

EFFECTIVE AUG 30, 2022

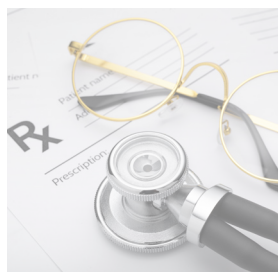
NEW PHARMACY RULES

The Board recently revised/promulgated several pharmacy rules as part of its ongoing efforts to increase patient safety, implement standards of practice, and streamline Board regulation. The summary below highlights new rule provisions that will be effective August 30, 2022. Licensees should review the new rule provisions in their entirety to ensure compliance:



20 CSR 2220-2.010 (Pharmacy Standards of Operation): All provisions below will be effective on August 30, 2022:

- **General Operations:** Section 20 CSR 2220-2.010(1)(A) was amended to prohibit pharmacies from introducing any policies, procedures, systems, practices that jeopardize, inhibit, or threaten patient safety or the safe provision of pharmacy services. This includes enforcing any metrics, quotas, or performance/target goals that endanger safe patient care. Remember, patient safety is your first priority!
- **Staff Training/Competency:** Individuals practicing or assisting in the practice of pharmacy must be appropriately trained and competent to perform the duties assigned. The Board recommends that licensees document training and establish a plan for assessing staff's initial and ongoing competency (see 20 CSR 2220-2.200 for sterile compounding requirements)



- **Pharmacy Resources:** The following resources must be physically maintained at the pharmacy or immediately accessible electronically:
 - a. A current print or electronic edition of statutes and rules governing the pharmacy's practice, including, but not limited to, Chapter 338 and 195, RSMo, 20 CSR 2220-2.220 (Board's rules) and, if applicable, BNDD rule chapter 19 CSR 30 governing controlled substances.
 - b. Generally recognized reference(s) or other peer-reviewed items that include the following items/topics:
 - All drugs approved by the United States Federal Drug Administration (FDA), as appropriate to the practice site. Note: This resource may be different based on the pharmacy services provided (e.g., nuclear pharmacy vs. community/ambulatory pharmacy)
 - Pharmacology of drugs
 - Dosages and clinical effects of drugs; and
 - Patient information and counseling



Pharmacies may maintain the above information in one or multiple references, provided the information is regularly retrievable on inspection.

- **Regulatory Sign:** All pharmacies located in Missouri must post a sign that indicates the pharmacy is licensed and regulated by the Missouri Board of Pharmacy and includes the Board's current mailing and e-mail addresses. The required Board regulation sign is enclosed with this package. The sign must be prominently posted in close proximity to the pharmacy in a manner and location that is easily viewable and readable by the public.

Pharmacies may also create their own signs or display an electronic sign, provided the sign's lettering equals or exceeds the sign issued by the Board. Electronic copies of the required Board signage will be available on the Board's website before August 30th for copying/reproduction. Electronic signs must be constantly visible by the public during the pharmacy's normal business hours. [20 CSR 2220-2.010(1)(L)3.]

- **Electronic Signage:** To accommodate technology, the "No Pharmacist On Duty" sign required to be posted when a pharmacist is not on duty can now be displayed in print or electronically. Signs must be prominently displayed on all entrances doors and the pharmacy's prescription counter. Sign lettering must be at least two (2) inches in height (paper or electronic). [20 CSR 2220-2.010(1)(A)]



- **Identification Badges:** Effective August 30, 2022, all Board licensees and registrants must wear an identification badge or a similar identifying article that identifies the licensee's/registrant's name and title when practicing or assisting in the practice of pharmacy (e.g., pharmacist, pharmacy technician, intern pharmacist).

The type of ID badge/article is in the pharmacy's discretion. Reusable or hand-written badges are acceptable. At the discretion of the permit holder, the badge may include the licensee's/registrant's full name, first name and last initial, or first name (e.g., Jane Doe, Jane D., or Jane). [20 CSR 2220-2.010(1)(L)1.] Pharmacy's should establish policies/procedures for allowed identification badges to ensure consistency and easy public identification.



- **License Posting:** In light of the ID badge requirement, 20 CSR 2220-2.010(1)(L) has been amended to allow pharmacists to maintain pharmacist, intern pharmacist and pharmacy technician licenses/registrations in a central location on the pharmacy's premises along with a 2" x 2" photo that is attached to the license (e.g., on the pharmacy wall or in a binder or cabinet). **The photo requirement is new for technicians and intern pharmacists** and will be effective on August 30, 2022.

Licenses/registrations must be immediately retrievable during an inspection or available to the public if requested. Licensees/registrants working at more than one (1) pharmacy must have proof of licensure in their possession while practicing/assisting in the practice of pharmacy (e.g., wallet card, current online verification from the Board's website). By statute, the pharmacy's license must still be conspicuously posted in the pharmacy permit area [§ 338.300, RSMo]

- **Sanitation:** For sanitation purposes, pharmacy staff must wear disposable gloves when physically touching individual med-



ication/dosage units (tablets, capsules, etc.) Gloves are not required when handling outer containers/vials/packaging, although it may be best practice in some instances. [20 CSR 2220-2.010(1)(I)]

- **Medication Storage:** 20 CSR 2220-2.010(1)(G) currently requires that temperatures in medication storage areas must be thermostatically controlled within appropriate temperature requirements. Beginning August 30, 2022, temperatures in drug storage areas must be recorded and reviewed at least once each day the pharmacy is in operation. This includes all rooms, areas, refrigerators, or freezers where drugs are stored. Alternatively, pharmacies may use a continuous temperature monitoring system if the system: (1) maintains ongoing documentation of temperature recordings, and (2) alerts a pharmacist when temperatures are outside of the required range and provide the amount of variance. **Real-time alerts are recommended (e.g., audible alert, electronic notification, phone call).** At a minimum, continuous monitoring systems should alert the pharmacist in sufficient time to allow the pharmacist or his/her designee to quickly respond to temperature issues to ensure drug integrity. A continuous temperature monitoring system is optional and is not required if the pharmacy otherwise records and reviews medication storage area temperatures daily.
- **Off-Site Storage:** Off-site storage facilities/warehouses used by a pharmacy to store pharmaceuticals or required/confidential pharmacy at a separate address or premises from the main facility must be equipped with a functioning alarm system. Breaches of security must be reported to the Board electronically or in writing within fifteen (15) days of the breach. Security breach notifications can be e-mailed/mailed to the Board office at: pharmacy@pr.mo.gov or 3605 Missouri Blvd., Jefferson City, Missouri 65109 (e-mails are preferred). Proof of the required notification should be kept in the pharmacy's records. [20 CSR 2220-2.010(1)(J)]
- **Pharmacist-In-Charge Requirements:** 20 CSR 2220-2.010(1)(M) has been amended to provide that the designated pharmacist-in-charge (PIC) must be actively engaged in pharmacy activities at the pharmacy and must be physically present at the pharmacy for a sufficient amount of time as needed to effectively supervise pharmacy operations and ensure pharmacy compliance. In line with a standards-based practice approach, the Board chose not to include a uniform hour/day requirement in the rule that may not be appropriate for all pharmacies. Instead, the Board encourages PICs and permit holders to evaluate pharmacy demand/workload and engage in open dialogue to collaboratively develop a solution/work schedule.
- **PIC Changes:** A Change of Pharmacist-in-Charge application must now be submitted to the Board within fifteen (15) days of the PIC change. [20 CSR 2220-2.010(1)(M)1.] Pharmacy owners have indicated that finding a new PIC may take additional time and expressed concerns with adversely impacting patients if the pharmacy is forced to unexpectedly close due to a PIC vacancy (death, illness, other emergency). In response, 20 CSR 2220-2.010 was amended to allow pharmacies to appoint an interim supervising pharmacist for up to thirty (30) days, if a new PIC cannot be immediately designated despite reasonable diligence.

 - a. For Missouri resident pharmacies, the Interim Supervising Pharmacist must hold a current and active Missouri pharmacist

license. For non-resident pharmacies, the Interim Supervising Pharmacist must be licensed as a pharmacist in the state where the pharmacy is located.

- b. Written notification of an interim supervising pharmacist designation must be immediately e-mailed to the Board office at: pharmacy@pr.mo.gov or faxed to the Board office at: (573) 526-3464. Additionally, the interim supervising pharmacist must complete an Interim Supervising Pharmacist Designation form with the Board agreeing to be responsible for pharmacy compliance while serving as the interim supervising pharmacist. No fees are required for the interim supervising pharmacist designation/designation form.
 - c. A documented controlled substance inventory must be taken when the interim supervising pharmacist is designated. Proof of compliance will be requested during an inspection.
 - d. Interim supervising pharmacists may only serve for thirty (30) days. A Missouri Change of Pharmacist-in-Charge application must be submitted when a permanent PIC is designated. A Pharmacist-In-Charge must be officially designated with the Board after the thirty (30) day period; A new Interim Supervising Pharmacist cannot be named.
- **Mandatory Reporting:** The following notifications must be submitted to the Board electronically or in writing within fifteen (15) days of the action:
 - a. Any adverse action by another licensing state, jurisdiction, or government agency against the licensee, registrant, or permit holder, as defined/required by § 338.075.
 - b. For Pharmacies: Any final action taken against a pharmacist, intern pharmacist, or pharmacy technician for conduct that might have led to disciplinary action under § 338.055, or resignation of a licensee/registration in lieu of such disciplinary action.

Required notifications must include the pharmacy's name and permit number, name and contact information of the person making the notification, the licensee's/registrar's name and license/registration number, date of action, and the reason for action.

20 CSR 2220-2.090 (Pharmacist-In-Charge):

The rule has been significantly streamlined to eliminate unnecessary language. The rule has also been amended to emphasize the PIC's co-responsibility for managing pharmacy compliance and to ensure appropriate PIC involvement with pharmacy operations.

- Similar to 20 CSR 2220-2.010(1)(M), the amended rule provides the PIC must be actively engaged in pharmacy activities at the pharmacy and must be physically present at the pharmacy for a sufficient amount of time as needed to effectively supervise pharmacy operations and ensure pharmacy compliance (see Pharmacist-In-Charge Requirements above).
- PICs must be consulted and given an opportunity to provide input prior to implementing any policy, procedure, system, or practice that will modify or expand the delivery of pharmacy services.
- Pharmacy permit holders must provide the PIC designated time to review pharmacy compliance on a regular basis while not engaged in medication dispensing or providing patient services. The Board recommends establishing a specific day/time for the required PIC review in advance; Proof of compliance will be requested during an inspection.
- To address pharmacy working conditions, the permit holder must establish policies and procedures for regularly reviewing staffing and resource needs with the PIC, including policies and procedures for requesting additional staff or staffing modifications. The mode/method of collaboration is in the permit holder's discretion but should provide the PIC a meaningful opportunity to discuss staffing concerns/needs.
- The PIC must have authority to temporarily suspend or restrict pharmacy operations or activity if deemed reasonably necessary or appropriate to ensure pharmacy compliance or the safe provision of pharmacy services, pending final direction of approval from the permit holder. A clear and documented permit holder/PIC communication and action plan is key here and will limit pharmacy interruptions.

Questions? Visit the Board's website for additional information.