Pharmacist-In-Charge FAQ

This FAQ contains basic compliance information for licensees designated as Pharmacist-In-Charge (PIC) and does not constitute a comprehensive review of all regulatory requirements. To ensure compliance, licensees should independently review all applicable state and federal law governing pharmacy practice.

Q: **What are my responsibilities?**
A: Under Missouri law, the pharmacist-in-charge (PIC) is responsible for ensuring pharmacy compliance with all state and federal law. Rule 20 CSR 2220-2.090 contains a detailed listing of specific PIC responsibilities/duties. These duties include ensuring:

- The pharmacy is under the supervision of a Missouri-licensed pharmacist whenever prescriptions are compounded, dispensed or sold;
- The pharmacy is clean and sanitary at all times;
- Traffic in the prescription area is restricted to authorized personnel so that proper controls can be maintained over drug inventory;
- The pharmacy complies with all state/federal controlled substance laws, including, all security, dispensing and recordkeeping requirements;
- All licenses/registrations are current and displayed (pharmacists, technicians);
- Excessive or suspicious controlled substance requests are verified prior to dispensing;
- Prescription files are properly maintained;
- The pharmacy has all required equipment/reference materials. Equipment must be in good working order;
- Pharmacy policies/procedures are current and comply with Missouri law;
- The pharmacy maintains sufficient controls to prevent diversion, deter theft and to maintain the safety and integrity of legend drug inventory;
- Controlled substance disposals are conducted and documented as required by state/federal law;
- No outdated drugs are dispensed or maintained in the pharmacy’s active inventory, including prescription and related nonprescription items;
- The pharmacy complies with state/federal labeling, drug distribution and patient counseling laws;
- Automated dispensing and storage systems comply with state/federal law, and;
- The pharmacy has a technician list that includes each technician’s name, registration number and duties.

[This list is a general summary only. 20 CSR 2220-2.090 contains additional duties/responsibilities which should be carefully reviewed before assuming PIC duties.]

Q: **Can I be PIC for multiple pharmacies?**
A: Yes. However, you will be held responsible for actively supervising and monitoring each pharmacy. Licensees are strongly cautioned to consider the volume and nature of each pharmacy’s activities prior to accepting PIC responsibilities at multiple pharmacies.
**Q:** What should I do after being named PIC?
**A:** An inventory of all Schedule II – V controlled substances must be conducted on the day you begin serving as PIC. The Board also recommends the following:

- Immediately assess the pharmacy’s compliance. The Board’s [Pharmacy Self-Assessment Guide](https://renew.pr.mo.gov/licensee-search.asp) contains detailed assessment standards that can be used to assist you.
- Thoroughly review [20 CSR 2220-2.090](https://renew.pr.mo.gov/licensee-search.asp) governing PIC responsibilities. Remember, you are now responsible for compliance!
- Verify that all licenses/registrations are current. License/registration status may be verified online at [https://renew.pr.mo.gov/licensee-search.asp](https://renew.pr.mo.gov/licensee-search.asp).
- Verify that the pharmacy’s permit reflects the appropriate classification(s). **Note:** A Class-H (Sterile Compounding) permit is required for compounding bladder irrigation products.
- Review all pharmacy policies/procedures and make appropriate changes.
- Review the pharmacy’s security equipment and procedures for compliance/adequacy.
- Review previous BNDD and Board inspection reports to identify compliance issues. Make sure compliance concerns have been corrected.
- Verify that pharmacists providing immunization services or administering medication by medical prescription order have complied with all requirements of [20 CSR 2220-6.040](https://renew.pr.mo.gov/licensee-search.asp) and/or [20 CSR 2220-6.050](https://renew.pr.mo.gov/licensee-search.asp). Specifically review any immunization protocols.
- Remember to complete all applicable BNDD or DEA forms/notifications (i.e.- DEA required Power of Attorney forms).

**Q:** How often is a PIC required to be on-site?
**A:** Missouri law doesn’t impose a specific time or minimum number of hours. However, PICs should be actively engaged in monitoring the pharmacy’s activities. Never agree to serve as PIC unless you are able to meet all PIC supervision and monitoring requirements.

**Q:** Can I be personally disciplined for pharmacy violations?
**A:** **YES.** Pursuant to § [338.210.5](https://renew.pr.mo.gov/licensee-search.asp), RSMo, a PIC’s pharmacist license can be disciplined for pharmacy violations. This does not mean that violations will automatically result in discipline. However, as PIC, you are personally responsible for supervising pharmacy staff and monitoring pharmacy compliance.

**Q:** What should I expect during an inspection?
**A:** The Board’s [Pharmacy Inspection Guide](https://renew.pr.mo.gov/licensee-search.asp) contains detailed information about the inspection process and a list of required records/documents that your inspector will review. The Board utilizes the inspection process to educate licensees. Fully utilize the time with your inspector to discuss compliance questions/concerns. **Note:** An inspection will be completed even if the PIC is absent. Make sure records/documents are readily retrievable by pharmacy staff.

**Q:** What are the most common compliance violations?
**A:** The Board’s “Compliance Top 10” brochure identifies the most commonly observed compliance violations and is available on the Board’s [website](https://renew.pr.mo.gov/licensee-search.asp). However, PICs should review all pharmacy activities to ensure full compliance. The Board has published several resources that can assist in your review, including, the [Missouri Pharmacy Self-Assessment Guide](https://renew.pr.mo.gov/licensee-search.asp) and the [Missouri Pharmacy Practice Guide](https://renew.pr.mo.gov/licensee-search.asp). The [Pharmacy Practice Guide](https://renew.pr.mo.gov/licensee-search.asp) contains detailed compliance information on a variety of compliance requirements as well as related inspection notes and reference citations.
Q: **What is the “Compliance Is Key” Initiative?**
A: In July of 2011, the Board announced its *Compliance Is Key* initiative. The goal of the initiative is to **increase public safety** by promoting voluntary pharmacy compliance through education, assessment and awareness. Information on the *Compliance Is Key* initiative and additional education/compliance materials are available on the Board’s website at [http://pr.mo.gov/pharmacists.asp](http://pr.mo.gov/pharmacists.asp). Free CE is also available!

Q: **What policies and procedure manuals are required?**
A: The following **written** policy and procedure manuals are required (if applicable to the pharmacy’s services):

a. **Class I Services (consultant pharmacy in residence)**
   - 20 CSR 2220-2.010(10)(B)

b. **Technician responsibility/supervision**
   - 20 CSR 2220-2.090(2)(CC)

c. **Long-term care**
   - 20 CSR 2220-2.140(2)

d. **Nuclear services**
   - 20 CSR 2220-2.500(2)(E)

e. **Renal dialysis services**
   - 20 CSR 2220-2.600(2)(E)

f. **Class J services**
   - 20 CSR 2220-2.650(1)(C)

g. **Automated systems**
   - 20 CSR 2220-2.900(1)(B)

h. **Administration by medical prescription order**
   - 20 CSR 2220-6.040(4)(C)

i. **Sterile Products**
   - 20 CSR 2220-2.200(2)

Manuals can be maintained electronically but must be readily retrievable during an inspection.

Q: **What are Missouri’s technician requirements?**
A: Any person who assists in the practice of pharmacy must be registered with the Board as a pharmacy technician. [See 20 CSR 2220-2.700] Additionally, “any person other than a pharmacist or permit holder who has independent access to legend drug stock on a routine basis” must be registered. The PIC is responsible for determining if registration is required.

Technicians may assist in any area of pharmacy practice. However, technicians must be under the “direct supervision and responsibility” of a Missouri-licensed pharmacist at all times. [20 CSR 2220-2.700]. Additionally, technicians may not perform any activity that requires the “professional judgment” of a pharmacist. Prohibited activities include, but are not limited to:

- Receiving or providing refill transfer information for controlled substance prescriptions [20 CSR 2220-2.120];
- Drug utilization review;
- Patient counseling, and;
- Final verification of a prescription before dispensing. All prescriptions labeled, prepared or compounded by a technician must be finally checked by a pharmacist before dispensing, including, reconstituted products.

Technicians cannot sell, compound, dispense or distribute prescriptions when the pharmacist is absent- even if previously checked by a pharmacist. Technicians are also prohibited from taking verbal prescription orders, processing refills, generating labels or entering prescription data in the pharmacist’s absence. Note: The Board has determined that technicians may accept written prescriptions from patients when the pharmacist is absent.

Q: **When should technician disciplinary action be reported to the Board?**
A: Written notification of technician disciplinary action must be filed with the Board within fifteen (15) days after the action. This requirement applies to any final disciplinary action that constitutes grounds for discipline under § 338.055, RSMo, including, but not limited to, probation, suspension,
demotion or reassignment. PICs must also report technicians who voluntarily resign while a complaint/report is pending that alleges conduct that may be cause for discipline under § 338.055.

Notification of Technician Action forms may be filed online, e-mailed to compliance@pr.mo.gov or faxed to the Board office at (573) 526-3464.

Q: What should I do if I am no longer PIC?
A: You are required to immediately notify the Board when you stop serving as PIC. Notifications can be e-mailed to the Board at pharmacy@pr.mo.gov or faxed mailed to the Board office.

If you are the new PIC, you can begin serving as PIC immediately after the change. However, a fully completed Pharmacist-In-Charge Change application must be promptly submitted to the Board. Documentation of the application mailing date should be maintained in the pharmacy's records. Applications not received in a timely fashion may result in the PIC designation being voided or other disciplinary review/action.

Q: What if I have questions?
A: Please see the following Board contact numbers. Questions may also be addressed to your inspector (see Inspector Contact List). Note: Inspectors are frequently in the field and may not be immediately available to respond to your inquiry. In the event of an emergency, please contact the Board office.

- Compliance Questions
  (573) 751-9056/compliance@pr.mo.gov
- Intern Licensure
  (573) 751-0092/intern@pr.mo.gov
- Drug Distributors
  (573) 526-6985/drugdistributor@pr.mo.gov
- Pharmacist Licensure
  (573) 751-0092/pharmacist@pr.mo.gov
- General Questions
  (573) 751-0091/pharmacy@pr.mo.gov
- Pharmacy Licensure
  (573) 526-6985/pharmacy@pr.mo.gov
- Legal Questions
  (573) 751-0093/lawquestions@pr.mo.gov
- Technician Registration
  (573) 522-2425/technician@pr.mo.gov
- Tax Compliance/HB 600 Suspensions
  (573) 751-0093/tammy.siebert@pr.mo.gov

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MO. Bureau of Narcotics and Dangerous Drugs (BNDD)
(573) 751-6321
http://health.mo.gov/safety/bndd/

- DEA- Kansas City
  (913) 825-4100
  www.deadiversion.usdoj.gov

- DEA- St. Louis
  (314) 538-4600
  www.deadiversion.usdoj.gov
Additional Compliance Tips

Avoid compliance issues by practicing some of the following:

- Be as familiar as you can with state and federal pharmacy and drug laws/regulations. Knowing what you’re accountable for will help in designing your overall pharmacy management plans.
- Regularly review the law for updates and changes and educate pharmacy staff.
- Establish an open communication plan for discussing compliance concerns/questions. *Compliance is a team effort!*
- Schedule a time to physically review the pharmacy’s operations—especially during peak business hours. A commitment to actively monitoring the pharmacy can go a long way.
- Review inspection reports with pharmacy staff and discuss compliance areas.
- Periodically review the pharmacy’s records for compliance (i.e., compounding log, pharmacist signature log). Remember, the “little” things are important.
- Sign up for the Board’s newsletter and electronic e-alerts for additional compliance information. Licensees can register online at [www.nabp.net/indexmobop.asp](http://www.nabp.net/indexmobop.asp) or by e-mailing MissouriBOPNewsletter@nabp.net.

Additional Resources

- Pharmacy Self-Assessment Form [http://pr.mo.gov/pharmacists.asp](http://pr.mo.gov/pharmacists.asp)