NEXT BOARD MEETING

Our next board meeting will be held on September 21, 2023, at the Board of Pharmacy office located at 6360 I-55 North, Suite 400, Jackson, MS. The meeting will begin at 9:00 am.

DRAFT FDA GUIDANCE: PROHIBITION ON WHOLESALING UNDER SECTION 503B OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

FDA released draft guidance this month providing current thinking on Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act. To review the draft guidance in full click here.

Please note that MS Board of Pharmacy Article XXXI still prohibits pharmacies, both 503A and 503B, from offering compounded product to practitioners or to other pharmacies for resale or dispensing.

New Board Members: David Hudson & Michael Gilbow

New Board Members David Hudson and Michael Gilbow officially took their oath of office at the July 13, 2023, Pharmacy Board Meeting. Board President Ronnie Bagwell presided. David Hudson and Michael Gilbow replaced former Board President, Todd Barrett and Board Member, Guy Phillips. They will serve a five-year term ending in 2028. We look forward to working with David and Michael and congratulate them on their appointments.

PATIENT CONTROLLED SUBSTANCES - RECEIPT, DISPOSAL, & DESTRUCTION

In the 2022 update to the DEA Pharmacist

Manual, the DEA provided guidance regarding patients bringing medications from home to the hospital (see page 84 of document). On June 13, 2023, the DEA released a Question & Answer regarding Abandoned Controlled Substances at Registered Practitioner locations. Please note that the DEA defines "practitioner" broadly to include but not limited to providers, investigators, pharmacies, and hospitals. Entities that have the potential for patients to bring dispensed controlled substances into their facility should carefully review their procedures for compliance.



ALL THINGS LICENSING



Renewals

The 2024 DME renewal period recently closed on June 30, 2023, but the Gateway will remain open to allow those who missed the deadline an opportunity to renew. Note: There is a \$50.00 late fee. If you do not wish to renew and/or need to close the DME permit, please log into the Gateway and submit a permit closure request.

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

Profile Changes

Any changes to your profile may be made by logging into the Gateway and submitting the desired change request at any time. For name changes, the system will allow you to make the request. You will need to upload the required documentation for staff approval. All employment and address changes can also be made via the Gateway. For assistance with the online system, contact our Licensing Division at (601) 899-8880.

Student Sidebar Chatter

The Student Extern/Intern Controlled Substance
Registration expires six months from the prospective
graduation date. Register with the Gateway to access
your registration. Upon issuance of your Mississippi
pharmacy intern/extern student registration, you will
need to register with the National Association of Boards
of Pharmacy (www.nabp.pharmacy) at no charge to
you. You will be assigned an NABP number.

Make sure to review your student registration expiration date, this date should be six (6) months 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



Pharmacist Fill Up

We no longer mail wallet cards or stickers. To obtain, a wallet card, you may log 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

The MS Board of Pharmacy no longer grants a temporary "pending" status for technicians that have successfully submitted all application components except background check results. Until the registration has been issued, only technicians that are reflecting "active" on the licensing verification portal should be allowed in the dispensing area of a pharmacy.

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).

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 address indicated on the instruction sheet as soon as possible. Failure to do so will result in expiration of your application. For assistance with the online system, contact our Licensing Division at 601–899–8880.

PIC changes must be completed in a timely manner to prevent any interruption in operations. 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.

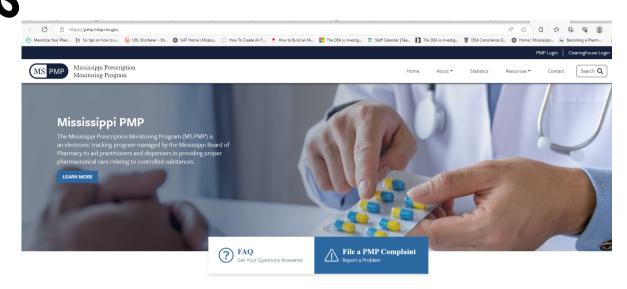
If the PIC has not renewed his/her pharmacist license, the system will NOT allow the renewal of their facility's permit.

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.

PMP Update



Great news!! PMP has a fresh new look. Check it out!



Please make sure your pharmacy has updated to the new clearinghouse SFTP server. This is required to be done in order for your pharmacy to report properly. If you are unsure if this update has been made at your pharmacy, please contact the clearinghouse directly using the link provided, https://pmpclearinghouse.zendesk.com/hc/en-us.

If you have changed your employment, email, or any other information regarding your profile you do not need to create another account. Simply send an email with the updated information. You may send these requests via email to mspmpassistembp.ms.gov.

As a reminder to pharmacies that are eligible for a waiver of reporting to the MSPMP, paper versions are not accepted. PMP waivers are done electronically. 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.

Reporting of controlled substances II–V and gabapentin is required every 24 hours. This includes zero reporting. All controlled substances II–V are to be reported with a valid DEA number. Should you need assistance with your reporting account for the MSPMP please contact 1–855–567–4767 and ask to speak to the clearinghouse.

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

COMPLIANCE CHECK



Reminder: CE Audit Changes

We now gather documentation for our CE audits electronically. In 2022, we began auditing when the pharmacist license renewal season opened. Licensees attested to completing CE from the previous licensing year. This meant for the 2022 renewal season, you attested to completing CE from January 1, 2021 through December 31, 2021. In 2023, when you launch your pharmacist renewal application, you will receive notification if you have been chosen for the CE audit. Whether or not chosen for the CE audit, you will still attest to completing CE from January 1, 2022 through December 31, 2022. If chosen for the audit, you will need to provide documentation of CE obtained from January 1, 2022, through December 31, 2022 by uploading it to the gateway. If you have any questions regarding the upcoming changes to our CE audits, please reach out to us at 601–899–8880 or email us at compliance@mbp.ms.gov

Compliance Tips from the Field

- 1. When checking in controlled substances, don't obscure or mark through the quantity received. Compliance agents need to be able to read that number, and so do you!
- 2. Please keep the previous annual controlled substance inventory available for inspection by Board of Pharmacy compliance agents until the new annual controlled substance inventory is taken. Remember for DEA inspections, you will need to have the past 2 years available for inspection.
- 3. Review of procedures for a loss of controlled substances:
 - a. Notify the MS Board of Pharmacy immediately upon loss of controlled substances OR even suspicion of loss of controlled substances. You may reach out to your Compliance Agent directly or call us at 601–899–8880 or email: compliance@mbp.ms.gov.
 - b. Be discreet about any possible loss or possible diversion investigation.
 - c. Complete a controlled substance inventory within 48 hours.
 - d. Continue investigating. If the loss is confirmed and diversion is suspected, let us know ASAP.
 - e. Submit a written report to the BOP within fifteen days of the loss. Your report would include a copy of the controlled substance inventory completed within 48 hours of initial loss. You would also need to include a copy of Form 106 that you filed with DEA.
 - f. See DEA update with final ruling on filing Form 106 effective July 24, 2023 (only electronic submissions will be accepted) (Reporting Theft or Significant Loss of Controlled Substances)



COMPLIANCE CHECK



Compounding Practices

We often receive inquiries from other healthcare professionals regarding compounding practices for IV Hydration clinics. Please view the <u>compounding practice letter</u> which provides information that would be helpful to other healthcare professionals. These healthcare professionals would also need to contact their specific licensing agency for directions on the standards to which they would be held by that licensing agency.

FRAUDULENT PRESCRIPTION ACTIVITY NOTICE



We are seeing an increase in fraudulent prescription activity specifically for alprazolam (mostly 2mg strength) and for promethazine products (including plain and DM). Please be diligent in verifying that a valid prescriber-patient relationship exists when reviewing prescriptions presented for these medications. Reach out to the prescriber to verify should you have questions about the validity of the prescription especially if the patient is not known to you.

ARTICLE XXXII—PHARMACEUTICAL DRUG FACILITY PERMITS: UPDATED APRIL 26, 2023

While this <u>article</u> primarily governs operations of drug facilities, there are several items of interest to pharmacies (503A & 503B) as well. Please review the article in its entirety for relevance to your practice. Some potential areas of interest include:

- Exemptions to wholesale distribution
- Due Diligence to identify suspect/illegitimate products.
- Prohibition of wholesaler to obtain pharmaceutical products from dispensers/pharmacies outside of returns.

Prohibition of dispensers/pharmacies to sell or transfer pharmaceutical products to a wholesaler outside of retur

