the loss of any controlled substances. The consultant pharmacist shall notify the Board immediately upon his/her notification with a plan to investigate the loss. A written report shall be submitted to the Mississippi Board of Pharmacy within fifteen (15) days; this written report shall include a copy of the inventory required by this ARTICLE.
   E. When a facility has a change in ownership or a change in the consultant pharmacist listed on their permit (pharmacist-in-charge), or is permanently closed, a complete inventory shall be made of all controlled substances at the time of the change. A copy of this inventory shall be kept with other records of controlled substances in the facility and a copy shall be sent to the office of the Board of Pharmacy. When a facility is permanently closed, the consultant pharmacist (pharmacist-in-charge) shall notify the Board in writing within fourteen (14) days by what means and as to whom controlled substances were transferred or disposed of.
   F. Every facility permitted by the Mississippi Board of Pharmacy shall take an annual inventory of all controlled substances on hand on or about May 1 but no later than May 15. A facility may conduct the controlled substance inventory at another date as long as the annual inventory is conducted during the same period each year. This inventory shall be maintained with the other controlled substance records of the facility.

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

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-dementional 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 it's 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© (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).~~

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

ARTICLE XXXII PHARMACEUTICAL 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 asunsalable).
   (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 naturaldisasters, 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 timefor 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 tothe 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 thepermitted 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.

Mississippi Board of Pharmacy
March 23, 2023

AGENDA

I. CALL TO ORDER/ESTABLISH A QUORUM

- **PRAYER AND PLEDGE**
- **WELCOME AND SPECIAL INTRODUCTIONS**

II. CONSENT AGENDA & WEBSITE DECLARATION

- **APPROVE AND SIGN MINUTES**
- **CONTINUING EDUCATION REQUEST**
- **APPROVE ISSUANCE OF PHARMACIST LICENSES**
- **Consultant Waiver Requests**
  - **Bhakti Patel, Crystal Holmes-Carter, Diane Morris, Tiffany Flippin, Charlesteine Boyle**
- **Medical Equipment Advisory Committee Minutes**
- **TRAVEL REQUESTS- Council on Licensure, Enforcement and Regulation (CLEAR), March 28-30, Raleigh, NC; May 15-17 Austin., TX- Compliance Agents**

III. EXECUTIVE DIRECTOR REPORT

- **VOLUNTARY SURRENDERS-**
  - **Jacob Brewer-Technician**
  - **Kalilah Burchfield-Technician**
  - **Arlaychja Clay-Technician**
  - **Darrien Hardnett-Technician**
  - **Tatyana Johnson-Technician**

- Jamaya Rand-Technician
- Taylor Spence-Technician
- Andrew Hendon-Pharmacist
- Kayla Massey-Pharmacist

IV. REGULATION WORKING GROUP

- ARTICLE XXXII
- DEFINITIONS
- ARTICLE L
- ARTICLE LI
- USP 795, 797. and 800

V. GENERAL BUSINESS

- DOH PMP MOU (Tabled from January)

VI. RESPONDENTS

• Journey Medical Corporation	Respondent
• JG Pharma	Respondent
• Walgreens #10694	Respondent

VII. PETITIONERS

• Jordan Rodenbaugh	Petitioner
• Austine Onyia	Petitioner
• Kenith Turner	Petitioner
• Christian Muenyi	Petitioner
• McGowan d/b/a Acute Care Pharmaceuticals	Petitioner
• Tip Allen Williams	Petitioner
• Sajani Barot	Petitioner
• Nicole Gricreria	Petitioner

MISSISSIPPI
BOARD OF PHARMACY

MENU

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Board Meetings

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Meetings of the Mississippi Board of Pharmacy will be held in the Board Room of the Mississippi Board of Pharmacy, 6360 I-55 North, Suite 400, Jackson, Mississippi.

Board Meetings for the first half of 2023 will be held on the following dates at 9:00 a.m.:

- January 19
- March 23
- May 18

The meetings of the Mississippi Board of Pharmacy are open to the public. However, due to limited space, there may be standing room only.

To subscribe to the Mississippi Public Meeting Notice webpage please visit: **https://www.ms.gov/dfa/pmn**

Board Meeting Agendas and Minutes

Posted agendas are proposed and subject to change. MBP Board Meeting minutes will be posted after they are approved at the following Board Meeting.

On March 22, 2023, came the matter of Journey Medical Corporation, an unpermitted virtual manufacturer, herein also referred to as Respondent, pursuant to a "Notice of Hearing and Complaint" filed by the Mississippi Board of Pharmacy.

BEFORE THE MISSISSIPPI BOARD OF PHARMACY

IN THE MATTER OF:

JOURNEY MEDICAL CORPORATION
9237 VIA DE VENTURA BLVD.
SUITE 135
SCOTTSDALE, AZ 85258

PHARMACEUTICAL DRUG FACILITY
UNPERMITTED VIRTUAL MANUFACTURER

JURISDICTION

The Mississippi Board of Pharmacy has jurisdiction of the subject matter and person of Journey Medical Corporation, an unpermitted virtual manufacturer, pursuant to Section 73-21-97 (I)(n), Mississippi Code of 1972, Annotated.

STATEMENT OF CHARGES

Journey Medical Corporation, is alleged to have committed a violation of Mississippi Code Annotated Section 73-21-105 (1) which provides in relevant part:

> Every facility/business that engages 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, and every reverse distributor located in or outside this of state that conducts business with pharmacies in this state, shall register biennially or annually, to be determined by the board, with the Mississippi State Board of Pharmacy by applying for a permit on a form supplied by the board and accompanied by a fee as set by subsection (4) of this section.

Specifically, Journey Medical Corporation, conducted business as a virtual manufacturer selling drugs to Varahi, Inc. d/b/a Germantown Pharmacy, Pharmacy Permit No. 18397, on June 27, July 26, September 12, September 26 and September 29 of 2022, and has not obtained a permit from the Board to operate as a virtual manufacturer.

SETTLEMENT AGREEMENT

Pursuant to discussions between Board Counsel and Counsel for the Respondent, an Agreement to Settle this matter is found to be in the best interest of all parties involved. It is hereby Agreed as follows:

FINDINGS OF FACT

The Mississippi Board of Pharmacy, after being presented clear and convincing evidence, makes the following findings of fact:

(1) The Respondent was properly notified of the charges by a duly processed "Notice of Hearing and Complaint" along with a sworn affidavit detailing those charges as provided for in

Section 73-21-99, Mississippi Code of 1972, Annotated, and the Respondent has been afforded all due process required by law.

(2) The Respondent was subject to jurisdiction of the Board pursuant to Section 73-21-97 (1)(n), Mississippi Code of 1972, Annotated.

(3) The Respondent does not contest the violation as charged.

(4) The Respondent was represented by counsel during the hearing.

(5) The Respondent neither admits nor denies the charges.

(6) The Respondent agrees to the disciplinary action stated below as imposed by the Board.

FINAL ORDER OF THE BOARD

This ORDER OF THE BOARD is effective immediately. A certified copy of this ORDER shall be served on the Respondent and a copy maintained in the office of the Board.

- Pursuant to Section 73-21-103 (1)(d)(vii). Respondent shall pay a monetary fee in the amount of Twenty-Five Thousand Dollars ($25.000.00).
- Pursuant to Section 73-21-103 (1)(d)(iii). Respondent shall pay the cost of investigation and proceeding in the amount of Five Hundred Dollars ($500.00).
- The total monetary fee and cost of investigation shall be Twenty- Five Thousand Five Hundred Dollars ($25.500.00).

I hereby agree to the findings and terms of this Agreed Order:

DocuSigned by:
Ramsey Alloush
827C3795C00F40D

Representative of Journey Medical Corporation

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ORDERED AND AGREED TO, this the 23rd day of March, 2023.

Todd Barrett, President

Ronnie Bagwell, Vice-President

Ryan Harper, Secretary

Jillian Foster

Guy Phillips

Craig Sartin

Tony Waits

On March 22, 2023, came the matter of JG Pharma, Inc., an unpermitted virtual manufacturer, herein also referred to as Respondent, pursuant to a "Notice of Hearing and Complaint" filed by the Mississippi Board of Pharmacy.

BEFORE THE MISSISSIPPI BOARD OF PHARMACY

IN THE MATTER OF:

JG PHARMA, INC.
9237 E. VIA DE VENTURA BLVD.
SUITE 135
SCOTTSDALE, AZ 85258

PHARMACEUTICAL DRUG FACILITY
UNPERMITTED VIRTUAL MANUFACTURER

JURISDICTION

The Mississippi Board of Pharmacy has jurisdiction of the subject matter and person of JG Pharma, Inc., an unpermitted virtual manufacturer, pursuant to Section 73-21-97 (1)(n), Mississippi Code of 1972, Annotated.

STATEMENT OF CHARGES

JG Pharma, Inc., is alleged to have committed a violation of Mississippi Code Annotated Section 73-21-105 (1) which provides in relevant part:

> Every facility/business that engages 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, and every reverse distributor located in or outside this of state that conducts business with pharmacies in this state, shall register biennially or annually, to be determined by the board, with the Mississippi State Board of Pharmacy by applying for a permit on a form supplied by the board and accompanied by a fee as set by subsection (4) of this section.

Specifically, JG Pharma, Inc. conducted business as a virtual manufacturer selling drugs to Varahi, Inc. d/b/a Germantown Pharmacy, Pharmacy Permit No. 18397, on June 24, July 28, August 22, September 12, September 26 and September 29 of 2022, and has not obtained a permit from the Board to operate as a virtual manufacturer.

SETTLEMENT AGREEMENT

Pursuant to discussions between Board Counsel and Counsel for the Respondent, an Agreement to Settle this matter is found to be in the best interest of all parties involved. It is hereby Agreed as follows:

FINDINGS OF FACT

The Mississippi Board of Pharmacy, after being presented clear and convincing evidence, makes the following findings of fact:

(1) The Respondent was properly notified of the charges by a duly processed "Notice of Hearing and Complaint" along with a sworn affidavit detailing those charges as provided for in

Section 73-21-99, Mississippi Code of 1972, Annotated, and the Respondent has been afforded all due process required by law.

(2) The Respondent was subject to jurisdiction of the Board pursuant to Section 73-21-97 (1)(n), Mississippi Code of 1972, Annotated.

(3) The Respondent does not contest violation as charged.

(4) The Respondent was represented by counsel during the hearing.

(5) The Respondent neither admits nor denies the charges.

(6) The Respondent agrees to the disciplinary action stated below as imposed by the Board.

FINAL ORDER OF THE BOARD

This ORDER OF THE BOARD is effective immediately. A certified copy of this ORDER shall be served on the Respondent and a copy maintained in the office of the Board.

- Pursuant to Section 73-21-103 (1)(d)(vii), Respondent shall pay a monetary fee in the amount of Twenty-Five Thousand Dollars ($25.000.00).
- Pursuant to Section 73-21-103 (1)(d)(iii), Respondent shall pay the cost of investigation and proceeding in the amount of Five Hundred Dollars ($500.00).
- The total monetary fee and cost of investigation shall be Twenty-Five Thousand Five Hundred Dollars ($25,500.00).

I hereby agree to the findings and terms of this Agreed Order:

DocuSigned by:
Ramsey Allouch
B27CB795C00F40D

Representative of JG Pharma, Inc.

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ORDERED AND AGREED TO, this the 23rd day of March, 2023.

Todd Barrett, President

Ronnie Bagwell, Vice-President

Ryan Harper, Secretary

Jillian Foster

Guy Phillips

Craig Sartin

Tony Waits

Came on March 23, 2023, the matter of Walgreens #10694, Permit to Operate as a Pharmacy, Permit Number 07595/1.2, herein also referred to as Respondent, pursuant to a "Notice of Hearing and Complaint" filed by the Mississippi Board of Pharmacy. Board members Ronnie Bagwell and Craig Sartin served on the Investigative Review Committee and did not participate in this hearing.

BEFORE THE MISSISSIPPI BOARD OF PHARMACY

IN THE MATTER OF:

WALGREENS #10694
5780 TERRY RD.
BYRAM, MS 39272

PERMIT TO OPERATE AS A PHARMACY, NUMBER 07595/1.2

JURISDICTION

The Mississippi Board of Pharmacy has jurisdiction of the subject matter and person of Walgreens #10694, Permit to Operate as a Pharmacy, Permit Number 07595/1.2, pursuant to Section 73-21-97(1)(f), Mississippi Code of 1972, Annotated.

STATEMENT OF CHARGES

Walgreens #10694, Permit to Operate as a Pharmacy, Permit Number 07595/1.2, is alleged to have committed the following violation:

Mississippi Board of Pharmacy Administrative Rules, Rule 2.1 F:

Violation of any of the provisions of the Mississippi Pharmacy Practice Act or rules or regulations adopted pursuant to such Act; or violation of pharmacy or drug laws of any other state or the federal government or the rules/regulations pertaining thereto.

Mississippi Pharmacy Practice Regulations Article IX ACTION AGAINST PERMITS, Paragraph 1, B:

1. The Board of Pharmacy may refuse to issue or renew, or may suspend, summarily suspend, place on probation, revoke, reprimand, or restrict the permit of any permitted facility and/or impose a monetary penalty upon one or more of the following grounds:
   B. Any act by any person in the conduct of the activities of the facility which is a violation of the rules and regulations of the Board of Pharmacy.

Mississippi Pharmacy Practice Regulations Article VII, RESPONSIBILITY OF PHARMACIST-IN-CHARGE (PIC), Paragraph 1. A:

> The pharmacist-in-charge is responsible for assuring that all personnel are properly registered or licensed with the Board and that all pharmacy permits are current and appropriate for the type of pharmacy operation being conducted.

Specifically, on December 19, 2022, it was revealed that Romiyah Johnson had performed pharmacy technician duties at Walgreens #10694, Pharmacy Permit Number 07595/1.2, although she was not lawfully registered with the Board as a pharmacy technician. As the pharmacist-in-charge (PIC), Cassidy Barnett, License to Practice Pharmacy, Certificate of Registration Number E-100365, was responsible for ensuring that all employees were properly registered with the Board.

FINDINGS OF FACT

The Mississippi Board of Pharmacy, after being presented clear and convincing evidence, makes the following findings of fact:

(1) The "Notice of Hearing and Complaint" along with a sworn affidavit detailing those charges was hand delivered at least thirty (30) days prior to the hearing.

(2) The Respondent has been afforded all due process required by law.

(3) The Respondent was issued a Permit to Operate a Pharmacy Number 07595/1.2, and as such was subject to jurisdiction of the Board pursuant to Section 73-21-97 (1)(f), Mississippi Code of 1972, Annotated.

(4) The Respondent did not appear for the hearing and the hearing was held in absentia.

(5) The Respondent committed the violations as charged.

FINAL ORDER OF THE BOARD

This ORDER OF THE BOARD is effective immediately. A certified copy of this ORDER shall be served on the Respondent and a copy maintained on file in the office of the Board.

- Pursuant to Section 73-21-103(1)(d)(i), Mississippi Code of 1972, Annotated, Respondent shall pay a monetary penalty in the amount of One Thousand Dollars ($1,000.00) for a violation of Count 1.
- Pursuant to Section 73-21-103(1)(d)(iii), Mississippi Code of 1972, Annotated, Respondent shall pay and the cost of investigation and conduct of a proceeding in the amount of Five Hundred Dollars ($500.00).
- The total monetary penalty and cost of investigation in the amount of One Thousand Five Hundred Dollars ($1,500.00) shall be paid by the Respondent within thirty (30) days of this Order.

All members participating in the hearing affirmed this Order.

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ORDERED AND AGREED TO, this the 23rd day of March, 2023.

Todd Barrett, President

Ronnie Bagwell, Vice-President

Ryan Harper, Secretary

Jillian Foster

Guy Phillips

Craig Sartin

Tony Waits

Came on March 23, 2023, the matter of Jordan Rodenbaugh, herein also referred to as Petitioner, pursuant to a request to petition the Mississippi Board of Pharmacy.

BEFORE THE MISSISSIPPI BOARD OF PHARMACY

IN THE PETITION OF:

JORDAN B. RODENBAUGH
103 BAY OAKS DRIVE
BAY SAINT LOUIS, MS 39520

LICENSE TO PRACTICE PHARMACY NUMBER T-101087

JURISDICTION

The Mississippi Board of Pharmacy has jurisdiction of the subject matter pursuant to Section 73-21-103(2), Mississippi Code of 1972, Annotated.

PROCEEDINGS

Petitioner requests approval of the transfer of her license to Mississippi. The Board heard testimony concerning the treatment and recovery of Petitioner.

ACTION OF THE BOARD

Based upon the clear and convincing evidence presented at the petition hearing, all members of the Board present voted to approve the transfer of the Petitioner's license. The Petitioner shall be subject to the following conditions and restrictions:

- The Petitioner shall enter into a contract with the Mississippi Association of Recovering Pharmacists ("MARP") and comply with the terms of that contract, which shall include random drug and alcohol screens, including the use of Peth blood alcohol testing. The MARP contract shall expire ten (10) years from the date of this Order.
- Petitioner shall abstain from the use of alcohol or the unauthorized use of controlled substances or other habit-forming legend drugs.
- Petitioner shall not take any mood-altering drug which has not been prescribed for her.
- Petitioner shall immediately inform the Board in writing (by email or fax) of all medications prescribed for her, stating the name of the drug, the number and strength of the doses prescribed, the dosage regimen and the name and registration number of the prescriber.
- The Petitioner shall submit a urine specimen, serum specimen or hair sample when requested by the Board or any agent of the Board of Pharmacy.
- The Petitioner shall only work day shifts.
- The Petitioner's access to controlled medications shall be monitored.
- The Petitioner is not authorized to work in a pharmacy alone, but rather shall work with another pharmacist.
- The Petitioner is not authorized to have a key to the pharmacy in which she works.
- The Petitioner is not authorized to work in a supervisory role.
- The Petitioner shall have a workplace monitor who is informed by the Petitioner of her history in order to be adequately observed in the workplace.
- The Petitioner is not authorized to work more than fifty (50) hours per week.

- Petitioner shall keep the Board informed at all times as to place of her employment as a Pharmacist and any change in residential address.
- Petitioner shall submit a written quarterly report (on a form prescribed by the Board) to the Board, due the first week of January, April, July and October, detailing her personal and professional well-being.

This ORDER OF THE BOARD is effective immediately. A certified copy of this ORDER shall be served on the Petitioner and maintained in the office of the Board.

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ORDERED AND AGREED TO, this the 23rd day of March, 2023.

Todd Barrett, President

Ronnie Bagwell, Vice-President

Ryan Harper, Secretary

Jillian Foster

Guy Phillips

Craig Sartin

Tony Waits

Came on March 23, 2023, the matter of Austine Onyia, Intern/Extern Registration IE-08723, herein also referred to as Petitioner, pursuant to a request to petition the Mississippi Board of Pharmacy.

BEFORE THE MISSISSIPPI BOARD OF PHARMACY

IN THE PETITION OF:

AUSTINE ONYIA
1401 HIGHWAY 80 EAST
APT. D-45
CLINTON, MS 39056

INTERN/EXTERN REGISTRATION NUMBER IE-08723

JURISDICTION

The Mississippi Board of Pharmacy (Board) has jurisdiction of the subject matter pursuant to Section 73-21-103(2), Mississippi Code of 1972, Annotated.

PROCEEDINGS

The Petitioner's intern/extern registration expired November 30, 2021, prior to him taking the MPJE. The Petitioner requests that the Board renew his intern/extern registration in order for him to be able to earn the hours needed to take the MPJE. The Board heard testimony concerning the Petitioner's request.

ACTION OF THE BOARD

The Board renewed the Petitioner's intern/extern registration for one (1) year from the date of this Order.

A certified copy of this ORDER shall be served on the Petitioner and maintained in the office of the Board.

All members participating in the hearing affirmed this Order.

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ORDERED AND AGREED TO, this the 23rd day of March, 2023.

Todd Barrett, President

Ronnie Bagwell, Vice-President

Ryan Harper, Secretary

Jillian Foster

Guy Phillips

Craig Sartin

Tony Waits

Came on March 23, 2023, the matter of Kenith E. Turner, Intern/Extern Registration IE-08912, herein also referred to as Petitioner, pursuant to a request to petition the Mississippi Board of Pharmacy.

BEFORE THE MISSISSIPPI BOARD OF PHARMACY

IN THE PETITION OF:

KENITH TURNER
415 LEXINGTON AVENUE
JACKSON, MS 39209

INTERN/EXTERN REGISTRATION NUMBER IE-08912

JURISDICTION

The Mississippi Board of Pharmacy (Board) has jurisdiction of the subject matter pursuant to Section 73-21-103(2), Mississippi Code of 1972, Annotated.

PROCEEDINGS

The Petitioner's intern/extern registration expired January 27, 2023. The Petitioner requested that the Board renew his intern/extern registration in order for him to be able to earn the hours needed to retake the NAPLEX. The Board heard testimony concerning the Petitioner's request.

ACTION OF THE BOARD

The Board renewed the Petitioner's intern/extern registration for one (1) year from the date of this Order.

A certified copy of this ORDER shall be served on the Petitioner and maintained in the office of the Board.

All members participating in the hearing affirmed this Order.

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ORDERED AND AGREED TO, this the 23rd day of March, 2023.

Todd Barrett, President

Ronnie Bagwell, Vice-President

Ryan Harper, Secretary

Jillian Foster

Guy Phillips

Craig Sartin

Tony Waits

Came on March 23, 2023, the matter of McGowan Enterprises d/b/a Acute Care Pharmaceuticals, herein also referred to as Petitioner, pursuant to a request to petition the Mississippi Board of Pharmacy. Ronnie Bagwell recused himself from the deliberation and voting on this matter.

BEFORE THE MISSISSIPPI BOARD OF PHARMACY

IN THE PETITION OF:

MCGOWAN ENTERPRISES d/b/a
ACUTE CARE PHARMACEUTICALS
12195 DEARBON PLACE
POWAY, CA 92064

PHARMACEUTICAL DRUG FACILITY PERMIT
TO OPERATE AS A WHOLESALE DISTRIBUTOR

JURISDICTION

The Mississippi Board of Pharmacy has jurisdiction of the subject matter pursuant to Section 73-21-103(2), Mississippi Code of 1972, Annotated.

PROCEEDINGS

On January 19, 2023, the Board entered an Order imposing a monetary penalty pursuant to Section 73-21-103(1)(d)(iii) on the Petitioner in the amount of One Million Twenty-One Thousand Two Hundred Twenty-Four Dollars and Eleven Cents ($1,021,224.11) for doing business without a permit. The Petitioner requests that the Board reverse its January 19, 2023 Order, or in the alternative, reduce the total monetary penalty to One Thousand Two Hundred Twenty-Four Dollars and Eleven Cents ($1,224.11).

ACTION OF THE BOARD

Based upon the clear and convincing evidence presented at the petition hearing that the Petitioner has taken corrective actions, the Board voted to amend the January 19, 2023 Order to hold all but Ten Thousand Dollars ($10,000.00) of the monetary penalty and the cost of investigation in abeyance for five (5) years from the date the amended Order. The remaining balance of the monetary penalty held in abeyance shall hereby be discharged on March 23, 2028, if the Petitioner remains in compliance with both state law and the regulations of the Board during the five (5) year abeyance period. All other provisions of the January 19, 2023, Board Order shall remain unchanged.

A certified copy of this ORDER shall be served on the Petitioner and maintained in the office of the Board.

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ORDERED AND AGREED TO, this the 23rd day of March, 2023.

Todd Barrett, President

Ronnie Bagwell, Vice-President

Ryan Harper, Secretary

Jillian Foster

Guy Phillips

Craig Sartin

Tony Waits

Came on March 23, 2023, the matter of Tip Allen Williams, Pharmacist Certificate of Registration Number D-07671, herein also referred to as Petitioner, pursuant to a request to petition the Mississippi Board of Pharmacy.

BEFORE THE MISSISSIPPI BOARD OF PHARMACY

IN THE PETITION OF:

TIP ALLEN WILLIAMS
103 CHARTRES DRIVE
MADISON, MS 39110

LICENSE TO PRACTICE PHARMACY NUMBER D-07671

JURISDICTION

The Mississippi Board of Pharmacy has jurisdiction of the subject matter pursuant to Section 73-21-103(2), Mississippi Code of 1972, Annotated.

PROCEEDINGS

The Mississippi Board of Pharmacy entered an Order on February 17, 2022, which revoked the license of the Petitioner for addiction to or dependence on alcohol, controlled substances or other habit-forming legend drugs or the unauthorized use, possession or theft of controlled substances or other habit-forming legend drugs. The Board also imposed a penalty in the amount of Two Thousand Dollars ($2,000.00) and charged the Respondent for the cost of investigation in the amount of Two Hundred and Fifty Dollars ($250.00). On September 15, 2022, the Petitioner appeared before the Board with a request to reinstate the license of the Petitioner. No action was taken by the Board and the request of the Petitioner was denied. The Petitioner requests the Board to reinstate his license and allow him to pay the Two Thousand Two Hundred and Fifty Dollars ($2,250.00) penalty and costs issued in the February 17, 2022, Board Order over a twelve (12) month payment period.

The Board heard testimony concerning the request of the Petitioner.

ACTION OF THE BOARD

Based upon the clear and convincing evidence presented at the petition hearing, all members of the Board present voted to reinstate the Petitioner's license and to allow payment of the penalty and costs imposed in the February 17, 2022, Board Order in equal installments, over a twelve (12) month payment period.

The Petitioner shall be subject to the following conditions and restrictions:

- The Petitioner shall enter into a contract with the Mississippi Association of Recovering Pharmacists ("MARP") and comply with the terms of that contract, which shall include random drug and alcohol screens, including the use of Peth blood alcohol testing and hair sample testing. The MARP contract shall expire ten (10) years from the date of this Order.
- Petitioner shall abstain from the use of alcohol or the unauthorized use of controlled substances or other habit-forming legend drugs.
- Petitioner shall not take any mood-altering drug which has not been prescribed for him.

- Petitioner shall immediately inform the Board in writing (by email or fax) of all medications prescribed for him, stating the name of the drug, the number and strength of the doses prescribed, the dosage regimen and the name and registration number of the prescriber.
- The Petitioner shall submit a urine specimen, serum specimen or hair sample when requested by the Board or any agent of the Board of Pharmacy.
- The Petitioner shall only work day shifts.
- The Petitioner's access to controlled medications shall be monitored.
- The Petitioner is not authorized to work in a pharmacy alone, but rather shall work with another pharmacist.
- The Petitioner is not authorized to have a key to the pharmacy in which he works.
- The Petitioner is not authorized to work in a supervisory role.
- The Petitioner shall have a workplace monitor who is informed by the Petitioner of his history in order to be adequately observed in the workplace.
- The Petitioner is not authorized to work more than fifty (50) hours per week.
- Petitioner shall keep the Board informed at all times as to place of his employment as a Pharmacist and any change in residential address.
- Petitioner shall submit a written quarterly report (on a form prescribed by the Board) to the Board, due the first week of January, April, July and October, detailing his personal and professional well-being.

This ORDER OF THE BOARD is effective immediately. A certified copy of this ORDER shall be served on the Petitioner and maintained in the office of the Board.

All members participating in the hearing affirmed this Order.

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ORDERED AND AGREED TO, this the 23rd day of March, 2023.

Todd Barrett, President

Ronnie Bagwell, Vice-President

Ryan Harper, Secretary

Jillian Foster

Guy Phillips

Craig Sartin

Tony Waits

Came on March 23, 2023, the matter of Sajani Barot, Pharmacist Certificate of Registration Number T-12769, herein also referred to as Petitioner, pursuant to a request to petition the Mississippi Board of Pharmacy.

BEFORE THE MISSISSIPPI BOARD OF PHARMACY

IN THE PETITION OF:

SAJANI BAROT
159 BRIDGEWATER CROSSING
RIDGELAND, MS 39157

LICENSE TO PRACTICE PHARMACY NUMBER T-12769

JURISDICTION

The Mississippi Board of Pharmacy has jurisdiction of the subject matter pursuant to Section 73-21-103(2), Mississippi Code of 1972, Annotated.

PROCEEDINGS

Petitioner requests reinstatement of her license to practice pharmacy, which expired on December 31, 2017. The Board heard testimony concerning the Petitioner's request.

ACTION OF THE BOARD

Based upon the clear and convincing evidence presented at the petition hearing, all members of the Board present voted to approve reinstatement of the Petitioner's license in Mississippi, if the following conditions are met:

- The Petitioner pays license renewal fees in arrears of Six Hundred Thirty Dollars ($630.00) plus a late fee of Fifty Dollars ($50.00);
- The Petitioner pays controlled substance registration fee of Fifty Dollars ($50.00);
- The Petitioner pays a background check fee of Forty Dollars ($40.00);
- The Petitioner shall complete a background check, which results in no disqualifying criminal convictions;
- The Petitioner shall obtain an intern registration and work as an intern for a Board approved pharmacist and site for twenty (2) clock hours for each of the six (6) years the Petitioner was without a Mississippi license for a total of one hundred and twenty (120) hours;
- That Petitioner provide a record from the preceptor pharmacist showing the satisfactory completion of the intern hours;
- The Petitioner shall receive a passing score on the Multistate Pharmacy Jurisprudence Examination (MPJE);
- The Petitioner shall provide proof of completing fifteen (15) hours of continuing education for the current licensing period.

This ORDER OF THE BOARD is effective immediately. A certified copy of this ORDER shall be served on the Petitioner and maintained in the office of the Board.

ORDERED AND AGREED TO, this the 23rd day of March, 2023.

Todd Barrett, President

Ronnie Bagwell, Vice-President

Ryan Harper, Secretary

Jillian Foster

Guy Phillips

Craig Sartin

Tony Waits

Came on March 23, 2023, the matter of Nichole Gricreria, herein also referred to as Petitioner, pursuant to a request to petition the Mississippi Board of Pharmacy.

BEFORE THE MISSISSIPPI BOARD OF PHARMACY

IN THE PETITION OF:

NICHOLE GRICRERIA
1203 MARKET STREET
APT. 401
PASCAGOULA, MS 39567

REGISTRATION AS A PHARMACY TECHNICIAN

JURISDICTION

The Mississippi Board of Pharmacy (Board) has jurisdiction of the subject matter pursuant to Section 73-21-103(2), Mississippi Code of 1972, Annotated.

PROCEEDINGS

The Petitioner withdrew from the William Carey University School of Pharmacy on February 23, 2021. The Petitioner applied for a pharmacy technician registration on December 21, 2022. The Petitioner requests that the Board grant her application for registration as a pharmacy technician. The Board heard testimony concerning the Petitioner's request.

ACTION OF THE BOARD

The Board approved the Petitioner's application for registration as a pharmacy technician.

A certified copy of this ORDER shall be served on the Petitioner and maintained in the office of the Board.

All members participating in the hearing affirmed this Order.

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ORDERED AND AGREED TO, this the 23rd day of March, 2023.

Todd Barrett, President

Ronnie Bagwell, Vice-President

Ryan Harper, Secretary

Jillian Foster

Guy Phillips

Craig Sartin

Tony Waits