



THE SCRIPT

QUARTERLY NEWSLETTER
MISSISSIPPI BOARD OF PHARMACY

NEXT BOARD MEETING

Our next board meetings will be held on

- July 11, 2024
- September 19, 2024
- November 21, 2024

at the Board of Pharmacy's office located at 6311 Ridgewood Road, Suite E 401 Jackson, MS. The meeting will begin at 9:00 a.m.

USP 800 READINESS REMINDER

Is your pharmacy compounding hazardous medications? Article XXXI: Compounding Guidelines incorporated USP 800 with the April 12, 2024, Update. Remember that the MS Board of Pharmacy has set 1/1/2025 as the final deadline for full compliance with USP 800 to avoid potential state-level enforcement actions.

503B PHARMACY OUTSOURCERS

503B Outsourcers are permitted as outsourcing pharmacies in MS per Article VI. The 503B Compounding Outsourcing Pharmacy designation was created in Title 1 of the Drug Quality and Security Act of 2013 under Section 503B of the FD&C Act. The creation of this designation was in the aftermath of the national 2012 meningitis outbreak from contaminated steroid injections. While traditional compounding pharmacies (503A pharmacies) are required to follow USP compounding guidelines, 503B pharmacies are required to adhere to FDA Current Good Manufacturing Practice (cGMP) standards. All pharmacies are required to register in each applicable state, but 503B pharmacies are also required to be registered with the FDA. There are approximately eighty 503B pharmacies registered with the FDA. The current listing can be found on the [FDA website](#). Any 503B partner you utilize must be registered with the FDA and the MS Board of Pharmacy.

Proposed FDA guidance on the Prohibition on Wholesaling Under 503B has suggested that 503B pharmacies may distribute products to pharmacies and other intermediaries for further dispensing. However, Mississippi Pharmacy Practice Regulation, Article XXXI Compounding Guidelines does not permit pharmacies to offer compounded human drug products to practitioners or other pharmacies for resale or dispensing. We believe this regulation is consistent with the original intent of 503B outsourcing pharmacies supplying products only to hospitals and clinics for administration by a clinician. In Mississippi, products compounded by a 503B outsourcing pharmacy may not be dispensed to a patient unless the 503B directly dispenses the product to the patient.

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) UPDATE

Partnership for DSCSA Governance (PDG) & FDA recently held a joint public meeting regarding the DSCSA Stabilization Period Midway Checkpoint. Below are some key takeaways and updates from the meeting:

- The stabilization period ends on November 27, 2024, and FDA has no plans to further extend the full implementation of DSCSA.
- [Small Dispenser Exemption until 11/27/2026 Announced](#): On June 12, 2024, FDA Announced a Small Dispenser Exemption for dispensers where the corporate entity that owns the dispenser has a total of 25 or fewer full-time employees as pharmacists or pharmacy technicians.
- [Waivers, Exceptions, and Exemptions \(WEE\)](#): authorized trading partners or stakeholders may request an exemption for other products or transactions from certain requirements but are encouraged to request exemptions ASAP instead of waiting until the end of the stabilization period.

[Check out the NABP DSCSA Resource Page for Dispensers for more information on DSCSA](#)

SMALL DISPENSER EXEMPTION: WHAT DOES IT MEAN?

Any corporate entity that owns a dispenser or a group of dispensers that has a total of 25 or fewer full-time pharmacist and technician employees was granted a time-limited exemption to specific requirements of the DSCSA that were scheduled to be enforceable 11/27/2024, to include:

- Implementation of Enhanced Drug Distribution Security
- Verification down to the Product Identifier

What is NOT covered by the small dispenser exemption?

- Ensuring all trading partners are authorized trading partners
- Product Identifiers: Product must contain appropriate product identifiers including NDC or GTIN, Serial Number, Lot Number, Expiration Date in a human and machine-readable format.
- Product Tracing: Must have transaction information, statement, and history data and comply with associated elements
- Verification Processes to ensure the received product is not suspect or illegitimate

ALL THINGS LICENSING



RENEWALS

We have closed out the June 30, 2024, Medical Equipment Supplier Permit renewals. Note: Renewals completed after June 30, 2024, will be assessed a late fee.

Our Licensing Division is readily available to assist with any renewal questions and/or Gateway issues. Do not hesitate to contact us.

DBA NAMES

When completing renewal or amendment applications, **leave the DBA name field blank if your facility does not have a DBA name or DBA name change**. In addition, please do not re-enter the facility's legal name as the DBA name.



KEEP YOUR PROFILE UP TO DATE: A QUICK GUIDE



To keep your profile up to date, you should log into the Gateway and submit any necessary changes. For name changes, follow the system prompts to submit a request and upload the required documentation for staff approval. You can also update your employment and address details directly through the Gateway. If you need help with the online system, please contact our Licensing Division at (601) 899-8880 for assistance.

PHARMACIST FILL UP

Reminder: Updated wallet cards are available by logging into your Gateway profile, download the card, and print if desired. Any request for duplicate wall certificates may be made by logging into your Gateway profile and submitting a duplicate certificate application request. There is a \$25.00 processing fee.

TECH BITE

All Pharmacy Technicians are required to maintain updated employment information/status via his/her gateway. If you have not reported your employment, log in today and provide this information.

If you have not already done so, please create a profile with NABP at www.nabp.pharmacy. This account is FREE and will assign you a NABP e-Profile number, which you will need to report to our office by telephone or email (licensing@mbp.ms.gov).

Student Sidebar Chatter

In the past, pharmacy school students'-controlled substances registrations expiration date was set for six (6) months from the graduation date. This has changed to one (1) year following the graduate's graduation date. **Make sure to review your student registration expiration date, this date should be one (1) year from your anticipated graduation date.** If this date does not correlate with this guideline, please contact our licensing division for correction.

If you have not already done so, please create a profile with NABP at www.nabp.pharmacy. This account is FREE and will assign you a NABP e-Profile number, which you will need to report to our office by telephone or email (licensing@mbp.ms.gov).

*Please notify the Board should you withdraw from pharmacy school. Student Intern/Extern registrations will become inactive upon withdrawal. Should you want to apply as a technician, you will be required to petition the Board for permission to do so.



ALL THINGS LICENSING



FACILITY HIGHLIGHT

Any changes to your permit (i.e., PIC/DR changes, address changes, business name changes, and/or ownership changes) may be made by logging into the Gateway and submitting the desired change application at any time. Supporting documentation uploaded may be required for staff approval. For DR changes, make sure to mail your fingerprint card to the Board office address indicated on the instruction sheet as soon as possible. Failure to do so may result in the expiration of your application. For assistance with the online system, contact our Licensing Division at (601) 899-8880.

PIC changes must be completed within 15 days to prevent any interruption in operation. Make sure that there are two emails listed on the record (one for the PIC and one for an admin, in the event that the PIC vacates his/her position). This will ensure all notices regarding the PIC change application process will be received by the facility.

*If the PIC has not renewed his/her pharmacist license, the system will NOT allow the renewal of their facility's permit.

MAKE SURE EACH USER HAS HIS/HER OWN PROFILE, USERNAME, AND PASSWORD.
PROFILES/PASSWORDS SHOULD NOT BE SHARED. THE LICENSING DIVISION STAFF WILL NOT GIVE ACCESS TO A PROFILE TO ANYONE EXCEPT THE PROFILE OWNER.

NOTE: In cases where there is a DR change, a new profile must be created for the new incoming DR. The previous DR's profile cannot be edited to change the name to reflect the incoming DR's.

COMPLIANCE CHECK



REMINDER: CE AUDIT CHANGES

When you launch your pharmacist renewal application, you will receive notification if you have been chosen for the CE audit. If chosen for the audit, you will need to provide documentation of CE obtained from **January 1, 2023, through December 31, 2023** by uploading it to the gateway within 5 days. You are responsible for providing the documentation within the requested time frame. Please be sure to follow through to avoid any disciplinary action related to not providing the required CE documentation or not providing the documentation within the required time frame. If you have any questions regarding CE audits, please reach out to us at 601-899-8880 or email us at compliance@mbp.ms.gov.

TELEHEALTH PRESCRIBERS: VERIFY MS LICENSURE

Be sure to verify that out-of-state doctors and nurse practitioners have a MS license if they are providing telehealth services in MS. You can verify via the following links for doctors and nurse practitioners respectively: <https://gateway.msbl.ms.gov/verification/search.aspx> or [License Verification | Mississippi Board of Nursing \(ms.gov\)](#).



INTRODUCING THE BULLPEN REPORT: A COMPLIANCE RESOURCE



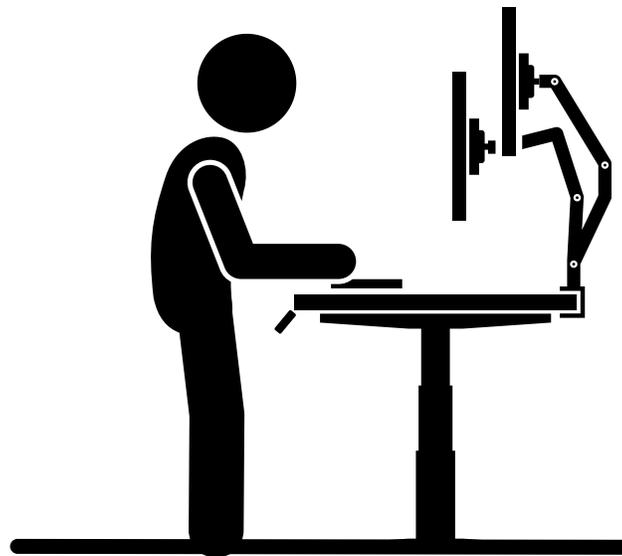
MS Board of Pharmacy's Compliance Division is thrilled to announce the launch of the Bullpen Report, an innovative platform designed to enhance understanding of compliance for our licensees. The Bullpen Report will feature useful tips and reminders to help you stay on top of your compliance responsibilities. From important deadlines to practical tips for day-to-day operations, these insights are designed to be actionable and easy to implement. By fostering a better understanding of compliance issues, we hope to create a community of well-informed professionals who are committed to upholding the highest standards in pharmacy practice. Our first bullpen report on Loss Reporting, Inventories, and Accountability Audits was launched in April 2024. Check out [Continuing Education | Mississippi Board of Pharmacy \(ms.gov\)](#) for current trainings available.

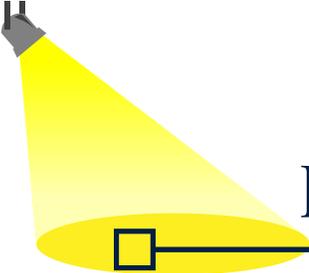
COMPLIANCE CHECK



PIC CORNER

- **Prolonged Absences** -The Pharmacist in Charge (PIC) shall be responsible for complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy. If a pharmacist in charge will be out of the pharmacy (medical leave, maternity leave, or any prolonged absence from the pharmacy), the PIC should consider if they wish to remain Pharmacist in Charge of the permit. When you are absent from the day-to-day events in the pharmacy for a prolonged length of time, and you remain PIC, the **responsibility** is still yours. For example, if the pharmacy has a loss of controlled substances that are not reported (diversion or burglary), the PIC will be held responsible by the Board. Another example would be that an employee was caught diverting medication in the pharmacy, police arrested the employee, and the employee was terminated, but the Board was not notified. These are both examples in which the PIC was out for a prolonged absence when these violations occurred, and both received disciplinary action. The best course of action will be to remove yourself from the permit if an extended absence is expected to avoid disciplinary consequences.
- **Accountability Audits**- Have you had an opportunity to conduct an **accountability audit** yet using either the Word or Excel version of the form? If so, we would love your feedback on how it went. Please complete this **short survey**.



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Spotlight on Pharmacy Benefit Managers

Maximum Allowable Cost and MAC Appeals:

MS Statute 73-21-156 states that a PBM must provide a reasonable administrative appeal procedure for pharmacies to challenge a MAC list and reimbursements under a MAC list for a specific drug if it is below the pharmacy acquisition cost or does not meet the requirements of 73-21-156. Pharmacies are encouraged to follow the MAC appeal process and notify the MS Board of Pharmacy of any instances where responses do not appear compliant to state statute.

MAC Appeals and Contract Rate:

MS Statute 73-21-156 defines MAC as a listing of drugs or other methodology used by a PBM to set the maximum allowable payment to a pharmacy or pharmacist for a generic, brand, biologic or other prescription drug. The statute gives many examples of items that may be included in price setting but states that MAC includes any term that a PBM or health care insurer may use to establish reimbursement rates. [Click here](#) to see the full definition.

Our office is aware of denied MAC appeal responses from plans that state:

“You were reimbursed at your contracted rate and not at MAC.”

This response does not seem to take into account 73-21-156’s provision that any term that is used to set reimbursement is considered MAC.

MAC Appeals and Rebates:

MS Statute 73-21-156 defines “pharmacy acquisition cost” as the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy’s billing invoice.

Our office understands that pharmacies are sometimes receiving MAC appeal responses that are requesting additional information beyond the billing invoice to include potential rebate information and agreements. These requests are not aligned with the outlined appeal process in [73-21-156 Section 4](#) that states the requirements for an appeal procedure for reimbursement being below the “pharmacy acquisition cost”.

MAC Appeals and Other Wholesaler:

MS Statute 73-21-156 allows a PBM to respond to submitted MAC appeals with the National Drug Code of the pharmaceutical wholesaler operating in MS where the drug may be currently obtained at the MAC price. However, this response is only valid if it is the wholesaler where the pharmacy obtains the majority of its prescription drugs. If a pharmacy receives information on a MAC appeal stating to obtain the product from a non-primary wholesaler, they are encouraged to inform the PBM that it is not the wholesaler where they obtain the majority of their prescription drugs.

PMP Update



Please notify the MS PMP directly in the event your permit is set to inactive or closed. Also, please notify the MSPMP directly should your pharmacy have a change of DEA number so that we can update our records to reflect accurate reporting.

As a reminder, error corrections are required. Please refer to the Data Submission Guide should you need assistance. https://pmp.mbp.ms.gov/sites/default/files/pmp/forms-documents/MS-PMP-Data-Submission-Dispenser-Guide_v3.0.pdf

The MSPMP serves as a tool for dispensers to assist in making an informed decision when providing pharmaceutical care for their patients. Any suspicion of diversion of any type should be reported to the appropriate authority. If you are unsure who to report any type of incident to, you can always contact the PMP directly.

Should an individual require a copy of their PMP report, they are required to contact the MS PMP directly and follow the appropriate steps. PMP users are not permitted to share PMP reports with anyone at any time.

If you have changed your employment, email, or any other information regarding your profile please do not create another account. This includes transitioning from a pharmacist's delegate PMP account to a pharmacist account. Simply send an email with the updated information. You may send these requests via email to mspmpassist@mbp.ms.gov.

Pharmacies that are eligible for a waiver of reporting to the MSPMP, please remember that paper versions are not accepted. PMP waivers are done online in the MS Board of Pharmacy's licensing gateway. Application and renewal for a waiver takes place with your pharmacy's permit.

Feel free to call or email with any questions 601-899-0138, mspmpassist@mbp.ms.gov, or visit our website at www.pmp.mbp.ms.gov.

