

Welcome to 2021!

MS BOP UPDATES

Electronic Prescribing for Controlled Substances (EPCS) for Part D prescriptions are slated to be enforceable on January 1, 2022, by CMS. Adoption of EPCS for Part D prescriptions was previously established in the SUPPORT Act with a deadline set of January 1, 2021, for prescribers established by the CY 2021 Physician Fee Schedule. CMS delayed enforcement to allow additional time for waiver and enforcement process development. CMS is encouraging early adoption of EPCS prior to enforcement.







Any pharmacy that does not dispense controlled substances and holds a waiver with the MSPMP will now renew that waiver through the MSBoard of Pharmacy gateway system. Your waiver

will renew with your permit each time. Paper waivers can no longer be accepted. Please call or email with any questions.

If your pharmacy requires the collection of identification when dispensing controlled substances, please refer to the dispenser guide for a complete list of identification numbers that could be used and where they should be input, refer to page 42–43 of the <u>Mississippi PMP Data Submission</u> guide.

Please be sure to log in to you MSPMP account and check your dashboard for any announcements that may be sent through the MSPMP. You can also find a copy of the MSPMP Aware User Guide on your dashboard. Simply click on 'Menu' and look under 'Training'. This document is also provided on the MSPMP website at <u>Mississippi PMP AWARXE</u>

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

ALL THINGS LICENSING

Pharmacist Fill Up

• The continuing education requirement is as follows: Fifteen (15) hours are required each licensure period. At least two (2) hours of continuing education received each year must be related to opioid abuse and prevention or some other drug of abuse or addiction-related issue. At least two (2) hours of continuing education received each year must be obtained via a live seminar. Live webcasts are valid for this requirement. If you are a PIC, your facility information will display under your gateway profile. In order to manage, update, renew, or amend this record; click on the facility permit tile that needs to be amended. Multiple facilities may be added to your gateway profile for management. If at any time, you encounter any issues or concerns, do not hesitate to contact our Licensing Division.

Tech Bite

 Pharmacy Technicians' first-time renewing MUST be nationally certified in order to be allowed to renew their pharmacy technician registration. MBP does not require continuing education credits for technicians, this is mandatory by the national technician certification entities only.

Facility Highlight

 Duplicate copies of permits may be downloaded via the gateway at any time by the PIC, DR, and/or permit holder logging into the system and click on the permit tile and select "Print Wall Certificate" under PERMIT OPTIONS on the lower left.

<u>F.A.Q</u>

Visit the Frequent Asked Questions (FAQ) section of our website (www.mbp.state.ms.gov) to take advantage of a great resource for locating answers to questions and issues you may encounter. If you are unable to find an answer to a question you have, please feel free to contact us via email at licensingembp.ms.gov.

Stay Up-to-Date

Don't be left out! Like us on Facebook and LinkedIn and follow us on Twitter for news, updates, and information related to Pharmacy.



Student Sidebar Chatter

• The Student Extern/Intern Controlled Substance Registration expiration date is six (6) months from the prospective graduation date. Make sure you are registered via the gateway to access your registration.

The New Licensing System is HERE!

As many of you know by now, not just by our many emailing and social media announcements, but from using it, our new licensing system is here! Yes, you do have to register to use the gateway. Unfortunately, the old legacy system would not allow for the conversion of usernames and passwords. If it is any consolation, you are welcome to use the same credentials that were previously used.

We want to thank everyone for their cooperation and patience in making this feat a smooth transition. Staff is available to assist you in navigating the gateway.

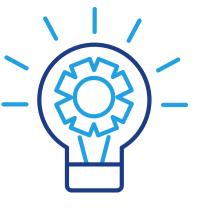
After the initial registration, the system guides you through the renewal process. Please note, the menu items are on the lower left of the screen, and the license choices are in the middle of the dashboard's page. When changes are needed to the user's record, click on "My Profile" in the top upper right corner of the screen. If you encounter any issues or concerns, please do not hesitate to contact our Licensing Division by telephone (601) 899-8880 or by email (licensing@mbp.ms.gov). We are receiving an abundance of telephone calls and emails, and we are doing our very best to respond promptly. Please keep in mind that we respond in the order of when the contact is received.

Remember, all contact from our office will be by email. Users may download a copy of licenses, registrations, and/or permits by clicking on the tile under the "Personal Licenses & Registrations" section and/or under the "Facility Permits" section (for PIC's and/or DR's). To ensure that you are kept up to speed with any updates from the Board, please update your contact information, especially your current email address.

Compliance Updates

DEA Pharmacist Manual Revision

The 2020 edition of the <u>Pharmacist's Manual: An Informational Outline of the Controlled Substances Act</u> has been released by DEA's Diversion Control Division. The guide is provided to help pharmacists understand the federal Controlled Substances Act and its regulations pertaining to the pharmacy profession. It is crucial to read and be familiar with this information. If a DEA agent enters your pharmacy, full compliance with the Code of Federal Regulations is expected.



Unsolicited Inspections or Individuals Claiming to be Representatives of the Board

There have been reports that individuals will call or appear and identify as a representative of the Mississippi Board of Pharmacy. Please demand identification, and if any doubt, call the Board office immediately. If the office is closed and their identity cannot be verified, please deny entrance to your pharmacy until verification may be obtained. Also, reports have been that someone will come to your pharmacy and perform an inspection. Please do not allow individuals access to your pharmacy department unless you have verified their identity. Most pharmacies are familiar with their Compliance Agent, and cell numbers are on the business card.

Pharmacist-In- Charge Responsibilities

The Pharmacist in Charge 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.

Federal Track and Trace Requirements Now in Place

As of November 27, 2020, pharmacies must now buy and sell certain drug products that include a product identifier on their packages to meet requirements of the Drug Supply Chain Security Act (DSCSA) of 2013 – also known as the "track-and-trace" law. Dispensers should be familiar with the requirements and have knowledge of what to do if a product identifier is not on the package. Under the law, all "Products" (as defined by the DSCSA) packaged by manufacturers, must be affixed or imprinted with a product identifier that features the products' National Drug Code, plus a unique serial number, lot number, and expiration date. More information is included on the FDA website. The informative draft guidance is located at fda.gov

Compounding Statistical Report

The Compounding Statistical Report is required to be filed with the Mississippi Board of Pharmacy no later than January 31st of each year for every pharmacy that has a compounding certificate. This form is located on our website mbp.ms.gov

HHS Guidance for Immunization Administration

The Board recently sent an email regarding HHS criteria for pharmacists and pharmacy technicians immunization administration by the HHS Guidelines. Please find this information on our <u>website</u>.

Administrative Rules and Regulations

It is the responsibility of each pharmacist to know the Administrative Rules and Regulations set forth by the Mississippi Board of Pharmacy. For a full list of this information please visit the **Regulations page** on our website.

Spotlight on Pharmacy Benefit Managers

Welcome to 2021. My hope and prayers are for a healthy and prosperous New Year for all. We expect 2021 to be a very eventful year in Pharmacy – especially as it relates to PBMs.

The Supreme Court of the United States issued its landmark ruling in Rutledge v. Pharmaceutical Care Management Association (PCMA), determining whether community pharmacies are protected from abusive payment practices. The unanimous (8 to 0) decision ruled in favor of the interests of patients and community pharmacies, who have been fighting for years to regulate pharmacy benefit managers (PBMs), the controversial middlemen that manage prescription drug benefits for health insurers, Medicare Part D drug plans, and large employers. With this ruling, states will have greater authority to protect their local businesses and their patients from PBM overreach. This ruling will go a long way in setting the parameters for PBM operations in the future.

On a state level, the legislative changes to the Prompt Pay Act (HB 708) have taken effect on January 1st. It will be interesting to see if PBMs respect the changes in the law. Please contact me if you suspect a PBM is non-compliant. I will do all I can to assist in a resolution to the issue(s) and hold PBMs accountable to the laws of the State.

Many have asked how the Board will handle PBM complaints as it relates to HB 708. Much of this will be 'flushed out' after January 1st, when we receive complaints and begin the process of responding. We will first try to work directly with the PBM to resolve the issue(s). The following is a summary of the steps required for Board action, if necessary.

- Upon receipt of a PBM complaint, I will initially review the complaint. This will include consultation with the complainant, legal counsel, etc.
- Although the Board of Pharmacy does not follow an absolute judicial process, the Board must follow general rules of evidence and due process.
- If it is determined sufficient evidence exists, I will work with the complainant to procure the necessary evidence to support the complaint. The complainant must provide this evidence.
- Once the file is complete, the case is brought before the Investigative Review Committee (IRC). The IRC then determines the next step, which could include no action, reprimand, or a formal hearing before the Board.
- If the IRC recommends a hearing, then formal notice must be given to the respondent (PBM in this case), including a scheduled hearing before the Board.
- The Board would then make a final decision.

Throughout this process, there are many other possibilities, such as continuance requests by the respondent, requests for settlement before a hearing. (The Board must approve any settlement.) It is also important to remember – the process cannot move forward without the support of the complainant, which is usually the Pharmacist or Pharmacy. In the past, the process has stopped because of the fear of PBM retribution to the pharmacy. I am personally looking forward to the possibility of holding PBMs accountable to the laws of Mississippi.

With warmest regards,

Steve Parker