

MISSOURI PHARMACY PRACTICE GUIDE

2020



Missouri Board of Pharmacy
pr.mo.gov/pharmacists



MESSAGE FROM THE BOARD

The Missouri Board of Pharmacy is pleased to provide the *Missouri Pharmacy Practice Guide*. The Pharmacy Practice Guide is designed to increase licensee compliance by providing guidance on basic provisions of Missouri's law governing pharmacy practice.

The Board has served Missouri citizens through the regulation and licensing of the pharmacy profession since 1909. The Board is an autonomous Board within the Division of Professional Registration, an agency of the Missouri Department of Commerce and Insurance. The Board's mission is to serve and protect the public in the practice of pharmacy by providing an accessible, responsible and accountable regulatory system that:

- Protects the public;
- Licenses only qualified professionals; and
- Enforces practice standards.

The Board consists of seven (7) members, including, one (1) public member and six (6) licensed pharmacists actively engaged in the practice of pharmacy in Missouri.

Additional pharmacy resources and compliance materials are available on the Board's website at pr.mo.gov/pharmacists. The Board also provides license and regulatory updates via e-alerts and the Board's electronic newsletter. Interested parties can sign up for the Board's newsletter and e-alerts at public.govdelivery.com/accounts/MOIFP/subscribers/new?preferences=true.

The Missouri Pharmacy Practice Guide is provided for informational purposes only and does not constitute a rule statement of general applicability or binding law. Additionally, the Practice Guide does not constitute a comprehensive review of all governing law or controlled substance requirements. To ensure compliance, licensees should independently review [Chapter 338](#), RSMo, 20 CSR 2220 and all applicable state and federal laws. Statutes/rules may have changed since this document was issued. In the event of a conflict or inconsistency, duly promulgated or enacted state or federal law shall control. The Board expressly reserves the right to revise the contents as deemed appropriate or necessary. Questions regarding this document can be e-mailed to MissouriBOP@pr.mo.gov.

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SECTION A: REGULATORY INFORMATION

A.1 BOARD AUTHORITY

Pursuant to [Chapter 338](#), of the Revised Statutes of Missouri, the Board has regulatory authority over the practice of pharmacy in Missouri which includes, but is not limited to, monitoring compliance, conducting investigations/inspections and licensing pharmacists, intern pharmacists, pharmacy technicians, pharmacies, drug distributors, drug outsourcers and third-party logistics providers. The Board's administrative rules are promulgated in [Chapter 20 CSR 2220](#) of the Missouri Code of State Regulations.

- The Missouri Bureau of Narcotics and Dangerous Drugs (“BNDD”) regulates controlled substance distribution in Missouri. However, the Board monitors and inspects compliance with applicable controlled substance drug laws. For controlled substance questions, contact BNDD at (573) 751-6321 or e-mail bndd@health.mo.gov. *E-mail is preferred.*
- The Missouri Department of Health and Senior Services (DHSS) has regulatory jurisdiction over pharmacy services provided within the “licensed premises” of a Missouri hospital (see [Chapter 197](#)). However, Class-B hospital pharmacies are under the Board's jurisdiction (see [D.9](#)). DHSS related hospital questions should be addressed to (573) 751-6303 or info@health.mo.gov.

A.2 COMPLIANCE AND EDUCATION

The Board is committed to promoting voluntary compliance through education and awareness. A variety of free practice resources are available on the Board's website including:

1. **Brochures/Compliance Guides:** Brochures on a variety of compliance topics are available online at <https://pr.mo.gov/pharmacists-publications-resources.asp>, including, Inspector Tips for Preventing Drug Diversion, the Compliance Top 10, the Pharmacist Immunization/Administration Checklist and the Pharmacy Self-Assessment Guide. Resources are also available for technicians such as the Technician Compliance Guide and a free online Technician Quiz.
2. **Webinars:** The Board periodically hosts free webinars to discuss emerging compliance issues and trends. Pharmacist CE is available for attending live webinars. Recorded webinars are available on the Board's website for on-demand review at <http://pr.mo.gov/pharmacists-publications-resources.asp#videos>.
3. **Newsletters/E-Alerts:** Sign-up for the Board's newsletter and e-alerts at public.govdelivery.com/accounts/MODIFP/subscriber/new to receive webinar notices and other regulatory updates, including, notification of technician disciplinary actions.

A.3 DISCIPLINARY AUTHORITY

The Board may impose discipline if a licensee/registrant, or any officer, owner, pharmacist-in-charge or manager-in-charge, has committed any act identified in [§ 338.055.2](#). Grounds for disciplinary action include, but are not limited to:

1. Using a controlled substance or alcoholic beverage to an extent that such use impairs a licensee's/registrant's ability to practice;
2. Being finally adjudicated and found guilty, or entering a plea of guilty or nolo contendere, for any criminal offense reasonably related to the qualifications, functions or duties of any profession licensed or regulated by [Chapter 338](#), for any offense an essential element of which is fraud, dishonesty or an act of violence, or for any offense involving moral turpitude (this includes a suspended imposition of sentence or “SIS”);
3. Obtaining or attempting to obtain any fee or other compensation by fraud, deception or misrepresentation;
4. Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by [Chapter 338](#);
5. Violating, or assisting or enabling any person to violate, [Chapter 338](#) or any Board rule;
6. Assisting or enabling any person to practice or offer to practice without the required Board license, registration or permit;



SECTION A: REGULATORY INFORMATION

7. Violating any professional trust or confidence;
8. Violating state or federal drug laws/regulations;
9. Intentionally substituting or changing the content, formula or brand of any drug prescribed without prior prescriber approval; or
10. Using any controlled substance unless it is prescribed, dispensed, or administered by an authorized health care provider. See [§ 338.055](#) for a list of all disciplinary grounds.

Disciplinary action may include, but is not limited to, public censure, probation, suspension or revocation. If revoked, the Board may prohibit a licensee from reapplying for licensure for up to seven (7) years.

B.1 GENERAL REQUIREMENTS

No person may perform, or offer to perform, the practice of pharmacy in the state of Missouri without a current and active Missouri pharmacist license. (See § 338.010.1 or Section C.1 for the definition of “*practice of pharmacy*”). A pharmacist license is not required for legally registered practitioners of medicine, dentistry, podiatry, veterinary medicine or optometry that are lawfully compounding or dispensing their own prescriptions. [§ 338.010.1]

In addition to a Missouri pharmacist license, additional certification and/or Board notification is required for pharmacists performing the following services:

- Administering Medication By Prescription Order (See Section L)
- Immunizing by Protocol (See Section M)
- Medication Therapy Services (See Section N)

B.2 NAME, ADDRESS & EMPLOYMENT CHANGES

The following requirements apply to all Missouri licensed pharmacists:

- **Name Changes:** Name changes must be submitted to the Board in writing along with legal documentation of the change (e.g., marriage certificate, court order, divorce order). Once received, your name will be officially changed in the Board records. A **Duplicate License Request** application should be submitted if you would like your pharmacist license to be reissued under the new name (applications are **online**; fees will apply).
- **Employment Changes:** Employment changes must be submitted to the Board no later than fifteen (15) days after the change. [20 CSR 2220-2.010(1)(Q)]. Changes can be submitted online at renew.pr.mo.gov/pharmacists-coa.asp.
- **Address Changes:** Address changes should be submitted as soon as possible to ensure sufficient communication. Correspondence returned to the Board because of an incorrect address will not be resent until a correct address is provided. [20 CSR 2220-2.010(1)(N)]. Changes can be submitted online at renew.pr.mo.gov/pharmacists-coa.asp.

B.3 RENEWALS/CONTINUING EDUCATION

Pharmacist licenses must be renewed by October 31st of every even numbered year (e.g., 2020, 2022, 2024). To renew, pharmacists must file a renewal application with the required fee and complete 30 hours of approved continuing education (CE) (or 3.0 CE units). [20 CSR 2220-7.080].

CE must have been earned from November 1st and October 31st of the current even-numbered renewal years. For example, licensees renewing in 2020 must have completed 30 CE hours from November 1, 2018 to October 31, 2020. Although the CE deadline is October 31st, CE must be completed before a renewal is submitted. CE may not be carried over from prior renewal years.

Eligible CE must be provided by either an ACPE accredited provider or approved by the Board in advance. To be approved, non-ACPE classes/courses must be:

- Offered by a governmental or regulatory agency and approved by the Board, or
- Related to the practice of pharmacy as approved by the Board.

Pharmacists must attest that their CE is complete as part of the renewal application. Submitting a false attestation is grounds for discipline. Do **not** renew online or submit a paper application until your CE is complete. If CE is not complete by the end of the renewal period, pharmacists can choose to go inactive until the required CE is finished. Please contact the Board office for additional information on going inactive. Inactive licensees are not eligible to practice.

SECTION B: PHARMACIST LICENSING

Applications to approve a non-ACPE accredited course may be found at: pr.mo.gov/boards/pharmacy/375-0419.pdf and should be submitted at least thirty (30) days prior to the date of the program. Only non-ACPE courses have to be pre-approved. The Board will not approve non-ACPE classes that have already been taken.

Missouri law does not require continuing education in specific categories, except for pharmacists who are:

- Immunizing by protocol (*See Section M*)
- Providing medication therapy services (*See Section N*), or
- Counseling bleeding disorder patients (*See D.13*)

Licensees should review [20 CSR 2220-7.080](#) for a complete listing of Missouri CE requirements. A CE Compliance Chart is also provided below. The Board randomly audits CE compliance. Proof of CE must be maintained in the licensee's records for two renewal cycles and provided on request.

| Who? | Number of hours required | CE DATE RANGE (Your CE must be earned in this date range) | Can I use it as part of my 30 hours? | Notes |
|--|---|--|--------------------------------------|---|
| All Missouri licensed pharmacists (In-state & out-of-state) [20 CSR 2220-7.080] | 30 | 11/1 - 10/31 of EVEN numbered years (e.g., Nov. 1, 2018 - Oct. 31, 2020; Nov. 1, 2020 - Oct. 31, 2022, etc.) | Yes | |
| Pharmacists dispensing/providing patient counseling on blood clotting factor concentrates [20 CSR 2220 - 6.100(3)] | 4 hours of approved CE related to blood clotting factor concentrates, infusion treatment or therapy or blood clotting disorders or diseases | 11/1 - 10/31 of evennumbered years (e.g., Nov. 1 2018 - Oct. 31, 2020; Nov. 1, 2020 - Oct. 31, 2022, etc.) | Yes | The CE requirement only applies to certain pharmacists dispensing blood clotting factor concentrates and pharmacists who provide patient counseling regarding blood-clotting factor concentrates to bleeding disorder patients. See 20 CSR 2220-6.100(3) for definitions of "blood-clotting product" and a "bleeding disorder patient" and for more information on who needs to comply. |
| Pharmacist Immunizing by Protocol [20 CSR 2220-6.050(3)] | 2 hours of approved CE related to administering vaccines or CDC immunization guidelines | 11/1 - 10/31 of even numbered years (e.g., Nov 1, 2018 - Oct. 31, 2020; Nov. 1, 2020 - Oct. 31, 2022, etc.) | Yes | CE may also be used to satisfy your biennial pharmacist CE requirements; Notifications of Intent to Immunize by Protocol can now be renewed with your pharmacist license. |
| Pharmacists with a Certificate of Medication Therapeutic Services ("MTS Certificate") [20 CSR 2220-6.070] | 6 hours of approved CE related to medication therapy management | 11/1 - 10/31 of evennumbered years (e.g., Nov. 1 2018 - Oct. 31, 2020; Nov. 1, 2020 - Oct. 31, 2022, etc.) | Yes | The Board will accept approved MTS CE related to any drug therapy or disease state management. These courses generally have an "01" Drug Therapy Related ACPE universal activity number (Example: ACPE Universal Activity Number: xxxx-xxxx-xx-xxx-x01-x). |
| Intern Pharmacists/ Pharmacy Technicians | NO CE REQUIREMENTS | NO CE REQUIREMENTS | N/A | |

SECTION B: PHARMACIST LICENSING

Suicide Prevention: Section 324.046 provides training in suicide assessment, referral, treatment and management may qualify for pharmacist continuing education credit. However, non-ACPE accredited courses must be pre-approved by the Board. Credit will not be given for courses taken before the Board approves them. CE in suicide prevention is recommended by the Board but not required.

B.4 INACTIVE LICENSES [20 CSR 2220-7.080(9)]

Pharmacists may only place their license on inactive status during the biennial pharmacist renewal period and cannot request to go inactive at any other time. Once processed, an inactive pharmacist license will be issued by the office. Inactive licenses must be renewed biennially; Continuing education is not required to renew as inactive. Inactive licensees may not practice pharmacy in the state of Missouri. However, inactive licensees are still eligible for the 50-year gold certificate.

To return to active status, licensees must file an application with the Board and submit proof of the required continuing education for each renewal period that the licensee was inactive. For example, licensees who are inactive for three renewal periods must submit proof of ninety (90) hours of continuing education (30-hours for each renewal period).

B.5 JURY DUTY

Section 494.430.1(5), RSMo, allows a pharmacist to be excused from jury duty if he/she is providing health care services to patients and serving as a juror would be detrimental to patient health. This exemption is not automatic and must be granted by a judge.

B.6 MILITARY LICENSEES

A Missouri pharmacist license is not required for pharmacists serving in the United States armed forces, or pharmacists employed by the U.S. government or any U.S. agency/bureau, who are engaged in the practice of pharmacy while in the discharge of their official duties. This exemption only applies to pharmacy services provided as part of the pharmacist's federal/military duties or employment. A Missouri pharmacy license is required if the pharmacist is practicing outside of his/her federal or military duties (e.g., independently practicing at a retail pharmacy). [[§ 338.020.2, RSMo.](#)]

Late Renewals/CE Exemption: A pharmacist may renew his/her license for no fee if the pharmacist's license expired while on active duty in the U.S. armed services/Coast Guard/state militia, or expired while in training or education prior to being inducted into the military. [[Section § 338.060.2](#)] Renewal applications must be submitted within one (1) year after terminating the applicable military service, training or education. Section 41.946, RSMo, waives Missouri's CE requirements for licensees who did not renew their license while completing military service.

To submit a late renewal or to request a CE exemption, pharmacists must provide an affidavit attesting that the pharmacist was engaged in military service as provided by [§ 338.060.2](#), RSMo. Alternatively, the Board will accept official discharge documentation. The affidavit/documentation must include:

- The pharmacist's name,
- The date service/training/education began and ended, and
- The status of termination (e.g., completed, honorably discharged, etc.). *Note: The late renewal allowance does not apply if dishonorably discharged.*

For questions about military renewals/licensing, e-mail pharmacist@pr.mo.gov.

Exam Reimbursement: Veterans may be eligible for reimbursement from Veterans Affairs for the Board's licensing exam fees. Visit the [Veterans Affairs website](#) to learn more about how the GI Bill can pay the cost of a license or certification test or call 888-GIBILL-1 (888-442-4551), or for the hearing-impaired call 800-829-4833.

B.7 REPORTING DISCIPLINARY/ADVERSE ACTIONS

Pharmacists must self-report the following information to the Board within seven (7) days after the action:

1. Any final adverse action taken by another licensing state, jurisdiction or governmental agency against any license to practice or operate as a pharmacist, intern pharmacist, pharmacy technician, pharmacy, drug distributor, drug manufacturer or drug outsourcing facility,
2. Any surrender of a license or authorization to practice as a pharmacist, pharmacy, drug distributor, drug manufacturer, pharmacy technician, intern pharmacist or drug outsourcer, and
3. Any exclusion to participate in any state or federal funded health care program for fraud or abuse or for submitting any false/fraudulent claim for payment or reimbursement (e.g., Medicare, Medicaid or MoHealthNet). [[§ 338.075](#)]

Notifications can be submitted on the Board's [website](#) using the [Discipline/Adverse Action Reporting Form](#). Each report is reviewed on a case-by-case basis to determine if further review or action is necessary. An investigation may not be initiated in every case. Licensees will be contacted if additional information is needed.

SECTION C: PHARMACIST SCOPE OF PRACTICE

Pharmacists play a vital role in protecting Missouri patients and ensuring effective medication outcomes. As medication experts, patients and healthcare providers rely on your medical judgment and expertise. Pharmacy services must be safely and competently provided at all times. Pharmacists should know and practice within their education, training and experience and in compliance with applicable state and federal law.

C.1 AUTHORIZED ACTIVITIES

A Missouri licensed pharmacist may perform any act within the scope of the practice of pharmacy which includes:

- Consulting with patients and other health care practitioners about the safe and effective use of drugs and devices, including, providing patient education;
- Interpreting, implementing, and evaluating prescriptions/medication orders;
- Handling or facilitating dispensing;
- Compounding or dispensing medication pursuant to a prescription/medication order;
- Participating in drug selection and drug utilization reviews;
- Prescribing nicotine replacement therapy products as defined by § 338.665, RSMo;
- Executing state-issued standing orders as authorized by law
- Providing medication therapy services;**
- Administering vaccines by protocol**
- Administering medication by prescription drug order; and**
- Offering or performing any act or service necessary in the conduct, operation, management and control of a pharmacy. [§ 338.010]

**See sections L-N for additional training/requirements for these services.

C.2 SUPERVISING PHARMACY STAFF

Pharmacy technicians and intern pharmacists must be adequately supervised to ensure pharmacy services are safely and accurately performed and comply with state/federal law. Technicians and intern pharmacists must be under the “direct supervision and responsibility” of a Missouri-licensed pharmacist at all times. [§ 338.035.5, 20 CSR 2220-2.700]. When no pharmacist is on duty, a sign must be posted on the prescription counter and on all entrance doors informing the public that “no pharmacist is on duty.” [20 CSR 2220-2.010(1)(A)]. The “no pharmacist on duty sign” does not have to be posted if the pharmacist is in the pharmacy building but briefly absent from the pharmacy area (e.g., restroom breaks).

All prescriptions must be finally verified/checked by a pharmacist, including, reconstituted products. Additionally, a pharmacist must verify that prescription/medication order data entered into an electronic prescription data processing system by a pharmacy technician or intern pharmacist was accurately inputted. [20 CSR 2220-2.080(1)]. Remote supervision is not allowed in Missouri at this time. See E.6 for additional information on staff supervision requirements and authorized technician/intern pharmacist duties.

- The Board has determined that technicians/intern pharmacists may accept written prescriptions from patients for dispensing when no pharmacist is on duty. [20 CSR 2220-2.010(1)(B)]. However, technicians/intern pharmacists cannot take verbal prescription orders or count, fill, compound or enter a prescription if the pharmacist is absent. Technicians/Intern pharmacists cannot come in early to process prescriptions before a pharmacist arrives or hand out or dispense prescriptions when no pharmacist is on duty, even if the prescription was previously checked by a pharmacist.
- The Board has reviewed several cases where technicians were able to illegally change prescription records or inventory figures using a pharmacist’s computer credentials. In most instances, the pharmacist either stepped away from the computer without logging off or left their log-on credentials unattended. This is a significant security/diversion risk. Computer passwords or log-on information should be protected from unauthorized use at all times. The Board recommends that pharmacists log off or lock their computers when away from their workstations.

SECTION C: PHARMACIST SCOPE OF PRACTICE

C.3 PRESCRIPTIVE AUTHORITY

Section 338.010.1 was amended in August 2019 to grant pharmacists authority to prescribe a prescription or over-the-counter “nicotine replacement therapy product.” [See C.8 for additional information]. While not full prescriptive authority, pharmacists may also:

- Dispense naloxone hydrochloride without a prescription pursuant to Missouri’s statewide standing order or by protocol (See C.9)
- Initiate or modify medication therapy or devices with a certificate of medication therapeutic plan authority and medication therapy services protocol. This includes selecting a new or different medication or discontinuing medication (See Section N for requirements),
- Administer vaccines under protocol with a Missouri licensed physician (see Section M), and
- Dispense an emergency supply of non-controlled medication if the pharmacist is unable to obtain refill authorization from the prescriber. (See H.12)

C.4 NON-DISPENSING ACTIVITIES OUTSIDE OF A PHARMACY

The practice of pharmacy may only be performed on the premises of a Missouri-licensed pharmacy. However, 20 CSR 2220-6.055 allows a Missouri-licensed pharmacist to perform the following non-dispensing activities outside of a licensed pharmacy:

- | | |
|--|--|
| 1) Patient counseling/education | 12) Reviewing, selecting, and developing formularies or plan/practice guidelines |
| 2) Obtaining patient history/information | 13) Reviewing compliance with benefit guidelines |
| 3) Reviewing patient records/medical histories | 14) Managing inventory, including purchasing and ordering |
| 4) Patient assessment/evaluation, as authorized by Missouri law | 15) Managing/reviewing information systems |
| 5) Medication therapy management | 16) Patient medication review |
| 6) Billing and insurance claim submissions/ review | 17) Consulting with other health care professionals |
| 7) Drug utilization review | 18) Patient referrals |
| 8) Assessing payor eligibility/coverage | 19) Medication therapy management |
| 9) Pharmacy compliance audits/evaluations | 20) Prescription order entry/review, provided that a pharmacist may only accept a prescription on the premises of a Missouri licensed pharmacy |
| 10) Administering drugs, vaccines, or biologicals, as authorized by law and the rules of the Board | |
| 11) Peer review/peer consultations | |

Pharmacists operating under 20 CSR 2220-6.055 are prohibited from meeting with patients in the pharmacist’s residence or living quarters.

Pharmacy technicians can only assist a pharmacist with immunizations outside of a licensed pharmacy. A pharmacy permit is required if the technician will be assisting with any other function at an off-site location. Authorized off-site activities are currently under review by the Board and may be subject to change.

C.5 TELE-PHARMACY

Missouri law doesn’t define “tele-pharmacy” and use of the term may vary depending on the practice setting. However, 20 CSR 2220-6.055 allows pharmacists to electronically or remotely provide a variety of non-dispensing pharmacy services from within or outside of a pharmacy as detailed in section C.4.

Missouri pharmacists cannot remotely supervise technicians or remotely perform final product/label verification, however, the Board is reviewing this issue. Licensees should monitor the Board’s website for additional updates.

SECTION C: PHARMACIST SCOPE OF PRACTICE

C.6 CONSULTING ACTIVITIES/CLASS- I PHARMACIES

A Missouri licensed pharmacist may provide consulting services without a Missouri pharmacy permit, as a non-dispensing activity authorized by [20 CSR 2220-6.055](#). Although the Board issues a Class-I Consultant pharmacy permit, a class-I permit is only required if:

- 1) The pharmacist will be using pharmacy technicians at the Class-I site,
- 2) The pharmacist will be accepting prescriptions from patients at the location, or
- 3) The pharmacist will be doing business under or using the name of “pharmacy”, “apothecary” or “drug store” or any similar symbols, words or phrases are used in any form to advertise retail products or services. [[§ 338.210; 338.260, 20 CSR 2220-6.055](#)]

The Board is frequently asked if a pharmacist in another state can be used to perform DUR or prescription order review for a Missouri licensed pharmacy. A pharmacist may perform non-dispensing activities at a facility located outside of Missouri for, or on behalf of, a Missouri pharmacy if:

- *The individual is a Missouri licensed pharmacist, or*
- *The individual is working at a facility that is licensed as a Missouri pharmacy and operating under a Class J Shared Services arrangement with another Missouri licensed pharmacy.*

C.7 PATIENT MEDICAL TESTING

The federal Centers for Medicare & Medicaid Services (CMS) regulates all non-research laboratory testing on humans pursuant to the Clinical Laboratory Improvement Amendments (CLIA). CLIA regulates three categories of testing: (1) high complexity testing, (2) moderate complexity testing and (3) CLIA waived testing that does not pose a significant risk of patient harm if the test is performed correctly. Missouri law does not address pharmacies or pharmacists performing CLIA testing, including, CLIA waived testing. Absent statutory direction, licensees performing authorized CLIA testing should consult with legal counsel to ensure compliance.

Testing services should comply with professional standards of practice and be consistent with the pharmacist’s education, training and experience. Pharmacists should be competent in the services provided and must comply with all applicable state/federal law. *Note: Pharmacists are not allowed to diagnose under Missouri law.*

C.8 NICOTINE REPLACEMENT THERAPY PRODUCTS

Section [338.010.1](#) was amended in August 2019 to grant pharmacists authority to prescribe a prescription or over-the-counter “nicotine replacement therapy product.” A “nicotine replacement therapy product” is defined as:

Any drug or product, regardless of whether it is available over-the-counter, that delivers small doses of nicotine to a person and that is approved by the federal Food and Drug Administration for the sole purpose of aiding in tobacco cessation or smoking cessation. [[§ 338.665](#)]

This definition would include products like nicotine gum, patches, lozenges, nasal spray and inhalers. According to currently approved FDA labeling, Zyban® and Chantix® do not contain nicotine and would therefore not constitute a “nicotine replacement therapy product” as defined by [§ 338.665](#).

Although the new law is currently effective, the Board is required to promulgate rules in conjunction with the Missouri Board of Registration for the Healing Arts to implement the new allowance. A draft rule is currently under development. **Pharmacists cannot begin prescribing nicotine replacement therapy products until the required joint rules are finalized.** Interested parties should monitor the Board’s website and e-alerts for future rule developments.

Once the required rules are complete, pharmacists will be able to independently prescribe a nicotine replacement therapy product. A physician protocol or collaborative practice agreement is **not** required. Instead, the pharmacist would be the official prescriber of record and prescriptions under [§ 338.665](#) may be transmitted to/filled by another pharmacy for dispensing.

SECTION C: PHARMACIST SCOPE OF PRACTICE

C.9 NALOXONE DISPENSING

Missouri pharmacists may dispense/distribute naloxone HCL without a prescription either:

1. Under protocol with a Missouri licensed physician, or
2. Pursuant to a statewide standing order issued/approved by the Missouri Department of Health and Senior Services (“DHSS”), or
3. To a qualified first responder agency as defined by [§ 190.255](#).

No additional Board or DHSS licensure, certification or training is required. However, pharmacists should educate themselves on proper naloxone use and administration before dispensing.

A variety of naloxone educational materials are available on the [Board's website](#), including:

- The [Opioid Overdose Prevention Toolkit](#) published by the United States Substance Abuse and Mental Health Services Administration (SAMHSA), and
- An [Opioid Safety and Naloxone Brochure](#) for Missouri patients and caregivers. (*Complimentary copies can be requested by e-mailing MissouriBOP@pr.mo.gov or by contacting the Board office. Quantities may be limited.*)

DISPENSING BY STANDING ORDER

DHSS has issued a statewide naloxone standing order that authorizes any Missouri licensed pharmacist to dispense naloxone without a prescription subject to the standing order. A copy of the standing order is available on the [Naloxone Resources](#) page on the Board's website. Licensees should review the standing order for current dispensing requirements, including, authorized products, eligible candidates, quantity limits and directions for use.

All naloxone recipients/purchasers under the standing order must receive education regarding overdose risk factors, signs of an overdose, overdose response steps and naloxone use. Recommended educational materials are available at <http://mohopeproject.org/education>. A variety of resources and educational materials are also available online in the Board's [Naloxone Resource Center](#).

Record Keeping: All naloxone sales/dispensing under the statewide protocol must be documented in the pharmacy's records. If dispensing as a prescription, all prescription recordkeeping requirements apply and a [§ 338.059](#) compliant prescription label must be attached. If sold as a distribution, the pharmacy must have a record of the sale. The Board recommends documenting:

- The transaction date
- Product name, strength and dosage form,
- Quantity, and
- Lot number and expiration date.

Sales/distribution records must be kept for two (2) years. Prescription records must be maintained for five (5) years.

Note: The patient's name is not required to distribute naloxone if the patient refuses to provide one.

BILLING INSURANCE OR MEDICAID FOR NALOXONE:

Each insurance plan is different and may contain different billing requirements for Naloxone. Licensees should contact the patient's insurance company for eligibility/payment questions, the Board cannot provide billing or insurance advice.

MO HealthNet has advised the Board that prescriptions for naloxone may be billed to MO HealthNet for eligible enrollees. Questions regarding MO HealthNet billing should be directed to MO HealthNet's Pharmacy Help desk at 800-392-8030.

SECTION C: PHARMACIST SCOPE OF PRACTICE

DISPENSING BY PROTOCOL

Pharmacists may sell or dispense naloxone under a protocol with a Missouri licensed physician that authorizes the pharmacist to dispense without a prescription. The Board anticipates reviewing protocol standards in the future. In the interim, the Board suggests that naloxone protocols include provisions/requirements for:

- Pharmacist education and training
- Emergency notification and documentation
- Patient education and counseling, and
- Protocol review, signatures and timeframe.

A [sample protocol template](#) is available on the Board's website. Licensees should maintain proof of the authorizing physician's licensure in the pharmacy's records.

Section 195.206 provides naloxone may be sold by protocol to any individual or entity. No dispensing limits or quantity restrictions are imposed by statute. However, the physician protocol may include additional restrictions on eligible recipients/quantities.

Similar to dispensing under the statewide standing order, all naloxone sales/dispensing must be documented in the pharmacy's records. If dispensing as a prescription, all prescription recordkeeping requirements apply and a [§ 338.059](#) compliant prescription label must be attached. If sold as a distribution, the pharmacy must keep a record of the sale. The Board recommends documenting:

- The transaction date
- Product name, strength and dosage form
- Quantity,
- The lot number and expiration date, and
- The patient's or entity's name, if known. *Note: The patient's name is not required to distribute naloxone if the patient refuses to provide one.*

Sales/distribution records must be kept for two (2) years. Prescription records must be maintained for five (5) years.

The Board has been asked if the patient's name or address is required before dispensing/ distributing naloxone. Patients are not required to give their name or address under the standing order. Additionally, DHSS and the Missouri Department of Mental Health have expressed concerns that patients may be discouraged from purchasing naloxone if they are asked for detailed personal data. Naloxone can save lives. Pharmacies are strongly encouraged to eliminate any unnecessary barriers or paperwork that might discourage citizens from seeking help.

BILLING INSURANCE OR MEDICAID FOR NALOXONE

The Missouri Department of Insurance has advised that each insurance plan is different and may contain different Naloxone billing requirements. Licensees should contact the patient's insurance company for eligibility/payment questions, the Board cannot provide billing or insurance advice.

MO HealthNet has advised the Board that prescriptions for naloxone may be billed to MO HealthNet for eligible enrollees. Questions regarding MO HealthNet billing should be directed to MO HealthNet's Pharmacy Help desk at 800-392-8030.

SECTION C: PHARMACIST SCOPE OF PRACTICE

FIRST RESPONDER AGENCIES

Section 190.255 allows a Missouri licensed pharmacy or drug distributor to also sell naloxone to a “qualified first responder agency” without a prescription. A “qualified first responder agency” is defined as “any state or local law enforcement agency, fire department or ambulance service that provides documented training to its staff related to the administration of naloxone in an apparent narcotic or opiate overdose situation.” A protocol is not required to provide naloxone to a qualifying first responder agency.

Naloxone sales to a qualified first responder agency should be documented by invoice. Prescriptions cannot be used to document the sale. Invoices should include:

- a) The date of sale;
- b) Product name;
- c) Quantity Sold;
- d) The identity of the qualified first responder agency; and
- e) Names and address of both parties.

Invoices must be maintained in the pharmacy’s/distributor’s records for two (2) years and filed separately from prescription records.

ADMINISTERING NALOXONE

Section 195.206 provides:

6. Any person who administers an opioid antagonist to another person shall, immediately after administering the drug, contact emergency personnel. Any person who, acting in good faith and with reasonable care, administers an opioid antagonist to another person whom the person believes to be suffering an opioid-related overdose shall be immune from criminal prosecution, disciplinary actions from his or her professional licensing board, and civil liability due to the administration of the opioid antagonist.

Based on this statute, the Board would not require a pharmacist to comply with 20 CSR 2220-6.040 when administering naloxone in good faith to a patient in an emergency overdose situation.

D.1 PHARMACY DEFINITION

No person or entity may open, establish, operate or maintain a pharmacy in the state of Missouri without a valid Missouri pharmacy permit. A pharmacy includes, but is not limited to, any place:

- Where the practice of pharmacy is offered or conducted or where the practice of pharmacy is provided by a pharmacist or someone acting under the pharmacist’s supervision or authority.
- Where drugs, chemicals, medicines, prescriptions, or poisons are compounded, prepared, dispensed, sold or offered for sale at retail;
- Where the words “pharmacist”, “apothecary”, “pharmacy”, “drugstore”, “drugs” or any other similar symbols, words or phrases are used in any form to advertise retail products or services; or
- Where patient records or other information is maintained for the purpose of engaging or offering to engage in the practice of pharmacy or to comply with any relevant laws regulating the acquisition, possession, handling, transfer, sale or destruction of drugs, chemicals, medicines, prescriptions or poisons. [[§ 338.210](#); [338.260](#)]

See C.4 for authorized non-dispensing activities without a pharmacy permit.

D.2 PHARMACY CLASSIFICATIONS

The Board issues the following classes of pharmacy permits [[§ 338.220](#), [20 CSR 2220-2.020\(9\)](#)]:

| CLASS | DESCRIPTION |
|------------------------------------|---|
| Class A (Community/ Ambulatory) | Required to provide pharmacy services to the general public (e.g., retail). |
| Class B (Hospital Pharmacy) | A pharmacy owned, managed, or operated by a hospital as defined by § 197.020 or a hospital clinic or facility under common control, management or ownership of the same hospital or hospital system. [§ 338.220.6]. * <i>Licensure is not required for hospital pharmacies operating under the jurisdiction of the Missouri Department of Health and Senior Services. See D.9 for additional information.</i> |
| Class C (Long-Term Care) | Required for pharmacies dispensing drugs/devices to patients residing in a long-term care facility which would include a nursing home, retirement facility, mental care facility or any other facility that provides extended health care to resident patients. <i>See also Section Q.</i> |
| Class D (Non-Sterile Compounding) | Required for pharmacies providing non-sterile compounding as defined by 20 CSR 2220-2.400(3) , in batch quantities using bulk active ingredients. [See 20 CSR 2220-2.400]. |
| Class E (Radiopharmaceutical) | Required for any pharmacy providing radiopharmaceutical services and where radiopharmaceuticals and chemicals classified as legend drugs are prepared, compounded, dispensed, stored, sold or used for nuclear medicine procedures. [See 20 CSR 2220-2.500 and section D.10]. |
| Class F (Renal Dialysis) | Required for pharmacies dispensing renal dialysis solutions and other drugs/devices associated with dialysis care. Renal dialysis pharmacies may not be open to the general public and may only dispense renal dialysis solutions and renal dialysis associated drugs, supplies or devices. [See 20 CSR 2220-2.600]. |

SECTION D: PHARMACY LICENSING

| CLASS | DESCRIPTION |
|---|---|
| Class G (Medical Gas) | Required for pharmacies providing oxygen and other prescription gases by prescription for therapeutic use. |
| Class H (Sterile Product Compounding) | Required for sterile compounding pharmacies, as defined by 20 CSR 2220-2.200 . |
| Class I (Consultant) | Available for locations where the practice of pharmacy is conducted but is not used for procuring, storing, possessing or owning drugs. |
| Class J (Shared Service) | Required for pharmacies engaged in shared serves with/for another pharmacy such as, filling/refilling medication, central fill services, drug utilization review or therapeutic interventions. <i>See D.11 [20 CSR 2220-2.650]</i> . |
| Class K (Internet) | Required for pharmacies receiving, reviewing, preparing, compounding, dispensing or offering for sale any drugs, chemicals, medicines or poisons for new prescriptions originated from the internet for more than 90% of the pharmacy's total new prescription volume on any day. <i>See the Ryan Haight Act for additional federal requirements .</i> |
| Class L (Veterinary) | Required for entities only selling, dispensing, or filling prescription drugs for animal use. [See 20 CSR 2220-2.675]. Note: Class-A pharmacies do not need an additional Class L permit. <i>Note: Class-A pharmacies do not need an additional Class L permit.</i> |
| Class M: Specialty (Bleeding Disorder) | Required for pharmacies providing blood-clotting products and ancillary infusion equipment or supplies to patients with bleeding disorders. <i>See 20 CSR 2220-6.100.</i> |
| Class N: Automated Dispensing System (Health Care Facility) | Required for pharmacies operating automated/mechanical systems in a health care facility to store, package or dispense medication. <i>See 20 CSR 2220-2.900.</i> |
| Class O: Automated Dispensing System (Ambulatory) | Required for pharmacies operating automated/mechanical systems in a ambulatory setting to store, package or dispense medication. <i>See 20 CSR 2220-2.900.</i> |
| Class P: Practitioner Office/ Clinic | Required for pharmacies operating in a practitioner's office/clinic. ** A pharmacy permit is not required for practitioner office dispensing to their own patients. Final Board rules have not been promulgated. ** <i>A pharmacy permit is not required for practitioner office dispensing to their own patients. Final Board rules have not been promulgated to implement this license class.</i> |

Pharmacies may only engage in the pharmacy activities allowed for the class(es) reflected on the pharmacy's permit. To add or delete a class, a [Change of Classification Application](#) must be filed with the Board. Pharmacies may not function under an added class until the Board has issued a new permit reflecting the new classification.

Pharmacies must comply with all regulations governing each class listed on the pharmacy's permit even if they are not actually performing the activities. For example, a Class H Sterile Product pharmacy must comply with the Board's sterile compounding rules even if the pharmacy isn't currently compounding.

D.3 LICENSE REQUIREMENTS

Applicants for a resident or non-resident pharmacy permit must file an [application](#) with the Board and meet the following requirements:

- The pharmacy must designate and be under the supervision of a “pharmacist-in-charge”;
- Equipment and facilities must be operated in a manner that will not endanger the public health or safety;
- The pharmacy must be equipped with proper pharmaceutical and sanitation appliances;
- The pharmacy must be maintained in a clean, sanitary and orderly manner; and
- Proposed/current operations must comply with [Chapter 338](#) and all applicable state/federal law. [[20 CSR 2220-2.010\(1\)\(C\) – \(F\)](#), [20 CSR 2220-2.020](#)]

Pharmacies may be owned by unlicensed persons/entities. However, the practice of pharmacy may only be conducted by licensed pharmacists.

In-state pharmacies must pass a Board inspection prior to licensure. See [D.4](#) for non-resident pharmacies.

D.4 NON-RESIDENT PHARMACIES

Pursuant to [20 CSR 2220-2.025](#), pharmacies located outside of Missouri may not ship, mail or deliver a filled prescription/medication order into Missouri without first obtaining a Missouri pharmacy permit. To be eligible for licensure, a non-resident pharmacy must:

- Be located in the United States or a U.S. territory,
- Have a current and active pharmacy license in the state/territory where the non-resident pharmacy is physically located,
- Designate a pharmacist-in-charge who is either a Missouri licensed pharmacist or who holds an active pharmacist license in the non-resident pharmacy’s licensing state/territory, and
- Submit a copy of the pharmacy’s most recent state inspection. For sterile compounding applicants, the inspection must have occurred within the last eighteen (18) months. For all other pharmacy applicants, the inspection must have occurred within the last twenty-four months.** [[20 CSR 2220-2.025](#)]

A non-resident pharmacy permit cannot be renewed if the applicant does not hold a valid pharmacy license in their home state. [[§ 338.270](#)]

*** If a state inspection is unavailable, [20 CSR 2220-2.025](#) provides a non-resident pharmacy applicant may also submit an inspection from the Verified Pharmacy Program (VPP) operated by the National Association of State Boards of Pharmacy. Alternatively, the Board can accept an equivalent third-party inspection by an entity approved by the Board or by a Board inspector (pending availability/resources). Contact the Board office for approval of an inspection entity other than a state agency or NABP.*

D.5 PHARMACIST-IN-CHARGE

All licensed pharmacies must designate a licensed pharmacist to serve as “pharmacist-in-charge” (PIC). [20 CSR 2220-2.010(1)(M)]. In conjunction with the permit holder, the PIC is personally responsible for supervising pharmacy activities and for ensuring full compliance with all state and federal drug laws. A pharmacist may serve as PIC for more than one pharmacy. However, the PIC must be actively engaged in the operation of each pharmacy.

Rule 20 CSR 2220-2.090 contains a detailed listing of PIC responsibilities/duties. Pharmacists should carefully review the rule prior to assuming PIC responsibilities, as you may be held personally responsible for compliance violations. Do not agree to serve as PIC if you cannot adequately supervise and monitor the pharmacy.

The Board has a number of compliance resources on its website that would be helpful to new PICs including, a [Pharmacy Self-Assessment Guide](#) that can be used to assess the pharmacy’s compliance status before an inspection. Newly designated PICs should sign up for the Board’s e-alerts and also review:

- The nature and volume of the pharmacy’s activities, and
- The pharmacy’s prior compliance history, including, previous inspection reports/compliance notices and any prior disciplinary orders. Make sure violations have been addressed and corrected. Contact your inspector if you have questions about your previous inspections.

In the event of a PIC change:

- The former PIC must immediately notify the Board in writing or via e-mail when he/she stops serving as PIC. [20 CSR 2220-2.010(1)(M)]. E-mail notifications are preferred and should be sent to pharmacy@pr.mo.gov. Pharmacy operations may not continue until a new PIC has been designated.
- The new PIC may begin serving immediately after designation. However, the permit holder must promptly submit a fully completed [Pharmacist-In-Charge Change Application](#) to officially complete the change. [20 CSR 2220-2.010(1)(M)]. Applications not received in a timely fashion may result in the PIC designation being voided or other disciplinary review/action. The mailing date should be documented and maintained in the pharmacy’s records.
- The permit holder and new PIC must complete a controlled substance inventory at the time of the PIC change that includes all Schedule II through V controlled substances, including, Schedule V pseudoephedrine containing over-the-counter products. Documentation of the inventory must be maintained in the pharmacy’s records. To ensure accuracy, the Board recommends that the former and new PIC jointly conduct the inventory.
- Extended Leave: If a PIC will be on extended leave (e.g., vacation, maternity leave), the PIC and permit holder should review the pharmacy’s operations to determine if a new PIC should be named. If a new PIC is named, an official [Pharmacist-In-Charge Change](#) application must be filed. A second [Pharmacist-In-Charge Change](#) application must be filed when the previous PIC resumes PIC duties. Both PIC changes would require a separate controlled substance inventory.

Under § 338.210.5, the PIC is responsible for pharmacy compliance even if pharmacy policies/procedures are set corporately or by the pharmacy’s owners.

D.6 CHANGE OF OWNERSHIP

Pharmacy permits are issued for a named permit holder and are not transferable. Accordingly, a permit becomes void on the effective date of an ownership change and a new pharmacy permit is required for the new owners. [20 CSR 2220-2.020(3)].

- *Sole Proprietors*: A pharmacy owned by a sole proprietor will be deemed to have changed ownership if: 1) the proprietor enters into a partnership with another individual or business entity, or 2) the proprietor dies. [20 CSR 2220-2.020(3)]
- *Corporations, LLCs, LLPs*: A new pharmacy permit is required if a corporation, limited liability partnership (“LLP”), or limited liability company (“LLC”) begins or transfers ownership of a pharmacy. A new permit is required regardless of the relationship between the previous and subsequent owners. [20 CSR 2220-2.020(3)]

A Change of Ownership application is not required if:

- The pharmacy is owned by a corporation and the owners of the stock change. However, individuals/entities must notify the Board in writing within thirty (30) days of acquiring more than twenty-five percent (25%) of a pharmacy’s ownership, or;
- The members or partners of a LLP or LLC change, as long as the partnership or company is not dissolved by the change. Partner/member changes must be reported to the Board in writing within ten (10) days. [20 CSR 2220-2.020(3)].

Once a completed [Change of Ownership Permit Application](#) has been filed, the Board may issue a temporary pharmacy permit to allow the new ownership to continue operating until a new permit is issued.

New or amended DEA/BNDD controlled substance registrations may also be required in the event of a change of ownership.

D.7 CHANGE OF LOCATION/REMODELING

Pharmacy permits are only valid for the address identified on the permit. A [Pharmacy Location Change application](#) must be filed with the Board before the pharmacy moves to a new location (an inspection is required for in-state pharmacies). [20 CSR 2220-2.020(4)]. If approved, the Board will issue a permit for the new location with the previous permit number. Licensees may not begin operating at the new location until a new license is issued. *Note: Permit holders should notify the Board in writing if the pharmacy’s address changes but not the location. An amended permit will be issued without charge.*

Remodeling: Under rule [20 CSR 2220-2.020\(4\)\(A\)](#), a pharmacy remodel includes:

1. Any change in the storage conditions of Schedule II substances (this includes adding new storage or re locating existing storage),
2. Any new connections to water/sewer resources (this includes relocating an existing sink), or
3. Any changes in the overall physical security of drugs stored in the pharmacy (this can include acquiring additional pharmacy space).

A remodel is different from a change of location. A remodel involves modifications within an existing structure. A change of location is a move out of the current structure to a different structure. A Pharmacy Location Change application is not required for remodeling within an existing structure. However, a remodeling affidavit and project plans must be sent to the Board office or to your inspector no later than thirty (30) days before the remodeling begins. The required affidavit must include a description of the proposed changes and the projected completion date. [20 CSR 2220-2.020(4)(A)]. Official blueprints are not required- a diagram or rough blueprint sketches are acceptable.

Your inspector will notify you once the remodeling plans are approved or if additional information is needed. An

inspection is not required but may be conducted if deemed appropriate.

A move to a temporary structure outside of the existing building during a facility renovation is considered a change of location. A move back to the renovated area is considered a second location change. Both moves require a separate [Location Change application](#) (and an inspection for resident pharmacies).

Licensees should check with BNDD and the DEA to determine if a new or amended controlled substance registration is also required for a change of location or remodel.

Class-B Hospital pharmacies must notify the Board if modifications constitute a remodel under 20 CSR 2220-2.020(4)'s definitions. This applies even if the activity occurring within the licensed pharmacy is regulated by DHSS.

D.8 TERMINATING BUSINESS

Prior to terminating business, the PIC and the permit holder should ensure proper arrangements have been made for all inventory and pharmacy records. An [Out-of-Business Notification Form](#) must be filed with the Board within fifteen (15) days after the permit holder stops operating and the pharmacy's permit must be returned to the Board office. [\[20 CSR 2220-2.015\(1\)\]](#).

The closing pharmacy may transfer or dispose of medication in accordance with state and federal law. [\[20 CSR 2220-2.015\(2\)\]](#). Pharmacies may not transfer misbranded, outdated or adulterated drugs, except for proper disposal. A drug distributor license is not required for a one-time transfer of medication/devices if the pharmacy is terminating business. [\[20 CSR 2220-2.015\(3\)\]](#).

A complete inventory of all controlled substances transferred or disposed of must be completed on the termination date and a copy of the inventory must be included in the records of each permit holder involved in the transfer. [\[20 CSR 2220-2.015\(2\)\(A\)\]](#). Controlled substances must be transferred via invoice or, if applicable, a DEA-222 form/CSOS.

Records: The closing pharmacy must designate a secure location where pharmacy records will be kept after the pharmacy is closed. The Board recommends informing patients of where/how to locate prescription records in the future. Records transferred to an unlicensed location must be retrievable within seven (7) working days of a Board request. [\[20 CSR 2220-2.015\(1\)\(C\)\]](#)

D.9 CLASS-B HOSPITAL PHARMACY

A Class B Hospital Pharmacy is defined as:

- A pharmacy owned, managed, or operated by a hospital as defined by [§ 197.020](#), or
- A "hospital clinic or facility" that is under common control, management or ownership of the same hospital or hospital system. [\[§ 338.165.1\(3\)\]](#).

A Class B pharmacy can provide pharmacy services to the general public, including, to hospital staff and hospital outpatients. A separate Class A Community/Ambulatory pharmacy permit is not required, however, a specialized permit classification would be required for any specialty pharmacy services under the Board's jurisdiction (e.g., Class D-Non-sterile Compounding, Class H- Sterile Compounding, Class J- Shared Services).

Hospital clinics/facilities eligible for a Class-B permit may be located within a Missouri licensed hospital or separately operated at an offsite location. For example, offsite facilities such as infusion clinics, physician clinics, long-term care facilities, ambulatory surgical centers or other healthcare facilities may be licensed as a Class-B pharmacy, provided the clinic/facility meets the common ownership/operation requirements (*this list is not exhaustive*). The governing hospital or hospital system is not required to be licensed with the Board unless the hospital/hospital system is also providing pharmacy services under the Board's jurisdiction. Applicants should consult with legal counsel to determine if a hospital clinic/facility is under "common control, management or ownership of the same hospital or hospital system." The Board cannot provide legal advice.

Once approved, a Class-B permit will be issued for a specific location/address. Applicants may choose to license all or portions of a building under a Class-B permit (e.g., a designated room or floor). Additionally, multiple areas at the same address may be included under a single permit. For example, a Class-B permit may include drug rooms that are located on different floors within the same building, however, each area would be required to comply with Board requirements. A separate Class-B permit would be required for facilities located at different addresses. (*See C.4 for non-dispensing activities outside of a pharmacy*).

CLASS-B LICENSURE FOR MISSOURI HOSPITALS

Under [Chapter 197](#), RSMo, DHSS has regulatory jurisdiction over pharmacy services provided within the “licensed premises” of a Missouri hospital. A Class-B Hospital Pharmacy permit is not required for hospitals “solely providing services within the practice of pharmacy under the jurisdiction of, and the licensure granted by” DHSS. [[§ 338.220.6, RSMo](#)]. Hospitals solely providing pharmacy services under DHSS’ jurisdiction may choose to be licensed as a Class-B pharmacy although not required.

Section 197.052, RSMo, defines the hospital premises as: “*tracts of property which are adjacent but for a common street, single intersection, or highway, as such terms are defined in section 300.010, and its accompanying public right-of-way.*” Licensees should contact DHSS and their legal counsel to determine what areas are under DHSS’ jurisdiction. The Board cannot provide legal advice.

DHSS has advised that inclusion in the hospital premises is not automatic. Instead, buildings/areas must be officially designated with DHSS as part of the hospital’s license. According to DHSS, this may be done in the hospital’s initial DHSS license/renewal application or hospitals may separately notify DHSS to amend their license. Hospitals should contact DHSS to verify that all desired buildings/areas have been properly designated, including any newly added facilities. Pharmacy services provided in buildings/areas that have not been officially included as part of the DHSS licensed hospital premises would be regulated by the Board.

The Board is aware of dually operating Class-B pharmacies providing pharmacy services under DHSS’ jurisdiction and pharmacy services under the Board’s jurisdiction at the same location. Class-B pharmacies may share pharmacy space with a DHSS regulated hospital; the Board does not require physical separation of facilities or drug inventory. However, proper security must be maintained over drug stock at all times. Additionally, pharmacy services under the Board’s jurisdiction must comply with all applicable Board statutes/rules.

AUTHORIZED CLASS-B ACTIVITIES

[Section 338.220](#), RSMo, grants two specific allowances to Class B Hospital pharmacies:

- 1) Class B Hospital pharmacies may dispense medication by prescription or by “medication order”; and
- 2) Class B Hospital pharmacies may distribute medication to other hospital clinics or facilities that are under common control, management or ownership of the same hospital or hospital system without a Missouri drug distributor license.

DISPENSING BY PRESCRIPTION/MEDICATION ORDER

[Section 338.220](#) authorizes Class-B pharmacies to dispense medication pursuant to a patient-specific prescription or a patient-specific medication order. Prescriptions must comply with all state and federal requirements. A “medication order” is defined as an order for a legend drug or device that is:

1. Authorized or issued by an authorized prescriber acting within the scope of his or her professional practice or pursuant to a protocol or standing order approved by the medical staff committee, and
2. To be distributed or administered to a patient by a health care practitioner or lawfully authorized designee at a hospital or a “hospital clinic or facility” that is under the “common control, management or ownership of the same hospital or hospital system.” [[Section 338.165.1](#)] A qualifying hospital clinic or facility could include offsite physician

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clinics, urgent-care centers, long-term care facilities, infusion clinics, physical therapy units or other healthcare facilities, provided the clinic or facility is under common control, management or ownership of the same hospital or hospital system.

Missouri law is silent on a pharmacist's authority to perform generic or biosimilar substitution on a medication order. Please consult an attorney for guidance. Medication orders must comply with all state/federal controlled substance requirements.

LABELING

Labeling must comply with § 338.059, RSMo (see H.3). The Board has been asked about labeling requirements for Class-B pharmacies dispensing medication to a healthcare provider for onsite administration to a patient. The Board intends on addressing this issue by rule in the future. In the interim, Board Inspectors will not cite Class-B pharmacies for violations of § 338.059's labeling requirements if:

- 1) Medication is given to a healthcare practitioner for use or administration to a patient onsite of a Class-B pharmacy or within the licensed premises of a DHSS licensed hospital, and
- 2) The medication/prescription container labeling is accurate and complies with DHSS' medication labeling requirements, and
- 3) The medication/prescription container is not "given to the patient for use/administration" offsite. The Board will not consider medication to have been given to the patient for offsite use/administration if administration is initiated onsite but continued offsite via an external or implanted medical delivery device that is programmed by a healthcare professional.

DISTRIBUTION WITHOUT A MISSOURI DRUG DISTRIBUTOR LICENSE

Section § 338.165.6 provides a Class B Hospital pharmacy may distribute medication to a "hospital clinic or facility" for patient care or treatment without a Missouri drug distributor license (see *chart below*). Once again, a "hospital clinic or facility" is defined as a clinic or facility under common control, management or ownership of the same hospital or hospital system. A Class-B Hospital pharmacy is required to keep a record of all distributions.

Although a Missouri drug distributor license is not required, pharmacies may still be required to register with the DEA as a controlled substances distributor under federal law if the total dosage units of all controlled substances distributed by the pharmacy exceeds five-percent (5%) of all controlled substances dispensed during the previous calendar year. *Note: Controlled substances may only be distributed to a BNDD/DEA controlled substance registrant via invoice or via CSOS/DEA-222 form (schedule IIs).*

A Class B pharmacy may not distribute compounded preparations to other entities or compound for office stock. However, an FDA registered drug manufacturer or a 503(b) drug outsourcing facility may provide compounded preparations for office use, provided the entity is also licensed as a Missouri drug distributor (for manufacturers) or a Missouri drug outsourcer (for 503(b) drug outsourcing facilities). (See 1.2 for additional information)

HOSPITAL/CLASS-B DRUG DISTRIBUTION LICClass-B Licensed Hospital Pharmacy:

- A drug distributor license is **not** required to:
 - 1) Distribute to a hospital clinic or facility under common control, management or ownership
 - 2) Receive returned medication that was distributed by the Class-B pharmacy to a hospital or clinic

Hospitals WITHOUT a Class-B Pharmacy License:

- A drug distributor license is **not** required to:
 - 1) Distribute to another hospital (under same or different ownership)
 - 2) Distribute to a healthcare entity under common control or ownership
 - 3) Receive returned medication distributed by the hospital or healthcare entity under common control or ownership

Hospital Owned Clinics/Other Entities:

- A drug distributor license **is** required to distribute a medication to any entity, including::
 - 1) A hospital (under same or different ownership)
 - 2) Another clinic or hospital entity (under same or different ownership)
 - 3) A Class-B pharmacy or other pharmacy

*This does not include returning medication received from a Class-B pharmacy or hospital; A drug distributor license is not required to return medication back to the entity that it was received from.

RECORD-KEEPING

Class-B pharmacies must comply with all Board record-keeping requirements applicable to pharmacies. The Board has determined that Class-B pharmacies may maintain dispensing, distribution and administration records in the same electronic or manual system used by the hospital or other hospital clinics/facilities (e.g., a common EMR), provided the records must be readily retrievable on inspection or if requested by the Board. *Note: Controlled substance records must still be separately maintained/retrievable as required by state/federal law.*

DRUG REPACKAGING FOR HOSPITAL SYSTEM DISTRIBUTION

The Board has been asked to provide guidance on repackaging of non-sterile drugs by a hospital* or Class-B pharmacy for distribution to a healthcare entity under the same common control or ownership as the hospital. The following guidance on Board rules is being provided for informational purposes.

This guidance only applies to repackaging of non-sterile drugs for distribution to a healthcare entity that is under the same common control or ownership of the hospital*. This guidance does **not** address:

- Repackaging for use within the same hospital at which the repackaging occurs
- Repackaging of sterile products
- Repackaging of compounded preparations
- Repackaging occurring outside of the hospital premises or outside of a Class-B pharmacy
- Repackaging occurring outside of Missouri
- Distribution to a healthcare entity that is not under the same common control or ownership as the hospital

* A hospital is limited to hospitals as defined by Chapter 197, RSMo, or a hospital operated by the state.

| Facility Where Repackaging is Occurring | Board of Pharmacy Requirements |
|---|---|
| Class B pharmacy located within or outside of the hospital premises | <ul style="list-style-type: none"> Comply with 20 CSR 2220-2.130 Drug Repackaging and § 338.059.2 labeling. No drug distributor license required per 20 CSR 2220-5.020. |
| Hospital with BOP drug distributor license only | <ul style="list-style-type: none"> Comply with chapter 20 CSR 2220-5, including 20 CSR 2220-5.030(4) which provides: <ul style="list-style-type: none"> (4) In addition to standards listed in this rule for drug distributors, drug repackagers must observe federal standards for— <ul style="list-style-type: none"> (A) Packaging; (B) Record keeping; (C) Expiration dating; (D) Plant facilities; (E) Equipment; (F) Personnel; (G) Production and control procedures; (H) Containers; and (I) Testing |
| Hospital with no BOP license | <ul style="list-style-type: none"> No Bd. of Pharmacy jurisdiction. Does not require a drug distributor license per 20 CSR 2220-5.020. DHSS would regulate this activity for hospitals under their jurisdiction. |

Distribution by entities outside of a hospital premises or a Class-B pharmacy would require a Missouri pharmacy permit or drug distributor license at that location. Note: Hospitals/Licensees should contact DEA/BNDD for controlled substance requirements and should also consult FDA for registration requirements if distributing outside of their own-system.

D.10 CLASS-E RADIOPHARMACEUTICALS (NUCLEAR)

The Board’s Class-E pharmacy rule, [20 CSR 2220-2.500](#), was significantly revised November 30, 2019. The revised rule was developed in conjunction with industry stakeholders and updates/modernizes rule requirements. Licensees should review the new rule in its entirety to ensure compliance.

Licensing

A Class-E Radiopharmaceuticals pharmacy permit is required for any location that provides radiopharmaceutical services and where radiopharmaceuticals and chemicals classified as legend drugs are prepared, compounded, dispensed, stored, sold or used for nuclear medicine procedures. [\[20 CSR 2220-2.500\(3\)\]](#) To be eligible for licensure, the applicant must hold a current Nuclear Regulatory Commission (NRC) and/or an Agreement State radioactive materials license.*

A Class-E permit is not required for:

1. Nuclear medicine facilities of hospitals or clinics where radiopharmaceuticals are compounded or dispensed under the supervision of a licensed physician authorized by the NRC or Agreement State regulations.*
2. Clinical laboratories licensed by the NRC or an Agreement State to handle radioactive materials, to obtain the services of a nuclear pharmacist, or to have a pharmacy permit, provided the laboratory is not engaged in the commercial sale or resale of radiopharmaceuticals.

Class-E pharmacies must be under the supervision of an authorized nuclear pharmacist who holds a Missouri pharmacist

license and who:

- Is certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties, or
- Has attained status as an authorized nuclear pharmacist or an authorized user of radioactive material as specified by the NRC or Agreement State Regulations.

Class-E pharmacies preparing, compounding or repackaging sterile preparations must also have a Class-H Sterile Compounding permit. Class-E pharmacies are no longer required to have a Missouri Drug Distributor license to provide non-patient specific nuclear preparations for a prescriber's use, provided the Class-E pharmacy complies with 20 CSR 2220-2.500

***ATTENTION:** An "agreement state" is defined as any state that has entered into an agreement under subsection 247b of the Atomic Energy Act of 1954, in which the U.S. Nuclear Regulatory Commission has relinquished to the state the majority of its regulatory authority over source material, by-product and special nuclear material in quantities not sufficient to form a critical mass. Missouri is not an agreement state.

Facility Requirements

Class-E pharmacies must have adequate space and equipment that is commensurate with the scope of services provided. Additionally, Class-E pharmacies must comply with:

- All applicable facility/equipment requirements of the NRC or an Agreement State. [20 CSR 2220-2.500(4)]
- 20 CSR 2220-2.400 governing sterile compounding, and
- All applicable provisions of 20 CSR 2220-2.200 (Compounding Standards of Practice)

At a minimum, Class-E pharmacies handling radiopharmaceuticals must have a:

1. Radiopharmaceutical nonsterile and sterile preparation/dispensing area;
2. Radioactive material shipping/receiving area;
3. Radioactive material storage area; and
4. Radioactive waste decay area.

Additionally, radionuclide generators must be stored and operated in an ISO 8 or better classified area. Nuclear pharmacy restricted areas must be totally enclosed and lockable and must be secured to prevent unauthorized access.

References

Class-E pharmacies must have a current copy of or electronic access to the following references:

- Statutes and rule governing the pharmacy's practice, including, but not limited to, Chapter 338 and Chapter 195, RSMo, 20 CSR 2220 and 19 CSR 30 governing controlled substances (if applicable), and
- NRC or Agreement state regulations governing the safe storage, handling and dispensing of radioactive materials, including, but not limited to, Title 10 and Title 18 of the United States Code of Federal Regulations.

Prescription/Contingency Prescription Drug Orders

Radiopharmaceuticals may only be dispensed pursuant to a prescription drug order or a contingency prescription drug order from a practitioner or facility authorized by the NRC or Agreement State to possess, use and administer radiopharmaceuticals or the practitioner's/facility's designated agent. [20 CSR 2220-2.500(5)(C)].

- A "prescription drug order" is defined as a prescription drug order for a specific patient for a diagnostic or therapeutic purpose. [20 CSR 2220-2.500(1)(1)(L)]
- A "contingency prescription drug order" is defined as a radioactive prescription drug order issued for contingency material for a diagnostic purpose. [20 CSR 2220-2.500(1)(1)(E)]

Prescription drug orders/contingency prescription drug orders may only be taken by an authorized nuclear pharmacist or

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by an intern pharmacist or authorized nuclear pharmacy technician who is under the supervision of an authorized nuclear pharmacist (see below for verbal therapeutic prescription drug orders). [20 CSR 2220-2.500(5)(C)] An “authorized nuclear pharmacy technician” is defined as a person who has successfully completed:

- A nuclear pharmacy technician training program provided by an accredited college program,
- A program that meets the American Pharmacist’s Association’s (APhA) Guidelines for Nuclear Pharmacy Technician Training Programs, or
- An equivalent company sponsored program that meets APhA guidelines for nuclear pharmacy technician training.

Technician training programs do not have to be pre-approved by the Board, however, documentation of the required training should be maintained in the pharmacy’s records.

Only an *authorized nuclear pharmacist* can receive verbal therapeutic prescription drug orders which are defined in 20 CSR 2220-2.500(1) as a radioactive prescription issued for a specific patient for a therapeutic purpose. [20 CSR 2220-2.500((5)(C))]. Verbal therapeutic prescription drug orders may not be received by an intern pharmacist or a pharmacy technician.

Prescription Records

Class-E pharmacies prescription records must include:

- The dispensing date and the calibration time of radiopharmaceuticals,
- The patient’s name for therapeutic prescription drug orders and blood-containing products, and
- All information required by 20 CSR 2220-2.018

Labeling

Radiopharmaceutical unit dose containers (the “pig”) must be labeled with:

1. The name and address of the pharmacy,
2. The name and address of the authorized prescriber/facility where the prescription drug order/contingency prescription drug order is to be administered,
3. The dispensing date and a unique readily retrievable identifier,
4. The standard radiation symbol
5. The words “Caution Radioactive Material”
6. The name of the procedure (if known)
7. The name or generally recognized and accepted abbreviation of the radiopharmaceutical, radionuclide, and chemical form
8. The requested amount of radioactivity at the calibration date and time
9. The radiopharmaceutical beyond-use date
10. The quantity dispensed,
11. If applicable, Molybdenum-99 content to *United States Pharmacopoeia* (USP) limits of <0.15uCi Mo-99 per 1mCi Tc-99m at time of administration or product expiration; and
12. The patient’s name or, in the absence of a patient name, “Physician’s Use Only,” “Contingency Prescription Drug Order,” “Per Physician’s Order” or similar wording. If no patient name is used, the pharmacy must be able to retrieve the name of the patient from the authorized prescriber/facility within three (3) days if requested. However, the patient’s name must appear on the label when the prescription is for a therapeutic or blood-containing radiopharmaceutical.

FDA approved radiopharmaceuticals are not subject to the above unit dose container labeling requirements or the radiometric measurement requirements of 20 CSR 2220-2.500 if the Class-E pharmacy does not process the radioactive drugs in any manner nor violate the original manufacturer product packaging/labeling. [20 CSR 2220-2.500(5)(D)]

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The immediate inner container label of a radiopharmaceutical to be dispensed must be labeled with—

1. The standard radiation symbol
2. The words “Caution Radioactive Material”
3. The identity of the radiopharmaceutical
4. The unique, readily retrievable identifier of the radiopharmaceutical, and
5. The patient’s name or, in the absence of a patient name, “Physician’s Use Only,” “Contingency Prescription Drug Order,” “Per Physician’s Order” or similar wording. [20 CSR 2220-2.500(5)(E)]

Dispensing/Delivery

Radiopharmaceuticals may only be dispensed to:

- A practitioner or facility authorized by the NRC or an Agreement State to possess, use and administer such drug, or
- A person who is authorized to possess the drug in accordance with NRC/Agreement State regulations.

Radiopharmaceuticals may not be dispensed directly to a patient under any circumstances.

Class-E pharmacies must have on file a copy of the current radioactive materials license for each licensed facility requesting a radiopharmaceutical before the radioactive drug is dispensed to the facility. Radiopharmaceuticals may only be delivered to the authorized address or locations listed in, or temporary job sites authorized by, the NRC/Agreement state license. The authorized physician ordering a radiopharmaceutical is recognized as the patient’s authorized designee for delivery purposes under 20 CSR 2220-2.013.

A Class-E pharmacy may accept returns and waste as authorized by the NRC/Agreement State regulations.

**A Class-E pharmacy may distribute radionuclide elutions to other authorized users to meet a drug shortage.
20 CSR 2220-2.500(E)*

D.11 CLASS-J SHARED SERVICES

A Class-J Shared Services pharmacy permit is required if two (2) or more pharmacies are engaged in, or have an arrangement to provide, functions related to the practice of pharmacy for or on behalf of the other pharmacy. Shared service activities that require a Class-J permit include, but are not limited to:

- *Receiving prescriptions/medication orders*
- *Prescription/order clarification or modification,*
- *Obtaining prescriber authorization,*
- *Data entry*
- *Compounding*
- *Dispensing*
- *Pharmacist verification*
- *Patient counseling,*
- *Patient profile maintenance*
- *Medication therapy services*
- *Medication administration*
- *Drug utilization review or*
- *Obtaining refill authorization.*

To participate in a Class-J shared services arrangement both pharmacies must:

- 1) Have a separate Class-J pharmacy permit for each shared services location; and
- 2) Have the same owner or have a written contract outlining the shared services to be provided by each party and each party’s responsibilities; and
- 3) Either share a common electronic database or have real time, on-line access to each pharmacy’s electronic medication/prescription records that allows both pharmacies to access the patient’s complete profile.

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Each pharmacy participating in a shared service arrangement must have a Class-J permit. Additionally, both pharmacies must maintain a policy and procedure manual that includes:

- 1) Each pharmacy's duties, including, authorized Class-J duties;
- 2) A mechanism for tracking the prescription/medication order during each step in the process;
- 3) Security provisions for protecting the confidentiality and integrity of patient information;
- 4) Procedures for ensuring safe and appropriate prescription delivery in compliance with [20 CSR 2220-2.013](#), and
- 5) A designation of the pharmacy responsible for offering patient counseling as required by [20 CSR 2220-2.190](#) (see *below*).

A pharmacy participating in Class-J Shared Services with a pharmacy that is not under common ownership must notify patients that their prescription or medication order may be filled or compounded by another pharmacy. Notification may be made verbally, electronically or in writing.

Once filled, prescriptions or medication orders must be labeled in accordance with state and federal law. For purposes of [§ 338.059](#), either the name and address of the pharmacy responsible for offering patient counseling may be listed on the label or the name and address of the pharmacy responsible for dispensing to the patient, as designated by the pharmacies by contract.

A Class-J permit is not required if a completed and labeled prescription is delivered from one Missouri licensed pharmacy to another Missouri licensed pharmacy for administration by a pharmacist or other licensed health care professional on the same premises as the pharmacy. The receiving pharmacy must maintain documentation of the medication received, the providing pharmacy's name and address, the receipt date and the patient's name. The receiving pharmacy is also responsible for ensuring compliance with all applicable patient counseling requirements. **This exemption only applies if a completed and labeled prescription is delivered to the receiving pharmacy. If additional manipulation or compounding is required by the receiving pharmacy, a prescription/medication order is required and the prescription/medication order must be dispensed as the receiving pharmacy's own prescription/order.*

QUALITY ASSURANCE PROGRAM

Class-J pharmacies must maintain a quality assurance program that is designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care and resolve identified problems. Proof/documentation of your quality assurance program may be requested during an inspection.

Transferring prescription information between Class-J pharmacies that share a real-time, on-line database is not considered a "prescription transfer" under [20 CSR 2220-2.120](#). However, other controlled substance laws may apply.

Central-fill pharmacies dispensing controlled substances must comply with state and federal controlled substance laws.

D.12 Class-L Veterinary Pharmacy

A Class-L Veterinary pharmacy permit is required for entities only dispensing or providing legend drugs for animal use. Class-L pharmacies must comply with all applicable provisions of [Chapter 338](#), RSMo, and the rules of the Board. However, rule [20 CSR 2220-2.675](#) authorizes the following activities to accommodate Class-L dispensing:

1. **Facility Standards:** In lieu of a separate and distinct pharmacy area, Class-L services can be provided in the same space or area as other business operations/activities provided there is a defined area for storing legend drugs. The defined drug area must be clean and sanitary and legend drugs must be properly identified at all times. Additionally, medication must be stored within the appropriate temperature requirements as provided by the manufacturer or the latest edition of USP. Appropriate sewage disposal and a hot and cold water supply must be available. The water supply may be located outside of the pharmacy provided it is accessible to pharmacy staff (*This exemption does not apply if sterile or non-sterile compounding is performed*). [[20 CSR 2220-2.675\(4\)\(F\)](#)]

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2. **Pharmacy Supervision:** Class-L pharmacies may operate without a pharmacist physically present on-site, provided the PIC reviews the activities and records of the pharmacy's operations on a monthly basis. The date of the PIC monthly review must be documented in the pharmacy's records. This exemption does not apply and a pharmacist must be on site:
 - If controlled substances are stored at or provided by the pharmacy, or
 - Whenever compounding is performed (sterile or non-sterile). [20 CSR 2220-2.675(6)]
3. **Dispensing Without A Pharmacist:** Class-L pharmacies may accept, fill or dispense non-controlled legend drugs for animal use without a pharmacist present, provided the pharmacy has specific policies and procedures for operating without a pharmacist. This exemption does not apply to controlled substances. Controlled substances must be verified by a pharmacist before dispensing.
 - The PIC must review the prescription records for all legend medication provided without a pharmacist present each month. The PIC should be designated as the dispensing pharmacist for these prescriptions/orders unless verified by another pharmacist. The date of the required monthly PIC review must be documented in the pharmacy's records.
 - Patient/client counseling must be offered each time medication is dispensed/provided by a Class-L pharmacy, as required by 20 CSR 2220-2.190. If the pharmacist is not on-site, a written offer to counsel with a toll-free telephone number for contacting a pharmacist must be provided.
 - The pharmacy must have policies and procedures for reporting and handling dispensing errors. All dispensing errors must be reported to the PIC within twenty-four (24) hours.
 - This exemption does not apply to controlled substances. Controlled substances must be verified by a pharmacist before dispensing.

Class-L pharmacies may only dispense medication for animal use. An additional permit is required to dispense drugs for humans (e.g., Class-A).

Class-A or Class-B pharmacies may dispense or provide legend drugs for both human and animal use under their Class-A/Class-B permit. An additional Class-L license is not required. However, Class-A or Class-B pharmacies would need an additional Class-L permit to use the Class-L exemptions (e.g., dispensing without a pharmacist).

Prescription Requirements: To be valid for dispensing, prescriptions for animal use must comply with § 338.056, RSMo, and § 338.196. Additionally, prescriptions must include:

- 1) The client's/owner's name and the class, species, or identification of the animal, herd, flock, pen, lot, or other group being treated;
- 2) The prescriber's name, if an oral prescription, or signature, if a written prescription;
- 3) Name, strength, and dosage form of the drug and directions for use;
- 4) The number of refills, when applicable;
- 5) The quantity prescribed in weight, volume, or number of units;
- 6) For controlled substances, the address of the prescriber and the patient; and
- 7) The prescriber's DEA number when the prescription is for a controlled substance. [20 CSR 2220-2.675(7)]

Prescription records must be maintained as required by Chapter 338, RSMo, and the rules of the Board (See Section K).

Effective August 28, 2018, § 338.056 allows a pharmacist to substitute a generic product unless the prescriber prohibits substitution. 20 CSR 2220-2.675 will need to be amended to reflect the new statutory language. In the interim, pharmacists dispensing medication for animal use may substitute a generic as authorized by § 338.056. Specific prescriber authorization to substitute is no longer statutorily required. (See H.7 for additional information)

Labeling: Legend medication for animal use must be labeled in accordance with § 338.059, RSMo. Labels must also include:

- 1) The class, species, or identification of the animal, herd, flock, pen, lot, or other group being treated; and
- 2) If applicable, the veterinarian's specified withdrawal, withholding, or discard time for meat, milk, eggs, or any other food which might be derived from the treated animal(s). [20 CSR 2220-2.675(9)]

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Compounding: Compounding can only be performed when a pharmacist is on site. Compounding must comply with [20 CSR 2220-2.200](#) (non-sterile compounding) and [20 CSR 2220-2.400](#) (non-sterile compounding).

Controlled Substances: Class-L pharmacies must comply with all state/federal controlled substance laws, including, all security and prescription/order requirements. A pharmacist must be present and onsite during pharmacy operations if controlled substances are sold or provided.

Policies and Procedures: Class-L pharmacies must maintain a policy and procedure manual that includes policies/procedures for:

1. Accepting, compounding, dispensing, or filling prescriptions;
2. Accepting, dispensing or providing prescriptions in a pharmacist's absence, if applicable;
3. Drug storage and security;
4. Handling drug recalls;
5. Offering patient/client counseling;
6. Contacting the pharmacist-in-charge for consultation during the pharmacy's business operations or in the event of an emergency; and
7. Reporting and handling dispensing errors, including, provisions for notifying the PIC of dispensing errors within the required twenty-four (24) hours.

The policy and procedure manual must be reviewed annually by the PIC and must be available on inspection or at the request of the Board.

D.13 Class M Specialty (Bleeding Disorder)

A Class-M pharmacy permit is required for pharmacies providing or offering to provide blood-clotting factor or products to patients with bleeding disorders. Section [338.400](#), RSMo, and rule [20 CSR 2220-6.100](#) contain additional requirements for Class-M pharmacies that are:

- Dispensing blood-clotting factor concentrates, and
- Dispensing blood clotting products to "established patients" or that offer or advertise to provide blood-clotting products specifically for bleeding disorder patients.

DISPENSING BLOOD-CLOTTING FACTOR CONCENTRATES

Class-M pharmacies dispensing blood-clotting factor concentrates to new or existing patients are required to comply with the following:

- 1) Barring extenuating circumstances, blood clotting factor concentrates must be dispensed within plus or minus ten percent (+/- 10%) of prescribed assays, or as otherwise authorized or directed by the prescriber. [[20 CSR 2220-6.100\(2\)\(E\)](#)].
- 2) **Prescription Changes/Substitutions:** Prescriptions for blood-clotting factor concentrates must be dispensed as written or as authorized by the prescriber. If the prescriber authorizes changing or substituting the blood-clotting factor concentrate originally prescribed, the patient/patient's designee must be notified and counseled regarding the change or substitution prior to dispensing via the patient's identified preferred contact method (see below). Counseling is mandatory unless refused by the patient/designee. [[20 CSR 2220-6.100\(2\)\(A\)](#)].
- 3) **Automatic Refills:** Unless previously authorized by the patient or the patient's designee, the patient must be contacted for authorization to dispense prior to shipping a refill of any blood-clotting product. Authorization may be given verbally or in writing and must be documented in the pharmacy's prescription records. The Board also recommends documenting the method/manner of authorization (e.g., written or verbal). [[20 CSR 2220-6.100\(2\)\(D\)](#)].

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- 4) **Delivery Requirements:** If requested, blood-clotting factor concentrates must be shipped and delivered to the patient within two (2) business days for established patients in non-emergency situations and three (3) business days for new patients. Non-emergencies include, but may not be limited to, routine prophylaxis requests. Appropriate cold chain management and packaging practices must be used. [20 CSR 2220-6.100(2)(B)].
- 5) **Pharmacy Contact:** A toll free number for the pharmacy must be provided to patients to report problems with a delivery or product. The toll free number must be provided each time a prescription is dispensed (both new and refill). [20 CSR 2220-6.100(2)(C)].
- 6) **Preferred Contact Method:** The patient or the patient’s designee must be asked to designate a preferred contact method for receiving notifications in the event of a recall or withdrawal of the concentrate dispensed or any related ancillary infusion equipment and supplies. [20 CSR 2220-6.100(2)(C)]. The preferred contact method must be documented in the patient’s prescription records.
- 7) **Recall/Withdrawal Notifications:** The patient and the prescriber must be notified by the pharmacy within twenty-four (24) hours after notification from the manufacturer or from any state/federal entity of a recall or withdrawal of any concentrate or ancillary infusion equipment/supplies. Notification is only required if the manufacturer or state/federal entity requires or recommends patient notification. The pharmacy is required to contact the prescriber to obtain a new prescription if necessary to dispense a substitute or alternative product. [20 CSR 2220-6.100(2)(F)1.].

If attempts to contact the patient via the preferred contact method are unsuccessful, notification must be mailed to the patient/patient’s designee within the required twenty-four (24) hours or the next business day. The time, date, and method(s) of notification must be documented in the pharmacy’s records and maintained for two (2) years from the date of recall or withdrawal. [20 CSR 2220-6.100(2)(F)].

Examples of currently known blood-clotting factor concentrates include:

| Blood-Clotting Factor Concentrates** | Not a Blood-Clotting Factor Concentrate |
|---|---|
| <ul style="list-style-type: none"> • Recombinant Factor VII & Recombinant-activated Factor VIIa; | <ul style="list-style-type: none"> • Aminocaproic Acid; |
| <ul style="list-style-type: none"> • Recombinant Factor VIII & plasma-derived Factor VIII; | <ul style="list-style-type: none"> • Desmopressin Acetate; |
| <ul style="list-style-type: none"> • Recombinant Factor IX & plasma-derived Factor IX; | <ul style="list-style-type: none"> • Warfarin; and |
| <ul style="list-style-type: none"> • von Willebrand factor products; | <ul style="list-style-type: none"> • Heparin |
| <ul style="list-style-type: none"> • Bypass products for patients with inhibitors; | |
| <ul style="list-style-type: none"> • Prothrombin complex concentrates; and | |
| <ul style="list-style-type: none"> • Activated prothrombin complex concentrates. | |

** As currently approved by the FDA

DISPENSING BLOOD-CLOTTING PRODUCTS

In addition to the requirements above, 20 CSR 2220-6.100(3) establishes requirements for Class-M pharmacies dispensing blood clotting products to “established patients” or that offer or advertise to provide blood-clotting products specifically for bleeding disorder patients.

- An “established patient” is defined as a bleeding disorder patient that has been dispensed a legend blood-clotting product by the pharmacy on more than three (3) occasions in a single calendar year. [20 CSR 2220-6.100(1)(C)].
- A “blood-clotting product” is defined as:

A medicine approved for distribution by the federal Food and Drug Administration that is used for the treatment and prevention of symptoms associated with bleeding disorders, including but not limited to recombinant Factor

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VII, recombinant-activated Factor VIIa, recombinant Factor VIII, plasma-derived Factor VIII, recombinant Factor IX, plasma-derived Factor IX, von Willebrand factor products, bypass products for patients with inhibitors, prothrombin complex concentrates; and activated prothrombin complex concentrates. [§ 338.400(4)]

Except as otherwise provided by § 338.400, RSMo, a “blood clotting product” does not include medical products approved solely for the treatment or prevention of side effects of a blood-clotting drug or medication. [20 CSR 2220-6.100(1)(B)].

- A “bleeding disorder” is defined as:
A medical condition characterized by a deficiency or absence of one (1) or more essential blood-clotting components in the human blood, including all forms of hemophilia, acquired hemophilia, von Willebrand’s disease, and other bleeding disorders that result in uncontrollable bleeding or abnormal blood-clotting. [20 CSR 2220-6.100(1)(A)]

A “bleeding disorder” does not include bleeding conditions secondary to another medical condition or diagnosis, except for acquired hemophilia. [20 CSR 2220-6.100(1)(A)].

Class-M pharmacies that are providing blood clotting products to established patients, or that offer or advertise to provide blood-clotting products specifically for bleeding disorder patients, have to comply with the following:

- 1) **Board Notification:** The pharmacy must notify the Board annually if the pharmacy intends on providing legend blood-clotting products to bleeding disorder patients. Notification must be made on or before January 31st of each year and should be submitted online at: pr.mo.gov/pharmacists-onlineservices.asp. [20 CSR 2220-6.100(3)(A)].
- 2) **Pharmacist Availability:** A pharmacist must be available twenty-four (24) hours a day, seven (7) days a week, every day of the year, either on-site or on call, to fill prescriptions for blood-clotting products within the shipping/delivery time frames referenced below. [20 CSR 2220-6.100(3)(C)].
- 3) **Supply Requirements:** The pharmacy must identify, or make arrangements with, a supplier(s) who can provide all brands, assays and vial sizes of FDA approved blood-clotting products, including both, plasma and recombinant products. A list of identified suppliers must be maintained at the pharmacy and available during inspection. Products do not have to be pre-purchased. Instead, the pharmacy must have an identified supplier if a product is needed. [20 CSR 2220-6.100(3)(B)].
- 4) **Ancillary Supplies:** Ancillary equipment and supplies required to infuse blood-clotting products intravenously must be available for purchase, including, but not limited to, syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, and cold compression packs. Items must be restocked in a reasonable amount of time but in no event later than seven (7) calendar days. [20 CSR 2220-6.100(3)(H)].
- 5) **Shipping/Delivery Requirements:** If requested by an established patient, the pharmacy must provide for the shipment and delivery of blood-clotting products to the patient within two (2) business days after receiving a prescription or refill request. For new patients, shipment/delivery must be made within three (3) business days. In the event of an emergency, established patients must be provided access to blood-clotting products within twelve (12) hours after notification from the prescriber that an emergency supply is needed. Emergency requests must be documented in the pharmacy’s records.

If the pharmacy is waiting for action from a third-party payor prior to shipping/delivery (e.g. authorization, certification, etc.), the patient must be notified that the prescription is ready and any alternate payment options must be explained. Notification must be made as soon as reasonably practicable but in no event later than the required delivery timeframe. Pharmacies may delay shipping/delivery until payment is confirmed.

- 6) **Hazardous Waste:** Hazardous waste disposal containers must be provided or available for purchase at the pharmacy (e.g., - Sharps containers). [20 CSR 2220-6.100(3)(G)].
- 7) **National Register:** The pharmacy must register with the National Patient Notification System, or its successor, to receive recall notifications for all products included in the National Patient Notification System. Registration is free and may be completed online at www.patientnotificationsystem.org/. Contact information must be kept current and accurate. [20 CSR 2220-6.100(3)(K)].
- 8) **Nursing Services:** Contact information must be available for a nurse/nursing service with experience in providing infusion related nursing services or nursing services for bleeding disorder patients, if the nursing services are not

provided by the pharmacy. [20 CSR 2220-6.100(3)(I)].

- 9) **Insurance Information:** If requested, the pharmacy must explain any known insurance copayments, deductibles, coinsurance payments or lifetime maximum insurance payment limits. [20 CSR 2220-6.100(3)(J)]. The Board recognizes that licensees may have limited access to or knowledge of benefit information. 20 CSR 2220-6.100(3)(J) provides the pharmacy may rely on information supplied by the patient's insurer.
- 10) **Policy & Procedure Manual:** The pharmacy must establish a written policy & procedure manual to ensure compliance with § 338.400 and 20 CSR 2220-6.100 and that includes policies/procedures for: processing prescriptions, partial fills, providing/documenting recall notifications, emergency dispensing and cold chain management/packaging (*This list is not exhaustive; See 20 CSR 2220-6.100(4) for all policy and procedure requirements*). Policies and procedures must be reviewed annually. Documentation of the annual review must be maintained in the pharmacy's records. [20 CSR 2220-6.100(4)].
- 11) **Pharmacist Training/Continuing Education:** Pharmacists engaged in dispensing or filling blood-clotting factor concentrates for established patients or who provide patient counseling on blood clotting factor concentrates to bleeding disorder patients must have sufficient knowledge, experience and training to perform the duties assigned. Additionally, pharmacists engaged in counseling bleeding disorder patients must complete four (4) continuing education hours (0.40 CEU) related to blood-clotting factor concentrates, infusion treatment/ therapy or blood-clotting disorders or diseases each biennial renewal period. [20 CSR 2220-6.100(3)(D)]. The required CE hours can be used to meet the biennial pharmacist CE requirements.



SECTION E: PHARMACY STANDARDS OF OPERATION

E.1 GENERAL REQUIREMENTS

Pharmacies must be operated in a manner that will protect the public health and that will ensure pharmacy services are safely and accurately provided at all times. Pharmacy compliance requirements will differ based on the pharmacy's permit classification and activities. This section summarizes general operational standards applicable to all pharmacies. Licensees should thoroughly review [Chapter 338](#) and the rules of the Board to ensure compliance.

E.2 FACILITIES

To protect the public health, pharmacies must be maintained in a clean and sanitary condition at all times. Animals are not allowed in the pharmacy, except for service animals as defined by the American with Disabilities Act [[20 CSR 2220-2.010\(F\)](#)]

E.3 LICENSE POSTING

The pharmacy's permit and the licenses/registrations of all pharmacists, intern pharmacists and technicians working in the pharmacy must be conspicuously posted in the pharmacy permit area. [[20 CSR 2220-2.010\(1\)\(K\)](#), [20 CSR 2220-2.700\(1\)\(B\)](#)]. Pharmacist licenses must be accompanied by a 2"x 2" photo. In lieu of posting, pharmacists working at more than one pharmacy must have proof of licensure in their possession (e.g., license wallet card, online license verification). [[20 CSR 2220-2.010\(1\)\(L\)](#)].

E.4 REQUIRED EQUIPMENT/REFERENCES

Pharmacies must be equipped with proper equipment and reference manuals for the pharmacy services provided. [[20 CSR 2220-2.010\(1\)\(C\) – \(D\)](#)]. Equipment should be in good working order and properly maintained. The Board does not approve specific brands or products. However, the following minimum equipment is required:

- Any basic equipment recognized by the latest edition of the *United States Pharmacopeia (USP)*, the *United States Pharmacopeia/Drug Information (USP/DI)* or *Remington's: The Science and Practice of Pharmacy*;
- A suitable machine/device for numbering prescriptions or assigning a unique identifier;
- Printing equipment for prescription labels;
- The current or latest edition of a reference manual(s) which includes all FDA approved drugs and information on pharmacology, dosages and clinical effects of drugs, and patient information; and
- A current edition of [Chapter 338](#), RSMo, the Board's rules and any other statutes/rules governing the pharmacy's practice (e.g., [Chapter 195](#) governing controlled substances or BNDD/DEA rules)

Reference materials can be maintained electronically or in print. However, the materials must be accessible to pharmacy staff and immediately retrievable during an inspection.



SECTION E: PHARMACY STANDARDS OF OPERATION

E.5 DRUG STORAGE AREAS/REFRIGERATION

Adequate refrigeration and storage space must be available for drug inventory. Medication must be properly stored at all times within the proper temperature and humidity requirements. Drug storage areas must be thermostatically controlled within the temperature requirement(s) provided by the manufacturer or USP. [20 CSR 2220-2.010(1)(G)]. To ensure compliance, drug storage areas should have a thermometer or other temperature monitoring device that is checked regularly. Staff should be trained on what appropriate temperature(s) should be and what to do if a temperature reading is out of range.

Food and beverage items that are not in their original, sealed manufacturer packaging must be stored separately from medication and medication-related devices. Open food or beverages used in compounding or intended for patient use with medication may be stored in the same area as drugs and drug-related devices as long as the items are separated from other inventory and sanitary conditions are maintained at all times. [20 CSR 2220-2.010(1)(G)]

Outdated, distressed, misbranded or adulterated drugs must be physically separated from the active inventory and maintained in a separate area. [20 CSR 2220-2.090(2)(V)]. Segregated areas must be adequately marked or identified to ensure outdated, misbranded or adulterated drugs do not re-enter the pharmacy's active inventory.

Licensees should review package labeling as some products have special storage and temperature requirements and may not be stored in certain refrigeration/freezer units (e.g., dormitory style refrigerators). Other products may have limited expiration dating once the package is opened.

E.6 PHARMACY SUPERVISION

Pharmacy staff must be adequately supervised at all times to ensure pharmacy services are safely and accurately performed. A pharmacist must be present and on duty when the pharmacy is in operation and whenever prescriptions are being compounded, prepared, distributed or dispensed. Pharmacy technicians may assist in any area of pharmacy practice. However, technicians may not work independently and must be under the "direct supervision and responsibility" of a Missouri-licensed pharmacist at all times. [20 CSR 2220-2.700]. (See *Section O (Pharmacy Technicians)* & *Section P (Intern Pharmacists)* for authorized staff functions).

When no pharmacist is on duty, a sign must be posted on the prescription counter and on all entrance doors informing the public that "no pharmacist is on duty." Sign lettering may be no smaller than two inches (2") in height. [20 CSR 2220-2.010(1)(A)]. The "no pharmacist on duty sign" does not have to be posted if the pharmacist is in the pharmacy building but briefly absent from the pharmacy area (e.g., restroom breaks).

The Board has determined that technicians/intern pharmacists may accept written prescriptions from patients for dispensing when no pharmacist is on duty. [20 CSR 2220-2.010(1)(B)]. However, technicians/intern pharmacists cannot take verbal prescription orders or count, fill, compound or enter a prescription if the pharmacist is absent.

Technicians cannot come in early to process prescriptions before a pharmacist arrives or hand out or dispense prescriptions when no pharmacist is on duty, even if the prescription was previously checked by a pharmacist.

Remote supervision of pharmacy technicians/intern pharmacists is not allowed in Missouri at this time.

SECTION E: PHARMACY STANDARDS OF OPERATION

INTERN VS. TECHNICIAN AUTHORIZED DUTIES

The chart below is NOT exhaustive and does not include all potential tasks that may be performed by an intern pharmacist or pharmacy technician. All authorized activities must be performed under the direct supervision of a Missouri licensed pharmacist. X=Activities not allowed

| | Intern Pharmacist* | Pharmacy Technician* |
|---|--|----------------------|
| <i>Administer Medication by Rx Order</i> | ✓ | X |
| <i>Advise/Counsel Patients on OTC Items</i> | ✓ | X |
| <i>Dispense Rx to Patient (after verification by a pharmacist)</i> | ✓ | ✓ |
| <i>Drug Utilization Review</i> | ✓ | X |
| <i>Enter Rx Data</i> | ✓ | ✓ |
| <i>Immunize by Protocol</i> | ✓ <i>*If under the direct supervision of a pharmacist authorized to immunize by protocol.</i> | X |
| <i>Modify Medication Therapy under MTS protocol</i> | X | X |
| <i>Patient Counseling</i> | ✓ | X |
| <i>Prepare/Compound Rx</i> | ✓ | ✓ |
| <i>Receive Rx</i> | ✓ | ✓ |
| <i>Receive or provide controlled substance transfer information</i> | X | X |
| <i>Request refill authorization</i> | ✓ | ✓ |
| <i>Verify Final Product</i> | X | X |

*See [section O](#) & [section P](#) for additional information on authorized pharmacy technician and intern pharmacist duties.

E.7 STAFFING

Pharmacies should maintain sufficient staffing to ensure pharmacy services are being safely and accurately provided. Missouri does not mandate a staffing ratio (e.g., pharmacist-to-technician). However, the Board is concerned about patient safety if staffing levels are inadequate to appropriately provide patient care and supervise the pharmacy. Licensees should consider the type of services provided by the pharmacy when calculating staffing levels, including, prescription volume and any other factor that may impact pharmacy services. For example, additional staffing may be needed at certain periods of the day or during peak periods such as immunization season.

Licensees should also consider pharmacist workload. As the practice of pharmacy expands, pharmacists are being asked to do more. Pharmacists should have sufficient time, staff and rest breaks to function safely.

All staff must be appropriately licensed or registered to work. License status may change throughout the year due to discipline, non-renewal or tax compliance issues. The Board recommends designating a specific person who is responsible for checking licensure status for staff at a regularly set interval. (See [O.7](#) for additional technician license/disciplinary information).

In addition to Board disciplinary actions, the federal Department of Health and Human Service, Office of the Inspector General Exclusion List (OIG List) includes entities/persons excluded from participating in Medicare, Medicaid and other federal health care programs. Employers participating in qualified federal programs are generally prohibited from employing individuals on the OIG list. For additional information, visit OIG's website at oig.hhs.gov/exclusions/index.asp.

SECTION E: PHARMACY STANDARDS OF OPERATION

MoHealthNet also maintains a list of providers that have been terminated from participating in the MoHealthNet program which is available online at: mmac.mo.gov/providers/provider-sanctions/

REQUIRED STATE/FEDERAL WAIVERS

WAIVERS: Both state and federal law prohibit an employer from hiring individuals with certain controlled substance related convictions without an employment waiver [see 21 CFR 1301.76(a); 19 CSR 30-1.034]. Specifically, employers are required to obtain a DEA waiver for employees with felony controlled substance related convictions. A Missouri BNDD waiver is required for both misdemeanor and felony controlled substance related convictions. Waivers may be required even if the Board has issued a license/registration. A waiver is required for every location where the individual is employed

Licensees should conduct thorough background checks to ensure compliance. The Board is legally prohibited from sharing confidential criminal history information. Questions about controlled substance waivers should be addressed to BNDD or the DEA. (See also [DEA Request for Waiver Q&A](#))

E.8 SECURITY

Pharmacies must maintain adequate security to deter drug theft/diversion. [20 CSR 2220-2.010(1)(H)]. Confidential records must also be secured to prevent theft, diversion or unauthorized access. Pharmacies located in facilities that have public access after the pharmacy's normal hours of operation must have sufficient alarm systems or locking mechanisms that are able to detect and prevent unauthorized access into the pharmacy (e.g., access via the ceiling or above gates/doors). Licensees should consider counter heights, wall/ceiling barriers and areas that might be easily accessed by the public. The Board has investigated medication being stolen by customers who were able to reach into will-call bins or over prescription counters. At other times, prescriptions were left unattended at the register. *Note: Licensees must also comply with all controlled substance security requirements.*

Additional diversion prevention tips and resources are available on the [Board's website](#).

Resources/videos on preventing or handling pharmacy robberies are available at www.rxpatrol.com. This website is provided for informational purposes only and is not sponsored or endorsed by the Board.

E.9 VACUUM TUBE DELIVERY SYSTEMS [20 CSR 2220-2.800]

Vacuum tube systems may be used to deliver medication to a patient if the system is designed and engineered to ensure drug security and to ensure that drugs are correctly and efficiently delivered. The system must be dedicated solely to delivering medication from within a licensed pharmacy and cannot be used for other departments or combined/attached to any other system (e.g., grocery delivery). The system must be turned off and medication may not be delivered if the pharmacy is closed or when there is no pharmacist on duty.

Vacuum tube systems must allow pharmacy personnel and the consumer to communicate effectively both orally and in writing. A direct and identifiable line of sight must be maintained with the consumer. Alternatively, a video camera and audio system may be used to identify consumers. The video monitor/audio system must be in good working order or use must be discontinued until corrections/repairs are made. At a minimum, video monitors must be at least twelve inches (12") wide. Backlighting or other factors that may inhibit video/audio performance must be considered before operation.

Recipients must be positively identified before drugs are delivered via a vacuum tube system. [See 20 CSR 2220-2.800(2) for vacuum systems installed before September 1, 1988].

SECTION E: PHARMACY STANDARDS OF OPERATION

E.10 AUTHORIZED MEDICATION SOURCES

Licensees may only receive/purchase medication from:

- 1) A Missouri-licensed drug distributor, drug outsourcer or third-party logistics provider,
- 2) A Missouri licensed pharmacy or
- 3) A pharmacy licensed in another U.S. state or territory. (See D.9 for Class-B pharmacy/hospital exemptions)

Licensees receiving medication from a non-resident pharmacy that is not licensed in Missouri must comply with the following:

1. The receiving Missouri pharmacy must maintain proof the non-resident pharmacy has a current pharmacy license in the state/territory where the drug is shipped/distributed from,
2. An invoice record must be maintained which documents the name and address of the non-resident pharmacy, the purchase/transfer date and the name, strength, and quantity of the drug received. See 20 CSR 2220-5.020(1) for additional drug distribution exemptions, and
3. The total amount of medication distributed/received from a non-resident pharmacy that is not licensed in Missouri cannot exceed five-percent (5%) of the pharmacy's annual prescription drug sales. [§ 338.315.2]

Medication receipts/transfers must be documented by invoice (non-controlled and schedule III-V drugs) or via CSOS or a DEA 222 form (schedule II).

E.11 DRUG SAMPLES

Unless otherwise allowed by federal law, drug samples may not be dispensed by, or maintained in, the pharmacy. [20 CSR 2220-2.010(8)].

E.12 OFFSITE STORAGE SITES

Medication and confidential pharmacy records may be stored off-site at a different location/address than the pharmacy if the off-site location is registered with the Board. [20 CSR 2220-2.010(1)(I), (J)]. To register an offsite facility, licensees should e-mail their license number along with the location/address of the offsite facility to the Board office at pharmacy@pr.mo.gov.

Off-site record storage locations must meet the following requirements:

- Adequate security must be maintained to protect confidentiality and prevent unauthorized access. The off-site location must be equipped with an alarm system;
- No record less than two years old may be stored off site;
- Security breaches must be reported to the Board within fifteen (15) days; and
- Records stored off-site must be made available for inspection within two business days, if requested.

Pharmacies may share storage space at an off-site facility if each pharmacy's records and/or drug inventory can be individually identified and are securely stored to prevent unauthorized access. Offsite facilities may be inspected by the Board for compliance. *Note: Offsite storage would include storing records at another pharmacy and would require Board notification.*

SECTION E: PHARMACY STANDARDS OF OPERATION

E.13 POLICIES AND PROCEDURES

Effective policies and procedures promote consistency and can help prevent compliance violations. Generally, Missouri law requires the following pharmacy policies and procedures:

| Policy/Procedure Type | Regulation | Annual Review Required |
|--|--------------------------|------------------------|
| General | 20 CSR 2220-2.090 (2)(P) | |
| Class C: Long Term Care | 20 CSR 2220-2.140 | |
| Class F: Renal Dialysis | 20 CSR 2220-2.600 | |
| Class H: Sterile Products Compounding | 20 CSR 2220-2.200 | √ |
| Class I: Consultant in a Residence | 20 CSR 2220-2.010 (10) | |
| Class J: Shared Service | 20 CSR 2220-2.650 | |
| Class L: Veterinary | 20 CSR 2220-2.675 | √ |
| Class M: Specialty (Bleeding Disorder) | 20 CSR 2220-6.100 | √ |
| Classes N & O: Automated Dispensing System | 20 CSR 2220-2.900 | |
| Administration by Prescription Order | 20 CSR 2220-6.040(4)(B) | |
| Automated Filling Systems | 20 CSR 2220-2.950 | √ |
| Drug Take Back | 20 CSR 2220-2.095(3) | |
| Electronic Recordkeeping Systems | 20 CSR 2220-2.083 | √ |
| Prescription Deliveries | 20 CSR 2220-2.013(1) | |
| Technician Duties | 20 CSR 2220-2.090(2)(CC) | |

Note: Additional policies and procedures may be required by other state/federal law (e.g., DEA, BNDD).

Policies/procedures should be reviewed on a regular basis and updated as needed. Relevant changes should be shared and discussed with pharmacy staff to ensure compliance. Policies and procedures can be maintained electronically but must be readily retrievable during an inspection.

SECTION E: PHARMACY STANDARDS OF OPERATION

E.14 BOARD REPORTING/NOTIFICATIONS

Pharmacies are required to notify the Board of the following (*this chart does not include controlled substance reporting requirements*):

| WHAT NEEDS TO BE REPORTED? | WHEN? | STATUTE/RULE |
|--|--|--|
| Breach of security (Bd. registered offsite warehouse/ storage facility) | Within fifteen (15) days after breach | 20 CSR 2220-2.010(1)(I), (J) |
| Breach of security (Class-I Consultant pharmacy electronic data processing system) | Within seven (7) days of a confidentiality breach | 20 CSR 2220-2.010(10)(C) |
| Change of Classification | Prior to performing new classification activities | § 338.220 |
| Change of Location | Prior to operating at new location | 20 CSR 2220-2.020(4) |
| Change of Ownership | Prior to operating under new ownership. <i>Note: Individuals/ Entities acquiring more than 25% of a pharmacy's ownership must notify the Bd. within 30 days</i> | 20 CSR 2220-2.020(1)/20 CSR 2220-2.020(3)(B) |
| Change of Partners/Members (Pharmacy LLPs or LLCs) | Within ten (10) days after the partnership/membership change | 20 CSR 2220-2.020(3)(C) |
| Final disciplinary action against a technician or a qualifying voluntary resignation (See E.15) | Within fifteen (15) days after action/ resignation | § 338.013 |
| Final adverse action, license surrender or federal exclusion involving or against the pharmacy (See E.15) | Within seven (7) days after action/ exclusion | § 338.075 |
| Final disciplinary action against a pharmacist employed to provide health care services or a qualifying voluntary resignation (See E.15) | Within fifteen (15) days after action/ resignation | § 383.133 |
| Intent to provide legend blood-clotting products to bleeding disorder patients (Class-M Pharmacies) | On or before January 31st annually | 20 CSR 2220-6.100(3)(A) |
| Out of Business Notification | Within fifteen (15) days after terminating business | 20 CSR 2220-2.015(1) |
| Pharmacy Remodeling | Remodeling affidavit & project plans filed with Board within thirty (30) days before the change | 20 CSR 2220-2.020(4)(A) |
| PIC Change | Promptly after new PIC is designated | 20 CSR 2220-2.010(1)(M) |
| Recall of a compounded preparation deemed to be misbranded, adulterated or sterile preparations deemed to be non-sterile or if end-preparation testing results are out of specification. | Within three (3) business days after the recall. **Prescriber notification also required** | 20 CSR 2220-2.200(21), 20 CSR 2220-2.400(8)(C) |
| <u>Sterile Compounding</u> : Any environmental sample as part of a remedial investigation that exceeds USP Chapter 797 action levels | Within three (3) days of detection | 20 CSR 2220-2.200(20)(C) |

SECTION E: PHARMACY STANDARDS OF OPERATION

| | | |
|---|---------------------------|-------------------------|
| Theft/diversion of or from a collection receptacle used to collect medication for destruction under 20 CSR 2220-2.095 | Within fourteen (14) days | 20 CSR 2220-2.095(4)(F) |
|---|---------------------------|-------------------------|

E.15 REPORTING OF DISCIPLINE/ADVERSE ACTIONS

The following disciplinary/adverse actions must be reported to the Board:

| TYPE OF ACTION | STATUTE | WHO IS REQUIRED TO REPORT? | WHAT SHOULD BE REPORTED? | WHEN |
|-----------------------------------|-----------|---|--|---|
| Technician Discipline/Resignation | § 338.013 | Licensed pharmacies & hospitals | <ul style="list-style-type: none"> Any final disciplinary action taken against a technician for conduct that may constitute grounds for discipline under § 338.055 Any technician who voluntary resigns if a complaint or report has been made against the technician which could have led to final disciplinary action and the actions alleged in the complaint/report are cause for discipline under § 338.055 | Within fifteen (15) days after action/resignation. |
| Pharmacist Discipline/Resignation | § 338.133 | Any entity that employs a pharmacist to provide health care services (<i>this includes, but is not limited to, pharmacies, hospitals, ambulatory surgical centers, long-term care facilities and nursing homes</i>) | <ul style="list-style-type: none"> Any final disciplinary action against the pharmacist that might have led to disciplinary action under § 338.055 The voluntary resignation of any pharmacist against whom any complaints or reports have been made which might have led to disciplinary action. | Within fifteen (15) days of the <u>final</u> disciplinary action/resignation. |

SECTION F: PRESCRIPTION REQUIREMENTS

F.1 DISPENSING AUTHORITY

Except as otherwise provided by state or federal law, licensees may only dispense medication pursuant to a “prescription” or “prescription drug order” from an authorized prescriber for a specific patient. [§ 338.095]. Class B pharmacies are also authorized to dispense by medication prescription order (See D.9). A “prescription” or “prescription drug order” is defined as:

A lawful order for medications or devices issued and signed by an authorized prescriber within the scope of his professional practice which is to be dispensed or administered by a pharmacist or dispensed or administered pursuant to section 334.104, RSMo, to and for the ultimate user. The terms “prescription” and “drug order” do not include an order for medication requiring a prescription to be dispensed, which is provided for the immediate administration to the ultimate user or recipient. [§ 338.095].

F.2 AUTHORIZED PRESCRIBERS

To be valid for dispensing, a prescription must have been written by a prescriber that is licensed in the United States or a U.S. territory who is legally authorized to prescribe. [§ 338.095; 20 CSR 2220-2.020(11)]. Missouri law recognizes the following prescriptive authority:

| PRESCRIBER | AUTHORITY |
|---|---|
| Assistant Physicians | Both controlled & non-controlled prescriptive authority under a collaborative practice agreement with a Missouri licensed physician. See Section G for Mid-Level Practitioners. |
| Advanced Practice Registered Nurses | Both controlled & non-controlled prescriptive authority if under a collaborative practice agreement with a Missouri licensed physician. See Section G for Mid-Level Practitioners. |
| Physicians | Both controlled & non-controlled authority. |
| Dentists, Veterinarians, Podiatrists and Optometrists | Both controlled & non-controlled authority. May prescribe within their scope of practice. |
| Physician Assistants | Both controlled & non-controlled prescriptive authority if under a collaborative practice agreement with a Missouri licensed physician. See Section G for Mid-Level Practitioners. |
| Out-of-State Prescribers | Must be legally authorized to prescribe in the prescriber’s licensing state/territory. The prescription may be filled even if similar prescriptive authority is not recognized in Missouri. (e.g., out-of-state chiropractors, pharmacists or psychologists with prescriptive authority). |
| Non-U.S. Prescribers | Prescriptions from a prescriber licensed in a foreign country or jurisdiction (e.g., Canada, Mexico) cannot be filled unless the practitioner is also licensed and legally authorized to prescribe in a U.S. state or territory. [§ 338.095; 20 CSR 2220-2.020(11)]. |
| Military Prescribers | The Board does not have jurisdiction over pharmacy practice on military bases. Prescriptions from a member of the armed forces may be filled by a Missouri pharmacy if the prescription complies with federal requirements. |

Licensees are responsible for ensuring valid prescriptive authority and, if applicable, proper controlled substance authority. The DEA publishes a state listing of authorized controlled substance prescribers at www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf. The National Association of Boards of Pharmacy (NABP) also publishes a state-specific listing in its Annual Survey of Pharmacy Law that can be purchased at nabp.pharmacy. Note: These resources are not maintained by the Board and the Board cannot guarantee their accuracy.

SECTION F: PRESCRIPTION REQUIREMENTS

Self-Prescribing: Physicians cannot prescribe controlled substances for themselves unless it is a medical emergency (see § 195.070.5, RSMo). Physicians may prescribe non-controlled drugs for themselves, however, the practice is discouraged by the Board of Healing Arts.

Family Members: Physicians may prescribe controlled or non-controlled drugs for a family member, as long as the physician maintains the same records for family members as he/she would for any other patient and all other prescription requirements are met. Please consult the Board of Healing Arts for additional guidance.

F.3 PRESCRIPTION FORMAT

Effective August 28, 2018, prescriptions from a Missouri prescriber no longer have to be in two-line format (e.g., two signature lines on opposite ends of the bottom of the prescription). However, two-line prescriptions may still be filled if otherwise valid. Prescriptions from non-Missouri prescribers must be in the format approved in the state/territory where the practitioner is licensed. *See H.7 for Generic Substitution.*

Security Paper: Paper prescriptions with an electronic signature must be applied to security paper that will detect or identify if the prescription/medication order has been copied or altered (e.g., watermark, microprint, heat detection/rub features). [20 CSR 2220-2.085]. Paper or computer generated prescriptions that are physically signed by the prescriber do not need to be on security paper. BNDD has confirmed that security paper is strongly recommended but not required for controlled substance prescriptions. *Note: CMS may require tamper resistant paper for Medicaid reimbursement.*

F.4 PRESCRIPTION REQUIREMENTS

To be valid for dispensing, prescriptions must include:

- 1) The date of prescribing;
- 2) The name of the patient(s), or if an animal, species and owner's name;
- 3) A written signature or valid electronic signature that complies with 20 CSR 2220-2.085. For verbal prescriptions, the prescriber's name must be documented;
- 4) Name, strength & dosage of the drug, device or poison prescribed and the directions for use;
- 5) The number of refills, if applicable;
- 6) The quantity prescribed in weight, volume, or number of units;
- 7) Any change or alteration made to the prescription dispensed based on contact with the prescriber to show a clear audit trail, including, but not limited to, a change in quantity, directions, number of refills, or substitution authority;
- 8) For controlled substance, the patient's address along with the prescriber's address and DEA number. [See 20 CSR 2220-2.018]; and
- 9) Prescriptions from a Missouri mid-level practitioner must include the name, telephone number and address of both the physician and the prescribing mid-level practitioner [Physician Assistants: § 334.735.4(3), (Assistant Physicians: 20 CSR 2150-2.240(2)(E)7.; Advanced Practice Registered Nurses: 20 CSR 2150-5.100(2)(G)7.] See Section G for Mid-Level Practitioners. *See Section G for Mid-Level Practitioners.*

Controlled substance prescriptions must also include:

- The address of the prescriber and the patient,
- The dosage form
- The prescriber's Drug Enforcement Administration (DEA) number, and
- Any other information required by state/federal law.

Prescriptions must be consecutively numbered or assigned a unique, readily retrievable identifier. [20 CSR 2220-2.010(2); 20 CSR 2220-2.017]. The Board anticipates further defining a "unique identifier" by rule. In the interim, prescriptions should be uniquely labeled in a manner that allows individual retrieval.

SECTION F: PRESCRIPTION REQUIREMENTS

F.5 PRESCRIPTION CHANGES

Changes in prescription or medication orders may only be communicated by the prescriber or the prescriber's duly authorized representative. Once received, authorized changes should be documented on the prescription or in the pharmacy's prescription records. Pending further DEA guidance, BNDD has provided the following information for schedule II controlled substances:

Methods of changing C-II controlled substance prescriptions:

1. A prescriber may provide a written change to the pharmacy that the pharmacy must attach to the original prescription. The written change must document the date and name of the person authorizing the change. The change may be mailed, emailed, or faxed.
2. The change may be communicated orally. The pharmacy must record the date, changes, and person authorizing the changes on the front or back of the prescription.

| What may be changed/added on a controlled substance prescription with permission | What CAN NEVER be changed/added |
|---|---|
| <ul style="list-style-type: none">• Date written• Patient's address (complete physical address, not P.O. Box)• Drug form• Drug strength• Quantity to be dispensed• Prescriber's address• Prescriber's DEA number• Directions for use• Substitutions permitted• Refill information• Reasons for extended supplies for Schedule II prescriptions. | <ul style="list-style-type: none">• Patient's name• Drug name• Prescriber's name• Prescriber's signature |

See [BNDD's Interim Schedule II Policy](#) for full guidance.

F.6 PATIENT-PRACTITIONER RELATIONSHIP

Prescriptions must be based on a valid patient-practitioner relationship. [20 CSR 2220-2.020(11)]. Additionally, the practitioner must have performed a valid medical evaluation as required by law. [20 CSR 2220-2.020(11)]. A prescription may not be filled if the pharmacist knows, or should reasonably know under the circumstances, that the prescription was based solely on an internet-based questionnaire. [20 CSR 2220-2.020(11)]. See [F.13](#) for Telehealth/Telemedicine.

If the pharmacist knows or has reason to believe the patient is not under the prescriber's care at the time the prescription is presented, the pharmacist is required to consult with the prescriber to determine if the prescriber intends for the medication to be dispensed. Confirmation should be documented in the prescription record.

Retired, Deceased, Inactive or Disciplined Prescribers: Missouri law does not definitively address filling/refilling of prescriptions that were validly written before a prescriber passes away, stops practicing or is disciplined. Except as otherwise provided by law, pharmacists may dispense an otherwise valid prescription that was lawful when it was originally written. However, pharmacists should use their professional judgment when dispensing additional refills and should advise patients to consult with another practitioner as soon as possible. Contact [BNDD](#) for guidance on dispensing controlled substances. See [Section H.13](#) for emergency dispensing options.

SECTION F: PRESCRIPTION REQUIREMENTS

F.7 AUTHORIZED SIGNATURES

Prescriptions/medication orders may be signed as follows:

| | Non-Controlled Substances (Paper, Faxed, Scanned or Electronic) | Controlled Substances (Paper, Faxed) | Controlled Substances (Electronic/ E-Prescribed) |
|----------------------|---|---|--|
| Manual Signature | ✓ | ✓ | X |
| Electronic Signature | ✓ | X | ✓ |
| Stamped Signature | X | X | X |

Prescriptions must be signed by the prescriber as authorized by law. [§ 338.056] The prescriber's staff/agent may prepare the prescription, however, the prescriber must manually or electronically sign the prescription before it is issued. With the exception of Schedule II controlled substances, licensees may obtain a verbal prescription if the prescriber's signature is invalid.

- **Manual Signatures:** Prescribers may manually sign a prescription in the same manner used for signing a check or other legal document. Rubber-stamped signatures are not valid.
- **Electronic Signatures (Non-Controlleds):** If signed electronically, the prescriber's electronic signature must be either an exact electronic replica of the prescriber's signature or a confidential digital key code, number or other identifier that denotes prescriber authorization (e.g., "electronically prescribed by John Smith, MD"). [20 CSR 2220-2.085] Paper prescriptions that are electronically signed must be applied to secure paper that will detect or identify if the prescription has been copied or altered (see F.3).
- **Controlled Substances:** Controlled substance prescriptions must comply with state/federal law. Generally, all paper and faxed controlled substance prescriptions must be manually signed by the prescriber. According to BNDD, digitally scanned signatures are not acceptable. Electronic controlled substance prescriptions must comply with all DEA and BNDD electronic prescribing requirements.

F.8 PRESCRIPTION LIMITS

The following Missouri prescription limits generally apply (*controlled substance guidance provided by BNDD*):

See [Section G](#) for other Mid-Level Practitioner Requirements

| | Non-Controlleds | Schedule II Controlled Substances | Schedule III-IV Controlled Substances | Schedule V Controlled Substances |
|-----------------------|-----------------|---|---|--|
| Prescription Validity | One (1) year | Six (6) Months | Six (6) Months | One (1) Year |
| Quantity Limits | As prescribed | 30-Days/ 90-Days with documented medical reason | 90-Days | 90-Days |
| Refills | As prescribed | May not be refilled | Up to five (5) refills within six (6) months | As prescribed |

According to BNDD, out-of-state prescribers may prescribe controlled substances according to the authority of their home state (including Mid-Level Practitioners). When prescribed by an out-of-state prescriber, the above controlled substance quantity limits apply if the patient is a Missouri patient. If the patient is an out-of-state patient, the quantity limits of the prescriber's home state apply. [See § 195.080]

SECTION F: PRESCRIPTION REQUIREMENTS

In 2019, BNDD amended its rules to incorporate portions of the federal Comprehensive Addiction and Recovery Act which allow partial dispensing of Schedule-II controlled substances as authorized by state law. BNDD's rule changes are included in 19 CSR 30-1.064. Questions regarding the amended rule should be addressed to BNDD.

INITIAL OPIOID PRESCRIPTIONS

Section 195.080 has been amended to limit “initial prescriptions” of an opiate for acute pain to a seven (7) day supply. An “initial prescription” is defined in § 195.010(12) as a prescription:

- 1) Issued to a patient who has never been issued a prescription for the drug or its pharmacy equivalent; or
- 2) Issued to a patient who has not used or been prescribed or administered the medication within the five (5) months prior to the current prescription being issued.

Section 195.010(1) defines acute pain as:

Pain, whether resulting from disease, accidental or intentional trauma, or other causes, that the practitioner reasonably expects to last only a short period of time. “Acute pain” shall not include chronic pain, pain being treated as part of cancer care, hospice or other end of life care, or medication-assisted treatment for substance use disorders;

**Note: 195.080's supply limits only apply to opioids and do not apply to other drug classifications such as stimulants.*

Except as provided below, the 7-day supply limit applies to all healthcare practitioners excluding veterinarians.

Exemptions: Section 195.080.2 exempts patients from the 7-day supply limit if the prescriber determines more than a 7-day supply is required to treat the patient’s acute pain based on his/her medical judgment. Prescribers exceeding the 7-day limit are required to document in the patient’s medical record the condition triggering the need for the extended supply and that a non-opioid alternative was not appropriate to address the patient’s condition.

The 7-day supply limit also doesn’t apply to opioid prescriptions for:

- Patients currently undergoing cancer treatment or sickle cell disease
- Patients receiving palliative care
- Patients receiving hospice care from a hospice certified under Chapter 197, RSMo
- Residents of a long-term care facility licensed under Chapter 198, RSMo, and
- Patients receiving treatment for substance abuse or opioid dependence.

BNDD may issue additional guidance on this in the future. In the interim, the following examples are being provided by the Board for informational purposes:

- **Example 1:** A patient presents a tramadol prescription issued for acute pain on September 1st for a 30-day supply. The patient indicates she hates taking medication and hasn’t used or been prescribed anything in over a year. Absent further information, the prescription would be considered an “initial prescription” and the 7-day supply limit would apply because the patient has not used or been prescribed/ administered tramadol within the 5 months prior to the current prescription being issued.
- **Example 2:** A patient presents a hydrocodone prescription issued for acute pain on September 1st for a 30-day supply. The patient is asked and says she had a tramadol prescription filled at another pharmacy in July but has never been prescribed or used hydrocodone. Absent further information, the prescription would be considered an “initial prescription” and the 7-day supply limit would apply because the patient has not used or been prescribed/ administered *hydrocodone* within the 5 months prior to the current prescription being issued.
- **Example 3:** A patient presents an oxycodone prescription issued on September 1st for a 30-day supply. The patient is undergoing treatment for colon cancer. Absent further information, the prescription would not be considered an “initial prescription” and the 7-day supply limit would not apply because the patient is currently undergoing cancer treatment.

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- **Example 4:** A patient was just discharged from the hospital and presents a prescription on the same day for a 20-day supply of oxycodone. The patient was administered oxycodone during the hospital stay. According to BNDD, if the patient received the same drug while in a hospital, their prescription on discharge can be for more than seven (7) days).
- **Example 5:** A patient presents a Norco® prescription issued on September 1st for a 30-day supply. The patient is a regular customer and has a 30-day supply of Lortab® filled at the pharmacy every month. The prescription would not be considered an “initial prescription” and the 7-day supply limit would not apply because the patient has been prescribed hydrocodone within the five (5) months prior to the current prescription being issued.
- **Example 6:** A patient is prescribed hydrocodone to treat chronic pain from a back injury. The prescription would not be considered an “initial prescription” and the 7-day supply limit would not apply because the patient is being treated for chronic pain and not acute pain.

The Board understands licensees may not have access to the patient’s medical records to concretely determine if a prescription is an “initial prescription.” However, pharmacists still have a corresponding responsibility to ensure the validity of controlled substance prescriptions. The Board recommends that licensees make a good faith effort to determine if a controlled substance prescription is limited to a 7-day supply. This may include:

- Checking the patient’s dispensing records,
- Talking with the patient/caregiver and asking what medication he/she has used or been prescribed within the last 5 months. Ask about medication that may have been administered in the emergency room or a doctor’s office,
- Contacting the prescriber,
- Checking your county’s or city’s prescription drug monitoring program (if applicable); and/or
- Any other action deemed appropriate in the pharmacist’s professional judgment. (This list is not exhaustive)

Each patient should be evaluated on a case-by-case basis. Train pharmacy staff on what they should be asking. Once again, pharmacists should make a good faith effort to meet their corresponding responsibility. The Board recommends that licensees document their efforts as proof of compliance.

BNDD has provided the following answers to frequently asked questions:

- *Does the 7-day limit apply to prescriptions from out of state prescribers? No.*
- *If the prescriber issues an initial acute pain prescription that is subject to the 7 day limitation for greater than the allowed amount, what happens to the remaining quantity? The remaining quantity is void.*
- *If the prescriber issues an initial acute pain C-III prescription that is subject to the 7 day limitation with refills, what happens to the refills? The refills are void.*
- *If the prescriber issues an initial acute pain prescription that is subject to the 7 day limitation for greater than the allowed amount, does the pharmacy have to notify the prescriber they did not dispense the full quantity? No.*

Missouri prescribers and pharmacists play a crucial role in combatting Missouri’s opioid crisis. Proper opioid prescribing and pain treatment can be complicated. Open dialogue with patients and prescribers is necessary to navigate the balance between pain control and opioid addiction. Questions regarding the 7-day supply limit should be addressed to BNDD at (573) 751-6321 or bndd@health.mo.gov (e-mail is preferred)

SECTION F: PRESCRIPTION REQUIREMENTS

F.9 VERBAL/TELEPHONE PRESCRIPTIONS

Pharmacists may accept a verbal or telephone prescription communicated by the prescriber or the prescriber's duly authorized agent. Verbal/telephone prescriptions must be promptly reduced to writing or electronically recorded in the pharmacy's prescription records. [§ 338.095]. All prescription information required by 20 CSR 2220-2.018 must be recorded, including, if substitution is permitted. [§ 338.056.4]

- **Non-Controlled Substance Transfers:** Non-controlled prescriptions may be verbally received/transferred by a pharmacist or a technician/intern pharmacist acting under the pharmacist's direct supervision.
- **Controlled Substance Transfers:** Controlled substance prescription transfers may only be communicated between two pharmacists. Pharmacy technicians or intern pharmacists may not provide or receive controlled substance transfers. (See F. 12)

F.10 FAXED/SCANNED PRESCRIPTIONS

Faxed/scanned prescriptions are defined as an "electronic image transmission" under 20 CSR 2220-2.085 and may be filled by a pharmacy provided the faxed/scanned prescription includes all prescription information required by § 338.056 and 20 CSR 2220-2.018 and meets all other prescription requirements.

Pharmacists should use their professional judgment and take appropriate measures to verify the authenticity of a faxed/scanned prescription. Faxed/scanned prescriptions may only be sent by the prescriber or the prescriber's authorized agent. Pharmacies cannot fill prescriptions faxed or scanned by a patient.

Authorized Signatures:

- **Non-Controlled Substances:** Faxed/scanned non-controlled prescriptions may be manually or electronically signed as authorized by 20 CSR 2220-2.085. See Section F. 7 for signature requirements)
- **Controlled Substances:** Faxed controlled substance prescriptions have to be physically signed by the prescriber and must comply with all BNDD and DEA requirements. The DEA does not allow an electronically signed controlled substance prescription that is generated from a prescriber's software to be converted to fax. See 20 CSR 2220-2.085 and F.11 for additional electronic prescription requirements.

F.11 ELECTRONIC PRESCRIPTIONS

Non-Controlled Substance Prescriptions: Prescriptions for non-controlled drugs may be transmitted electronically by the prescriber or the prescriber's authorized agent either as an "electronic image transmission" or an "electronic prescription."

- An "electronic image transmission" is an exact visual image of a physical prescription that is then faxed, scanned or sent to the pharmacy in an electronic format. Electronic image transmissions must be manually or electronically signed (See F. 10)
- An "electronic prescription" is any prescription/medication order other than an "electronic image transmission" that is electronically transmitted to the pharmacy by the prescriber or the prescriber's authorized agent. [20 CSR 2220-2.085(1)]. Electronic prescriptions may be signed using an electronic signature that is either an exact electronic replica of the prescriber's signature or a confidential digital key code, number or other identifier that denotes prescriber authorization (e.g., "electronically prescribed by John Smith, MD"). [20 CSR 2220-2.085] Electronic prescriptions must be sent by the prescriber or the prescriber's authorized agent. Prescriptions sent electronically by the patient are not valid for dispensing.

Controlled Substances: E-prescribing of controlled substances is allowed in Missouri if the pharmacy and prescriber use software that has been certified to meet DEA requirements. Prescribing must also comply with all DEA electronic prescribing requirements. (See BNDD rules 19 CSR 30-1.048(9) and 19 CSR 30-1.062(4)).

SECTION F: PRESCRIPTION REQUIREMENTS

F.12 PRESCRIPTION TRANSFERS (ORIGINALS & REFILLS)

Upon request, a prescription/medication order may be transferred if:

1. The prescription/medication and or refills were authorized by the prescriber;
2. The prescription/medication order hasn't exceeded the maximum allowable time limit; and
3. The number of lawfully allowable refills has not been exceeded (if applicable) [20 CSR 2220-2.120].

Transfers may be requested by the patient or by another pharmacy at the patient's request. Once requested, the prescription/medication order must be transferred within one (1) business day of the request [20 CSR 2220-2.120(3)]. Transfer is mandatory if the requirements of 20 CSR 2220-2.120 have been met.

Prescriptions may only be transferred to or from a pharmacy licensed in a U.S. state/territory [20 CSR 2220-2.120(1)]. Prescriptions may not be transferred to an unlicensed entity or to a pharmacy that is not located in a U.S. state/territory.

The transferring and receiving pharmacy must record:

| TRANSFERRING PHARMACY | RECEIVING PHARMACY |
|---|--|
| <ul style="list-style-type: none">• The name and the location of the pharmacy where the prescription/medication order was transferred (e.g., address);• The transfer date;• The identity of the individuals transferring and receiving information (e.g., the pharmacist, pharmacy technician or intern pharmacist doing the transfer). <i>*Not required if the transferring/receiving pharmacies are under the same ownership and share the same electronic database;</i>• For controlled substances, the receiving pharmacy's DEA number and the full name of the pharmacists transferring and receiving the prescription information; and• The prescription/medication order must be immediately voided in the pharmacy's electronic system or the word "void" must be written on the face of the invalidated prescription. (see exception below for Class-C Long Term Care pharmacies). | <ul style="list-style-type: none">• An indication that the prescription/medication order was transferred;• The date the Rx/medication order was originally issued;• The date the prescription/medication order was first dispensed;*• The number of refills originally authorized <u>and</u> the number of remaining refills;• Date of last refill;*• The prescription number or other unique identifier;*• The name and location of the pharmacy that transferred the prescription/medication order;• The identity of the individuals transferring and receiving the information (not required if the transferring/receiving pharmacies are under the same ownership and share the same electronic database), and;• For controlled substances, the address and DEA # number of the transferring pharmacy and the full names of the pharmacists transferring and receiving the prescription/medication order; and• All other required information for an original prescription/medication order. <i>* Not required for original prescription transfers.</i> |

If a prescription/medication order is transferred using an electronic data processing record-keeping system, a notation or deactivation must be made on the transferred record to preclude any further dispensing. If the same prescription is transferred back into the pharmacy, the prescription must be treated as a new record, showing the original date issued and original expiration date [20 CSR 2220-2.080(9)].

*The Board is aware of pharmacies improperly denying transfers due to pharmacy disputes, unpaid patient accounts/bills or early refills. Legally valid transfer requests are mandatory. If the refill is too soon, the transferring pharmacy may call attention to the early refill but **cannot** refuse to transfer. The receiving pharmacy is responsible for reviewing the prescription before dispensing to prevent unauthorized refills.*

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Long-Term Care:

20 CSR 2220-2.120 was amended in 2019 to allow Class-C pharmacies to transfer up to a seventy-two (72) hour supply of a non-controlled prescription/medication order to a second pharmacy for initial dispensing without voiding the remaining prescription. The amount transferred must be deducted from the remaining prescription/medication order but the prescription at the transferring pharmacy no longer has to be voided.

Nursing home orders are not transferable if the patient is discharged from the facility. Additionally, refills associated with a nursing home order are not valid for use outside of the facility under 20 CSR 2220-2.140(5)(D).

Controlled Substances:

Transfer of a controlled substance prescription/medication order must comply with 20 CSR 2220-2.120 and all applicable state and federal controlled substance laws. Controlled substance prescriptions/medication order may only be transferred one (1) time, however, pharmacies electronically sharing a real-time database may transfer a controlled substance up to the maximum refills allowed by law and authorized by the prescriber. [20 CSR 2220-2.120(1)(E)]

TRANSFER OF CONTROLLED SUBSTANCES PRESCRIPTION INFORMATION FOR INTIAL DISPENSING

The Board continues to receive questions on when an unfilled new controlled substance prescription may be transferred from one pharmacy to another pharmacy for initial dispensing. The information below is our understanding of current DEA guidance as it relates to DEA-registered retail pharmacies: (this information is current as of December 2019; Licensees should check with DEA and BNDD to eNsure compliance with current law)

| TYPE OF CONTROLLED SUBSTANCE PRESCRIPTION | MAY BE TRANSFERRED | MAY BE FORWARDED |
|---|--------------------|------------------|
| WRITTEN | NO | NO |
| FAXED | NO | NO |
| VERBAL | NO | NO |
| ELECTRONIC (EPCS) | NO | YES** |

***The DEA has advised that the forwarding of an electronic prescription may only be accomplished by using a DEA compliant electronic prescription system (EPCS).*

F.13 TELEHEALTH/TELEMEDICINE

Section 191.1145 allows a Missouri licensed healthcare provider to provide “telehealth” or “telemedicine” services which are defined as:

The delivery of health care services by means of information and communication technologies which facilitate the assessment, diagnosis, consultation, treatment, education, care management, and self management of a patient’s health care while such patient is at the originating site and the health care provider is at the distant site. Telehealth or telemedicine shall also include the use of asynchronous store-and-forward technology.

A Missouri pharmacy may fill a prescription that is issued based on a valid “telehealth” or “telemedicine” exam. To be valid, a telemedicine prescription from a Missouri prescriber must meet the following requirements:

- The prescriber must be licensed to practice in Missouri, and
- The prescription must be based on a valid prescriber-patient relationship, and

SECTION F: PRESCRIPTION REQUIREMENTS

- The prescription must comply with all other state/federal prescription requirements, including, [20 CSR 2220-2.018, § 338.056](#) and any applicable controlled substance laws, [and](#)
- The telemedicine services must be within the provider’s “scope of practice” and meet the applicable standard of care. [[§ 191.1145, § 191.1146](#)]

A telemedicine prescription CANNOT be filled if:

- No legitimate practitioner-patient relationship exists, [or](#)
- The prescription was issued based solely on an internet request or an internet questionnaire, [or](#)
- The prescription was based solely on a telephone evaluation without a previously established and ongoing prescriber-patient relationship. [[§ 191.1146, § 334.108.\(3\) – \(.4\)](#)]

Pharmacists should use their professional judgment to determine if a valid prescriber-patient relationship exists. Determining the applicable standard of care will depend on the health care provider’s licensing regulations and applicable medical standards. The Board cannot give additional guidance here. However, licensees should be attentive to prescriptions that appear to be outside of the prescriber’s scope of practice.

The Board is aware that prescribers frequently issue prescriptions after consulting with a patient over the phone. A prescription may be issued based on a telephone evaluation if “a previously ongoing physician-patient relationship exists” between the prescriber and the patient being treated. [Sec. 334.108.3]. This exception would allow prescribers to continue their current practice of consulting with patients over the phone if the provider and patient have a previously established, ongoing relationship.

Mid-Level Practitioners: Missouri’s telehealth/telemedicine provisions are applicable to prescriptions issued by “any licensed health care provider” which would include APRNs, assistant physicians and physician assistants acting within their licensed scope of practice. However, mid-level practitioners must comply with all applicable prescribing and collaborative practice requirements.

Controlled Substances: The Ryan Haight Act and federal controlled substance laws include specific requirements for telemedicine and controlled substances. Licensees should consult with legal counsel, the DEA and BNDD to ensure compliance with applicable federal law. The Board cannot give legal advice. However, the DEA has issued the following caution:

The pharmacist who deliberately ignores a questionable prescription when there is a reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. Such action is a felony offense which may result in the loss of one’s business or professional license.

BNDD has also issued the following excerpted statement regarding telemedicine and controlled substance activities:

The Missouri BNDD has reviewed the telemedicine statutes and discussed them with the Drug Enforcement Administration (DEA). The statutes provide definitions and make determinations on the delivery of telemedicine. As always, a state licensing board would make determinations regarding proper clinical care. For controlled substance prescribing and dispensing, the following issues are relevant:

- *The controlled substance activity must be by an authorized and registered professional who is acting within their scope of professional practice and within the guidelines of Chapter 195, RSMo and its regulations.*
- *For Missouri practitioners who will be prescribing, the prescribers must have a professional Missouri license, a Missouri BNDD registration and a Missouri DEA registration. This registration must be at their primary practice location where they spend the most time.*
- *According to the DEA, pursuant to [21 USC 802\(54\)](#), if the telemedicine is taking place across state lines, the prescriber must be licensed and also have DEA registrations in both states; the state they are prescribing from and also the state where the patient is. If the patient is an in-patient admitted to a hospital, the hospital may have one of their local practitioners issue the drug orders or the hospital may allow that out of state consulting physician to use the hospital’s DEA number pursuant to [21 CFR 1301.22\(c\)](#).*

Pharmacists play a vital role in preventing prescription fraud and abuse. Licensees are reminded of their corresponding



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responsibility and should exercise sound professional judgment when determining if a telehealth/telemedicine prescription is legitimate.

Out-of-State Prescribers: The Board understands the Missouri Board of Registration for the Healing Arts will be reviewing the applicability of Missouri's telehealth/telemedicine provisions to out-of-state prescribers. In the interim, licensees are reminded that Board rule [20 CSR 2220-2.020\(11\)](#) provides:

A pharmacist shall not dispense a prescription drug if the pharmacist has knowledge, or reasonably should know under the circumstances, that the prescription order for such drug was issued on the basis of an Internet-based questionnaire or without a valid preexisting patient-practitioner relationship.

Prescriptions based solely on an internet-based questionnaire or that are issued without a valid preexisting patient-practitioner relationship are not valid in Missouri and cannot be filled, regardless of the location of the prescriber.

SECTION G: MID-LEVEL PRACTITIONERS

G.1 AUTHORIZED MISSOURI MID-LEVEL PRACTITIONERS

Chapter 334, RSMo, authorizes the following mid-level practitioners to prescribe both controlled and non-controlled substance under a collaborative practice agreement with a Missouri licensed physician:

- Advanced Practice Registered Nurses (APRN) [§ 334.104]
- Assistant Physicians (AP) [§ 334.037] ; and
- Physician Assistants (PA) [§ 334.747].

To prescribe controlled substances, an authorized Missouri mid-level practitioner must have a current BNDD and DEA registration. Mid-level practitioners cannot independently purchase, stock, dispense or administer controlled substances without a collaborative practice agreement with a Missouri licensed physician. *See G.4 for Non-Resident Mid-Level Practitioners.*

Assistant Physicians (AP) are different from Physician Assistants (PA). Assistant Physicians are recent medical school graduates who have not yet entered a residency program. Physician Assistants have medical training but do not have to be medical school graduates.

G.2 PRESCRIPTION REQUIREMENTS

To be valid for dispensing, prescriptions from a Missouri mid-level practitioner must include:

1. The date of prescribing;
2. The name of the patient(s), or if an animal, the species and owner's name;
3. The name, telephone number and address of the mid-level practitioner and the supervising/collaborating physician. For verbal prescriptions, the name of the mid-level practitioner should be documented;
4. For written prescriptions, the mid-level practitioner's manual signature or valid electronic signature as authorized by 20 CSR 2220-2.085 (*the supervising physician's signature is not required*);
5. Name, strength and dosage of drug, device or poison prescribed and the directions for use;
6. The number of refills, if applicable;
7. The quantity prescribed in weight, volume, or number of units;
8. For controlled substances, prescriptions must comply with all state and federal controlled substance laws and must also include the patient's address along with the mid-level practitioner's DEA number.
9. Any other change or alteration made to the prescription dispensed based on contact with the prescriber to show a clear audit trail, including, but not limited to, a change in quantity, directions, number of refills, or substitution authority. [See 20 CSR 2220-2.018, § 334.735.4 and 20 CSR 2200-4.200(3)(G).7].

Except as otherwise provided by law, prescriptions from mid-level practitioners must be based on a valid patient-practitioner relationship and must comply with all other prescription requirements applicable to physicians.

[See Section F]

G.3 REFILLS/QUANTITY LIMITS

The following refills/quantity limits are authorized for a Missouri mid-level practitioner (controlled substance guidance provided by BNDD):

The physician may limit authorized refills/quantity limits in the governing collaborative practice agreement. If limited, the collaborative practice agreement will control.

SECTION G: MID-LEVEL PRACTITIONERS

| | Missouri Advanced Practice Registered Nurses | Missouri Assistant Physicians/ Physician Assistants |
|--|--|--|
| Non-Controlled Prescriptions | <ul style="list-style-type: none"> Valid for 1 year Refills/quantity limits as prescribed | <ul style="list-style-type: none"> Valid for 1 year Refills/quantity limits as prescribed |
| Schedule II | <ul style="list-style-type: none"> Hydrocodone products only (includes single ingredient products) Limited to a 5-day or 120-hour supply | <ul style="list-style-type: none"> Hydrocodone products only (includes single ingredient products) Limited to a 5-day or 120-hour supply |
| Schedule III (Opiates) | <ul style="list-style-type: none"> Limited to a 5-day or 120-hour supply Prescription valid for 6-months from date issued. No refills allowed*** | <ul style="list-style-type: none"> Limited to a 5-day or 120-hour supply Prescription valid for 6-months from date issued No refills allowed*** |
| Schedule III (Non-Opiates) | <ul style="list-style-type: none"> Full authority to prescribe 90-Day quantity limits • Prescription valid for 6-months from date issued. | <ul style="list-style-type: none"> Limited to a 5-day or 120-hour supply Prescription valid for 6-months from date issued. No refills allowed |
| Schedule IV & V | <ul style="list-style-type: none"> Full authority to prescribe 90-day supply limit for a single prescription C-IV: Prescription valid for 6-months from date issued C-V: Prescription valid for 12-months from date issued | <ul style="list-style-type: none"> Full authority to prescribe 90-day supply limit for a single prescription C-IV: Prescription valid for 6-months from date issued C-V: Prescription valid for 12-months from date issued. |
| Buprenorphine | <ul style="list-style-type: none"> Up to a 30-day supply for patients receiving medication assisted treatment for a substance use disorder. Must complete required federal training & have an “X” DEA number. No refills allowed*** | <ul style="list-style-type: none"> Up to a 30-day supply for patients receiving medication assisted treatment for a substance use disorder. Must complete required federal training & have an “X” DEA number. No refills allowed*** |
| Family Members (Controlled Substances) | No authority; Cannot prescribe controlled substances for family members as defined below [§195.070] | No authority; Cannot prescribe controlled substances for family members as defined below. [§ 334.037.12 ; § 334.747] |
| Self-Prescribing (Controlled Substances) | No authority; Cannot prescribe controlled substances for themselves | No authority; Cannot prescribe controlled substances for themselves [§ 334.037.12 ; § 334.747] |

*** According to BNDD, a new prescription can be written for an additional 5-day supply (30-days for buprenorphine), however, a new prescription and prescription number would have to be generated. BNDD would consider these new prescriptions and not refills.

“Family” is defined by the state’s medical board as a spouse, parent, grandparent, great-grandparent, child, grandchild, great-grandchild, brother, sister, aunt, uncle, nephew, niece, mother-in-law, father-in-law, brother-in-law, sister-in-law, daughter-in-law or son-in-law (adopted and step members are included). [[20 CSR 2150-5.100\(3\)\(G\)\(10\)](#)].

MID-LEVEL PRACTITIONER CONTROLLED SUBSTANCE STATUTES/RULES

- APRN: [§ 195.070](#); [20 CSR 2150-5.100](#)
- Assistant Physicians: [[§ 334.037](#); [20 CSR 2150-2.240](#)]
- Physician Assistants: [[§ 334.747](#); [20 CSR 2150-7.135](#)]

SECTION G: MID-LEVEL PRACTITIONERS

G.4 NON-RESIDENT MID-LEVEL PRACTITIONERS

Prescriptions from non-resident mid-level practitioners may be filled in Missouri if the prescription is valid in the prescriber's home state. The following refills/quantity limits would apply unless otherwise restricted by the prescriber's home state (*controlled substance guidance provided by BNDD*):

| Out-of-State Midlevel Practitioner | |
|--------------------------------------|---|
| Non-Controlled Prescriptions | <ul style="list-style-type: none"> As authorized by the prescriber's home state |
| Schedule II | <ul style="list-style-type: none"> Rx valid for 6-months from date issued No refills <p>Supply limit:</p> <ul style="list-style-type: none"> MO patient: 30-Day supply/ 90-Day supply with documented medical reason Non-MO patient: As allowed in home state |
| Schedule III (Opiates & Non-Opiates) | <ul style="list-style-type: none"> Rx valid for 6-months from date issued Refills as allowed in home state. <p>Supply limit:</p> <ul style="list-style-type: none"> MO patient: 90-Day supply Non-MO patient: As allowed by home state. |
| Schedule IV & V | <ul style="list-style-type: none"> C-IV prescription valid for 6-months from date issued C-V prescription valid for 12-months from date issued Refills as allowed in home state. <p>Supply limit:</p> <ul style="list-style-type: none"> MO patient: 90-Day supply. Non-MO patient: As allowed in home state. |
| Family Members | <ul style="list-style-type: none"> As allowed by home state |
| Self-Prescribing | <ul style="list-style-type: none"> As allowed by home state |

Prescriptions from a non-resident mid-level practitioner may be filled even if similar prescriptive authority is not recognized in Missouri for the same mid-level practitioner (e.g., a non-resident chiropractor).

The DEA publishes a state listing of mid-level practitioners authorized to prescribe controlled substances online at https://www.dea diversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf.
 Note: This resource is not maintained by the Board and the Board cannot guarantee its accuracy.

H.1 GENERAL REQUIREMENTS

Licensees may dispense medication pursuant to a valid patient-specific prescription or prescription drug order from an authorized prescriber or, for Class-B hospital pharmacies, pursuant to a medication order. Licensees must implement effective practices and procedures to ensure misbranded, adulterated, counterfeit or outdated drugs are not dispensed. The Board defines “misbranded” and “adulteration” consistent with state and federal law, including, but not limited to, Sections 501 and 502 of the Food, Drug and Cosmetic Act [21 USC § 351, § 352], § 196.095 and § 196.100, RSMo.

As identified in section E.5, outdated, distressed, misbranded or adulterated drugs must be physically separated from the active inventory and maintained in a separate area. [20 CSR 2220-2.090(2)(V)].

Reheating/Resealing: The Board has received questions regarding sealing/resealing drugs more than once in the type of packaging where intense heat is utilized to seal the packaging (e.g., blister cards). USP discourages the practice because the effect of reheating on the medication is unknown. As noted by USP, several manufacturers also recommend against heat sealing drugs more than once. In accordance with USP, the Board discourages the practice.

H.2 FINAL PRODUCT VERIFICATION

Except as otherwise provided by law, a pharmacist must personally inspect and verify the accuracy of all prescriptions/medication orders before dispensing, including, the accuracy of the contents and the affixed label. Intern pharmacists and pharmacy technicians may assist with dispensing, however, a Missouri-licensed pharmacist must physically inspect and verify the medication’s accuracy prior to dispensing. [20 CSR 2220-2.010(1)(B)]. Pharmacy technicians and intern pharmacists cannot verify the final product even if directly supervised by a pharmacist.

Technology may be used to assist in verification, however, pharmacists should use their clinical skill and judgment to make sure the right medication is dispensed to the right patient with the correct instructions for use. *See H.24 for automated filling systems.*

See the following rules for exceptions to the final verification requirements:**

- 20 CSR 2220-2.600 (Class-F: Renal Dialysis Pharmacy)
- 20 CSR 2220-2.675 (Class-L Veterinary Pharmacy/Section D. 12)
- 20 CSR 2220-2.900 (Automated Dispensing Systems)
- 20 CSR 2220-2.950 (Automated Filling Systems/Section H. 23)

** Additional compliance requirements apply.

Remote final product verification is not currently allowed under Missouri law.

Licensees should take proactive steps to prevent and detect errors. The Board encourages licensees to report dispensing errors to the USP-ISMP Medication Errors Reporting Program. This confidential program gathers and analyzes data to help prevent future errors. Reports may be submitted online at www.ismp.org.

H.3 LABELING

A written/printed label must be affixed to each prescription container dispensed to a consumer that indicates:

- 1) The date the prescription was filled;
- 2) A prescription number or other unique identifier;
- 3) The patient’s name;
- 4) The prescriber’s directions for use;
- 5) The prescriber’s name;
- 6) The pharmacy’s name and address; (For Class-J pharmacies, either the name and address of the pharmacy

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responsible for offering patient counseling or the pharmacy responsible for dispensing to the patient may be listed on the label, as designated by the pharmacies by contract);

- 7) The exact name and dosage of the drug dispensed, and;
- 8) If a generic substitution is made, the drug manufacturer must be identified either on the label or in the pharmacy's records by name or abbreviation. [§ 338.059].

For controlled substance prescriptions issued by a Missouri APRN or physician assistant, the label must also include both the names of the prescribing mid-level practitioner and their collaborating physician [§ 195.100, RSMo]. The collaborating physician's name is not required on the label for controlled substances prescribed by an assistant physician.

Missouri law does not prohibit the addition of other label information. However, prescription labels should be clear and easily readable. *Note: These labeling requirements do not apply to internal drug "orders" for in-patients of a licensed hospital.*

Printing only a brand name on a dispensing label when a generic product is dispensed is misleading to the public and considered misbranding. Board inspectors have observed instances where the generic product is listed on the label with the statement "substituted for" followed by the brand name of the product. This is acceptable if the label is not misleading. However, Missouri law doesn't require that a brand name be on a label when a substitution is made.

H.4 PATIENT COUNSELING

Patient counseling is one of the most important patient care services that a pharmacist provides. Patients must be offered the opportunity to consult with a Missouri-licensed pharmacist each time a prescription is dispensed (new or refill). [OBRA 90 20 CSR 2220-2.190]. The offer to counsel may be extended by pharmacy staff. However, patient counseling may only be provided by a Missouri-licensed pharmacist or a Missouri-licensed intern pharmacist acting under the pharmacist's immediate supervision. [20 CSR 2220-2.190].

- If the medication is picked up by the patient or caregiver, a verbal offer to counsel must be made.
- If the medication is mailed or delivered to the patient, the patient must be given a written offer to counsel with their medication along with a toll-free telephone number for the dispensing pharmacy. [20 CSR 2220-2.190(1)]. The written offer must include a statement that the patient may call the pharmacy if the patient has questions. A phone number alone is insufficient. A written offer cannot be used to replace the required verbal offer when medication is picked up at the pharmacy.

When offering counseling, the patient should be clearly asked if he/she has any questions for the pharmacist or would like to speak with a pharmacist about their medication. Board inspectors have observed pharmacy staff asking patients broad questions such as, "Any questions?" or "Do you need anything else?" These open-ended questions may confuse the patient and lead to patients unintentionally declining counseling. Effective patient counseling can prevent dispensing errors and enhance medication compliance. The offer to counsel should clearly ask if a patient would like to speak with a pharmacist.

If counseling is requested, pharmacists should use their clinical skill to determine the best way to effectively communicate with the patient. Counseling should include matters that will, in the professional judgment of the pharmacist, enhance or optimize therapy and allow the patient to safely and appropriately use the prescribed medication or device/equipment. [20 CSR 2220-2.190(1)] At a minimum, pharmacists must provide any counseling required by state/federal law. The Board also recommends counseling patients on the following (as applicable):

1. The medication name and description;
2. The dosage, dosage form, route of administration and duration of therapy;
3. Any special directions or instructions for patient use, preparation or administration;
4. Significant side effects, adverse effects or interactions, and therapeutic contraindications;
5. Techniques for self-monitoring;

6. Proper storage;
7. Appropriate disposal methods;
8. Refill information;
9. Suggested action in the case of a missed dose or equipment/device malfunction; and
10. Any other matter deemed necessary or appropriate in the pharmacist's professional judgment to allow the patient to safely and appropriately use the prescribed medication, device or medical equipment and maximize therapeutic outcomes. *(This list is suggested and not mandatory)*

The Board has reviewed instances where pharmacists told a technician what to say to a patient in response to a counseling request, instead of the pharmacist personally talking with the patient. In other instances, technicians advised patients on how over-the-counter medication may interact with OTC medication or which OTC medication would complement the patient's medication therapy. Both of these activities constitute patient counseling and CANNOT be performed by technicians.

Counseling may be provided in-person or via an electronic mechanism that allows the pharmacist and patient/caregiver to communicate in real-time with the patient either verbally or face-to-face. Licensees must comply with all applicable state and federal laws when counseling, including, state and federal laws governing patient privacy/confidentiality, medication guides and federal risk evaluation and mitigation strategy (REMS) requirements.

Patient counseling is not required if:

- The patient is an inpatient of a hospital, institution or other setting where other licensed or certified health care professionals are authorized to administer medications, or;
- The patient or caregiver refuses consultation. [20 CSR 2220-2.190(4), (5)].

The Board is aware of instances where delivery drivers are delivering medication to the patient and verbally offering patient counseling that is promptly provided by a pharmacist electronically or on the phone. A toll-free number and written offer to counsel is not required in these instances if a verbal offer is given and the patient is able to consult with a pharmacist at the time the prescription is delivered either verbally or electronically (e.g., via video chat/tablet).

H.5 PATIENT PROFILES

Licensees are required to collect and maintain appropriate patient information to facilitate patient counseling. Appropriate information may include, but is not limited to the patient's name, address, telephone number, age, gender, clinical information, disease states, allergies and a list of other drugs prescribed. [20 CSR 2220-2.190(2)] The Board also recommends collecting any other information that may be needed to effectively provide patient care.

H.6 PATIENT IDENTIFICATION

Proper patient identification can prevent errors as well as medication theft. The Board has reviewed multiple cases where errors could have been prevented if the patient was correctly identified. In other cases, impersonators have been able to pick-up valid prescriptions using stolen patient information. To prevent confusion, the Board recommends using multiple identifiers to identify patients when necessary (e.g., birth date, address).

- Missouri law requires valid photo identification for patients purchasing Schedule 5 methamphetamine precursor products (e.g., pseudoephedrine, ephedrine, phenylpropanolamine) [19 CSR 30-1.074(3)]
- Licensees are required to positively identify recipients of medication dispensed via a vacuum tube delivery system. See E.9.

H.7 GENERIC SUBSTITUTION [§ 338.056]

Pharmacists may use their professional discretion to substitute a less expensive generic or interchangeable biological product when filling a prescription/medication order, unless:

- 1) The patient requests a brand name or biological product; or
- 2) The prescriber indicates substitution is prohibited in some manner or writes “brand medically necessary,” “dispense as written,” “do not substitute”, “DAW” or any similar language that indicates substitution is prohibited. [§ 338.056]

For verbal prescriptions, pharmacists must document the prescriber’s instructions on substitution. [§ 338.056.4].

If a generic product is substituted, the manufacturer’s name or abbreviation must be identified on the prescription label or in the pharmacy’s records. [§ 338.059(9)] A pharmacist may not substitute with a drug that has been rated by the FDA as inequivalent or a biological that has not been rated by the FDA as interchangeable, without approval by the prescriber.

Printing only a brand name on a dispensing label when a generic product is dispensed is misleading to the public and considered misbranding. Board inspectors have observed instances where the generic product is listed on the label with the statement “substituted for” followed by the brand name of the product. This is acceptable if the label is not misleading. However, Missouri law doesn’t require that a brand name be on a label when a substitution is made.

H.8 INTERCHANGEABLE BIOLOGICAL PRODUCTS [§ 338.055, § 338.056]

Pharmacists may substitute an interchangeable biological product for a prescribed biological product if substitution has been authorized by the prescriber. [See § 338.056, § 338.085]. An “interchangeable biological product” is defined as a biological product that the FDA:

- a) Has licensed and determined meets the standards for interchangeability under 42 U.S.C. § 262(k)(4); or
- b) Has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book). [§ 338.085.1]

The FDA’s list of interchangeable biologicals may be found at: www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm (Purple Book).

Patients must be informed that an interchangeable biological product has been substituted either verbally or in writing. [§ 338.085.2] Additionally, the prescriber must be notified of the substituted product name and manufacturer within five (5) days of dispensing. Prescriber notification is not required if no FDA approved interchangeable biological product exists for the product prescribed or the prescription is a refill and no changes have been made from the prior filling. [§ 338.085.3]. Notifications can be made in writing or electronically (e.g., e-mail, fax). Alternatively, notification can be made via an electronic record system that can be accessed by the prescriber (e.g., an EMR or an e-prescribing or electronic pharmacy/PBM system). Licensees must comply with all other Board rules applicable to generic substitutions, including, all labeling and recordkeeping requirements.

H.9 DRUG UTILIZATION REVIEW

Drug utilization review (DUR) is an important feature of patient care. The Board recommends that pharmacists use their clinical skills to review the patient’s profile to determine if medication is appropriate. Pharmacists should pay particular attention to items such as duplicate therapy, significant drug interactions/contra-indications, excessive or inappropriate dosing/instructions and any other relevant factor that may adversely impact the patient or medication therapy. While technology may be used to assist with DURs, pharmacists should not abandon their clinical skills.

The Board also recommends documenting why a DUR was overridden and the pharmacist responsible for the override. While not required by the Board's rules, this documentation is a good best practice that can be useful for more than just billing. Specifically, the documentation can help track/support clinical activities and may also be beneficial in the event of a staffing change or a patient complaint. The Board has reviewed a number of complaints/investigations where a DUR was overridden, however, the pharmacy was unable to produce any information to support why the override was appropriate. In some instances, the pharmacist reported having lengthy discussions with the prescriber but failed to note or record any of their activities. If you do it, document it!

H.10 FLAVORING

Licensees may flavor a legend product unless the prescriber indicates otherwise, however, OTC products may only be flavored by prescription. Licensees should indicate that the product was flavored on the patient's container and the added flavoring must be documented in the pharmacy's prescription record (e.g., in a flavoring book or in the prescription record). As defined by the Board's rules, flavoring does not constitute compounding. Licensees may not flavor a prescription dispensed by another pharmacy.

The Board is aware that USP is reviewing whether flavoring constitutes compounding. The Board has not adopted USP's proposed revision at this time but may reconsider this approach in the future. Flavoring does not constitute compounding under Missouri law.

H.11 SYRINGES & OVER-THE-COUNTER MEDICATION

Pharmacies dispensing a prescription for an over-the-counter medication must comply with all prescription requirements if the medication is dispensed and treated as a prescription.

Syringes: Missouri does not require a prescription in order to sell OTC insulin syringes to patients. However, other types of syringes are labeled as legend devices. Any syringe bearing the federal legend, "*Rx Only*" or "*Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician*" would require an order from a prescriber. Licensees should note the federal legend may be on the outer packaging label instead of the individual syringe label. Pharmacists are encouraged to look at both labels to determine if a syringe is a legend or OTC product.

H.12 CONSOLIDATION OF REFILLS [§ 338.202]

Section 338.202, RSMo, allows a pharmacist to consolidate refills of non-controlled maintenance medication up to a ninety-day (90) supply. "Maintenance medication" is defined as a medication prescribed for a chronic, long-term condition that is taken on a regular, recurring basis.

To consolidate, the maintenance medication must have been previously prescribed to the patient for at least a three-month period. Pharmacists may dispense up to the total number of authorized dosage units, however, no more than a 90-day supply may be dispensed at one time. The 90-day supply limit does not apply:

- 1) If the prescription is dispensed to a member of the U.S. Armed Forces serving outside of the United States, or;
- 2) The prescription was issued by a practitioner located in another state, provided the prescription must be issued "according to and in compliance" with federal law and the applicable state's law.

Consolidation is not allowed if the prescriber indicates that dispensing the initial amount followed by periodic refills is medically necessary. **Section 338.202** applies to non-controlled prescriptions only. Controlled substances cannot be consolidated.

The Board has been asked if the required 3-month patient use period has to be consecutive or if prior fills/refills must have been dispensed by the same pharmacy. Missouri law is silent on both of these questions. Absent further statutory

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clarification, licensees may consolidate refills for patients prescribed a maintenance medication for any 3-month period even if prior fills/refills were dispensed by another pharmacy.

Pharmacists should exercise their professional judgment when consolidating refills as consolidation may not be appropriate for all patients. The Board recommends informing patients if any additional costs/insurance requirements apply prior to dispensing.

H.13 EMERGENCY DISPENSING [§ 338.200]

Section § 338.200, RSMo, allows a Missouri pharmacist to dispense an emergency supply of medication if the pharmacist is unable to obtain refill authorization from the prescriber. Pharmacists may dispense an emergency supply if:

- In the pharmacist's professional judgment, interruption of therapy might reasonably produce undesirable consequences;
- The pharmacy previously dispensed or refilled a prescription from the prescriber for the same patient and medication;
- The emergency dispensing is documented in the patient's prescription record;
- The drug is not a controlled substance; and
- The pharmacist informs the patient or the patient's agent at the time of dispensing that prescriber authorization is required for future refills. Notification can be made verbally, electronically or in writing.

The emergency supply must be limited to the amount needed for the emergency period as determined by the pharmacist within his or her professional judgment. However, the total amount dispensed cannot exceed a seven-day supply. If the prescriber is deceased, incapacitated or unable to provide medical services, up to a thirty-day supply may be dispensed.

The prescriber or the prescriber's agent must be promptly notified after an emergency supply is dispensed. An emergency supply may not be dispensed if the pharmacist has knowledge that the prescriber has prohibited or restricted emergency dispensing for the patient.

The Board recognizes some medications are dispensed in manufacturer packaging that exceeds a seven day supply. However, § 338.200.2 provides the amount dispensed shall "not exceed a seven day supply" if the prescriber is not deceased or otherwise incapacitated. Pharmacists should consult with legal counsel and use their professional judgment as needed for the emergency period in such circumstances.

H.14 PRESCRIPTION DELIVERY SITES

Pursuant to **20 CSR 2220-2.013**, prescriptions filled by a Missouri pharmacy "may not be left at, accepted by, or delivered to a location, place of business or entity not licensed as a pharmacy." However, filled prescriptions may be delivered to the following locations at the request of the patient or the patient's authorized designee:

- The office of a licensed health care practitioner authorized to prescribe medication in the state of Missouri;
- A long-term care facility as defined by **20 CSR 2220-2.140** where the patient resides;
- A hospital, office, clinic or other medical institution that provides health care services;
- A residence designated by the patient or the patient's authorized designee, or;
- The patient's office or place of employment.

Prescriptions may be delivered to other non-pharmacy locations not specified in the rule only if the prescription is delivered directly to the patient or the patient's authorized designee. Additionally, prescriptions for veterinary use may be delivered to a residence, business, or clinic if requested by the customer. A Class-J pharmacy license is required if filled prescriptions are delivered to another pharmacy for patient pick-up.

Patient/designee authorization may be received verbally, electronically or in writing. The Board recommends documenting patient authorization and the requested location in the pharmacy's records. Rule **20 CSR 2220-2.013** applies to all

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Missouri licensed pharmacies delivering filled prescriptions regardless of delivery method (e.g., mail order, employee delivery or common carrier).

Pharmacies delivering medication as allowed by the rule must develop written policies and procedures “to ensure the safe and appropriate delivery of prescription drugs within the temperature ranges recommended by the manufacturer” or USP. Policies and procedures should be maintained at the pharmacy or accessible for review during an inspection or if requested by a Board designee. A prescription delivery policy/procedure is not required if the pharmacy doesn’t deliver filled prescriptions.

The Board understands licensees cannot control or predict the activities of third party carriers. The Board also recognizes extenuating circumstances may occur that are beyond a licensee’s controls. Licensees should establish policies and procedures to ensure delivery within appropriate temperature requirements given normal and customary delivery times. It is also recommended that licensees establish a mechanism for patients to report delivery concerns.

Return to Stock: Except as otherwise authorized for long-term care facilities, prescriptions left at a non-pharmacy location that are not picked up by the patient cannot be returned to stock.

Controlled Substances: Licensees must comply with all applicable controlled substance laws and regulations, including, but not limited to, all applicable security requirements. Contact the DEA or BNDD for additional questions.

- *Can pharmacies deliver to drop sites? No. Prescriptions may only be delivered to a site not specified in the rule if the prescription is delivered directly to the patient or the patient’s authorized designee.*
- *Prescriptions may be delivered to another pharmacy for dispensing/patient pickup if both pharmacies are in compliance with **20 CSR 2220-2.650** and Class J: Shared Services standards.*
- *The Board’s rules do not prohibit dispensing to patients outside of the United States, however, licensees should consult with the FDA and the applicable country/territory to ensure compliance with federal and international laws. Licensees should also consult with BNDD and the DEA if controlled substances are involved.*

H.15 EARLY FILLS/REFILLS

Board inspectors have observed medications being dispensed too soon to the same patient. In some instances, “early fills/refills” may result from filling prescriptions from different prescribers or refilling a prescription on a cycle that does not correlate with previously dispensed amounts. Under state and federal law, pharmacists have a professional obligation to ensure drugs are dispensed for bona fide purposes and are not being abused or diverted due to excessive purchases. Licensees should investigate dispensing patterns that indicate excessive consumption or improper compliance with prescribed directions.

H.16 OFFICE STOCK DISPENSING

To be valid for dispensing, prescriptions must be written by an authorized prescriber for a specific patient. [**§ 338.095**]. Pharmacies/pharmacists are not allowed to dispense drug products for office stock by prescription (see exemption below for veterinary products for animal use in **Section I.2**).

Pharmacies may, however, transfer medication to an authorized entity by invoice (non-controlled and schedule III-V drugs) or via a DEA 222 form or CSOS (Schedule II drugs). [**See F.12** for additional information on drug transfers]. A Missouri drug distributor license is required if the pharmacy annually transfers five-percent (5%) or more of the pharmacy’s total gross sales. Total gross sales are calculated based on the pharmacy’s total annual prescription drug sales, or if prescriptions are not sold, 5% of the pharmacy’s total drug purchases. [**§ 338.330(2); 20 CSR 2220-5.020(1)(B)**]. *See D.9 for Class B pharmacy exemptions.*

Pharmacies may need to register with the FDA as a repackager if the pharmacy repackages drugs for distribution to other pharmacies or practitioners (see H.9 for repackaging guidance for hospitals/Class-B pharmacies). Additionally, federal law may require that a pharmacy register with the DEA as a controlled substances distributor if the total dosage units of controlled substances distributed by the pharmacy exceeds five-percent (5%) of all controlled substances dispensed during the previous calendar year. *See I.2 for compounding for office use/distributing non-patient specific compounded veterinary preparations.*

H.17 TABLET SPLITTING

The Board is aware of licensees using or recommending tablet splitting to lower patient costs or due to insurance/supply issues. The Board is concerned that these practices may not be in the patient's best interest. As licensed professionals, pharmacists must provide medications in their proper form. Only drug products that are scored should be used in tablet splitting. This includes splitting tablets into half or quarter tablets. Drugs that are not scored will likely not split in a manner that will provide a uniform dose. Coated tablets may also present problems because any effect the coating provides may be compromised once the drug is split.

Before tablet splitting, pharmacists should verify that:

- 1) The literature, or other recognized compendia for the drug, recognizes or indicates that splitting of the specific brand of tablet can be accomplished safely and effectively;
- 2) The prescriber has approved any change in the prescription strength, and;
- 3) The patient has received detailed patient counseling to ensure the patient understands the changes made. If the patient is responsible for splitting the tablet, counseling should be provided on splitting techniques and the use of any related items (e.g., tablet splitters).

H.18 PREPACKAGING [20 CSR 2220-2.130]

To assist in dispensing, medication may be removed from the original manufacturer's container and stored in a dispensing container/system until dispensed to a patient (e.g., an automatic dispensing system). Only products that will be directly provided to the patient may be prepackaged.

Proper sanitation procedures must be utilized when prepackaging drugs. Drugs should not be handled with bare hands. Additionally, containers and equipment must be properly cleaned and maintained to prevent contamination. Reusable containers should be kept clean of tablet dust and other contaminants.

At a minimum, containers used for prepackaging must meet USP Class B container standards. Light sensitive containers must be used, if applicable. A label must be affixed to the prepacked drug container indicating the drug's name and strength, the manufacturer/distributor, lot number and the required expiration date. The maximum allowed expiration date is twelve (12) months or the manufacturer's expiration date, whichever is less. In lieu of the required label, licensees that store drugs in an automated counting device may record the required lot number/expiration date in the pharmacy's records, however, the information must be fully traceable and readily retrievable during an inspection.

H.19 PATIENT MED PAKS [20 CSR 2220-2.145]

In lieu of dispensing multiple containers, licensees may dispense medication in a single customized patient medication package ("patient med pak"). Patient med paks must comply with rule [20 CSR 2220-2.145](#). An authorized "patient med pak" is defined as a package prepared for a specific patient that consists of one or more containers which contain two (2) or more prescribed drugs. Patient med paks may only be used for solid oral dosage forms (e.g., tablets). Med paks may not contain controlled substances.

Prior to dispensing a med pak, pharmacists must consider:

- Any applicable compendia requirements or guidelines;
- The physical and chemical compatibility of the dosage forms placed in each container; and
- Any therapeutic incompatibilities if the medications are administered simultaneously. *The Board encourages licensees to report any observed or reported incompatibilities to USP.*

Med Pak containers must be non-reclosable or designed to show if the container has been opened. Containers must comply with the moisture permeation requirements for a Class B single-unit or unit-dose container, unless more stringent requirements exist for a drug contained in the med pak. USP has warned about potential physical and/or chemical

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incompatibilities when certain drugs are packaged together. Pharmacists must ensure that no interactions will occur when preparing multi-med packages.

Labeling: Med paks must be designed or each container labeled to indicate the day and time or period of time that the contents in each container should be taken. Med paks must also be labeled with:

- 1) The patient's name;
- 2) A serial number for the patient med pak and a separate serial number for each prescription order for each drug contained in the med pak;
- 3) The name, strength, physical description or identification and total quantity of each drug product;
- 4) Directions for use and any cautionary statements contained in the prescription order for each drug;
- 5) Any storage instructions or cautionary statements required by the official compendia;
- 6) The name of the prescriber for each drug product;
- 7) The preparation date and beyond-use date assigned. The beyond-use date may be no later than sixty (60) days from the date of preparation;
- 8) The name, address, and telephone number of the dispenser; and
- 9) Any other information, statements, or warnings required for any included drug.

If intact containers can be removed or separated from the patient med pak, each individual container must contain a label that identifies all medication in the container. While not required, the lot, manufacturer and expiration dates are strongly encouraged for recall and patient safety reasons.

Package Inserts: Package inserts/medication guides must be provided if required for any drug in the med pak. In lieu of an individual insert, required information may be incorporated into a single, overall insert for the entire med pak.

Records: In addition to the prescription, the following documentation must be maintained for each dispensed med pak:

- 1) The patient's name and address;
- 2) The prescription serial number for each drug contained in the med pak;
- 3) The name of the manufacturer/labeler and lot number for each drug;
- 4) The preparation date and the assigned beyond-use date;
- 5) Any special labeling instructions;
- 6) The name or initials of the preparing pharmacist; and
- 7) Information identifying or describing the design, characteristics, or specifications of the med pak. The med pak must be described in a manner that would allow an identical med pak to be made. [20 CSR 2220-2.145(F)4.]

Returns: Generally, med paks that have been delivered to an institution or to a patient cannot be returned to the pharmacy. However, 20 CSR 2220-2.145 provides a pharmacist may modify/repackage a med pak that has been delivered to an institution or patient if:

- 1) The med pak is returned to the pharmacy that originally dispensed the med pak;
- 2) The med pak is modified/repackaged per prescription order for the same patient to whom it was originally dispensed;
- 3) The med pak is assigned a new serial number;
- 4) The med pak is labeled in compliance with 20 CSR 2220-2.145. The med pak must retain the original beyond use date assigned to the med pak before modification/ repackaging;
- 5) Medications removed from the med pak are destroyed in compliance with state and federal law. Removed meds cannot be returned to stock or redispensed to either the same or a different patient, and;
- 6) The pharmacy maintains all records required by 20 CSR 2220-2.145 (see above).

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Except as otherwise allowed by [20 CSR 2220-2.145](#) for modification/repackaging purposes, medication that has been commingled with other drugs in a med pak may not be returned to stock, dispensed, or distributed except for destruction.

Compliance with [20 CSR 2220-2.145](#) is required even if the container is supplied by the patient (e.g., weekly med tray).

H.20 CHILD RESISTANT CONTAINERS

All dispensed prescriptions must be packaged in a child resistant container unless:

- The physician specifically requests that a non-child resistant container be dispensed. Pharmacists cannot honor blanket requests from a prescriber to never use safety caps for the prescriber's patients, or;
- The patient specifically requests a non-child resistant container. Patients may issue a blanket request for all prescriptions. However, a request on a single prescription cannot be used as a blanket waiver for subsequent prescriptions. The Board recommends documenting patient requests in writing.

The Board has signed an agreement with the Consumer Product Safety Commission ("CPSC") to assist in enforcing child resistant container laws. The Board is required to report significant violations of the child resistant container laws to the CPSC. Under federal law, violations may result in criminal or civil liability. The pharmacy related provisions of the Poison Prevention Packaging Act can be found at [16 CFR 1700.14](#)

H.21 RETURN TO STOCK

A prescription may be returned to stock if:

- 1) The patient did not receive the prescription; and
- 2) The prescription was maintained in the pharmacy's possession in accordance with the manufacturer's labeled storage requirements at all times. [[20 CSR 2220-3.040](#)]

The prescription must be maintained in the original patient container with the name of the drug, dispensing date and the prescription number visible on the container. Notations may be made on the label to distinguish it from active prescriptions being processed.

If returned to stock, the drug's expiration date must become the lesser of one (1) year from the dispensing date on the label or the manufacturer's original expiration date, if known. The pharmacy is required to delete the dispensing in the pharmacy's records and reverse/credit any third party payor claims (e.g., insurance).

Drugs returned to stock may not be poured back into the original stock container because the drug has undergone manipulation outside of its original container. The mixing of lot numbers is also prohibited. Drugs returned to a stock container will be deemed misbranded and/or adulterated in violation of state and federal law.

Except as otherwise authorized for long-term care facilities, prescriptions left at a non-pharmacy prescription delivery site authorized by [20 CSR 2220-2.013](#) that are not picked up by the patient cannot be returned to stock.

See [H.14](#)

Errors/Recalls: As authorized by federal law, the Board has allowed returns to the pharmacy if the wrong medication was dispensed to the patient or in instances of a drug recall. In no instance may medication returned by a patient be reused or returned to stock. [[20 CSR 2220-3.040\(3\)](#)].

See [Q.5](#) for returns from a LTC facility or from a hospital or hospice facility regulated by the Missouri Department of Health and Senior Services.

See [H.19](#) for med-pak returns

H.22 DRUG TAKE-BACKS

20 CSR 2220-2.095 allows Missouri pharmacies to accept both controlled and non-controlled medication from the public for destruction/disposal.

NON-CONTROLLED MEDICATION

Pharmacies may collect medication for destruction by providing a collection receptacle or via an authorized mail back program. No additional Board notification or registration is required to operate a take-back program, however, participating pharmacies must establish and follow policies/procedures for collecting/destroying medication.

- **Collection Receptacles:** Collection receptacles must be securely placed and maintained inside the pharmacy's physical building in a manner that prevents theft, diversion or unauthorized removal. Receptacles must be securely locked, substantially constructed containers that are equipped with inner liners for storing medication. Receptacles must be visible to pharmacy staff at all times and may not be located in or near exit doors. See **20 CSR 2220-2.095** for collection receptacles at long-term care facilities.
- **Mail-Back Programs:** For mail-back programs, the public must be provided pre-addressed, postage-paid mail-back packages for returning medication. Mail-back packages must be nondescript and cannot include any markings or other information that might indicate the package contains medication. Each package must include a unique identification number or other unique identifier to enable tracking.

Mail-back packages cannot be returned to the pharmacy. Instead, packages must be directly mailed to a collector that is authorized by the DEA or other federal law to destroy medication. Consumers cannot be required to provide personally identifiable information when mailing back medication.

Medication may be accepted from any member of the public. However, collection receptacles or mail-back programs cannot be used to dispose of unused/unwanted medication in the pharmacy's inventory (e.g., expired medication, medical waste). Collected medication must be rendered non-retrievable and destroyed in compliance with all applicable federal and state laws. Destruction may occur at the pharmacy or destroyed offsite by an entity authorized by state/federal law to destroy medication. Destruction records and inventories of inner-liners must be maintained for two (2) years and available on inspection/request (*see rule for additional recordkeeping requirements*). Collected medication cannot be resold or reused under any circumstances.

Pharmacies are not required to establish a drug collection program and participation is voluntary. Participating licensees should review **20 CSR 2220-2.095** in its entirety to ensure compliance

20 CSR 2220-2.095 does not apply to medication collected for return and reuse as authorized by 20 CSR 2220-3.040. (Return & Reuse of Drugs and Devices)

CONTROLLED SUBSTANCES

Section 195.265 allows licensees to collect returned controlled substances for destruction. Controlled substances may only be returned as authorized by state and federal law. Interested licensees have to modify their existing BNDD and DEA registrations to become a collector. DEA take-back requirements are available online at: www.deadiversion.usdoj.gov/drug_disposal/index.html. BNDD compliance information is available on BNDD's website at health.mo.gov/safety/bndd/collection-disposal-info.php.

DRUGS DONATED FOR REUSE

The Missouri Department of Health and Senior Services ("DHSS") regulates the Prescription Drug Repository program. Additional information is available on DHSS' website at health.mo.gov/safety/drugrepository. Additional federal requirements may apply for individuals exporting medication to another country for reuse or charity purposes. Question regarding exporting medication should be addressed to the FDA's Import Export Compliance Branch (IECB) at CDERExportCertificateProgram@fda.hhs.gov.

H.23 DISTRIBUTION VS. DISPENSING

Pharmacies may sell or transfer legend drugs or a drug-related device to another pharmacy or to an authorized prescriber/entity by invoice (schedule III-V drugs/non-controlleds) or via CSOS or a DEA 222 form (schedule II drugs). Except as allowed by law, prescriptions cannot be used to transfer medication for prescriber or facility use. Invoices must be maintained in the pharmacy's records separately from prescription records and must include:

- Date of distribution;
- Product name/strength;
- Quantity;
- The names/address of the parties; and
- If a controlled substance, DEA numbers for both the transferring pharmacy and the recipient.

Controlled substance transfers must comply with federal/state controlled substance laws. Pharmacies may not repackage drugs for distribution to other pharmacies or practitioners without being registered with the FDA as a repackager. [See D.9](#) for Class-B exemptions

A Missouri drug distributor license is required if the pharmacy annually transfers five-percent (5%) or more of the pharmacy's total gross sales. Total gross sales are calculated based on the pharmacy's total annual prescription drug sales, or if prescriptions are not sold, 5% of the pharmacy's total purchases. [[§ 338.330\(2\)](#); [20 CSR 2220-5.020\(1\)\(B\)](#)]. [See D.9](#) for Class-B exemptions.

Pharmacies that “borrow” or “loan” medication between themselves must maintain a record of the transactions (invoice/DEA-222). In a borrowing and payback scenario, the pharmacy must have two transaction records: one record documenting receipt of the products and one record documenting the return of the product. The same documentation must be maintained by the pharmacy loaning the product. Intra-store transfers must also be recorded/documented. See [D.8](#) for transferring medication when a pharmacy closes.

H.24 AUTOMATED FILLING SYSTEMS [[20 CSR 2220-2.950](#)]

Rule [20 CSR 2220-2.950](#) establishes requirements for pharmacists using an automated filling system (AFS) to dispense prescriptions. An AFS is defined as “an automated system used by a pharmacy to assist in filling a prescription drug order by selecting, labeling, filling or sealing medication for dispensing.” An AFS does not include:

- 1) Automated devices used solely to count medication (counting devices),
- 2) Vacuum tube drug delivery systems governed by [20 CSR 2220-2.800](#), or
- 3) Automated dispensing and storage systems used to dispense medication directly to a patient or to an authorized health care practitioner for immediate distribution or administration to a patient.

A pharmacist must inspect and verify the contents and label of every prescription filled by an AFS unless:

- A pharmacist verifies the accuracy of the prescription data used by or entered into the AFS for the specific patient prior to filling. The identity of the verifying pharmacist must be documented in the pharmacy's records and maintained for five years [[20 CSR 2220-2.950\(4\)\(C\)](#)]; and
- A pharmacist verifies the correct medication, repacked container, or manufacturer unit of use package was loaded in the AFS before initiating the fill process. [[20 CSR 2220-2.950\(4\)\(D\)](#)]. An electronic verification system may be used to verify manufacturer unit of use packages or repacked medication previously verified by a pharmacist. Repacked containers must comply with [20 CSR 2220-2.130](#); and
- The filling process is fully automated from the time the process is initiated until a completed prescription is produced that is ready for dispensing to the patient. [[20 CSR 2220-2.950\(4\)\(B\)](#)]. In other words, the AFS must either fill, label, and seal the prescription in the container or the prescription must be dispensed by the AFS in a manufacturer's unit of use package or a repacked pharmacy container. [[20 CSR 2220-2.950\(4\)\(E\)](#)]. No manual

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intervention with the medication or prescription may occur after the medication is loaded into the AFS. Pharmacy staff may prepare or package the final labeled product container for mailing, storage or delivery. However, no other manual intervention is allowed; and

- An electronic verification system is used to verify the proper prescription label has been affixed to the correct medication, repackaged container, or manufacturer unit of use package for the correct patient [20 CSR 2220-2.950(4)(F)]; and;^{*}
- Daily random quality testing is conducted by a pharmacist on at least two percent (2%) of the .prescriptions filled by the AFS on the date tested or 2% of the prescriptions filled by the AFS on the last day of system operation. The pharmacist-in-charge must determine how the sample is selected. Proof of compliance, random quality testing date(s) and testing results must be documented and maintained in the pharmacy's records and available for inspection. [20 CSR 2220-2.950(4)(G)]

^{*} Electronic verification systems must comply with 20 CSR 2220-2.950(1)(B). Video/camera verification systems alone do not qualify as electronic verification systems.

Significantly, pharmacies using an AFS in lieu of physical pharmacist verification must test the system before initial use, when restarting the system or after any modification to the AFS or electronic verification system that may change or alter the filling/electronic verification process.

Pharmacies using an AFS in lieu of physical inspection/verification of the final product by a pharmacist must maintain written policies and procedures to monitor and ensure the AFS is functioning properly and safely. 20 CSR 2220-2.950(5) contains a detailed listing of minimum policy/procedure requirements. Policies/procedures must address:

- System maintenance
- Accurate loading
- Sanitation, cross-contamination
- Expired/recall drugs
- Errors and malfunctions
- Testing
- Training
- System Access
- Tracking responsible persons
- Quality Assurance

AFS policies and procedures must be reviewed annually and maintained in the pharmacy's records for at least two (2) years.

The required AFS policies and procedures and mandatory testing only apply if a pharmacist is not physically inspecting and verifying the final product. Pharmacies physically verifying the final contents and label of medication filled or packaged by an AFS are not subject to the additional requirements of 20 CSR 2220-2.950(4) – (6).

H.25 EPINEPHRINE/ASTHMA MEDICATION

School Districts: Section 167.630, RSMo, authorizes Missouri school districts to obtain prefilled epinephrine auto syringes by prescription. Section 167.635 contains the same allowance for asthma related rescue medications. To obtain prefilled epinephrine auto syringes or asthma related rescue medications, a prescription is required from a licensed physician, a physician's assistant, or nurse practitioner. The school district must be designated as the patient and the school nurse's name must be on the prescription. Pharmacies may legally dispense prescriptions that comply with § 167.630 or § 167.635.

Authorized Entities: Section 196.990, RSMo, also authorizes pharmacists to dispense epinephrine auto-injectors to an "authorized entity" based on a prescription issued by a Missouri licensed physician in the name of the authorized entity (e.g., Jefferson City Parks and Recreation). An "authorized entity" is defined as:

Any entity or organization at or in connection with which allergens capable of causing anaphylaxis may be present including, but not limited to, restaurants, recreation camps, youth sports leagues, amusement parks, and sports arenas. "Authorized entity" shall not include any public school or public charter school;

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Only a Missouri licensed physician may issue an epinephrine prescription to an authorized entity under § 196.990. The prescription may not be written by a mid-level practitioner.

Prescriptions for an authorized entity are valid for 12-months and may be refilled as needed unless otherwise restricted by the physician. Quantity limits are as prescribed. The prescription must be maintained and documented in the same manner as other non-controlled prescriptions.

Section 196.990.4 contains mandatory training requirements for “expected auto-injector users” who may be administering or providing epinephrine to the public on behalf of an authorized entity. It appears the additional training requirements only apply to users that acquire epinephrine auto-injectors under a prescription issued in accordance with § 196.990. Pharmacists filling an epinephrine prescription from the pharmacy’s regular inventory for the entity identified on the prescription do not have to complete additional training unless the medication was received based on a prescription issued to the pharmacy under § 196.990.

The Board has been asked if pharmacists can provide the required training for auto-injector users. The statute provides:

Expected epinephrine auto-injector users [must] receive training in recognizing symptoms of severe allergic reactions including anaphylaxis and the use of epinephrine auto-injectors from a nationally recognized organization experienced in training laypersons in emergency health treatment or another entity or person approved by the department of health and senior services.

Licensees should contact the Department of Health for additional questions on qualifying training.

H.26 MEDICAL MARIJUANA

The Missouri constitution was amended in 2018 to allow the use of medical marijuana pursuant to rules promulgated by the Missouri Department of Health and Senior Services (DHSS). DHSS has established an online information portal which includes updates on medical marijuana regulation at <https://health.mo.gov/safety/medical-marijuana/index.php>. Licensees should contact DHSS with questions on medical marijuana or the new law. The Board does not have jurisdiction over the new provisions and cannot answer questions or provide guidance.

The Board has received multiple questions from licensees asking if pharmacists can own, advise or consult with a medical marijuana dispensary/cultivator. Licensees should consult with legal counsel on this issue- the Board cannot provide legal advice. However, the DEA had advised that federal controlled substance registrants are required to comply with federal law which still designates marijuana as a C-I controlled substance.

I.1 GENERAL REQUIREMENTS

A Class D (Non-Sterile Compounding) pharmacy permit is required for pharmacies performing non-sterile compounding in batch quantities using bulk active ingredients. Rule [20 CSR 2220-2.400](#) defines compounding as:

The preparation, incorporation, mixing and packaging or labeling of a drug or device as the result of a prescriber's prescription or prescription drug order based on the prescriber/patient/pharmacist relationship in the course of professional practice. Compounding also includes the preparation, incorporation, mixing and packaging or labeling of a drug or device, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing purposes.

A Class-H (Sterile Compounding) pharmacy permit is required for pharmacies performing sterile compounding. (See [Section J](#) for sterile compounding requirements).

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 considered compounding and requires compliance with the Board's compounding rules, including, completion of the compounding log (e.g., CutisPharma First® Kits).

Pharmacies may not compound preparations that have been withdrawn from the market due to safety.

As defined by the Board's rules, compounding does not include incorporating a flavoring agent. However, licensees should indicate that the product was flavored on the patient container and the added flavoring must be documented in the prescription record.

The Board has not addressed if or how it will adopt or enforce USP Chapter 800 Hazardous Drugs- Handling in Healthcare Settings (effective December 1, 2019). However, compliance with USP Chapter 800 may be required by other entities (e.g., accrediting agencies, insurers, etc.). Licensees should consult with legal counsel to determine how USP Chapter 800 will affect your practice.

I.2 PRESCRIPTION REQUIREMENTS/ COMPOUNDING FOR OFFICE USE

Except as otherwise provided by law, licensees may only dispense compounded preparations pursuant to a valid prescription or a medication order (see *veterinary exception below*). Compounded preparations may not be offered to pharmacies, practitioners or commercial entities for office use or for subsequent resale. [[20 CSR 2220-2.400\(12\)](#)] However, pharmacies/pharmacists may dispense a compounded preparation for a prescriber to administer in the prescriber's office if a valid prescription or medication order has been received for the individual patient. Please consult BNDD/DEA if a controlled substance is involved.

Compounding may only be done by prescription/medication order, regardless of the type of product (e.g., OTC, herbal). [[20 CSR 2220-2.400\(10\)](#)].

An FDA registered drug manufacturer or a 503 (B) drug outsourcing facility may also provide compounded preparations for office use, provided the entity is also licensed as a Missouri drug distributor (for manufacturers) or a Missouri outsourcer (for 503 (b) drug outsourcing facilities).

Veterinary Exception: Pursuant to [20 CSR 2220-2.400\(13\)](#), pharmacies may provide non-patient specific compounded preparations to a Missouri-licensed veterinarian to administer and dispense to the veterinarian's animal patients, provided the pharmacy complies with all controlled substance laws and maintains a record of distribution to the veterinarian that can be retrieved by the specific veterinarian. A prescription from the veterinarian is not required to distribute office stock supply.

Non-patient specific preparations dispensed to a veterinarian under [20 CSR 2220-2.400\(13\)](#) must be labeled with:

- The pharmacy's name, address and telephone number,
- Date of distribution (*the Board also recommends documenting the distribution date in the pharmacy's records*);
- Veterinarian's name;

- Preparation name, strength, dosage form and quantity;
- Name of each active or therapeutic ingredient included in the preparation;
- Preparation lot/batch number;
- Preparation beyond-use date;
- The statement: “Office Stock Compounded Preparation.”

Additionally, the preparation must be recorded in the pharmacy’s compounding log as required by [20 CSR 2220-2.400\(7\)\(A\)](#). In lieu of a prescription number or a readily unique identifier, the veterinarian’s name may be recorded in the compounding log.

Licensees should be aware that Missouri Veterinary Board rule [20 CSR 2270-4.031\(3\)\(H\)](#) provides:

A veterinarian may dispense no more than a seven (7) day supply per patient from an office stock compounded preparation provided by a licensed pharmacy. A patient-specific prescription must be issued to continue treatment beyond seven (7) days...

This provision is not enforced by the Board; Questions should be addressed to the Missouri Veterinary Board at (573) 751-0031 or vets@pr.mo.gov (e-mail is preferred).

This exemption only applies to preparations provided to a Missouri-licensed veterinarian. Compounding for veterinary office stock is not allowed if the receiving veterinarian is not a Missouri licensed veterinarian.

I.3 ANTICIPATORY COMPOUNDING

Medication may be compounded in “limited quantities” prior to receiving a valid prescription if there is a history of receiving/filling valid prescriptions pursuant to an established relationship between the pharmacist, patient and prescriber. [\[20 CSR 2220-2.400\(7\)\(C\)\]](#). For purposes of [20 CSR 2220-2.400](#), a “limited quantity” is defined as a three (3) month supply of a batched product or a one (1) year supply for compounded preparations intended for external use (e.g., creams, ointments, lotions or liniments). While advance preparation is allowed, a prescription is required for dispensing.

I.4 COMMERCIALY AVAILABLE PRODUCTS

Generally, Missouri law prohibits licensees from compounding preparations that are commercially available or that are essentially copies of commercially available products. “Essentially copies” includes different dosage forms (e.g., suspension vs. solution, tablet vs. capsule).

Licensees may only compound a commercially available product:

- 1) If the product is temporarily unavailable due to problems other than safety or effectiveness (e.g., on back order). Unavailability must be documented in the pharmacy’s records. [\[20 CSR 2220-2.400\(9\)\]](#). The Board recommends keeping any documentation from the manufacturer/distributor or the FDA Drug Shortage database, including, documentation of the dates the product was unavailable. The pharmacy must stop compounding the product once the product becomes available again; or
- 2) If a “specific medical need” for the prescription exists. [\[20 CSR 2220-2.400\(9\)\]](#). The “specific medical need” is deemed to be the *medical reason* why the commercially available product cannot be used. The nature of the “specific medical need” must be either documented on the prescription/medical order or some other documentation of the specific medical need must be noted in the pharmacy’s prescription records. [\[20 CSR 2220-2.400\(9\)\]](#). Notations should include the name of the person verifying the medical need, the date, and the specific medical need/reason given. Cost or convenience are insufficient to establish a “specific medical need.”

The Board does not consider compounding kits that include compounding ingredients to be commercially-available; A pharmacy may still compound these preparations without using the kit. However, if a specific compounding kit is prescribed, a pharmacist would need prescriber’s authorization to compound without using the kit.

I.5 PRODUCT VERIFICATION

The dispensing pharmacist must ensure compounded preparations are properly prepared, labeled, stored, dispensed and distributed. [20 CSR 2220-2.400(8)] Before release, the pharmacist must visually inspect bulk drug substances and all finished products for container closure integrity, visible particulates or other foreign matter/visual defects.

For quality purposes, the dispensing pharmacist must also ensure that:

- 1) Each person assisting in compounding is capable and qualified to perform their assigned duties;
- 2) All ingredients have their expected identity, quality and purity;
- 3) Reasonable assurance exists that compounding processes/procedures are always carried out by pharmacy staff as intended or specified; and
- 4) Compounding conditions/procedures are adequate for preventing mix-ups or other errors.

The Board has observed several instances of pharmacists compounding with expired ingredients. In many instances, the expired date was recorded in the compounding log signed by the pharmacist. Pharmacists should review all log entries for accuracy. Proactive steps should be taken to identify and remove expired drugs and ingredients.

I.6 LABELING

In addition to other prescription labeling requirements, the actual name of each active or therapeutic ingredient contained in a compound must be listed on the patient's prescription container or on an auxiliary label [20 CSR 2220-2.400(7)(F)]. If used, auxiliary labels may be generated in a number of ways such as through the pharmacy software program, computer generated on sheets of label paper, or even hand-written, if legible (this list is not exhaustive).

Ingredient abbreviations are not sufficient. For example, "Melox, Topir, Tram, Lido, Prilo" should be listed as "Meloxicam, Topiramate, Tramadol, Lidocaine, Prilocaine" on the container. If the computer system's drug field has limited character space, an auxiliary label applied to the container may be the best option to allow for the full names.

Additionally, compounding labels must identify the actual ingredient used. This means a specific brand name product should not be listed if a generic was used in the compound (i.e., "Maalox" should not be listed if a generic version was used). Additionally, ingredient labeling should not be over generalized (e.g., "antacid" is ambiguous and does not identify which product was used).

The Board's inspectors have observed a number of violations in this area. Review your compounding procedures and educate staff to ensure compliance with required labeling

I.7 BEYOND-USE DATES

Batched compounded preparations must be assigned an in-house batch/lot number and a "beyond-use date" after which a compounded preparation should not be used. [20 CSR 2220-2.400(7)(A)6.] Licensees should use their professional judgment when determining the appropriate beyond-use dates. Because compounded preparations are intended for immediate administration or following short-term storage, beyond-use dates must be assigned based on different criteria than those used to assign an expiration date for manufactured drug products. [20 CSR 2220-2.400(4)]. Licensees may be asked to explain or support their rationale. Beyond-use dates must be determined from the date the preparation is compounded.

Compounds that are not picked up by the patient and returned to stock are considered batched and must be assigned a batch number and a beyond-use date in the compound log and on the label.

I.8 INGREDIENTS/CONTAINERS [20 CSR 2220-2.400(6)]

Proper controls must be maintained over drug products/ingredients, containers and container closures to prevent contamination. Drug components must meet compendial standards (e.g., USP, NF). If non-compendial bulk drug substances are used, a certificate of analysis must be kept on file. [20 CSR 2220-2.400(8)2.] Non-drug substances must be contaminant free and maintain full potency.

Container systems must be stored and used in a manner that will adequately protect against foreseeable deterioration or contamination. Drug products, ingredients, containers and container closures may not be reactive, additive or absorptive in any way that would alter the safety, identity, strength, quality or purity of the compounded preparation beyond the desired result.

Compounding materials and preparation must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration. Excess products must be labeled with the name of the drug(s), an in-house lot number and the beyond-use date and must be stored and accounted for under conditions dictated by their composition and stability. [20 CSR 2220-2.400(6), (7)].

For bulk ingredients that don't bear an expiration date, the pharmacy is encouraged to contact the manufacturer to determine the actual expiration date. If one is not provided, the pharmacy is encouraged to develop procedures for establishing an in-house expiration date for the ingredient.

I.9 FACILITIES/EQUIPMENTS [20 CSR 2220-2.400(5)]

Compounding area(s) must be clean and sanitary at all times. Compounding areas must be free of infestation and trash must be disposed of in a timely manner.

Additionally, compounding equipment must be adequately and appropriately designed for the activities performed. Equipment surfaces may not be reactive, additive or absorptive so as to alter the safety, identity, strength, quality or purity of the drug product beyond that desired. [20 CSR 2220-2.400(6)(E)]. Equipment must be appropriately located to allow for proper use, cleaning and maintenance. [20 CSR 2220-2.400(5)(C)].

If drugs with special contamination precautions are used (e.g., penicillin), appropriate measures must be utilized to prevent cross-contamination. [20 CSR 2220-2.400(5)(B)]. Appropriate measures may include, but may not be limited to, dedicating or adequately cleaning equipment.

I.10 COMPOUNDING LOG

Pharmacies must maintain a separate compounding log that includes [20 CSR 2220-2.400(7)(A)]:

- 1) The compounding method used;*
- 2) The compounding date;
- 3) Identity of the compounding pharmacist;
- 4) A listing of the drug products/ingredients and their amounts by weight or volume;
- 5) Description of the compounding process and, if necessary for proper compounding, the order of drug product/ingredient addition (e.g., recipe/formula cards);*
- 6) The source, lot number and the beyond-use date of each drug product/ingredient, as well as an in-house lot number and a beyond-use date for bulk compounded preparations; and
- 7) A prescription number or a readily retrievable unique identifier for the compound. (Pharmacies compounding non-patient specific preparations for a Missouri-licensed veterinarian for administration/dispensing to the veterinarian's animal patients as authorized by 20 CSR 2220-2.400(13) may record the veterinarian's name in lieu of a prescription number/unique identifier)

* This information may be separately stored in the pharmacy's records if the records are immediately retrievable.

All prescriptions numbers/identifiers dispensed from a batch compound must be recorded individually on the compound log.

I.11 QUALITY CONTROL

Pharmacies must establish and maintain appropriate quality control measures over compounding methods. [20 CSR 2220-2.400(7)] Quality control measures must include:

- 1) Methods for compounding to ensure finished preparations have the identity, strength, quality and purity they purport or are represented to possess, and;
- 2) A description of the compounding process and the order for adding drug products/ingredients, if applicable.

Additionally, pharmacies must develop and maintain an outcome related drug monitoring system for evaluating the quality of compounding services. At a minimum, the monitoring system must evaluate/track infection rates, adverse drug reactions, recalls and prescriber/client complaints.

I.12 RECALLS

A recall must be initiated if a compounded preparation is deemed to be misbranded or adulterated. [20 CSR 2220-2.400(8)(C)]. In the event of a recall, the pharmacy must notify the prescriber of: 1) the nature of the recall, 2) the problem(s) identified and 3) any recommended action(s). If the compounded preparation could potentially cause patient harm, the same recall notification must be provided to the patient. Notification can be made verbally, electronically or in writing, however, licensees should use their professional judgment to determine the best way to effectively alert the prescriber or the patient. For example, a mailed letter may be inappropriate if immediate action is needed.

In addition to prescriber/patient notification, recall(s) must be reported to the Board in writing within three (3) business days. The Board recommends that licensees retain proof of the date and manner of the required recall/notification in the pharmacy's records.

I.13 ADVERTISING/SOLICITATION

Licensees may advertise or provide information regarding compounding services and the type of compounding offered. However, licensees may not compare compounded preparations to commercially available products or make specific claims without supporting data (e.g., designating a product as sustained release). [20 CSR 2220-2.400(12)]. Alternatively, licensees may not attempt to solicit business by making specific claims about compounded preparations without analytical data to support the claims for each compounded preparation. Licensees must have data for their specific preparations and may not rely on data obtained from other sources.

J.1 GENERAL REQUIREMENTS

A Class-H (Sterile Compounding) pharmacy permit is required for all pharmacies performing sterile compounding. Class H pharmacies must comply with all applicable provisions of state/federal law, including rule [20 CSR 2220-2.200](#) governing sterile compounding and [20 CSR 2220-2.400](#) which establishes standards of practice for both non-sterile and sterile compounding. Compliance with [20 CSR 2220-2.200](#) and [20 CSR 2220-2.400](#) is mandatory for all pharmacies holding a Class H Sterile Compounding pharmacy permit even if the pharmacy is not currently providing sterile compounding services.

In January 2017, the Board substantially revised its sterile compounding rule. The following major changes were included in the amendment and will be summarized below:

- Compounding definitions (equipment and classified areas)
- Risk-level classifications
- Garbing requirements
- Training requirements
- Cleaning & disinfection requirements
- Media-fill testing
- Environmental monitoring
- End-preparation testing
- Remedial investigations/recalls
- Policies/Procedures

The Board has not adopted USP Chapter 797 at this time. USP Chapter 797 is currently under revision; the Board intends on reviewing Missouri's regulations after USP Chapter 797 is finalized. Interested parties should monitor the Board's website for future information.

SECTION J: STERILE COMPOUNDING

J.2 COMPOUNDING DEFINITIONS

The following major definitions have been changed/included in the sterile compounding rule:

| DEFINITIONS | |
|-----------------------------------|---|
| Buffer area | An ISO Class 7 or better area where the primary engineering control (PEC) is physically located. The terms “clean room” and “clean zone” have been deleted throughout the rule |
| Class 100/ Class 10,000 area | Renamed to an ISO Class 5 or ISO class 7 area to match current ISO classifications. |
| Controlled Area | A separate room designated for preparing sterile preparations or an area designated for preparing sterile preparations that is separated from other activities/operations by a line of demarcation that clearly separates the area from other operations. |
| Isolator/Barrier Isolator | These terms have been deleted and changed to a “restricted access barrier system” or “RABS” (see definition below). |
| Primary Engineering Control (PEC) | A system that provides an ISO 5 environment for the exposure of critical sites when compounding sterile preparations. PECs include, but are not limited to, horizontal/vertical laminar airflow hoods, biological safety cabinets or a restricted access barrier system (RABS). All sterile compounding must occur in a PEC or in an ISO Class 5 environment. |
| Restricted Access Barrier System | A PEC that is comprised of a closed system made up of four (4) solid walls, an air-handling system, and transfer and interaction devices. The walls are constructed so as to provide surfaces that are cleanable with coving between wall junctures. The air-handling system provides HEPA filtration of inlet air. Transfer of materials is accomplished through air locks, glove rings, or ports. Transfers are designed to minimize the entry of contamination. Manipulations can take place through either glove ports or half suits. Examples of a RABS may include, but is not limited to, a compounding aseptic isolator (CAI) or a compounding aseptic containment isolators (CACI) |

J.3 COMPOUNDING RISK LEVELS

Rule 20 CSR 2220-2.200 establishes the following compounding risk levels:

| RISK LEVEL | AMENDED RULE |
|--------------|--|
| Risk Level 1 | <ul style="list-style-type: none"> • Preparations stored at controlled room temperature and assigned a beyond-use date of 48 hours or less • Preparations stored under refrigeration and assigned a beyond-use date of 7 days or less • Preps stored frozen and assigned a beyond-use date of 30 days or less |
| Risk Level 2 | <ul style="list-style-type: none"> • Preparations stored at controlled room temperature and assigned a beyond-use date greater than 48 hours • Preparations stored under refrigeration and assigned a beyond-use date greater than 7 days • Preparations stored frozen and assigned a beyond-use greater than 30 days • Batch prepared preparations without preservatives that are intended for use by more than 1 patient • Preparations compounded by complex or numerous manipulations (e.g. automated compounder) |
| Risk Level 3 | <ul style="list-style-type: none"> • Products compounded from nonsterile ingredients or compounding with nonsterile components, containers or equipment before terminal sterilization • Products prepared by combining multiple ingredients (sterile or nonsterile) by using an open-system transfer or open reservoir before terminal sterilization. |

J.4 COMPOUNDING IN CONTROLLED AREAS

In lieu of an ISO classified buffer area, the sterile compounding rule allows licensees to compound sterile preparations in a PEC that is located in a “controlled area.” The controlled area does not have to be a separate room. Instead, a controlled area can be a separate room or an area of the pharmacy that is clearly separated from other pharmacy activities/ operations by a line of demarcation. *NOTE: Risk Level 2 and 3 preparations can only be compounded in a controlled area if a RABS is used.*

Controlled areas must be cleaned and disinfected as required by the rule (see cleaning chart below). A sink with hot and cold running water must be near, but not in, the controlled area. Traffic flow in or around the controlled area must also be minimized and controlled to prevent contamination. Non-essential objects that shed particles shall not be brought into the controlled area (e.g., cardboard, paper towels, cotton gauze, etc). Significantly, pharmacy staff compounding in a controlled area must now be garbed as required by the rule for all risk levels (see garbing chart below). Pharmacy and cleaning staff must be educated and instructed on how to properly garb.

J.5 GARBING REQUIREMENTS

| RISK LEVEL | REQUIRED GARB |
|---------------------|--|
| <i>Risk Level 1</i> | <i>Non-shedding gown, hair cover, face mask, beard cover and gloves</i> |
| <i>Risk Level 2</i> | <i>Non-shedding gown, hair cover, face mask, beard cover, shoe covers and sterile gloves</i> |
| <i>Risk Level 3</i> | <i>Non-shedding gown, hair cover, face mask, beard cover, shoe covers and sterile gloves</i> |

All personnel entering the controlled or buffer area must be garbed appropriately. If a RABS is used for risk level 2 & 3 compounding, sterile gloves must be donned over RABS gloves.

J.6 TRAINING REQUIREMENTS & MEDIA FILL TESTING

Education and training of compounding staff is a vital part of maintaining sterility and preventing contamination. The sterile compounding rule requires that all pharmacy personnel receive suitable didactic and experiential training prior to compounding. All compounding staff must complete the following initial and ongoing aseptic technique skill assessment with media fill testing.

The aseptic technique skill assessment must include a direct visual observation/evaluation of aseptic competency during a process simulation (media fill test). The media fill test must represent the most challenging or stressful conditions that the individual encounters or performs (e.g., the highest risk or batch process). All sterile compounding personnel must complete and pass an initial assessment prior to compounding. A minimum of three media-fill tests must be completed during the initial assessment. The frequency of re-assessment differs based upon the risk level of compounding (see below). One media fill test must be completed for the ongoing testing.

- Risk Level 1: Prior to compounding and annually thereafter
- Risk Level 2: Prior to compounding and annually thereafter
- Risk Level 3: Prior to compounding and every six months thereafter

The visual observation portion of the aseptic technique skill assessment must include the following competencies:

- Proper aseptic technique, including use of first air and avoiding touch contamination
- Cleaning and disinfection
- Hand hygiene, garbing, and gloving
- Identifying, weighing and measuring of ingredients
- Maintaining sterility in ISO Class 5 areas
- Labeling and inspecting compounded sterile preparations for quality

Individuals who fail any written test, media fill test, or visual observation of hand hygiene, garbing or aseptic technique must be retrained and pass a reevaluation in the deficient area before beginning or resuming sterile compounding. Individuals who fail media-fill testing must pass 3 successive media fill tests prior to resuming sterile compounding. Training dates and testing/re-testing results must be documented in the pharmacy's records.

Media fill testing must be conducted in accordance with USP Chapter 797 and as referenced below:

SECTION J: STERILE COMPOUNDING

| | |
|---|--|
| Frequency of media fill testing | <ul style="list-style-type: none"> • Before compounding* • If the quality assurance program yields an unacceptable result or unacceptable techniques are observed • If the staff's risk level of sterile compounding changes (e.g., staff begins compounding risk level 3) • If there is a change in compounding methods |
| Frequency of media fill testing re-evaluation | <ul style="list-style-type: none"> • Risk level 1 & 2 (annually)* • Risk level 3 (every 6 months)* |
| # of media fill tests | <ul style="list-style-type: none"> • Initial training (3 media fill tests) • Ongoing reassessments (1 media fill test) |

*As part of the required aseptic technique skill assessment

J.7 CLEANING AND DISINFECTION

Controlled areas and buffer areas are to be cleaned and disinfected in accordance with USP Chapter 797. This would include the following requirements for all risk levels:

| AREA | FREQUENCY OF CLEANING/DISINFECTION |
|--|---|
| ISO Class 5 primary engineering control(s) | <ul style="list-style-type: none"> • Daily cleaning: germicidal cleaning agent followed by sterile alcohol • Frequent disinfection throughout the day using sterile alcohol (includes prior to compounding, between batches and after spills/surface contamination) |
| Counters & work surfaces | <ul style="list-style-type: none"> • Daily |
| Floors | <ul style="list-style-type: none"> • Daily |
| Walls | <ul style="list-style-type: none"> • Monthly |
| Ceilings | <ul style="list-style-type: none"> • Monthly |
| Storage shelving/supply bins | <ul style="list-style-type: none"> • Monthly |

- All cleaning tools must be low-lint and dedicated for use in the controlled or buffer area
- Sterile water for irrigation must be used for dilution of germicidal agents that will be used in the primary engineering control
- If compounding occurs less frequently than the required timeframes, cleaning/disinfection must occur prior to each compounding session
- Individuals performing cleaning and disinfection shall be trained prior to performing such activities. Training shall include direct visual observation of the individual's cleaning and disinfection process by qualified staff. The individual shall be annually reassessed for competency through direct visual observation.

J.8 ENVIRONMENTAL SAMPLING

All sterile compounding pharmacies shall establish and follow proper controls to ensure environmental quality, prevent environmental contamination and maintain air quality in ISO classified areas. The following environmental sampling is required:

| RISK LEVEL | FREQUENCY/TYPE OF ENVIRONMENTAL SAMPLING |
|--------------|---|
| Risk level 1 | <ul style="list-style-type: none"> Air sampling* of all ISO classified areas before initial compounding and then every 6 months |
| Risk level 2 | <ul style="list-style-type: none"> Air sampling* of all ISO classified areas before initial compounding and then every 6 months Surface sampling of all ISO classified areas every 6 months |
| Risk level 3 | <ul style="list-style-type: none"> Air sampling* of all ISO classified areas before initial compounding and then every 6 months Surface sampling of all ISO classified areas every 30 days |

*Air sampling must be done via volumetric sampling. Settling plates are not sufficient

In addition to environmental sampling for microbial organisms, all primary engineering controls and ISO classified areas must be certified to ensure facilities and equipment are operational. Hood and room certifications must be completed at the following frequencies:

- Prior to beginning any sterile compounding activities
- Every 6 months
- After any changes or major services occur to the primary engineering control or ISO classified area
- After the primary engineering control or room is relocated or the physical structure of the ISO classified area has been altered

Hood and room certification results shall be reviewed by a pharmacist once received (document the pharmacist review). Deficiencies or failures must be investigated and corrected prior to further compounding in the affected area.

J.9 END-PREPARATION EVALUATION

All final preparations must be inspected by a pharmacist to verify that the preparation was compounded accurately. This includes inspection for clarity, leaks, integrity, appropriate solution cloudiness or phase separation, solution color and volume. Background light or other means for visual inspection of preparations must be used as part of the inspection process. Alternate means of inspection shall be used if a visual inspection or exposure to the preparation may pose a health hazards (e.g., radiopharmaceutical). Additionally, risk level 3 preparations must be tested for sterility, endotoxins/pyrogens and potency as provided by the rule.

To ensure appropriate testing, the sterile compounding rule incorporates specific USP chapters for risk level 3 end-preparation testing.

- Sterilization methods:** Risk level 3 preparations must be sterilized using a method appropriate for the preparation and must be conducted in a method recognized by USP.
- Sterility testing:** All risk level 3 preparations must be tested for sterility according to USP Chapter 71.
- Pyrogen/endotoxin testing:** All parenteral risk level 3 preparations must be tested for endotoxins/pyrogens according to USP Chapter 151 or 85
- Potency testing:** All risk level 3 preparations assigned a BUD > 30 days must have laboratory validation of preparation stability and potency to support the BUD. Potency testing needs to be completed at least once. If the compounding methods change, potency testing must be completed again.

A compounded risk level 3 preparation may be dispensed prior to receiving the results of end product testing (referred to as emergency dispensing). This may occur when a risk level 3 preparation is needed for immediate administration and no alternative product or preparation is available. The prescriber must be informed that the preparation is being dispensed prior to the completion of appropriate testing. Documentation of the prescriber's approval for dispensing and the need for the emergency must appear in the prescription record. A separate authorization is required for each emergency dispensing (blanket authorization is not allowed)

J.10 REMEDIAL INVESTIGATIONS/RECALLS

All sterile compounding pharmacies are now required to conduct a remedial investigation if any environmental monitoring sample demonstrates a colony forming unit (CFU) count that exceeds USP Chapter 797 recommended action levels for the type of sampling (e.g., air/surface sampling)

A remedial investigation would include quarantining the affected area and any sterile preparations/ingredients that were prepared or used within the compounding process until the results of the investigation are known. Additionally, all affected areas must be re-sampled to ensure a suitable state of microbial control.

If an environmental monitoring sample taken from an ISO-5 classified area exceeds USP 797 action levels, the pharmacy must cease compounding in the affected area until resampling shows a suitable state of microbial control. However, a pharmacy may choose to continue compounding during the remedial investigation if they do the following:

- o Clean and disinfect the affected area by using a germicidal cleaning agent and a sporicidal agent followed by sterile alcohol
- o The beyond-use date of all preparations is lowered to 12 hours
- o The affected area is resampled under dynamic conditions. If the resampling exceeds USP 797 action levels, compounding must cease.

If an environmental monitoring sample taken from an ISO-7 classified buffer area exceeds USP 797 action levels, the pharmacy must cease compounding in the affected area until resampling shows a suitable state of microbial control. However, a pharmacy may choose to continue compounding during the remedial investigation if they do the following:

- o Clean and disinfect the affected area by using a germicidal cleaning agent and a sporicidal agent
- o The beyond-use date of all risk level 1 preparations is lowered to 24 hours; the beyond-use date for all risk level 2 or 3 preparations is lowered to 12 hours
- o The affected area is resampled under dynamic conditions. If two consecutive resamplings exceed USP 797 action levels, compounding must cease.

Licensees must notify the Board in writing within three (3) days if any resamples collected as part of the remedial investigation exceed USP 797 action levels. Notifications should include details surrounding the remedial investigation, sampling results and any corrective actions taken. Notifications may be emailed to Katie.Debold@pr.mo.gov or mailed to the Board office. Maintain a record of all corrective actions taken during the remedial investigation including the resampling results.

Recalls: A recall must be initiated if a sterile preparation is deemed to be misbranded, adulterated, non-sterile or if end preparation testing results are out of specification. The following notifications must be made in the event of a recall:

- Prescriber: Must be notified of the nature of the recall, the identified problem(s) and any recommended actions
- Patient: Must receive the same notification as the prescriber if the preparation has the potential to harm the patient
- Board: Must be notified within 3 business days of the recall

J.11 POLICIES & PROCEDURES

Pursuant to [20 CSR 2220-2.200\(2\)](#), sterile compounding pharmacies must maintain a policy and procedure manual that addresses all aspects of sterile compounding performed by the pharmacy. Policy & procedure manuals should be regularly reviewed and updated to ensure appropriate practices. At a minimum, manuals must be reviewed annually. [[20 CSR 2220-2.200\(2\)](#)]. Policy and procedure manuals and documentation of the annual review will be required during inspection.

Board inspectors continue to observe instances of incomplete or outdated policy and procedure manuals. In other cases, pharmacy staff have not been updated or trained on recent changes. Manuals should be accessible to and reviewed by all pharmacy staff, including, new hires. Staff should be retrained when substantive changes are made or if there is a breach in aseptic technique.

This section contains a brief overview of changes to the sterile compounding rule. Licensees should review 20 CSR 2220-2.200 in its entirety to ensure compliance with Missouri's sterile compounding requirements.

K.1 GENERAL REQUIREMENTS

Pharmacies are required to designate a primary record keeping system that may either be a non-electronic (manual) system or an electronic data processing system (“EDP”). [20 CSR 2220-2.010(2)]. All dispensing activities must be recorded in the designated system.

K.2 NON-ELECTRONIC (MANUAL) SYSTEMS

If a non-electronic record system is used, the pharmacy must maintain the following:

- A separate prescription file for Schedule I and II controlled substance prescriptions;
- A separate prescription file for Schedule III, IV and V controlled substance prescriptions; and
- A separate file for all other non-controlled drug prescriptions. [20 CSR 2220-2.010(3)-(4)]

The following information must be maintained in a non-electronic system for each original and refilled prescription:

- The date the prescription was prescribed and the date of initial dispensing, if different;
- A sequential prescription label number or other unique identifier;
- The name of the patient(s), or if an animal, species and owner’s name;
- The prescriber’s name for oral prescriptions or signature for written or faxed prescriptions. Electronic signatures must comply with 20 CSR 2220-2.085;
- For controlleds, the address of the prescriber and the patient and the prescriber’s DEA number;
- Name, strength and dosage of drug, device or poison dispensed and the directions for use;
- The number of refills authorized;
- The quantity dispensed in weight, volume, or number of units;
- The date of refill, if any;
- The identity of the pharmacist responsible for reviewing the accuracy of data on each original prescription;
- The identity of the pharmacist responsible for verifying the final product prior to dispensing on each original and refill prescription, if different;
- Any change or alteration made to the prescription based on contact with the prescriber to show a clear audit trail. This includes, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug, and;
- If additional refills are authorized and added to the prescription, a notation indicating the method and source of the authorization must be a part of the manual record or hard copy. The expiration date of the original prescription must remain the same.

The following information must also be recorded on the reverse side of the prescription for each refill:

- The date the drug, medicine or poison was dispensed;
- The dispensing pharmacist’s initials; and
- The amount of drug dispensed to the patient, if different from the face of the prescription. [20 CSR 2220-2.010(3)]

Prescriptions must be filed by the prescription number/unique identifier. [20 CSR 2220-2.010(2); 20 CSR 2220-2.017].

K.3 ELECTRONIC DATA PROCESSING SYSTEMS (EDP) [20 CSR 2220-2.080]

If an electronic data processing system (EDP) is designated, the system must allow for the separate identification/retrieval of Schedule II controlled substance prescriptions, the separate identification/retrieval of Schedule III-V controlled substance prescriptions and the separate identification/retrieval of other non-controlled prescriptions. Required prescription hard copies must be stored in a three-file system as listed in section K.2.

An EDP must be able to store and retrieve the following for each original and refill prescription:

- 1) *A unique, sequential prescription label number;*
- 2) *If applicable, a unique readily retrievable identifier;*
- 3) *Date the prescription was prescribed;*
- 4) *The date the prescription was initially filled and the date of each refill;*
- 5) *Patient's full name, or if an animal, the species and owner's name;*
- 6) *The patient's address or animal owner's address, if a controlled substance has been prescribed;*
- 7) *The prescriber's full name.*
- 8) *For controlled substances, the prescribers address and DEA #;*
- 9) *Name, strength and dosage of drug, device or poison dispensed and any directions for use;*
- 10) *Quantity originally dispensed;*
- 11) *Quantity dispensed on each refill;*
- 12) *Identity of the pharmacist responsible for verifying the accuracy of prescription data prior to dispensing on each original prescription;*
- 13) *Identity of the pharmacist responsible for reviewing the final product prior to dispensing on each original and refill prescription, if different from the pharmacist verifying prescription data;*
- 14) *The number of authorized refills and quantity remaining;*
- 15) *The manner in which the prescription was received by the pharmacy (e.g., written, telephone, electronic, or faxed); and*
- 16) *Any other change or alteration made in the original prescription based on contact with the prescriber to show a clear audit trail. This includes, but is not limited to, a change in quantity, directions, number of refills, or substitution authority. If additional refills are authorized, the EDP system must indicate the method and source of authorization.*
[20 CSR 2220-2.080(2)]

Information may be entered into the EDP system by a licensed pharmacist or by a pharmacy technician or intern pharmacist working under the pharmacist's direct supervision. [20 CSR 2220-2.080(1)]. However, the pharmacist is personally responsible for the accuracy of information inputted. [20 CSR 2220-2.080(1)].

PRODUCTION OF RECORDS

An EDP system must be capable of retrieving records within two (2) hours of a request by a Board inspector. Alternatively, the pharmacy must provide a computer terminal that will allow the inspector to immediately access the system. An inspector may request passcode/login information to access records [20 CSR 2220-2.080(7)].

DRUG UTILIZATION

EDP systems must be able to retrieve a drug utilization listing for any drug for the previous twenty-four (24) months. Information must be available by specific drug product, patient name or practitioner. Drug utilization reports must be provided within three (3) working days of a Board request. [20 CSR 2220-2.080(12)]

In 2013, the Board removed the requirement that a pharmacist maintain a bound logbook or separate file signed daily by the pharmacist to verify that prescription information was accurately entered (a.k.a. the “pharmacist signature log”). However, federal law still requires licensees to maintain a logbook or a signed printout for verifying controlled substance refill data. [See 21 CFR 1306.22(f)(3)]

K.4 PRESCRIPTION HARD COPIES

Non-Controlled Prescriptions: Section 338.100, RSMo, requires that the “original order” of each drug must be maintained by the pharmacy for at least five (5) years. Accordingly, a physical hard copy of all non-controlled prescriptions must be maintained by the pharmacy unless the pharmacy has an electronic record-keeping system as described in Section K. 5. This requirement applies regardless of how the prescription was received (e.g., manually, faxed, scanned or electronic). Hard copies must be filed by the consecutive number or the unique identifier. A prescription hard copy is not necessary if the pharmacy maintains an image of the transmitted prescription data in a compliant electronic record-keeping system (see K.5).

Controlled Substances: State and federal controlled substance laws provide the following requirements:

| TYPE | HARD COPY REQUIRED? |
|---------------------------|--|
| Written | Yes |
| Faxed | Yes |
| Verbal/Telephone | Yes |
| Transferred | Yes |
| Electronically Prescribed | <i>Under federal law, a hard copy is not required. However, state law requires that either a hard copy or an image of the transmitted data must be maintained in an electronic record keeping system (see K.5 below)**</i> |

K.5 ELECTRONIC RECORD KEEPING SYSTEMS (ERS)

In lieu of a physical prescription hard copy, pharmacies that have an electronic record keeping system that complies with § 338.100, RSMo, may maintain a digitized image (scan) of a prescription. Rule 20 CSR 2220-2.083 defines an electronic record keeping system, or “ERS”, as a system that provides “input, storage, processing, communications, output and control functions for digitized images of original prescriptions.”



SECTION K: PHARMACY RECORDS

An electronic data processing system (“EDP”) is different from an electronic record keeping system (“ERS”). To qualify as an ERS, the pharmacy’s system must be able to capture “an exact digitized image” (scanned image) of the actual prescription, including, the reverse side of the prescription, if applicable. Simply transferring or electronically recording prescription data is insufficient. Pharmacies that do not have a compliant ERS must still maintain a physical prescription hard copy.

Digitized prescription images in an ERS must be readily retrievable and capable of being provided or reviewed immediately or within (2) hours of a request from the Board or a Board inspector. To prevent loss, digitized images in the ERS must be stored, copied or saved onto secure storage media on a regular basis. Pharmacies with an ERS must maintain a written policy and procedure manual that includes policies/procedures for reviewing compliance.

Although 20 CSR 2220-2.083 allows prescriptions to be maintained in an ERS in lieu of a hard copy, state/federal controlled substance laws still require that pharmacies maintain a hard copy of certain controlled substance prescriptions. [See chart in K.4]. Licensees are required to comply with federal law even if the prescription is maintained in an ERS.

K.6 CONFIDENTIALITY

Patient records must be confidentially maintained in compliance with HIPAA and all state and federal law. The Board is aware that records may be reviewed by third-party entities conducting audit/review functions (e.g., pharmacy benefit managers, private consultants). Confidential records that do not relate to a third-party inquiry must be securely maintained to avoid unauthorized access/disclosure.

Pharmacies should exercise caution in discarding or destroying drug containers. Patient specific information should be removed before placing the container in the trash or giving the container to a reverse distributor.

SECTION K: PHARMACY RECORDS

K.7 RECORD RETENTION

(This chart includes select record keeping requirements and is not a complete listing. Licensees should review all relevant laws to ensure record keeping compliance.)

| PHARMACIST | | |
|--|--|--|
| <i>Continuing Education</i> | <i>Must be retained for two (2) reporting periods immediately prior to renewal</i> | <i>20 CSR 2220-7.080</i> |
| PHARMACY | | |
| <i>Audit of Class-I Consultant Pharmacy Records</i> | <i>3 Years</i> | <i>20 CSR 2220-2.010(10)(A)3.</i> |
| <i>Compounding Log</i> | <i>2 Years</i> | <i>20 CSR 2220-2.400(7)(E)</i> |
| <i>Compounding Records</i> | <i>2 Years</i> | <i>20 CSR 2220-2.400(7)(E)</i> |
| <i>Controlled Substance Prescription Orders</i> | <i>5 Years</i> | <i>§ 338.100, RSMo</i> |
| <i>Controlled Substance Transfer Records/DEA 222 forms</i> | <i>2 Years</i> | <i>21 CFR 1304.04</i> |
| <i>Controlled Substance Inventories</i> | <i>2 Years</i> | <i>§ 195.060, RSMo</i> |
| <i>Distribution Records</i> | <i>2 Years</i> | <i>20 CSR 2220-2.010(5)</i> |
| <i>Drug Invoices</i> | <i>2 Years</i> | <i>20 CSR 2220-2.010(5)</i> |
| <i>Immunization/Medication Administration Records</i> | <i>2 Years</i> | <i>20 CSR 2220-6.050(6)(D)2. 20 CSR 2220-6.040(6)(B)</i> |
| <i>Immunization Protocol</i> | <i>8 Years after termination</i> | <i>20 CSR 2220-6.050(5)(B)</i> |
| <i>Medication Therapy Services (MTS) Protocol</i> | <i>8 Years</i> | <i>20 CSR 2220-6.080(7)(B)</i> |
| <i>MTS Patient Records (generally)</i> | <i>7 Years</i> | <i>20 CSR 2220-6.080(7)</i> |
| <i>Prescription Orders</i> | <i>5 Years</i> | <i>§ 338.100, RSMo</i> |
| <i>Sterile Compounding Records</i> | <i>2 Years</i> | <i>20 CSR 2220-2.200(9)(A)</i> |

SECTION L: ADMINISTRATION BY RX ORDER

L.1 AUTHORIZED ACTIVITY

Section § 338.010, RSMo authorizes pharmacists who meet the following requirements to administer medication by prescription order: [20 CSR 2220-6.040]

| ADMINISTRATION REQUIREMENTS | |
|--|---|
| <i>Qualification Requirements</i> | <ul style="list-style-type: none"> • <i>Active Missouri RPh license</i> • <i>A Notification of Intent (NOI) filed with the Board (Notifications must be filed online. Note: An administration NOI is different from an NOI to immunize by protocol. Both NOIs must be filed/renewed if a pharmacist will be doing both.</i> • <i>Current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. The CPR/BLS program must include an in-person skill assessment.</i> • <i>Completion of a certificate program in medication administration and emergency procedures program accredited by ACPE or an entity approved by the Board. The certificate program must include training in:</i> <ul style="list-style-type: none"> • <i>Drug storage and handling</i> • <i>Informed consent-requirements</i> • <i>Pre- and post- administration assessment and counseling</i> • <i>Biohazard waste disposal</i> • <i>Identifying and treating adverse reactions, including anaphylactic reactions and needle sticks.</i> • <i>Administration techniques, including, hand-on training in routes of administration.**</i> |
| <i>Notification Renewal</i> | <p><i>NOIs must be refilled when your Missouri pharmacist license is renewed (every even-numbered year- 2020, 2022, etc.) To renew, pharmacists must have:</i></p> <ul style="list-style-type: none"> • <i>A current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. Certificate programs must include an in-person skill assessment.</i> <p><i>***Proof of CPR/BLS certification from prior years should be maintained in the event of an audit (e.g., prior certification cards/certificates)***</i></p> |
| <i>Missouri Licensed Intern Pharmacist</i> | <p><i>May administer if the intern:</i></p> <ol style="list-style-type: none"> 1) <i>Has a current and active CPR certification or qualifying BLS certification</i> 2) <i>Completes a qualifying administration and emergency procedures certificate program accredited by ACPE or an entity approved by the Board [See 20 CSR 2220-6.040].</i> 3) <i>Interns must be under the direct supervision of a pharmacist qualified to administer drugs</i> |
| <i>Authorized Medication/Vaccines</i> | <p><i>As prescribed, however, licensees must comply with CDC recommendations or manufacturer guidelines.</i></p> |

SECTION L: ADMINISTRATION BY RX ORDER

*** If a requested route of administration was not included in the original certificate program, the pharmacist must first be trained in that administration route by a licensed health care practitioner who is authorized to administer medication. No additional Board notification is required for the additional administration route. However, documentation of the training and training dates must be maintained at the pharmacy and available on request.*

Medication administration may only be delegated to an intern pharmacist who meets the rule's requirements. Pharmacy technicians cannot administer medication even if supervised.

L.2 PRESCRIPTION REQUIREMENTS

To administer medication, the prescription must contain:

- 1) The prescriber's name;
- 2) The patient's name;
- 3) The name of the drug and dose;
- 4) The route of administration;
- 5) The date of the original order; and
- 6) The date or schedule, if any, of each subsequent administration. [20 CSR 2220-6.040(5)]

Note: Prescriptions for administration by medical prescription order no longer have to include a statement that the drug is to be administered by a pharmacist. Prescriptions from non-Missouri prescribers have to comply with the law of the prescriber's state.

L.3 DRUG STORAGE

Drugs must be stored within the manufacturer's labeled requirements. Vaccines must be stored in accordance with CDC guidelines. Storage requirements apply at all times, including, when administering outside of a pharmacy.

L.4 PATIENT EVALUATION

Patients must be asked to remain in the pharmacy for a "safe amount of time" after a vaccine is administered to observe any adverse reactions. [§ 338.010.12] "Safe amount of time" is not defined in statute. Pending further rulemaking, pharmacists should use their professional discretion when determining the time needed to adequately assess adverse reactions. The appropriate waiting period should be identified in the pharmacist's policies and procedures. The Board recommends documenting if a patient refuses or fails to stay as requested.

L.5 POLICIES AND PROCEDURES

Additionally, pharmacists must have a current and accurate written policy and procedure manual that covers all aspects of administering medication by prescription order including, but not limited to, policies/procedures for:

- 1) Drug administration
- 2) Authorized routes of administration
- 3) Drug storage
- 4) Pre- and post- administration assessment and counseling
- 5) Disposing of biohazard waste and used/contaminated supplies
- 6) Identifying and handling acute adverse events or immunization reactions, including, anaphylactic reactions, and;
- 7) Recordkeeping and notification procedures/requirements..

SECTION L: ADMINISTRATION BY RX ORDER

L.6 RECORDS

The following records must be maintained for each administration:

- 1) The patient's name, address, and date of birth;
- 2) The date, route, and anatomic site of administration;
- 3) The medication's name and dose. For *vaccines* and *biologics*, the manufacturer, expiration date and lot number must also be recorded;
- 4) For vaccines, the name and address of the patient's primary health care provider ("PCP") as provided by the patient or an indication that PCP information was not given;
- 5) The nature of any adverse reaction and who was notified; and
- 6) The identity of the administering pharmacist. If medication was administered by an intern pharmacist, the identity of the intern pharmacist and the supervising pharmacist. [20 CSR 2220-6.040(6)]

Administration records and the required policy and procedure manual must be maintained at the pharmacy where the prescription order is maintained separate from the pharmacy's prescription records for a minimum of two (2) years. If the medication was not administered on behalf of a pharmacy, required records may be maintained at a secure location designated by the pharmacist, provided the records must be produced within three (3) business days of a board request.

L.7 REPORTING/NOTIFICATIONS [20 CSR 2220-6.040(7)]

ADMINISTRATION BY PRESCRIPTION ORDER NOTIFICATION REQUIREMENTS

| | WHEN? | NOTIFICATION REQUIREMENTS |
|--|---|---|
| <i>Primary Care Provider (Vaccines Only)</i> | ***See L.8 Below*** | ***See L.8 Below*** |
| <i>Adverse Events</i> | <i>Prescriber notification within twenty-four (24) hours after learning of an adverse event/reaction.</i> | <i>Prescriber notification is mandatory and cannot be waived.</i> |
| <i>State/Federal Entities</i> | <i>As required by law</i> | <i>As required by law</i> |
| <i>ShowMeVax Reporting</i> | ***See L.8 Below*** | ***See L.8 Below*** |

Notifications required by 20 CSR 2220-6.050 may be made in writing, electronically or via a common electronic record that is accessible to and shared by both the physician and pharmacist (e.g., a shared EMR/EHR). Documentation of the required notifications must be electronically retrievable on request or maintained at the pharmacy where the related prescription is maintained. If maintained at a pharmacy, notification records must be separate from the pharmacy's prescription records.

Licensees must also comply with all state and federal laws governing Vaccine Information Statements and informed consent.

L.8 SHOWMEVAX REPORTING [§ 338.010.13]

Effective August 28, 2018, vaccines administered by medical prescription order must be reported to ShowMeVax- Missouri's statewide immunization registry- unless the patient opts out of reporting. [§ 338.010.13] If the patient opts-out of ShowMeVax reporting, the pharmacist must notify the primary care provider (PCP), if provided, within 14 days. (See M.9 for ShowMeVax information and PCP notification requirements.)

M.1 GENERAL REQUIREMENTS

Pharmacists who meet the qualifications of [20 CSR 2220-6.050](#) may administer the following following vaccines pursuant to a written protocol with a Missouri licensed physician:

- Influenza
- Shingles
- Meningitis
- Pneumonia
- Hepatitis A/Hepatitis B
- Tetanus, diphtheria and pertussis (This includes combination products such as Tdap). [[§ 338.010](#)]

Licenses immunizing by protocol must comply with:

- All state and federal laws governing vaccine information statements and informed consent;
- Manufacturer guidelines, and;
- All applicable Centers for Disease Control (CDC) guidelines. In the event of a conflict between manufacturer guidelines and CDC guidelines, CDC guidelines control.

Unless otherwise restricted in the governing protocol, immunizations may be provided to patients that are seven (7) years or older or the CDC recommended age, whichever is higher. Immunizations may be delegated to an intern pharmacist who meets the requirements of [20 CSR 2220-6.050](#), however, immunizations may not be delegated to a pharmacy technician.

SECTION M: IMMUNIZATION BY PROTOCOL

M.2 IMMUNIZATION QUALIFICATIONS [§ 338.010 and 20 CSR 2220-6.050]

Pharmacists immunizing by protocol must meet the following requirements:

| IMMUNIZATION BY PROTOCOL REQUIREMENTS | |
|---------------------------------------|--|
| Qualifications | <ul style="list-style-type: none"> • Active Missouri RPh license • Protocol with a Missouri licensed physician • Notification of Intent filed with Board (must be filed online prior to immunizing) • Current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. The CPR/BLS program must include an in-person skill assessment. • Completion of a certificate program in administering vaccines accredited by ACPE or an entity approved by the Board or provided by a regionally accredited pharmacy or medical school/college. The certificate program must include training in: <ul style="list-style-type: none"> • Current CDC vaccine recommendations/guidelines for vaccines authorized by Chapter 338, including, immunization schedules • Basic immunology and vaccine protection • Pre- and post- vaccine screening or assessment • Physiology and techniques for administering vaccines, including, hands-on training in intramuscular, intradermal, subcutaneous and nasal administration routes and other common routes of vaccine administration • Identifying and treating adverse reactions, including anaphylactic reactions and needle sticks. |
| Notification Renewal | <p>NOIs must be refiled when your Missouri pharmacist license is renewed (every even-numbered year- 2020, 2022, etc.) To renew, pharmacists must have:</p> <ul style="list-style-type: none"> • A current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. • Two (2) CE hours (0.2 CEU) related to administering vaccines or CDC immunization guidelines. CE must be completed during the biennial renewal period (Nov. 1st to Oct. 31st of even numbered years) <p>***Proof of CPR/BLS certification from prior years should be maintained in the event of an audit (e.g., prior certification cards/certificates)***</p> |
| Missouri Licensed Intern Pharmacists | <p>May immunize if the intern:</p> <ol style="list-style-type: none"> 1) Has a current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. Certificate programs must include an in-person skill assessment. 2) Has completed a certificate program in administering vaccines that meets the same requirements as the required pharmacist certificate program, & 3) Is working under the direct supervision of a pharmacist qualified to immunize <p>***Immunizations may not be delegated to a pharmacy technician.***</p> |

SECTION M: IMMUNIZATION BY PROTOCOL

Section 338.010.12(3) requires that pharmacists post a certificate showing that he/she has met all immunization training requirements. The Board does not issue a separate immunization certificate/license. Instead, licensees should print and display their online license verification from the Board's website which will show if a Notification of Intent has been filed. Online license verifications can be retrieved by searching the licensee's name at <https://renew.pr.mo.gov/pharmacy-licensee-search.asp>. Posting an immunization training certificate does not meet the statutory requirement.

M.3 PROTOCOL REQUIREMENTS

To immunize, pharmacists must have a written protocol with a Missouri-licensed physician who is actively engaged in the practice of medicine. [20 CSR 2220-6.050(6)]. Protocols should clearly delineate the pharmacist's immunization authority. At a minimum, protocols must include:

1. *The identity and signature of the participating pharmacist and physician;*
2. *The time period of the protocol;*
3. *Authorized vaccines;*
4. *The patient or groups of patients who may be vaccinated;*
5. *Allowed routes and anatomic sites of administration;*
6. *Provisions for creating a prescription for each administration under the authorizing physician's name;*
7. *Emergency response procedures, including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;*
8. *The length of time the pharmacist is required to observe a patient for adverse events;*
9. *Disposal procedures for used and contaminated supplies;*
10. *The street addresses of any non-pharmacy locations where vaccines may be administered;***
11. *Record keeping and any notification requirements; and*
12. *Provisions for terminating the protocol at the request of any party at any time.*

Effective 9/30/18, protocol physicians no longer have to be within fifty (50) miles of the pharmacist. However, the protocol physician must be actively engaged in the practice of medicine.

Protocol Amendments: Amendments to the protocol must be manually or electronically signed and dated by all participating pharmacists and prescribers. Signatures may be included on the original protocol or on a separate document that is attached to the protocol. Pharmacists may be added to an existing protocol if the protocol is signed by both the newly added pharmacist and the authorizing physician(s). Existing pharmacists do not have to sign the protocol when a new pharmacist is added unless other protocol provisions are changed.

Immunization protocols may be valid for no longer than one (1) year; a new protocol must be signed each year. Protocols must be maintained for at least eight (8) years after the protocol is terminated. .

M.4 AUTHORIZED SITES

Unless restricted by protocol, pharmacists who meet 20 CSR 2220-6.050's immunization requirements may administer at any Missouri licensed pharmacy or at any non-pharmacy location identified in the governing protocol in advance. Effective 9/30/18, only non-pharmacy locations have to be listed in the required protocol.

SECTION M: IMMUNIZATION BY PROTOCOL

M.5 PATIENT EVALUATION

After immunizing, patients must be asked to remain in the pharmacy a “safe amount of time” to observe any adverse reactions. [§ 338.010.12(2)] The Board recommends defining the required waiting period in the governing protocol. In the absence of protocol language, pharmacists should use their professional discretion to determine the time needed to adequately assess adverse reactions. The Board recommends documenting when a patient refuses to stay..

M.6 PRESCRIPTION REQUIREMENTS

Within seventy-two hours (72) hours after administering a vaccine by protocol, the pharmacist must either obtain a prescription from the authorizing physician for the vaccine or create a prescription under the protocol physician’s name documenting the dispensing. [20 CSR 2220-6.050(7)(B)]. The protocol physician must be listed as the prescriber and not the pharmacist/intern pharmacist.

M.7 NOTIFICATIONS

Licensees must comply with the following notification requirements [20 CSR 2220-6.050(8)]:

| | TIMEFRAME | NOTIFICATION REQUIREMENTS | NOTIFICATION METHOD |
|--|--|--|---|
| <i>Authorizing Protocol Physician</i> | <i>As required by protocol</i> | <i>As required by protocol</i> | <i>As required by protocol</i> |
| <i>Primary Care Provider (If different from the authorizing physician)</i> | <i>See M.9 (ShowMeVax Reporting)</i> | <i>See M.9 (ShowMeVax Reporting)</i> | <i>See M.9 (ShowMeVax Reporting)</i> |
| <i>Adverse Events</i> | <i>Within twenty-four (24) hours after learning of a patient adverse event/ reaction</i> | <i>The authorizing physician and the patient’s primary care provider must be notified, if different.</i> | <i>In the pharmacist’s discretion unless defined in the protocol.</i> |
| <i>Vaccine Adverse Event Reporting System (VAERS)</i> | <i>Within thirty (30) days after learning of a patient adverse event/reaction</i> | <i>As provided by the U.S. Department of Health and Human Services</i> | <i>Online via the VAERS system</i> |
| <i>ShowMeVax</i> | <i>See Section M.9 below</i> | <i>See Section M.9 below</i> | <i>See Section M.9 below</i> |

Unless otherwise required by state/federal law, required notifications can be made manually or electronically. Alternatively, notifications can be made through a common electronic medication record that is accessible to and shared by both the physician and pharmacist (e.g., a shared EMR/EHR). [20 CSR 2220-6.050(6)] Proof of the required notifications must be maintained in the pharmacist’s records.

M.8 RECORDS

Pharmacists administering vaccines by protocol must document and maintain a record of:

1. *The name, address, and date of birth of the patient;*
2. *The date, route, and anatomic site of the administration;*
3. *The name, dose, manufacturer, lot number, and expiration date of the vaccine;*
4. *The name and address of the patient’s primary health care provider, as identified by the patient;*

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5. The name or identifiable initials of the administering pharmacist; and
6. Any adverse reaction and who was notified, if applicable.

Vaccination records must be maintained for at least two (2) years. If vaccines are administered on behalf of a pharmacy, records must be maintained at the pharmacy. If the vaccine is not administered on behalf of a pharmacy, records should be maintained at an address identified in the protocol.

For additional immunization compliance information, see the Board's Immunization Checklist online at [http://pr.mo.gov/boards/pharmacy/13863\[1\].pdf](http://pr.mo.gov/boards/pharmacy/13863[1].pdf).

M.9 SHOWMEVAX REPORTING [§ 338.010.13]

Pharmacists are required to report all vaccines administered to ShowMeVax unless the patient opts out of reporting. [§ 338.010.13] ShowMeVax is Missouri's statewide immunization registry operated by the Missouri Department of Health and Senior Services (DHSS). The registry offers health care professionals, schools and child care organizations a single location for recording immunization history and status and allows providers to monitor vaccine inventory and upcoming required doses for patients. ShowMeVax reporting is required for vaccines administered by medical prescription order and vaccines administered by protocol.

Patients must be informed on a manual or electronic form that their information will be entered into the ShowMeVax system and provided an opportunity to **opt-in** to reporting. The patient must manually or electronically sign the form acknowledging that their information will be reported to ShowMeVax. A sample [ShowMeVax Patient Notification Form](#) is available on the Board's website. However, licensees should consult with legal counsel to develop the appropriate notification form for your practice setting. Notification forms should be maintained in the licensee's records as proof of compliance.

If the patient **opts-out** of ShowMeVax reporting, pharmacists must provide the following information to the PCP in writing within fourteen (14) days after immunizing:

- 1) The patient's name
- 2) The vaccine(s) administered
- 3) The administration route
- 4) The anatomic site of administration, and
- 5) The administration date.

Written notifications may be transmitted electronically or by fax/e-mail. Pharmacists must maintain documentation that the required notification was provided. PCP notification is not required if the patient doesn't provide PCP information.

Section 338.010.13 does not identify when vaccines have to be reported to ShowMeVax. Pending additional rulemaking, licensees should report to ShowMeVax within fourteen (14) days after immunizing.

Licensees are required to register with the Missouri Department of Health and Senior Services ("DHSS") to report to ShowMeVax. Information on how to register is available on DHSS' website at <https://health.mo.gov/showmevax/smv-providers.php>. Registration is free.

Questions regarding ShowMeVax online reporting/registration should be directed to DHSS' Bureau of Immunizations at (877) 813-0933 or showmevaxsupport@health.mo.gov. The Board cannot answer ShowMeVax registration questions.

What About The Notifications Required by 20 CSR 2220-6.040 & 20 CSR 2220-6.050?

- The Board anticipates amending [20 CSR 2220-6.040](#) (Administration by Medical Prescription Order) and [20 CSR 2220-6.050](#) (Administration by Protocol) to incorporate § 338.010.13. In the interim, licensees may satisfy the rules' PCP notification requirements by reporting to ShowMeVax as outlined in [§ 338.010.13](#) within fourteen (14)



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days after immunization.

- Notification of adverse events must still be reported to the prescriber, the protocol physician and the patient's PCP within 24 hours, as required by both [20 CSR 2220-6.040](#) and [20 CSR 2220-6.050](#).

PCP notification is only required if the PCP's information is known. A good faith attempt should be made to collect PCP information (e.g., verbally or on the immunization authorization form). The Board suggests documenting if the patient doesn't provide PCP information.

N.1 GENERAL REQUIREMENTS

Pursuant to [§ 338.010](#), a Missouri licensed pharmacist may perform “medication therapy services” after obtaining a certificate of medication therapeutic plan authority from the Board. “Medication therapy services” are defined as:

[T]he designing, initiating, implementing, or monitoring of a plan to monitor the medication therapy or device usage of a specific patient, or to enhance medication therapeutic outcomes of a specific patient, by a pharmacist who has authority to initiate or implement a modification of the patient’s medication therapy or device usage pursuant to a medication therapy protocol. [20 CSR 2220-6.060\(1\)\(F\)](#)

Medication therapy services (“MTS”) are different from medication therapy management (“MTM”). As commonly defined, medication therapy management includes a group of pharmacist provided services designed to optimize patient therapeutic outcomes. Medication therapy management is within the scope of the practice of pharmacy and can be performed by any Missouri licensed pharmacist (e.g., Medicare Part D medication therapy management). A MTS certificate is only required if a pharmacist is engaged in or has authority to initiate or modify drug/device therapy (e.g., Coumadin/Vancomycin dosing).

Modification of drug therapy includes, but is not limited to:

- Selecting a new, different or additional medication or device (including initiating therapy);
- Discontinuing any current medication/device;
- Selecting a new, different or additional strength, dose, dosage form or dosage schedule; or
- Selecting, adding or changing a new or different route of administration.

Modification does not include dispensing a drug/device pursuant to a valid prescription from an authorized prescriber or generic substitution as authorized by [§ 338.056](#). Additionally, “medication therapy services” do not include administering medication by prescription order pursuant to [20 CSR 2220-6.040](#) or administering vaccines by protocol pursuant to [20 CSR 2220-6.050](#).

Prior to performing MT services, a pharmacist must have:

- A MTS certificate issued by the Board, and;
- A protocol with a Missouri licensed physician who is actively practicing medicine in Missouri.

All pharmacists performing MT services in Missouri are required to have a MTS certificate issued by the Board, including, pharmacists practicing in a hospital.

N.2 CERTIFICATION REQUIREMENTS

To be issued a MTS certificate, pharmacists must submit an application to the Board with the applicable fee and:

- Hold a PharmD degree from an ACPE accredited pharmacy school, or
- Hold a current certification from the Board of Pharmaceutical Specialties, the Commission for Certification in Geriatric Pharmacy or the National Certification Board for Diabetes Educators, or
- Have successfully completed a post-graduate MT certificate program accredited by ACPE, the American Society of Health-System Pharmacists, the American Society of Consultant Pharmacists, or the American Pharmacists

Association, or

- Have completed a qualifying post-graduate MT certificate course that included instruction in:
 - Assessing patient specific data and issues;
 - Establishing MT goals or medication related action plans for identified medication conditions and medication related concerns;
 - Assessing and addressing adverse reactions and adverse drug events;
 - Modifying and monitoring medication regimens;
 - Improving patient care and outcomes through MT services;
 - Evaluating treatment progress;
 - Assessing and monitoring pharmacokinetic and pharmacodynamic changes in medication regimen reviews;
 - Medication reconciliation;
 - Drug utilization review;
 - Applicable state or federal law;
 - Formulating and documenting personal medication records;
 - Documenting clinical outcomes;
 - Interpreting, monitoring, ordering, and assessing patient test results; and
 - Patient education and counseling.

N.3 SCOPE OF AUTHORITY

Licensees with a current MTS certificate may perform medication therapy services as authorized by their governing protocol. However, the following restrictions/prohibitions apply:

- Pharmacists may not initiate or modify any controlled substance.
- Pharmacists may not independently prescribe. Instead, medication may only be modified or initiated as authorized by a written protocol with a Missouri physician.
- MT services may not be delegated. Pharmacy technicians and intern pharmacists may assist in providing MT services under the supervision of a pharmacist. However, technicians and interns may not initiate or modify drug therapy or perform any act that requires the professional judgment of a pharmacist.

N.4 PROTOCOL REQUIREMENTS

Prior to performing MT services, pharmacists must have a written protocol with a Missouri licensed physician who is actively practicing medicine in the state of Missouri and whose practice location is no more than fifty (50) miles by road from the pharmacist.

The Board does not have a form or recommended protocol. However, protocols should clearly delineate the pharmacist's scope of authority. As detailed in [20 CSR 2220-6.080\(4\)](#), protocols must include:

- The names and signatures of the participating physician(s) and pharmacists(s);
- The effective date of the protocol;
- A description of MT services the pharmacist is authorized to provide. Authorized MT services must be within the

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skill, education, training and competence of the authorizing physician and pharmacist;

- A list of clinical conditions, diagnoses and diseases included in the written protocol and the type of medication therapy allowed in each case;
- The specific drugs or drug categories included in the protocol;
- A statement of the methods, procedures, decision criteria and plan the pharmacist is to follow when providing MT services;
- A description of any authority granted to the pharmacist to administer medication;
- A list of drugs the pharmacist is authorized to administer;
- A description of drug therapy related patient assessment procedures or testing the pharmacist may order or perform;
- Procedures for documenting the pharmacist's MT decisions;
- Procedures and requirements for communicating and reporting MT decisions to the authorizing physician;
- Criteria for timely communication between the pharmacist and authorizing physician;
- A statement prohibiting the pharmacist from delegating the responsibility of MT services;
- Methods for physician review of MT activities;
- Provisions allowing the authorizing physician to access patient records;
- Mechanisms and procedures that allow the authorizing physician to override, rescind or otherwise modify the protocol;
- Emergency response procedures the pharmacist is authorized to follow to address emergency situations, including, anaphylactic or other adverse medication reactions, adverse needle sticks or other adverse events;
- All notification requirements required by [20 CSR 2220-6.080\(5\)](#) (see N.9); and
- An address where required records will be maintained.

Protocols must be signed and dated by both the authorizing physician and pharmacist. If a protocol includes multiple physicians and pharmacists, a separate protocol is not required for each participating physician/pharmacist if all authorizing physicians and pharmacists sign and date a statement agreeing to be governed by the terms of the protocol.

Alternatively, MT services may be provided pursuant to a protocol approved by the “medical staff committee” of a hospital or hospital system. A “medical staff committee” is defined as the “committee or other body of a hospital or hospital system responsible for formulating policies regarding pharmacy services and medication management” (e.g., Pharmacy & Therapeutics Committee). Protocols approved by a medical staff committee can only be used to provide MT services to “individuals receiving medical diagnosis, treatment, or care at a hospital or a hospital clinic or facility.” A physician protocol is required for all other services.

Modifications/amendments to the protocol must be documented in writing and signed and dated by both the pharmacist and the authorizing physician prior to being implemented. Protocols may be rescinded by the authorizing physician or pharmacist with or without cause, provided the rescission is documented in writing.

Protocols must be reviewed and signed annually by the authorizing physician and pharmacist. The annual review date must be documented on the written protocol. Protocols do not have to be filed with the Board but must be available if requested. Additionally, both the pharmacist and authorizing physician must retain signed copies of the written protocol for 8 years after the protocol is terminated.

N.5 PHARMACY RESIDENTS

In lieu of an individual protocol, a pharmacy resident may perform MT services under the written protocol of another Missouri pharmacist if:

- The resident holds a MT certificate from the Board;
- The resident is enrolled in a residency training accredited by the American Society of Health System Pharmacists (ASHP) or that has a valid ASHP accreditation application pending, and;
- The resident is providing MT services under the supervision of a Missouri pharmacist with a current Board MT certificate.

N.6 PRESCRIPTION ORDERS

To provide MT services, a pharmacist must obtain a prescription order from their protocol physician authorizing the pharmacist to perform MT services for a specific patient. Prescription orders for MT services are valid for no more than one (1) year and may be transmitted verbally, electronically or in writing.

Pursuant to [20 CSR 2220-6.080\(2\)\(A\)](#), the prescription order must include:

- The patient's name, address and date of birth;
- The date the prescription order was issued;
- The clinical indication for MT services (e.g., the patient's diagnosis or disease);
- The authorizing physician's name and address; and
- The length of time for providing MT services, if less than one (1) year.

Prescription orders maintained in compliance with [20 CSR 2220-6.080\(2\)](#) will be deemed to comply with the general prescription requirements of [20 CSR 2220-2.018](#).

N.7 THERAPY MODIFICATIONS

Pharmacists with a MTS certificate may modify drug therapy or device usage as provided in the governing protocol. Pharmacists may only modify non-controlled medications; controlled substances may not be modified by a pharmacist. [[20 CSR 2220-6.080\(6\)\(B\)](#)]. If the modification results in a drug/device being dispensed, the modification must be documented by creating a prescription in the pharmacy's prescription records under the name of the authorizing physician. [[20 CSR 2220-6.080\(6\)\(A\)](#)]. All therapy modifications must be documented in the patient's record.

Prescriptions generated by a pharmacist under [20 CSR 2220-6.080\(6\)\(A\)](#) in the protocol physician's name may be dispensed by any licensed pharmacy. However, pharmacists may not sign their name or the physician's name to a written prescription generated under [20 CSR 2220-6.080\(6\)](#). Instead, modifications may be verbally submitted to the other pharmacy or e-prescribed under the protocol physician's name in accordance with governing law and protocol.

N.8 DOCUMENTATION OF SERVICES

Pharmacists must document and maintain an adequate patient record of MT services provided for each patient. At a minimum, the patient record must include:

- *The patient's name, birthdate, address and telephone number;*
- *The dates of any patient visits/consultations and the reason for the visit/consultation;*
- *Any pertinent assessments, observations or findings;*

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- Any diagnostic testing recommended or performed;
- The name of any medication or device modified;
- The strength, dose, dosage schedule or route of administration of any medication modified or administered;
- Referrals to the authorizing physician;
- Referrals for emergency care;
- Any contact with the authorizing physician concerning the patient's treatment or MT services plan;
- Any informed consent for procedures, medications or devices;
- Any changes/alterations made to the prescription order based on contact with the prescriber; and
- Any consultation with other treatment providers for the patient and the results of the consultation.

N.9 NOTIFICATIONS

Pharmacists are required to provide the following notifications [20 CSR 2220-6.080(5)]:

| TYPE | RECIPIENT | TIMEFRAME |
|---|--|-------------------------|
| Anaphylactic or adverse medication reactions, adverse needle sticks or other adverse events | Authorizing physician or physician's authorized designee | 24 Hours |
| Therapy modifications | Authorizing physician or physician's authorized designee | 24 Hours |
| Other notifications | As governed by protocol | As governed by protocol |

Notifications must be in writing unless otherwise authorized by protocol. Pharmacists providing MT services for, or on behalf of, a health care entity may satisfy the notification requirements if the notification is recorded in a patient medical record that the health care entity is required to maintain under state or federal law (e.g., an EMR). *Note: Protocols may include more stringent notification requirements.*

N.10 RECORDS

The following records must be maintained under 20 CSR 2220-6.080:

| TYPE | TIMEFRAME |
|--|---------------------------------------|
| Patient records required by 20 CSR 2220-6.080(7) | 7 years after termination of protocol |
| Protocols, including, protocol changes or amendments | 8 years after termination of protocol |
| Prescription orders for MT services | 7 years after termination of protocol |
| Other records required by protocol | As governed by protocol |

Records may be maintained electronically provided the record can be retrieved/reviewed on request. Records maintained at a pharmacy must be produced during an inspection or investigation. Records that aren't maintained at a pharmacy must be produced within three (3) business days.



SECTION N: MEDICATION THERAPY SERVICES

N.11 RENEWAL/CONTINUING EDUCATION

MTS certificates must be renewed biennially with the pharmacist's Missouri pharmacist license. MTS certificate holders are required to complete 6 hours of CE in courses/programs related to medication therapy management each pharmacist biennial renewal period. The required CE may be used to satisfy Missouri's biennial pharmacist CE requirements.

The Board will accept approved MTS CE related to any drug therapy or disease state management. These courses generally have an "01" Drug Therapy Related ACPE universal activity number (Example: ACPE Universal Activity Number: xxxx-xxxx-xx-xxx-x01-x).

O.1 REGISTRATION REQUIREMENTS

All pharmacy technicians must be registered with the Board. [[§ 338.013](#), [20 CSR 2220-2.700](#)]. A pharmacy technician is defined as:

1. Any person who assumes a supportive role or who is utilized to “perform routine functions. . .in connection with the receiving, preparing, compounding, distributing or dispensing of medication”, or
2. “Any person other than a pharmacist or permit holder who has independent access to legend drug stock on a routine basis.” [[20 CSR 2220-2.700](#), [20 CSR 2220-2.090\(2\)\(DD\)](#)]

To be registered, an applicant must submit an **application** with the applicable fee and undergo a criminal history background check. Missouri does not currently impose minimum education or certification requirements for technician registration. However, technicians should be appropriately trained to perform the tasks delegated. *Note: Additional training is required for sterile compounding.* [[20 CSR 2220-2.200\(3\)](#)].

Applicants may begin working as a pharmacy technician once a completed registration application has been mailed to the Board. To be complete, the application must include an official fingerprint receipt and the required fee. A copy of the application must be maintained at the pharmacy. [[§ 338.013](#)]. The Board also suggests keeping proof of mailing.

Pharmacies must maintain a current list of all pharmacy technicians authorized to access the pharmacy and their duties, as well as a policy and procedure manual for technician supervision. [[20 CSR 2220-2.090\(2\)\(BB\)](#), [\(CC\)](#)].

Prescription delivery staff that solely perform delivery functions do not have to be registered as technicians. However, technician registration may be required if additional functions are performed.

The pharmacist-in-charge is responsible for determining if an individual routinely has “independent access” to drug stock. The Board has determined that the ability to access the pharmacy does not automatically require technician registration (e.g., an employee has a key to the pharmacy). However, individuals who routinely use their access to independently enter the pharmacy must be registered.

O.2 SUPERVISION

A pharmacy technician may assist in any area of pharmacy practice, including, receiving, preparing, compounding or dispensing prescriptions. [[20 CSR 2220-2.700\(1\)](#)]. However, technicians may not work independently and must be under the “direct supervision and responsibility” of a Missouri-licensed pharmacist at all times. [[20 CSR 2220-2.700](#)]. When no pharmacist is on duty, a sign must be posted on the prescription counter and on all entrance doors informing the public that “no pharmacist is on duty.” The “no pharmacist on duty sign” does not have to be posted if the pharmacist is in the pharmacy building but briefly absent from the pharmacy area (e.g., restroom breaks). *See E.6 for additional signage requirements.*

The Board has determined that technicians may accept written prescriptions from patients for dispensing when no pharmacist is on duty. [[20 CSR 2220-2.010\(1\)\(B\)](#)]. However, technicians cannot take verbal prescription orders or count, fill, compound or enter a prescription if the pharmacist is absent. Technicians cannot come in early to process prescriptions before a pharmacist arrives or hand out or dispense prescriptions when no pharmacist is on duty, even if the prescription was previously checked by a pharmacist.

All prescriptions must be finally verified/checked by a pharmacist, including, reconstituted products. Additionally, a pharmacist must verify that prescription/medication order data entered by a pharmacy technician into an electronic prescription data processing system was accurately inputted. [[20 CSR 2220-2.080\(1\)](#)]. *Note: Remote supervision is not allowed in Missouri at this time.*

O.3 AUTHORIZED ACTIVITIES

Technicians may not perform any activity that requires the “professional judgment” of a pharmacist. [20 CSR 2220-2.700(1)]. Prohibited activities include, but are not limited to,:

- Final verification of a prescription before dispensing;
- Drug utilization review;
- Patient counseling;
- Receiving or providing transfer information for controlled substance prescriptions [20 CSR 2220-2.120(1)(D)];
- Immunizing or administering medication [20 CSR 2220-6.040 & 6.050]
- Modifying medication therapy [20 CSR 2220-6.080]

TECHNICIAN AUTHORIZED DUTIES

***The chart below is not exhaustive and does not include all potential tasks that may be performed by a pharmacy technician. All authorized activities must be performed under the direct supervision of a Missouri licensed pharmacist.
X= Activities not allowed***.

| | |
|---|---|
| <i>Administer Medication by Rx Order</i> | X |
| <i>Advise/Counsel Patients on OTC Items</i> | X |
| <i>Fill, Compound or Prepare a Prescription</i> | ✓ <i>*Final product must be verified by a pharmacist</i> |
| <i>Dispense Rx to Patient (after verification by a pharmacist)</i> | ✓ |
| <i>Drug Utilization Review</i> | X |
| <i>Enter Rx Data</i> | ✓ |
| <i>Immunize by Protocol</i> | X |
| <i>Modify Medication Therapy under MTS protocol</i> | X |
| <i>Offer Patient Counseling</i> | ✓ |
| <i>Patient Counseling</i> | X |
| <i>Receive Rx</i> | ✓ |
| <i>Receive or provide controlled substance transfer information</i> | X |
| <i>Request refill authorization</i> | ✓ |
| <i>Verify Final Product</i> | X |

**See E.6 for authorized pharmacy technician vs. intern pharmacist duties.

IMPORTANT NOTE ON PATIENT COUNSELING

OBRA-90 and Board rule 20 CSR 2220-2.190 require that patients must be offered an opportunity to consult with a pharmacist each time a prescription is dispensed (new and refill). Once requested, patient counseling may only be conducted by a pharmacist or an intern pharmacist operating under the pharmacist’s direct supervision.

The Board has recently reviewed instances where pharmacists told a technician what to say in response to a counseling request instead of the pharmacist personally talking with the patient. In other instances, technicians advised patients on how over-the-counter (OTC) medication may interact with the patient’s prescription medication or which OTC medication would complement their medication therapy. All of these activities constitute patient counseling that may only be performed by a pharmacist or supervised intern pharmacist.

Patient counseling is one of the most important clinical services a pharmacist can provide and can help identify dispensing errors. Make sure your technicians are compliant with the law and are not counseling patients, either directly or indirectly.

O.4 NAME, ADDRESS & EMPLOYMENT CHANGES

- **Name Changes:** Name changes must be submitted to the Board in writing along with legal documentation of the change (e.g., marriage certificate, court order, divorce order). Once received, your name will be officially changed in the Board records. A **Duplicate License Request** application should be submitted if you would like your technician registration to be reissued under the new name (applications are **online**; fees will apply).
- **Employment Changes:** Employment changes must be submitted to the Board no later than fifteen (15) days after the change. [20 CSR 2220-2.700(3)]. Changes can be submitted online at <https://renew.pr.mo.gov/pharmacists-coa.asp>.
- **Address Changes:** Address changes should be submitted as soon as possible to ensure sufficient communication. Correspondence returned to the Board because of an incorrect address will not be resent until a correct address is provided. [20 CSR 2220-2.700(2)]. Changes can be submitted online at <https://renew.pr.mo.gov/pharmacists-coa.asp>.

O.5 RENEWALS

Technician registrations are valid for one (1) year and expire annually on May 31st. A technician may not work if his/her registration is not renewed by May 31st. [§ 338.013.5]. Technicians who fail to renew by May 31st may submit a late renewal application until June 30th. Although the Board will accept the renewal application, the individual cannot work after May 31st until his/her registration has been renewed by the Board. Applicants wishing to renew after June 30th will be required to submit a new technician registration application and undergo a new criminal history background check.

Registration status may be checked on the Board's website at <https://renew.pr.mo.gov/pharmacy-licensee-search.asp>. Practicing without a valid registration and/or allowing unlicensed practice constitutes grounds for discipline. [§ 338.055.2(10)].

O.6 MANDATORY REPORTING OF TECHNICIAN DISCIPLINE [§ 338.013.10]

Pharmacies and hospitals are required to report to the Board any final disciplinary action taken against a technician for conduct that may constitute grounds for discipline under § 338.055. This requirement applies to any form of final disciplinary action, including, but not limited to, termination, probation, suspension, demotion or reassignment. Pharmacies and hospitals must also report any technician who voluntarily resigns if a complaint or report has been made against the technician which could have led to final disciplinary action and the actions alleged in the complaint/report are cause for discipline under § 338.055. (*See E.15 Reporting of Discipline/Adverse Actions.*)

Notification of technician actions must be filed with the Board in writing within fifteen (15) days after the action and must include:

- The name and permit number of the pharmacy;
- The name of the person making the notification;
- The technician's name and registration number;
- Date of action; and
- Reason for action. [20 CSR 2220-2.010(1)(P)]

Notification of Technician Action notices may be filed electronically on the Board's website.

O.7 DISCIPLINED/DISQUALIFIED TECHNICIANS

The Board is statutorily authorized to take the following licensure/disciplinary action against pharmacy technicians:

| TYPE OF ACTION | DESCRIPTION | AUTHORIZED TO WORK |
|------------------------------------|--|--|
| <i>Employment Disqualification</i> | <i>Technicians/Applicants disciplined or denied registration for cause under § 338.055, RSMo</i> | <i>NO</i> |
| <i>Conditional Registration</i> | <i>Technicians/Applicants disciplined under § 338.055, RSMo but allowed to continue working</i> | <i>Yes, subject to restrictions printed on the back of the printed registration.</i> |
| <i>HB 600 (Tax Suspension)</i> | <i>Technicians suspended by the Missouri Department of Revenue by operation of law for failure to file a tax return or delinquent state taxes.</i> | <i>NO</i> |

The [Employment Disqualification List](#), [Conditional Registration List](#) and [HB 600\(Tax\) List](#) are available on the Board's website. These lists are updated frequently. [Register](#) for the Board's e-alerts to receive free electronic updates when individuals are added to the lists.

Licensees are responsible for ensuring technicians are appropriately authorized to work. The Board recommends designating a specific person and setting regular intervals for checking the Board's listings.

In addition to Board actions, the federal Department of Health and Human Service, Office of the Inspector General Exclusion List (OIG List) includes entities/persons excluded from participating in Medicare, Medicaid and other federal health care programs. Employers participating in qualified federal programs are generally prohibited from employing individuals on the OIG list. For additional information, visit OIG's website at <https://oig.hhs.gov/exclusions/index.asp>. *Note: OIG exclusions/waivers also apply to pharmacists and interns.* MoHealthNet also maintains a list of providers that have been terminated from participating in the MoHealthNet program. MoHealthNet's list is available online at: <https://mmac.mo.gov/providers/provider-sanctions/>

REQUIRED STATE/FEDERAL WAIVERS

WAIVERS: Both state and federal law prohibit an employer from hiring individuals with certain controlled substance related convictions without an employment waiver [see 21 CFR 1301.76(a); 19 CSR 30-1.034]. Specifically, employers are required to obtain a DEA waiver for felony controlled substance related convictions. A Missouri BNDD waiver is required for both misdemeanor and felony controlled substance related convictions. Waivers may be required even if the Board has issued a license/registration.

Licensees should conduct thorough background checks to ensure compliance. The Board is legally prohibited from sharing confidential criminal history information. Questions about controlled substance waivers should be addressed to BNDD or the DEA.

O.8 TECHNICIAN COMPLIANCE RESOURCES

The Board has published a [Pharmacy Technician Guide](#) that includes specific compliance information for Missouri technicians. The Board has also published an online [Technician Quiz](#) that can be used to test staff's knowledge of Missouri's technician requirements. The free [online quiz](#) can be taken anonymously and can help assess a technician's understanding of Missouri law. Recordings of webinars on technician issues may be found <http://pr.mo.gov/pharmacists-publications-resources.asp#videos>.

P.1 LICENSE REQUIREMENTS

All intern pharmacists must hold an active Missouri intern pharmacist license issued by the Board. Intern pharmacist licenses must be renewed by December 31st of every even numbered year (e.g., 2020, 2022, 2024). Renewal information is mailed around October 1st of each renewal year. Intern pharmacists may not continue to practice or earn experiential hours if their license is not renewed and active.

Missouri requires 1,500 pharmacy practice experience hours to obtain a Missouri pharmacist license. The Board will only recognize or certify hours earned as a licensed intern pharmacist. Hours earned as a pharmacy technician cannot be used to satisfy the required intern pharmacy practice experience hours.

***The Board has published an *Intern Pharmacist Guide* for students enrolled at St. Louis College of Pharmacy (STLCoP) and UMKC School of Pharmacy and a separate *Intern Pharmacist Guide* for students not enrolled in or graduated from UMKC or STLCoP. The Guides are available on the Board's [website](#). Intern pharmacists/preceptors should review the brochures to ensure compliance with Missouri law.**

P.2 SUPERVISION/AUTHORIZED ACTIVITIES

Similar to pharmacy technicians, intern pharmacists must be under the “direct supervision” of a Missouri-licensed pharmacist or a Board approved preceptor at all times. [[§ 338.010.1, 20 CSR 2220-7.025\(3\)](#)]. Intern pharmacists may assist a pharmacist in any area of pharmacy practice while under supervision, including, receiving, preparing, compounding or dispensing prescriptions. Similar to pharmacy technicians, a pharmacist must verify the final product prepared by an intern pharmacist and verify the accuracy of any prescription/medication order data entry. [[20 CSR 2220-2.080\(1\)](#)].

Intern pharmacists may also perform the following activities while under the direct supervision of a Missouri licensed pharmacist:

- Patient Counseling
- Administering medication by prescription order ([see P.3](#)), and
- Immunizing by protocol ([see P.3](#)).**

Intern pharmacists may not:

- Verify the final product before dispensing, or
- Receive or provide transfer information for controlled substance prescriptions [[20 CSR 2220-2.120\(1\)\(D\)](#)]

Intern pharmacists may assist with medication therapy services, however, medication may only be modified by a pharmacist with a Board issued certificate of medication therapeutic plan authority ([See Section M](#)).

SECTION P: INTERN PHARMACISTS

INTERN VS. PHARMACIST TECHNICIAN AUTHORIZED DUTIES

***The chart below is not exhaustive and does not include all potential tasks that may be performed by a pharmacy technician. All authorized activities must be performed under the direct supervision of a Missouri licensed pharmacist.
X= Activities not allowed***.

| | INTERN PHARMACIST* | PHARMACIST TECHNICIAN* |
|--|---|------------------------|
| Administer Medication by Rx Order | ✓ <i>*If under the direct supervision of a pharmacist authorized to administer medication by protocol.</i> | X |
| Advise/Counsel Patients on OTC Items | ✓ | X |
| Dispense Rx to Patient (after verification by a pharmacist) | ✓ | ✓ |
| Drug Utilization Review | ✓ | X |
| Enter Rx Data | ✓ | ✓ |
| Immunize by Protocol | ✓ <i>*If under the direct supervision of a pharmacist authorized to administer medication by protocol.</i> | X |
| Modify Medication Therapy under MTS protocol | X | X |
| Patient Counseling | ✓ | X |
| Prepare/Compound Rx | ✓ | ✓ |
| Receive Rx | ✓ | ✓ |
| Receive or provide controlled substance transfer information | X | X |
| Request refill authorization | ✓ | ✓ |
| Verify Final Product | X | X |

P.3 IMMUNIZING/ADMINISTERING MEDICATION

Intern pharmacists may administer medication by medical prescription order if the intern pharmacist:

- 1) Is working under the direct supervision of a pharmacist qualified to administer medication by medical prescription order under [20 CSR 2220-6.040](#),
- 2) Completes a qualifying administration and emergency procedures certificate program accredited by ACPE or an entity approved by the Board [[See 20 CSR 2220-6.040](#)]; &
- 3) Has a current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. Certificate programs must include an in-person skill assessment.

Similarly, an intern pharmacist may immunize by protocol if the intern pharmacist:

- 1) Is working under the direct supervision of a pharmacist qualified to immunize under [20 CSR 2220-6.050](#),
- 2) Has completed a certificate program in administering vaccines that meets the same requirements as the required pharmacist certificate program [[See 20 CSR 2220-6.050](#)], and

- 3) Has a current healthcare provider level CPR or Basic Life Support (BLS) certification from the American Heart Association, American Red Cross or an equivalent organization. Certificate programs must include an in-person skill assessment,

Intern pharmacists do not have to file a Notification of Intent with the Board to administer medication by medical prescription order or to immunize by protocol.

P.4 INTERN SITE/PRECEPTOR INFORMATION

The Board has published an [Intern Pharmacist Guide](#) for students enrolled at St. Louis College of Pharmacy (STLCoP) and the UMKC School of Pharmacy and a separate [Intern Pharmacist Guide](#) for students/intern pharmacists not enrolled in or graduated from UMKC or STLCoP. The [Intern Pharmacist Guides](#) are available online and contain detailed information on earning experiential hours and intern site/preceptor approval and reporting requirements. Students earning experiential hours as part of the curriculum of an ACPE accredited pharmacy school/college should contact the applicable school for information on site and preceptor approvals and preceptor reporting of intern hours. (See the [Intern Guide](#) and [20 CSR 2220 Chapter 7](#) for exemptions/requirements).

For intern pharmacists earning hours outside of their pharmacy school/college curriculum (e.g. a summer job), an [Intern Site and Preceptor Application](#) is required if the intern pharmacist wants the Missouri Board of Pharmacy to certify the practice hours earned. Intern pharmacists may begin earning hours after Board approval of the site/preceptor. A [Preceptor's Affidavit of Intern Hours](#) must be submitted to the Board in order for the Board to certify the hours. The [Preceptor's Affidavit](#) must be signed by both the preceptor and intern pharmacist (the preceptor's signature must be notarized). The office recommends submitting hours quarterly or immediately after the internship/training period ends. The Board will not certify or recognize hours that are not reported to the Board.

Q.1 LICENSE REQUIREMENTS

A Missouri Class-C Long-Term Care pharmacy permit is required if a pharmacy provides prescription services to a long-term care (“LTC”) facility or dispenses legend drugs/devices to patients residing in a LTC facility. [20 CSR 2220-2.140]. A Class C permit is required regardless of the number of patients served (e.g., one patient or the entire facility) or the packaging used for the LTC patient (e.g., dispensing a bottle vs. a bubble pack). As used in the Board’s rules, a “long-term care facility” is defined as a “nursing home, retirement care, mental care or other facility or institution that provides extended health care to resident patients.” [20 CSR 2220-2.020(9)(C)].

Pursuant to 20 CSR 2220-2.140(2), Class C pharmacies must have a policy and procedure manual that includes:

- Methods for timely dispensing medication;
- Procedures for notifying the facility when a medication is not readily available;
- Labeling requirements and policies;
- Policies/procedures for appropriate medication destruction and/or returning unused medication, as authorized by state and federal law; and
- Policies/procedures for securing, delivering, storing and handling emergency kits.

Q.2 AUTHORIZED DISPENSING

Licensees may dispense legend drugs to a LTC resident upon receipt of a prescription or a “prescription drug order.” For purposes of LTC dispensing, a “prescription drug order” is defined as “an order originating from a long-term care facility that is initiated by a prescriber and entered into the patient’s medical record by the prescriber or qualified personnel for the purpose of initiating or renewing an order for a medication or device.” [20 CSR 2220-2.140(5)]. Generic substitution is authorized unless otherwise restricted by the prescriber. See H.7.

Pharmacies may maintain a separate file for LTC prescription drug orders, provided that a separate numbering system is used. [20 CSR 2220-2.140(5)(C)]. Pharmacies using interim dispensing/partial fill systems must have records that clearly record these dispensings as any other new or refill dispensing. Pharmacies using an electronic record keeping system must document interim dispensings/partial fills in the electronic system and may not record them in a manual record system.

Refills/Transfers: Nursing home orders are not transferable if the patient is discharged from the facility. Additionally, refills associated with a nursing home order are not valid for use outside of the facility. [20 CSR 2220-2.140(5)(D)]. As to prescriptions/medication orders, 20 CSR 2220-2.120 was amended in 2019 to allow Class-C pharmacies to transfer up to a seventy-two (72) hour supply of a non-controlled prescription/medication order to a second pharmacy for initial dispensing without voiding the remaining prescription. The amount transferred must be deducted from the remaining prescription/medication order but the prescription at the transferring pharmacy no longer has to be voided.

Q.3 PREPARATION/PACKAGING

Personnel packaging drugs must wear gloves when handling individual tablets and capsules. Drug containers must meet minimum USP requirements, including, but not limited to, single unit, unit dose and unit-of-use containers. [20 CSR 2220-2.140(2)(C)]. If applicable, light sensitive packaging must be used. Internal liners must always be replaced before refilling the container. If drugs are dispensed in a container other than the manufacturer’s original container, the container must bear the manufacturer’s expiration date or a twelve (12) month expiration date, whichever is less. [20 CSR 2220-2.140(3)].

The Board is aware of packaging used by long-term care pharmacies that involve plastic liners within a hard plastic container. These liners must be changed on each initial and refill dispensing.

Q.4 LABELING

Containers dispensed to LTC facilities must comply with all state and federal labeling requirements. [20 CSR 2220-2.140(5)(D)]. However, Missouri law authorizes the following exceptions for unit-dose containers:

- The drug name/strength, control number, expiration date and manufacturer's name may be included on the package instead of on the container label, and;
- The patient's name and directions do not have to appear on the container label if the LTC facility has a mechanism that will identify the medication each patient is to receive, the personnel administering the medication and the directions for administration. [20 CSR 2220-2.140(2)(B)].

A bubble card is not considered a unit-dose container and must bear a full prescription label. All drugs dispensed to a LTC facility must have an expiration date on the container.

In the event of a change in directions, a pharmacist may change the container label, however, the pharmacist must personally affix the revised label. Revised prescription labels may not be sent to the LTC facility for their staff to apply. [20 CSR 2220-2.140(2)(B)].

Q.5 RETURN, RE-USE & DISPOSAL

Licensees may receive non-controlled drugs returned from a long-term care facility, hospital or a hospice facility regulated by the Missouri Department of Health and Senior Services under 19 CSR 30-35.020, if:

- 1) The medication was originally dispensed by the pharmacist or pharmacy to the institution/facility;
- 2) The pharmacist has assurance from a person at the institution/facility responsible for the medication that the drugs were stored in accordance with the manufacturer's recommendations and USP standards; and
- 3) There is an established mechanism to trace the expiration date and the manufacturer's lot number for the returned medication.

Returned drugs from a long-term care facility, hospital or hospice facility may be reused if:

- 1) The drug products are returned sealed in the original manufacturer's tamper-evident packaging; or
- 2) The drug products were repackaged by a licensed pharmacy or an FDA-registered repackager and are returned sealed in the repackager's tamper-evident packaging, or;
- 3) The drug products are returned in unit-of-use packaging and the unused portions can be separated and reused without any further repackaging.

Returned medication from a long-term care/hospice facility or a hospital must be re-labeled to provide accurate patient and prescription information. The original lot numbers, expiration date(s) or beyond-use-date(s) may not be altered.

Patient multi-med paks may not be returned from the LTCF to the pharmacy except for a therapy change/repackaging. (See H. 19)

Controlled substances may not be returned from a LTC facility.

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