MISSOURI BOARD OF PHARMACY
NEWS UPDATE (12-21-2021)

VACCINE ASSISTANCE

The Board has been asked if pharmacies can use non-pharmacy healthcare providers to help provide both COVID-19 and non-COVID-19 vaccines (e.g., nurse, physician assistant, assistant physician). Pharmacies may use non-pharmacy healthcare providers to administer vaccines subject to the following:

1. The healthcare provider has their own authority or their own protocol/standing order with a physician, in compliance with their regulatory agency's requirements, that gives them the authority to administer the vaccine.
2. The healthcare provider administers the vaccine in compliance with their authority or protocol/standing order, including, any patient screening requirements.
3. The pharmacy may use their pharmacy software system to conduct billing/vaccine reporting for administrations provided by a healthcare provider. If a prescription number is assigned to the billing/reporting record, the computer record and any hard copy or image should clearly indicate that it is a billing record and not a prescription record.
4. The pharmacy must be able to account for pharmacy vaccine inventory administered by the healthcare provider via billing or distribution records.
5. For healthcare provider-administered vaccines, any hard copy vaccine administration record should be physically separated from pharmacy administration records.
6. The healthcare provider administering does not have to be registered as a pharmacy technician, unless they will have independent access to drug inventory (e.g., without a pharmacist present and supervising).

Disclaimer: This procedure has not been reviewed for insurance billing and liability concerns. For legal advice, please consult an attorney. Healthcare providers should contact their licensing Boards for their requirements.

IMPORTANT INFORMATION ON PHARMACY COMPOUNDING

The Federal Drug and Cosmetic Act (FDCA) provides drug products dispensed or distributed in the U.S. must comply with federal requirements related to:

1. Current good manufacturing products (cGMP),
2. Labeling with adequate directions for use, and
3. FDA approval before marketing. [See FDCA section [503(A)]

The FDCA exempts pharmacists and physicians from cGMPs, designated labeling requirements and FDA approval, if:

1) The pharmacy is in a state that has entered a compounding Memorandum of Understanding (MOU) with the FDA, or;

2) If the pharmacy's home state has not signed the MOU, the number of compounded products shipped interstate by the pharmacy/physician does not exceed 5% of the total prescription orders dispensed or distributed by the pharmacy or physician. [See FDCA section [503(A)]

In October 2020, the FDA adopted its final Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products, which is currently available for state signature. The Board approved signing the FDA MOU in April 2020, and subsequently promulgated rule 20 CSR 2220-2.425 (Required Pharmacy Reporting), which addresses reporting of needed compounding data to comply with MOU requirements. Under the Board's rule, pharmacies located in Missouri are required to file their initial compounding data reports with the Board by January 31, 2022.

In August 2021, the FDA announced it would extend enforcement of the MOU until October 27, 2022. A federal court later remanded the MOU back to the FDA for further consideration prior to final implementation.

In light of the pending litigation and delayed enforcement date, the Board will be exercising its enforcement discretion and will extend enforcement of 20 CSR 2220-2.425 until January 31, 2023. Pharmacies do not have to file their initial compounding data reports required under 20 CSR 2220-2.425 until January 31, 2023. The 2023 report will cover 2022 compounding data. The Board recommends that pharmacies begin collecting/tracking required compounding data now to meet the 2023 deadline.

Does My Pharmacy Have to Report?

Except as listed below, 20 CSR 2220-2.425 is applicable to all pharmacies located in Missouri that are compounding human drug preparations, **even if the pharmacy is not compounding from bulk ingredients or does not have a Missouri Class D (Non-Sterile Compounding) or Class H (Sterile Compounding) pharmacy permit**.

The Board does not consider flavoring a prescription to be compounding. Additionally, the Board does not consider reconstituting or mixing ingredients for an FDA approved non-sterile drug product to be compounding (e.g., Benzaclin®, Benzamycin®, Epaned® etc.). However, the use of compounding kits that include the compounding ingredients is compounding and would fall under 20 CSR 2220-2.425's reporting requirements (e.g., First® Kits).

EXEMPTIONS: According to FDA Guidance, the MOU does not apply to:

- Drugs intended for veterinary use
- Repackaged drug products *(The Board's rules would require reporting of repackaged compounded sterile preparation data)*
- Radiopharmaceuticals
- Biological products subject to licensure under section 351 of the Public Health Service Act, or
- Drugs compounded by outsourcing facilities under section 503B of the FD&C Act.

Pharmacies do not have to report compounding data to the Board for the products/preparations listed above. [See also 20 CSR 2220-2.425(4) and/or FDCA Section 503(A)]

What if my pharmacy does not have a Class D (Non-Sterile Compounding) or Class H (Sterile Compounding) pharmacy permit?

20 CSR 2220-2.425 applies to all pharmacies located in Missouri compounding human drug preparations, even if the pharmacy is not compounding from bulk ingredients or does not have a Missouri Class D (Non-Sterile Compounding) or Class H (Sterile Compounding) pharmacy permit. [See exemptions above]

Are Non-Resident Pharmacies Required to Report?

No. 20 CSR 2220-2.425 only applies to pharmacies located in Missouri. *(Non-resident licensing states may have other reporting requirements)*

What Does My Pharmacy Have To Report?

Pharmacies have to report the following compounding data to the Board annually:

(A) The number of prescriptions or medication orders for compounded human drug preparations/products that the pharmacy distributed or dispensed interstate during the previous calendar year;
(B) The number of prescriptions or medication orders for compounded human drug preparations/products that the pharmacy dispensed (or caused to be dispensed) from the facility in which the drug preparations/products were compounded during the previous calendar year (e.g., not picked up on-site by the patient or the patient's designee);
(C) The number of prescription or medication orders for compounded human drug preparations/products dispensed on-site at the pharmacy during the previous calendar year (e.g., picked up by the patient or the patient's designee);
(D) The sum of the figures from (A) and (B) above; and
(E) The quotient from dividing the figure in (A) by the figure from (D).

If the figure from section (E) above is greater than five tenths (0.5), the pharmacy must also report:

(A) The total number of prescription or medication orders for sterile compounded human drugs distributed or dispensed interstate during the previous calendar year;
(B) A list of the states where the pharmacy was licensed during the previous calendar year; and
(C) A list of the states into which the pharmacy distributed compounded human drug preparations/products during the previous calendar year.

What If My Pharmacy Doesn't Dispense/ Distribute Interstate?

Pharmacies are required to report compounding data under the Board's rule even if the pharmacy does not dispense/distribute compounded preparations outside of Missouri.

How Did The Board Develop The Reporting Requirements?

20 CSR 2220-2.425's reporting requirements and calculations were taken from the FDA's final Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products. To ensure consistency, the Board did not make any substantive changes to the MOU requirements.

What About Hospitals?

20 CSR 2220-2.425 only applies to entities under the Board's jurisdiction. The Board does not have jurisdiction over medication compounded by a Missouri licensed hospital under the Missouri Dept. of Health and Senior Services' jurisdiction, for administration to the patient within the "licensed premises" of the hospital. However, pharmacy compounding under the Board's jurisdiction would need to be reported to the Board.

When Are Pharmacy Reports Due?

Compounding data must be reported annually to the Board, on or before January 31st each year. Initial compounding reports were due by January 31, 2022. However, due to the FDA's delayed MOU enforcement, the Board has extended enforcement of 20 CSR 2220-2.425 until January 31, 2023. Initial compounding data reports under 20 CSR 2220-2.425 do not have to be filed until January 31, 2023.

The Board strongly encourages pharmacies to start collecting and tracking required compounding data now. Don't wait until January 2023!

How Can I Submit A Report?

Compounding data reports can be manually or electronically submitted to the Board office; A sample reporting form will be available on the Board's website in the fall of 2022.

Alternatively, pharmacies may electronically report compounding data to the Board via the National Association of Boards of Pharmacy's (NABP) Information Sharing Network. NABP's Information Sharing Network is currently a free electronic data exchange operated by NABP for collecting required pharmacy MOU data. Visit NABP's website for NABP registration and technology requirements.

The Board strongly recommends contacting NABP as soon as possible to avoid registration delays. *Note: Pharmacies may begin voluntarily reporting to NABP's Information Sharing Network now and do not have to wait until 2023.*

Questions?

- Questions regarding 20 CSR 2220-2.425 and Missouri's compliance requirements should be addressed to: compliance@pr.mo.gov or (573) 751-0091 *(e-mail is preferred)*.
- Questions regarding NABP's Information Sharing Network should be addressed to NABP at prof-affairs@nabp.pharmacy. The Board office cannot answer questions about the Information Sharing Network.

New Board Statement on Pharmacy Working Conditions

The Board recently mailed the following statement on pharmacy working conditions to all Missouri resident pharmacies:

(Issued 12-17-2021)

The Missouri Board of Pharmacy issued a guidance statement in April 2021 in response to complaints from licensees/registrants and the public regarding Missouri pharmacy working conditions. Despite the Board's guidance, the Board continues to receive an alarming number of complaints/calls regarding pharmacy working conditions in the state.

Examples of recent complaints/calls include (this list is not exhaustive):

1. *Pharmacies with excessive prescription backlogs due to lack of staffing resulting in patients not receiving their medication in a timely manner.*
2. *Pharmacy staff being required to provide the full range of pharmacy services despite being severely understaffed. For example, Board Inspectors recently observed pharmacies with stacks of prescriptions that were multiple days behind. Despite the backlog, pharmacy staff were still required to administer the full range of vaccines, provide COVID-19 testing, answer phones and service drive-thru lanes, with no or limited help. In several instances, requests to pharmacy management from pharmacy staff for additional help were either minimized or ignored.*
3. *Patients have reported excessive wait times when trying to reach a pharmacist by phone. Board Inspectors have personally been placed on hold with pharmacies for thirty (30) minutes to an hour. In some instances, the pharmacy's phone system automatically disconnected patients who were on hold for more than a specific time. In other instances, pharmacy phone lines were not being answered at all.*
4. *Pharmacy staff are still not being given sufficient lunch or rest breaks, or are still required to work an extended number of consecutive days without time off. When breaks are given, licensees/registrants have reported still being expected/required to work during their purported "break time."*

The Board recognizes that Missouri is still experiencing a pandemic and pharmacy demand continues to increase. These challenges may be complicated even more due to nationwide workforce shortages that are impacting Missouri pharmacies.

While the Board recognizes the challenges, the Board's mission is to protect the public. Patient safety should not be put at risk due to pharmacy working conditions, inappropriate staffing, or any other factor that prohibits licensees/registrants from safely and competently providing patient care. As the permit holder, you are responsible for ensuring patient safety. This includes having policies and procedures in place to ensure pharmacy staff have sufficient time, resources and support to provide pharmacy services.

***Effective immediately**, the Board will be investigating Missouri pharmacies if pharmacy working conditions are identified or exist that could threaten or endanger patient safety. This may include reviewing the pharmacy's operations and staffing model in light of the volume of prescription, vaccine and other clinical services. Failure to comply with Missouri law may result in disciplinary action by the Board, which could include up to suspension/revocation of the pharmacy's permit, or referral to the*

Missouri Attorney General's Office for emergency or other injunctive relief.

Don't wait for the Board to take action! Assess your pharmacy's operations now to make sure the pharmacy is operating safely.

1. *The Board understands permit holders have limited control over unanticipated absences/staff vacancies or unexpected increases in pharmacy workload. However, permit holders should have a plan in place for determining if the pharmacy can continue to offer the full range of pharmacy services or maintain normal pharmacy hours, when the pharmacy is understaffed. The Board has received reports of pharmacies taking proactive patient safety measures in these instances, such as temporarily suspending drive-thru service, changing pharmacy hours, or modifying vaccine services until additional staff is available to assist or pharmacy staff can catch up (e.g., vaccines by appointment only). If the pharmacy chooses to close early or temporarily change hours, the Board recommends posting a sign or other notification at the pharmacy and on the pharmacy's website to let patients know about the change as early as possible.*
2. *Have a plan in place for staff to report staffing shortages or to request additional help when needed, especially after-hours and on weekends. Make sure you communicate the plan to pharmacy staff and train pharmacy management on how to respond. Policies and procedures should be in place for taking appropriate action to ensure sufficient staffing.*
3. *Let patients know if the pharmacy is experiencing significant delays or cannot dispense prescriptions in a timely manner. Board Inspectors recently visited a pharmacy that was almost a week behind in dispensing due to a staffing emergency, but continued to accept new prescriptions without notifying patients that their prescriptions may not be filled for days. Delayed medication therapy can place patients at risk. Advise patients if the pharmacy is experiencing lengthy delays and give them a reasonable timeline on when their medication can be expected.*
4. *Review the pharmacy's workflow process to identify areas that may be exacerbating the strain on pharmacy staff. A well-designed system can help alleviate workload stress and enhance patient safety.*
5. *The Board has strong concerns with pharmacies not answering phones or placing patients on hold for an excessive amount of time. Pharmacist consultation is a vital part of patient care. Additionally, other pharmacies and prescribers may need to contact the pharmacy regarding prescriptions or prescription transfers, or to coordinate care. Permit holders should <u>immediately</u> review the pharmacy's operations to make sure patients can speak to a pharmacist within a reasonable amount of time.*
6. *As indicated in the Board's April 2021 guidance statement, licensees/registrants need time to mentally and physically recoup during these unprecedented times of increased demands on the state's healthcare workforce. The Board once again cautions all permit holders to review their policies/procedures to ensure licensees/registrants have adequate, <u>uninterrupted</u> breaks throughout the day to ensure competence and patient safety.*
7. *Finally, patient care is a team-based effort. Talk with pharmacy staff and ask what they need. Asking staff to manage an unsafe workload is unreasonable and dangerous. Patients deserve the best in patient care. Pharmacy staff <u>must have</u> sufficient time, resources and support to properly perform their professional duties.*

Patient safety is a joint effort by everyone on the healthcare team. The Board cautions Missouri

permit holders to take all necessary steps to address any pharmacy conditions that may endanger or threaten patient safety.

Can I submit an anonymous complaint? Generally, complaints must be in writing and signed by the person filing the complaint or include the complainant's name. To protect the public, the Board will accept an anonymous complaint that involves a potential patient safety issue, criminal activity, or substantial compliance issues, provided the complainant provides sufficient information to allow the Board to investigate. At a minimum, complaints should include:

- The name of the pharmacy and/or Board licensee/registrant,
- The pharmacy address (if applicable)
- The date(s) of the alleged conduct, and
- A clear description of why the complaint of the alleged activity. The Board cannot investigate complaints that do not include sufficient details to allow the Board to properly investigate (e.g., "XYZ Pharmacy is not complying with the law," or "XYZ Pharmacy is really bad").

Visit the Board's website for complaint forms and additional complaint information at: https://pr.mo.gov/pharmacists-file-a-complaint2.asp