RULES OF

Department of Commerce and Insurance

Division 2220—State Board of Pharmacy

Chapter 2—General Rules

TITLE 20 — DEPARTMENT OF COMMERCE AND INSURANCE
Division 2220 — State Board of Pharmacy
Chapter 2 — General Rules

20 CSR 2220-2.005 Definitions

PURPOSE: This rule defines the term "drug" as utilized in Chapter 338, RSMo, and the rules of the board.

(1) "Drug," "prescription drug," or "legend drug" means any drug or biological product —

(A) Subject to section 503(b) of the Federal Food, Drug and Cosmetic Act, including finished dosage forms and active ingredients subject to section 503(b);

(B) Required by federal law to be labeled with one (1) of the following statements, prior to being dispensed or delivered:

1. "Caution: Federal law prohibits dispensing without prescription";

2. "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

3. "Rx Only"; and

(C) Required by any applicable federal or state law or regulation to be dispensed by prescription only or that is restricted to use by practitioners only.

(2) For purposes of sections 338.300 to 338.370, RSMo, the term "drug," "prescription drug," or "legend drug" shall not include:

(A) An investigational new drug or biological product, as defined by 21 CFR 312.3(b), that is being utilized for the purposes of conducting a clinical trial/investigation of that drug or product if such clinical trial/investigation is governed by, and being conducted pursuant to, 21 CFR 312, et seq.;

(B) A legend drug or biological product being utilized for the purposes of a clinical trial/investigation that is governed by, and being conducted pursuant to, 21 CFR 312, et seq.; or

(C) A legend drug or biological product being utilized for the purposes of a clinical trial/investigation that is governed or approved by an institutional review board subject to 21 CFR 56 or 45 CFR Part 46.

AUTHORITY: section 338.010, RSMo Supp. 2010 and sections 338.140, 338.280, and 338.350, RSMo 2000. Emergency rule filed Sept. 3, 2010, effective Sept. 13, 2010, expired March 11, 2011. Original rule filed March 7, 2011, effective Aug. 30, 2011.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009; 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.280, RSMo 1951, amended 1971, 1981; and 338.350, RSMo 1989, amended 1993, 1995.*

20 CSR 2220-2.010 Pharmacy Standards of Operation

PURPOSE: This rule defines terms used in the regulations of the State Board of Pharmacy and outlines the conditions necessary for the operation of a pharmacy.

(1) Pharmacies must be safely operated at all times, in compliance with applicable state and federal law. Except as otherwise provided by law, pharmacies must also comply with the following:

(A) Pharmacies shall not introduce or enforce any policies, procedures, systems, or practices that jeopardize, inhibit, or threaten patient safety or the safe provision of pharmacy services. A licensed pharmacist must be physically present within the confines of the dispensing area of a licensed pharmacy whenever any person other than a licensed pharmacist compounds, prepares, dispenses, or any way provides a drug, medicine, or poison pursuant to a lawful prescription or medication order. The pharmacist must be able to render immediate assistance and able to identify and correct any errors before the drug, medicine, or poison is dispensed or sold. A sign advising the public that no pharmacist is on duty must be manually or electronically posted when no pharmacist is on duty at the pharmacy. The signs must be prominently displayed on all entrance doors and the prescription counter of the pharmacy. Sign lettering must be at least two inches (2") in height;

(B) Except as otherwise provided by law, a pharmacist shall personally inspect and verify the accuracy of the final contents of any prescription or medication order and the affixed label prior to dispensing;

(C) Adequate staffing and resources must be provided to allow licensees/registrants to safely and accurately provide pharmacy services. Pharmacies must be equipped with properly functioning pharmaceutical equipment for the pharmacy services performed as recognized by the latest edition of the *United States Pharmacopoeia* (USP) or *Remington's Pharmaceutical Sciences*;

(D) References/resources must be physically maintained or immediately accessible in electronic form at the pharmacy that include the following:

1. A current print or electronic edition of statutes and rules governing the pharmacy's practice, including, but not limited to, Chapters 338 and 195, RSMo, 20 CSR 2220 and, if applicable, 19 CSR 30 governing controlled substances;

2. Generally recognized reference(s) or other peer-reviewed resource(s) that include the following items/topics:

A. All drugs approved by the United States Federal Drug Administration (FDA) as appropriate to the practice site;

B. Pharmacology of drugs;

C. Dosages and clinical effects of drugs; and

D. Patient information and counseling;

(E) All Missouri and federal pharmacy licenses, permits, or registrations must be current and accurate, including the pharmacy's name, permit classification(s), and address;

(F) Individuals practicing or assisting in the practice of pharmacy must be appropriately licensed or registered with the board and appropriately trained and competent to perform assigned duties. Any person other than a pharmacist or permit holder who has independent access to legend drug stock on a routine basis in a pharmacy must be registered or licensed with the board as a pharmacy technician or intern pharmacist. Except as otherwise authorized by law, non-resident pharmacists providing pharmacy services for patients or pharmacies located in Missouri must hold a Missouri pharmacist license or must be working for a Missouri licensed pharmacy;

(G) Pharmacy facilities and equipment must be maintained in a clean and sanitary condition at all times and trash must be disposed of in a timely manner.

1. Appropriate sewage disposal and a hot and cold water supply within the pharmacy must be available. The required water supply may not be located in a bathroom.

2. Waste and hazardous materials must be handled and disposed of in compliance with applicable state and federal law.

3. The pharmacy must be free from insects, vermin, and animals of any kind. Animals are not allowed in pharmacies, except for service animals as defined by the Americans with

Disabilities Act (ADA);

(H) Adequate security and locking mechanisms must be maintained to prevent unauthorized access to the pharmacy and to ensure the safety and integrity of drugs and confidential records. Pharmacy traffic must be restricted to authorized persons so that proper control over drugs and confidential records can be maintained at all times. Pharmacies dispensing or stocking controlled substances must comply with all federal and state controlled substance security requirements;

(I) Medication and drug-related devices must be properly and accurately prepared, packaged, dispensed, distributed, and labeled under clean, and when required, aseptic conditions. Staff must wear disposable gloves when physically touching individual dosage units. Pharmacies shall not fill or refill any prescription or medication order after one (1) year from the date issued by the prescriber;

(J) Offsite storage. Pharmacies may maintain storage sites or warehouse facilities for the storage of pharmaceuticals or required/confidential pharmacy records at a separate address or premises from the main pharmacy, provided the storage facility is registered with the board. To register, the pharmacy must submit the following to the board in writing: the storage facility's address, hours of operation (if applicable), and the pharmacy permit numbers of the pharmacies that utilize the facility. No registration fee is required.

1. Adequate security and storage conditions must be maintained at these facilities to guarantee the security and integrity of records, medication, and drug-related devices. At a minimum, storage facilities must maintain a functioning alarm system. Any breach in security must be documented and reported to the board electronically or in writing within fifteen (15) days of the breach.

2. Medication stored at an offsite storage facility pursuant to this subsection may only be used by a pharmacy for the sole purpose of distributing drugs solely within its own pharmacy operations. A drug distributor license is required if an offsite storage facility is used to store/distribute medication for multiple pharmacies, regardless of pharmacy ownership.

3. No record less than two (2) years old may be stored offsite. Patient records stored at an offsite facility must be retrievable within two (2) business days of a request from the board or its authorized designee.

4. Storage and warehouse locations will be considered facilities of a pharmacy pursuant to section 338.240, RSMo, and will be subject to inspection by the board pursuant to section 338.150, RSMo;

(K) If the pharmacy is located in a facility that is accessible to the public and the pharmacy's hours of operation are different from those of the remainder of the facility, ceilings and walls must be constructed of a substantial material so that the pharmacy permit area is separate and distinct from the remainder of the facility. Drop down ceilings or other openings that would allow unauthorized access into the pharmacy are not allowed;

(L) Licensee/Registrant Identification and Signage.

1. All board licensees and registrants must wear an identification badge or similar identifying article that identifies their name and title when practicing or assisting in the practice of pharmacy (e.g., pharmacist, pharmacy technician, intern pharmacist).

2. The licenses/registrations for all pharmacists, technicians, and intern pharmacists regularly working in the pharmacy must be maintained in a central location on the premises of the pharmacy. Individual licenses/registrations must have a photo attached that is not smaller than two by two inches (2" x 2"). The required licenses/registrations must be immediately retrievable during an inspection or available to the public if requested. Licensees or registrants regularly working for more than one (1) pharmacy, temporarily working as a relief pharmacist outside of their regular pharmacy work location, or practicing pharmacy at a non-pharmacy location must have proper identification of their pharmacy license in their possession while practicing or assisting in the practice pharmacy (e.g., wallet card, current online verification).

3. A sign must be physically or electronically posted at the pharmacy indicating that the pharmacy is licensed and regulated by the Missouri Board of Pharmacy along with the board's current address, telephone number, and primary email address. The board will provide the required sign at no cost. Alternatively, licensees may post an electronic copy of the required sign, provided the size and type of the electronic sign and lettering equals or exceeds the board issued sign and the electronic sign is constantly visible by the public during the pharmacy's normal business hours. The required sign must be prominently posted in close proximity to the pharmacy in a manner and location that is easily viewable and readable by the public;

(M) All board licensed pharmacies must be under the supervision of a pharmacist-in-charge designated with the board who holds a current and active Missouri pharmacist license. The pharmacist-in-charge must be actively engaged in pharmacy activities at the pharmacy and must be physically present at the pharmacy for a sufficient amount of time as needed to effectively supervise pharmacy activities and ensure pharmacy compliance. For pharmacies located outside of Missouri, the designated pharmacist-in-charge must hold a current and active pharmacist license in the state where the pharmacy is located.

1. In the event the pharmacist-in-charge designated with the board changes, the pharmacy may not continue operations until a new pharmacist-in-charge is named, except as otherwise authorized by this rule. A change of pharmacist-in-charge application must be submitted to the board with the applicable fee within fifteen (15) calendar days after a new pharmacist-in-charge is designated. A controlled substance inventory must be taken at or immediately prior to a pharmacist-in-charge change as required by 20 CSR 2220-2.090.

2. If a new pharmacist-in-charge cannot be immediately designated after a pharmacist-in-charge change despite reasonable diligence, the pharmacy may appoint an interim supervising pharmacist for a period not to exceed thirty (30) days. The interim supervising pharmacist must meet the requirements of this rule and file a statement on a form approved by the board agreeing to be responsible for pharmacy compliance while serving as the interim supervising pharmacist. A documented controlled substance inventory must be taken when the interim supervising pharmacist is designated. Written notification of the interim supervising pharmacist designation must be immediately provided to the board at the board's electronic mail address or via facsimile on a form approved by the board along with the required interim supervising pharmacist form; and

(N) Licensees and registrants must maintain a current mailing address on file with the board. Licensees/registrants must notify the board electronically or in writing of any change in their mailing or employment address, within fifteen (15) days following the change;

(O) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter

338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

(2) Drug Storage. Drugs must be properly stored and maintained in a thermostatically controlled area within temperature and humidity requirements as provided in the Food and Drug Administration approved drug product labeling or the *United States Pharmacopeia* (USP).

(A) Temperatures in drug storage areas must be recorded and reviewed at least once each day the pharmacy is in operation. Alternatively, a continuous temperature monitoring system may be used if the system maintains ongoing documentation of temperature recordings that alerts a pharmacist when temperatures are outside of the required range and provides the amount of variance.

(B) No outdated, misbranded, or adulterated drugs or devices may be dispensed, distributed, or maintained within the pharmacy's active inventory, including prescription and related nonprescription items. Outdated, misbranded, or adulterated medication and medication for personal employee use must be quarantined in an area that is clearly identified and physically separate from medication maintained for dispensing, distribution, or other pharmacy use. Drugs for the personal use of pharmacy staff or personnel must be labeled in accordance with section 338.059, RSMo, or as otherwise required by law.

(C) 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, provided the items must be separated from other inventory and sanitary conditions are maintained at all times.

(D) Appropriate lighting, ventilation, and humidity must be maintained in areas where drugs are stored and dispensed. Medication may not be stored on the floor.

(E) Drug samples shall not be maintained in or dispensed by pharmacies, except as otherwise authorized by state and federal law, including, but not limited to, 21 U.S.C. section 353 and the federal Prescription Drug Marketing Act of 1987.

(3) Record Keeping. Pharmacy records must be accurately maintained in compliance with applicable state and federal law. Records required by Chapters 195 and 338, RSMo, or divisions 20 CSR 2220 and 19 CSR 30 shall be available for inspection, photographing, or duplication by a board representative.

(A) Pharmacies must maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of legend drugs. Each pharmacy shall designate either a primary manual or electronic record keeping system which will be used to record the dispensing of all prescriptions and medication orders. Poison sales may be recorded in a separate manual log. Except as otherwise authorized or required by law, at least three (3) separate files of prescriptions/medication orders must be maintained:

1. A separate file for Schedule I and II controlled substances;
2. A separate file for Schedules III, IV, and V controlled substances; and
3. A separate file(s) for all other prescriptions/medication orders.

(B) Distribution records. Unless otherwise authorized by law or the board, pharmacies shall maintain inventories and records of all legend drugs received and distributed that include:

1. The date of the transaction/distribution;
2. Product name, strength, and quantity;
3. The names of the parties;
4. The sender's address or, for drugs distributed by the pharmacy, the receiver's address; and
5. Any other information required by state or federal law.

(C) Unless otherwise provided by law, records required by Chapter 338 or 20 CSR 2220 that do not have a specified retention time must be kept for two (2) years and readily retrievable at the request of the board or the board's authorized designee. Records maintained at a pharmacy must be produced immediately or within two (2) hours of a request from the board or the board's authorized designee, or by making a computer terminal available to the inspector for immediate use to review the records requested. Records not maintained at a pharmacy must be produced within three (3) business days of a board request.

(4) Mandatory Reporting. Licensees, registrants, and permit holders must notify the board of any adverse action by another licensing state, jurisdiction, or government agency against the licensee/registrants/permit holder as required by section 338.075, RSMo, within fifteen (15) days of such action. Additionally, pharmacies must notify the board within fifteen (15) days of any final disciplinary action taken against a pharmacist, intern pharmacist, or pharmacy technician for conduct that might have led to disciplinary action under section 338.055, RSMo, or resignation of a licensee/registrant in lieu of such final disciplinary action. The notification must be provided in writing or electronically and include:

(A) The pharmacy's name and permit number;

(B) Name and contact information for person making the notification;

(C) The licensee's or registrant's name and license/registration number;

(D) Date of action; and

(E) Reason for action.

(5) A home health or hospice agency licensed or certified according to Chapter 197, RSMo, or any licensed nurses of such agency, may possess drugs in the usual course of business of such agency without being licensed as a pharmacist or a pharmacy.

(A) The following legend drugs/devices may be possessed by a home health or hospice agency identified in this section without a pharmacy license or permit:

1. Injectable dosage forms of sodium chloride and water;
2. Irrigation dosage forms of sodium chloride and water that carry a federal prescription only restriction;
3. Injectable dosage forms of heparin and alteplase in concentrations that are indicated for maintenance of venous access devices;
4. Injectable dosage forms of diphenhydramine and epinephrine;
5. Vaccines indicated for public health needs; and
6. Tuberculin test material.

(B) The agency shall have policies and procedures that address –

1. Specific drugs authorized to be possessed by the agency and the nurse;
2. Indications for use of the drugs possessed;
3. Receiving orders from an authorized prescriber for drug administration;
4. Leaving drugs with the patient for routine care

procedures;

5. Conditions for storing and transporting of the drugs by the agency and the nurse; and

6. Quantity of drugs possessed by the agency and the nurse.

(C) The nurse must have authorization from an authorized prescriber, such as an individual patient order, protocol or standing order, to administer the drugs.

(D) Up to a two- (2-) week supply of sodium chloride, water, and heparin may be left with the patient provided the patient or the patient's representative has been instructed verbally or in writing on how to perform the procedure. Drugs left with the patient shall be labeled with instructions for use. A record shall be made of all drugs left with the patient in the patient's medical record. Drugs left with the patient may not be returned to the agency.

(E) Drugs may be stored at the agency or transported by the nurse, and shall be stored or transported at all times in accordance with the manufacturer's storage requirements. Except as otherwise authorized by subsection (2)(C) of this rule, refrigerator units used by the agency for storing drugs shall not be used for storing non-drug items.

(F) All drugs must be received from a licensed pharmacy or drug distributor. The quantity of drugs possessed by an agency shall be limited to that necessary to meet the needs of the agency's patient population for two (2) weeks.

(6) In addition to the other requirements of this rule, a Class I pharmacy within a residence must be located in a physically separate room that has a door with a suitable lock. Patients are not allowed in a Class I pharmacy located within a residence. Class I pharmacies may be inspected by the board as authorized by law, including Class I pharmacies located in a residence. The permit holder must arrange for a designated representative to be present for inspection, if requested by the board. Other than a Class I pharmacy, no pharmacy permit will be issued to a location that is located in a residence regardless of zoning.

(7) Except as otherwise authorized by law, a licensee, permittee, or registrant of the board must cooperate with any investigation or inspection conducted by or on the board's behalf. Cooperation includes responding fully and promptly to questions, providing copies of records as requested, executing releases for records as requested, allowing photographs or digital image capture of any facility licensed or permitted by the board, and appearing at interviews, hearings, or meetings scheduled by the board or the board's authorized designee.

(8) Exemptions. At its discretion, the board may grant an exemption to the facility requirements of this rule for a time period designated by the board if such exemption is not contrary to law and the exemption will provide equal or greater protection of the public safety, health, or welfare. Exemption requests must be submitted in writing and identify the specific exemption requested, the grounds for exemption, the requested exemption length, and proposed procedures or safeguards for protecting the public safety, health, or welfare if the exemption is approved.

AUTHORITY: sections 338.240 and 338.280, RSMo 2016, and sections 338.010, 338.140, and 338.210, RSMo Supp. 2021. This rule originally filed as 4 CSR 220-2.010. Original rule filed July 18, 1962, effective July 28, 1962. Amended: Filed Nov. 9, 1966, effective Nov. 19, 1966. Amended: Filed Oct. 27, 1970, effective Nov. 6, 1970. Amended: Filed Dec. 31, 1975, effective Jan. 10, 1976. Amended: Filed May 21, 1979, effective Nov. 12, 1979. Amended: Filed April 14, 1982, effective July 11, 1982. Amended: Filed April 16, 1985, effective Sept. 27, 1985. Amended: Filed Nov. 4, 1985, effective March 13, 1986. Amended: Filed Dec. 15, 1987, effective April 28, 1988. Amended: Filed Oct. 12, 1988, effective March 11, 1989. Amended: Filed Jan. 30, 1991, effective July 8, 1991. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed June 29, 1999, effective Jan. 30, 2000. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed July 24, 2001, effective Feb. 28, 2002. Amended: Filed Feb. 18, 2003, effective Sept. 30, 2003. Amended: Filed May 13, 2005, effective Oct. 30, 2005. Moved to 20 CSR 2220-2.010, effective Aug. 28, 2006. Amended: Filed Aug. 21, 2006, effective April 30, 2007. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008. ** Amended: Filed Jan. 20, 2022, effective Aug. 30, 2022.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019, 2021; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.210, RSMo 1951, amended 2001, 2011, 2020; 338.240, RSMo 1951, amended 2011; and 338.280, RSMo 1951, amended 1971, 1981.*

***Pursuant to Executive Order 21-07, 20 CSR 2220-2.010, subsections (1)(A) and (1)(B) was suspended from March 20, 2020 through August 5, 2021.*

20 CSR 2220-2.011 Electronic Final Product Verification (Pharmacists)

PURPOSE: This rule establishes requirements for electronic final product verification by a pharmacist using qualifying technology.

(1) Pharmacist Verification. A Missouri licensed pharmacist may use an electronic verification system to verify the accuracy of a final prescription/medication order, provided –

(A) The electronic verification system allows the pharmacist to see an exact, clear, and unobstructed visual image or images of the filled prescription/medication order contents and the label affixed to the container. If multiple units are being dispensed, the pharmacist must be able to see and verify an image or images of each unit and each individual affixed label. A mechanism must be in place to record or communicate the pharmacist's verification approval;

(B) The identity of the pharmacist responsible for verifying the final product is documented in the pharmacy's records as required by 20 CSR 2220-2.080;

(C) Pharmacy technicians and intern pharmacists assisting the pharmacist with electronic verification must be trained and competent to perform the duties assigned and have a documented initial and annual assessment of competency using the pharmacy's approved electronic verification system;

(D) No further manipulation of the prescription/medication order occurs after the pharmacist's electronic verification is complete other than applying the required container lid or seal. For purposes of this section, manipulation does not include preparing a finished prescription/medication order for mailing, delivery, or storage; and

(E) Except as otherwise provided by law, compounded preparations cannot be verified via an electronic verification system. Compounded preparations must be personally verified by a pharmacist.

(2) Technology Requirements. Electronic verification systems must be maintained in good working order and must provide a clear, unobstructed visual image or images of the filled prescription/medication order contents and the affixed label for each individual prescription or medication order. Use of the electronic verification system must be terminated if the system

is not properly functioning and the root cause identified and corrected before further use. Prior to dispensing, a pharmacist shall review and authorize overrides performed by a pharmacy technician or intern pharmacist of any technology generated errors, warnings, alerts, or exceptions related to system functioning or medication verification/accuracy. Documentation of the pharmacist's review and authorization must be maintained in the pharmacy's records.

(A) The electronic verification system must be implemented and validated by a pharmacist prior to initial use to confirm proper functioning. The system must be revalidated by a pharmacist in accordance with the pharmacy's policies and procedures.

(B) Proof of compliance with validation/revalidation requirements must be documented and maintained in the pharmacy's records, including but not limited to the identity of the pharmacist performing the required validation/testing and validation/testing date(s) and results.

(3) Quality Assurance. Pharmacies using an electronic verification system as authorized by this rule must maintain an ongoing and documented quality assurance system that monitors the performance of the electronic verification system and the electronic assisted verification process to ensure proper and accurate functioning. The quality assurance system must include procedures for reporting dispensing errors and system malfunctions.

(4) Policies and Procedures. Pharmacies utilizing an electronic verification system pursuant to this rule must maintain current, written policies and procedures governing all aspects of electronic-assisted verification activities, including, but not limited to:

(A) Staff training and competency assessments;

(B) Operation of the quality assurance system, including reporting, investigating and addressing errors, system malfunctions, and other quality assurance issues;

(C) Testing, validation, and revalidation of electronic verification technology to ensure proper functioning; and

(D) System maintenance, including any routine or preventative maintenance.

(5) Recordkeeping. Except as otherwise provided herein, records required by this rule must be maintained electronically or in writing by the pharmacy for a minimum of two (2) years. Records must be made available for inspection or copying, and produced to the board or the board's authorized designee upon request.

(6) The provisions of this rule do not modify, amend, or supersede any provisions of law governing pharmacy technician or intern pharmacist supervision requirements.

AUTHORITY: sections 338.140 and 338.210, RSMo Supp. 2021, and sections 338.240, 338.280, and 338.400, RSMo 2016. Original rule filed Feb. 9, 2022, effective Aug. 30, 2022.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.210, RSMo 1951, amended 2001, 2011, 2020; 338.240, RSMo 1951, amended 2011; 338.280, RSMo 1951, amended 1971, 1981; and 338.400, RSMo 2011.*

20 CSR 2220-2.012 Technology Assisted Prescription/ Medication Order Verification (Intern Pharmacists and Pharmacy Technicians)

PURPOSE: This rule establishes requirements for pharmacy technicians/intern pharmacists performing technology assisted prescription/medication order verification under the supervision of a pharmacist.

(1) Definitions.

(A) "Authorized intern pharmacist" – An individual who holds a current and active Missouri intern pharmacist license and has completed employer-approved training in technology assisted verification using the pharmacy's approved technology assisted verification system.

(B) "Authorized pharmacy technician" – A currently registered Missouri pharmacy technician who –

1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies;

2. Has completed employer-approved training in technology assisted verification using the pharmacy's approved technology assisted verification system; and

3. Has assisted in the practice of pharmacy as a registered/ licensed pharmacy technician in the state of Missouri or another U.S. state or territory for a minimum of one (1) year.

(C) "Technology Assisted Verification" (TAV)–The process of verification of the final prescription or medication order and affixed label by an authorized pharmacy technician or authorized intern pharmacist using a technology assisted verification system that complies with this rule.

(D) "Technology Assisted Verification System" (TAVS) – An electronic system that utilizes barcode technology or another electronic process/method to electronically verify the final medication prescription or medication order has been properly dispensed and to electronically verify the prescription/medication order has been properly labeled for the correct patient.

(2) Pharmacy Technicians/Intern Pharmacists. A Missouri-licensed pharmacist may allow an authorized pharmacy technician or authorized intern pharmacist to verify the final prescription/medication order using a TAVS if –

(A) The medication is a non-controlled substance and will be dispensed in the original manufacturer's unopened unit of use package, or the non-controlled medication has been repackaged in compliance with 20 CSR 2220-2.130 and previously verified by a pharmacist;

(B) The authorized pharmacy technician or intern pharmacist is under the supervision of a Missouri-licensed pharmacist who is physically present within the dispensing area and able to provide immediate assistance. A current list of pharmacy technicians/intern pharmacists authorized to perform TAV must be maintained at the pharmacy along with proof of the required training and competency assessment;

(C) The authorized pharmacy technician/intern pharmacist is competent to perform the duties assigned and has completed a documented initial and annual assessment of competency using the pharmacy's approved TAVS. A pharmacist may not simultaneously supervise a total of more than two (2) pharmacy technicians or intern pharmacists performing TAV as authorized by this rule. The pharmacist-in-charge may petition the board to increase the number of supervised technicians/intern pharmacists for good cause;

(D) A pharmacist verifies the accuracy of prescription/ medication order data entry prior to dispensing and completes a prospective drug utilization review. The identity of the verifying pharmacist must be recorded in the pharmacy's records as required by 20 CSR 2220-2.080;

(E) The TAVS is used to verify the proper prescription label has been affixed to the correct manufacturer unit of use package

or repacked container for the correct patient. The identity of the authorized pharmacy technician or intern pharmacist performing the TAV and the supervising pharmacist must be documented in the pharmacy's records; and

(F) No manual manipulation of the prescription/medication order occurs after the TAV occurs. For purposes of this rule, manual intervention does not include preparing a finished prescription/medication order for mailing, delivery, or storage.

(3) Technology Requirements. Technology assisted verification systems must be maintained in good working order, and must verify prescriptions/medication orders and the affixed labels with one hundred percent (100%) accuracy. Use of the TAVS must be terminated and the root cause identified and corrected if a verification error is detected. Only a pharmacist shall be authorized to initiate the operation of a TAVS or override any technology generated errors, warnings, alerts, or exceptions related to TAVS functioning or medication verification/accuracy.

(A) The TAVS must be implemented and validated by a pharmacist prior to initial use to confirm the technology's accuracy and correctness. At a minimum, the TAVS must complete one thousand (1,000) consecutive product verifications during the initial validation process with a one hundred percent (100%) accuracy rate. A pharmacist must audit one hundred percent (100%) of product verifications completed during the initial validation process before dispensing and confirm accuracy. The required pharmacist audit may not be delegated to an intern pharmacist or a pharmacy technician.

(B) A pharmacist must conduct daily random quality testing on a sample size of prescriptions verified by the TAVS. The required sample size shall not be less than two percent (2%) of prescriptions/medication orders verified via the TAVS on the last day of system operation. Use of the TAVS must be terminated and the root cause identified and corrected if quality testing results show less than one hundred percent (100%) accuracy.

(C) A TAVS must be revalidated by a pharmacist in accordance with the pharmacy's policies and procedures.

(D) The required revalidation process must include a sampling of prescriptions/medication order verifications by the TAVS using a sample size that is sufficient to confirm the technology is properly and accurately functioning. A pharmacist must audit and verify one hundred percent (100%) accuracy of the sampled verifications prior to further use of the TAVS. The required pharmacist audit may not be delegated to an intern pharmacist or a pharmacy technician.

(E) Proof of compliance with validation, revalidation, and testing requirements must be documented and maintained in the pharmacy's records, including but not limited to the name, initials, or identification code(s) of the pharmacist performing the required validation/testing and validation/testing date(s) and results.

(5) Quality Assurance. Pharmacies using TAV as authorized by this rule must maintain an ongoing and documented quality assurance system that monitors the performance of the TAVS and the TAV process to ensure proper and accurate functioning. The quality assurance system must include procedures for reporting dispensing errors, system malfunctions, or other compliance concerns. Notification of any dispensing error involving a TAV that reaches the patient must be submitted to the board electronically or in writing within ten (10) days of discovery. The required notification must include the date of the incident, patient name, the technician or intern pharmacist who performed the TAV, a description of the error, the applicable prescription/medication order number or unique identifier, and the supervising pharmacist of record.

(6) Policies and Procedures. Pharmacies using TAV must maintain current, written policies and procedures governing all aspects of technology assisted verification activities, including but not limited to –

(A) Staff training and competency assessments;

(B) Operation of the required quality assurance system, including reporting, investigating, and addressing errors, system malfunctions, and other quality assurance issues;

(C) Testing, validation, and revalidation of the TAVS to ensure proper functioning; and

(D) System maintenance, including any routine or preventative maintenance.

(7) Recordkeeping. Records required by this rule must be maintained by the pharmacy electronically or in writing for a minimum of two (2) years. Records must be made available for inspection or copying and produced to the board or the board's authorized designee upon request.

(8) Applicability. Compliance with this rule is not required if a pharmacist physically verifies the final prescription/medication order and the affixed label before dispensing. Final prescription/medication order verification for a Class R Remote Dispensing Site pharmacy must comply with 20 CSR 2220-2.680.

AUTHORITY: sections 338.140 and 338.210, RSMo Supp. 2021, and sections 338.240, 338.280, and 338.400, RSMo 2016. Original rule filed Feb. 9, 2022, effective Aug. 30, 2022.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.210, RSMo 1951, amended 2001, 2011, 2020; 338.240, RSMo 1951, amended 2011; 338.280, RSMo 1951, amended 1971, 1981; and 338.400, RSMo 2011.*

20 CSR 2220-2.013 Prescription Delivery Requirements

PURPOSE: This rule establishes requirements for authorized prescription/medication order delivery sites.

(1) Every pharmacy delivering, mailing, or shipping a filled prescription or medication order shall develop and implement written policies and procedures to ensure the safe and appropriate delivery, mailing, and shipment of prescriptions/medication orders within the temperature requirements recommended by the manufacturer or the *United States Pharmacopeia* (USP). Except as otherwise provided herein, prescriptions/medication orders filled by a Missouri licensed pharmacy may not be left at, accepted by, or delivered to a location, place of business or entity not licensed as a pharmacy.

(2) At the request of the patient or the patient's authorized designee, licensees may deliver a filled prescription/medication order for an individual patient directly to the patient or the patient's authorized designee or to –

(A) The office of a licensed health care practitioner authorized to prescribe medication in the state of Missouri;

(B) A long-term care facility as defined by 20 CSR 2220-2.140 where the patient resides;

(C) A hospital, office, clinic, or other medical institution that provides health care services;

(D) A residence designated by the patient or the patient's authorized designee; or

(E) The patient's office or place of employment.

(3) At the request of a customer, legally filled prescriptions/medication orders for veterinary use may be delivered, mailed, or shipped to a residence, business, or clinic designated by the customer.

(4) Licensees shall comply with all applicable controlled substance laws and regulations, including but not limited to all applicable security requirements.

(5) Unless otherwise exempted by this rule or other law, all pharmacies delivering prescriptions/medication orders by mail or common commercial carrier to a patient, the patient's authorized designee, or a delivery location authorized by this rule pursuant to a patient's request must comply with the following:

(A) A reasonable attempt must be made to notify the patient verbally, electronically, or by other written means that a prescription/medication order will be shipped or mailed to the patient or the patient's authorized delivery location identified in section (2) prior to shipment/mailing. Proof of patient notification, or documentation of the date and method of notification, must be maintained in the pharmacy's records and readily retrievable if requested by the board or the board's authorized designee;

(B) Patients must be provided the following written instructions notifications with each prescription/medication order mailing or shipment in a manner that is clear, conspicuous, and easily visible by the patient or the patient's authorized designee:

1. Notification that the pharmacy is licensed and regulated by the Missouri Board of Pharmacy along with the board's current address, telephone number, and primary email address;

2. Instructions on how to detect if the integrity of a prescription or medication order has been compromised due to improper storage or temperature variations; and

3. Instructions and a mechanism for notifying the pharmacy verbally or electronically of any suspected or confirmed irregularity in the delivery of their medication, including but not limited to –

A. Timeliness of delivery;

B. Integrity of the prescription/medication order on delivery; and

C. Failure to receive the proper prescription/medication order;

(C) In addition to the requirements of section (1), pharmacies offering to mail or ship prescription/medication orders or regularly engaged in mailing or shipping prescriptions/medication orders must maintain current written policies and procedures that include policies/procedures for –

1. Mailing and shipping prescriptions/medication orders, including but not limited to notifying patients of shipments/deliveries as required in this rule and using/selecting proper packaging containers and materials to maintain physical integrity and stability of package contents per manufacturer product labeling or manufacturer specifications;

2. Handling reports or complaints that the integrity of a prescription/medication order was or may have been compromised or adulterated during mailing or shipment; and

3. Actions to be taken in the event of a suspected or confirmed temperature excursion, including but not limited to policies/procedures for notifying appropriate pharmacy staff. For purposes of the rule, a "temperature excursion" means any deviation from the manufacturer's temperature specifications or allowed excursion range or, in the absence of manufacturer specifications, applicable USP temperature standards;

(D) For purposes of this rule, a common commercial carrier means any person or entity who undertakes directly or indirectly to transport property for compensation for or on behalf of the pharmacy, including prescription drugs or devices. A common commercial carrier does not include pharmacy staff or employees delivering prescriptions/medication orders as part of their pharmacy job responsibilities, or transportation of a prescription/medication order from the pharmacy by a healthcare provider or an individual designee of the healthcare provider for administration to the patient by the healthcare provider or the healthcare provider's authorized designee.

(E) The provisions of subsections (5)(A) and (B) are not applicable to radiopharmaceuticals mailed/shipped to a medical facility for administration to the patient by an authorized healthcare provider, prescriptions/medication orders shipped or mailed from one pharmacy to another for subsequent dispensing to the patient as authorized by law, or prescriptions/medication orders mailed or shipped to a long-term care facility.

(6) Returns of medication delivered pursuant to this section shall be governed by, and handled in accordance with, Chapter 338, RSMo, and the rules of the board

(7) Records required by this rule must be maintained in compliance with 20 CSR 2220-2.010.

AUTHORITY: sections 338.095, 338.100, 338.240, and 338.280, RSMo 2016, and section 338.140, RSMo Supp. 2024. Original rule filed May 14, 2012, effective Nov. 30, 2012. Amended: Filed June 11, 2024, effective Dec. 30, 2024.*

**Original authority: 338.095, RSMo 1993, amended 2007; 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999, 2010, 2016; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.240, RSMo 1951, amended 2011; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.015 Termination of Business as a Pharmacy

PURPOSE: This rule establishes guidelines for the termination of business as a pharmacy.

(1) A licensed pharmacy who plans to terminate business activities shall file a written notice with the State Board of Pharmacy. The written notice shall be submitted to the State Board of Pharmacy in person or by registered or certified mail within fifteen (15) days after the date of termination. This notice shall be made on a form provided by the board or in letter form from the licensee and shall include the following information:

(A) The name, address, license (permit) number and effective date of closing;

(B) The name, address, and license (permit) number of the entity to which any of the stock/inventory will be transferred;

(C) The name and address of the location to which records, required to be maintained by law, have been transferred.

1. Any records that are transferred to an unlicensed location must be retrievable for board review within seven (7) working days of a request made by an authorized official of the board.

2. Any records that are transferred to a licensed (permitted) pharmacy or licensed drug distributor must be maintained in accordance with record requirements as set forth in section 338.100, RSMo.

(2) The licensee (permit holder) terminating business may transfer all drugs and records in accordance with the following:

(A) On the date of termination, a complete inventory of all controlled substances being transferred or disposed of shall be completed according to state and federal laws. This inventory shall serve as the final inventory of the pharmacy terminating business and as the initial inventory of the licensed entity to which the controlled substances are being transferred. A copy of the inventory shall be included in the records of each licensee or permit holder involved in the transfer.

(B) A pharmacy terminating business shall not transfer misbranded, outdated or adulterated drugs, except for purposes of proper disposal; and

(C) Upon the actual termination of business, the license (permit) of the pharmacy shall be returned to the State Board of Pharmacy for cancellation either in person or by registered or certified mail.

(3) A one (1)-time transfer of drugs and devices due to a termination of business that is in compliance with this rule will not require a pharmacy to seek licensure as a drug distributor under sections 338.330 and 338.333, RSMo.

(4) The requirements of this rule are not intended to replace or be in conflict with any other laws or regulations governing the appropriate licensure, change of ownership or change of location of a pharmacy.

(5) The termination date is the date on which the permit holder ceases to practice pharmacy as defined in sections 338.010 and 338.210, RSMo, at the permitted location.

AUTHORITY: sections 338.210 and 338.280, RSMo 1994. This rule originally filed as 4 CSR 220-2.015. Original rule filed May 4, 1995, effective Dec. 30, 1995. Moved to 20 CSR 2220-2.015, effective Aug. 28, 2006.*

**Original authority: 338.210, RSMo 1951 and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.016 Pharmacy Operations During an Emergency or Declared Disaster

PURPOSE: This rule establishes guidelines for temporary pharmacy operations during an emergency or declared disaster.

(1) Definitions.

(A) "Disaster Area" – A specified geographical area within the state that has been designated by the governor or federal authorities as an area that has been adversely affected by a natural or man-made disaster and that requires extraordinary measures to provide adequate, safe, and effective health care for the affected population.

(B) "Emergency Situation" – An emergency caused by a natural or man-made disaster that substantially prevents a Missouri licensed pharmacy from providing pharmacy services at the pharmacy's permitted location.

(C) "Home Pharmacy" – A Missouri licensed pharmacy that operates or applies for an emergency temporary pharmacy permit pursuant to this rule.

(D) "Emergency Declaration" – A state or federally declared emergency or disaster that impacts Missouri patients.

(2) Emergency Situations. A pharmacy that is substantially unable to provide pharmacy services at their permitted location due to an emergency situation may file a change of location application with the board to provide pharmacy services at a temporary site. No application fee shall apply. The location change must be approved by the board prior to changing locations and the designated location must successfully pass a board inspection.

(A) Approval of a temporary change of location under this rule will be based on the need, type, and scope of the emergency situation, as well as the ability of the pharmacy to ensure proper security and comply with state and federal drug laws.

(B) Unless otherwise approved by the board for good cause, temporary pharmacy permits shall be valid for up to six (6) months, if requested. A change of location application is required if the pharmacy will be operating at a temporary location for more than the allowed six (6) months or desires to permanently remain at the temporary site.

(C) The board may waive designated facility or pharmacy operational requirements at a temporary location to prevent the interruption of pharmacy services. Waiver requests must be submitted in writing and must demonstrate how the permit holder will maintain patient safety and ensure adequate security.

(D) A change of location application must be filed with the board when the home pharmacy is ready to return to their original permitted location. No fee will apply. The permitted location must pass a board inspection prior to resuming pharmacy services at the original location.

(E) Records must be maintained as required by Chapter 338, RSMo, and the rules of the board.

(F) Approval of a temporary location change does not interfere with any rights or privileges of a pharmacy permit holder at the original pharmacy location, or prevent a permit holder from applying for a change of location as outlined in the board's rules.

(3) Emergency Declarations/Disaster Areas. A Missouri licensed pharmacy located in Missouri may apply for an emergency temporary pharmacy permit to provide pharmacy services to Missouri patients impacted by an emergency declaration or located in a disaster area. Applications for an emergency temporary pharmacy permit must be submitted on a form provided by the board with the applicable fee, and must demonstrate that the temporary pharmacy is needed to ensure adequate pharmacy services are reasonably available for impacted patients. The following additional requirements apply, unless otherwise approved by the board:

(A) The temporary pharmacy permit shall be considered part of the home pharmacy's permit and not a separate pharmacy permit. The home pharmacy and the temporary pharmacy must have the same pharmacist-in-charge. The home pharmacy is responsible for ensuring compliance with all applicable state and federal law at a temporary pharmacy licensed under this rule;

(B) Unless otherwise approved by the board, temporary pharmacy permits will only be approved for a designated location and for the pharmacy classifications authorized on the home pharmacy's permit prior to the declared disaster or emergency declaration;

(C) Approval of an emergency temporary pharmacy permit will be based on the need, type, and scope of emergency or disaster, as well as the pharmacy's ability to maintain proper security and comply with applicable state and federal law, including, section 338.240, RSMo;

(D) The temporary location must successfully pass a board

inspection before a temporary pharmacy permit is issued. Additionally, temporary pharmacies must be available for inspection, as requested by the board or the board's authorized designee;

(E) The board may waive designated facility or pharmacy operational requirements to prevent the interruption of pharmacy services at an emergency temporary pharmacy. Waiver requests must be submitted in writing and must demonstrate how the permit holder will maintain patient safety and adequate pharmacy security, if approved. Controlled substances must be handled and dispensed in accordance with state and federal law;

(F) Temporary pharmacy permits issued under this section are valid for thirty (30) days but may be renewed at the discretion of the board. To renew, the home pharmacy must file a written request with the board and demonstrate that renewal of the temporary pharmacy permit is needed to protect the public health and ensure access to pharmacy services;

(G) Temporary pharmacies approved under this section must terminate services on the expiration date approved by the board or within five (5) days after the disaster area designation or emergency declaration is withdrawn or terminated, whichever is earlier; and

(H) Records must be maintained as required by Chapter 338, RSMo, and the rules of the board. Required records must be maintained at the home pharmacy after the temporary pharmacy permit closes, and must be available for inspection or copying by the board or the board's authorized designee.

AUTHORITY: sections 338.043 and 338.280, RSMo 2016, and sections 338.210, 338.220, and 338.333, RSMo Supp. 2020. This rule originally filed as 4 CSR 220-2.016. Original rule filed May 4, 1995, effective Dec. 30, 1995. Moved to 20 CSR 2220-2.016, effective Aug. 28, 2006. Amended: Filed May 13, 2019, effective Nov. 30, 2019. Rescinded and readopted: Filed April 8, 2021, effective Oct. 30, 2021.*

**Original authority: 338.043, RSMo 1990, amended 1997, 2001; 338.210, RSMo 1951, amended 2001, 2011, 2020; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014, 2020; 338.280, RSMo 1951, amended 1971, 1981; and 338.333, RSMo 1989, amended 2010, 2012, 2018.*

20 CSR 2220-2.017 Non-Electronic (Manual) Prescription Records

PURPOSE: This rule establishes requirements for non-electronic (manual) prescription record keeping.

(1) Pharmacies that maintain a non-electronic prescription record system shall maintain the following information in its system for each original and refilled prescription:

(A) The date the prescription was prescribed and the date of initial dispensing, if different;

(B) A unique, sequential prescription label number;

(C) If applicable, a unique readily retrievable identifier;

(D) The name of the patient(s), or if an animal, species and owner's name;

(E) The prescriber's name, if an oral prescription, signature if a written or faxed prescription. Electronic signatures shall comply with all applicable provisions of 20 CSR 2220-2.085;

(F) Name, strength and dosage of drug, device or poison dispensed and the directions for use;

(G) The number of refills authorized;

(H) The quantity dispensed in weight, volume, or number of units;

(I) The date of refill, if any;

(J) The identity of the pharmacist responsible for reviewing the accuracy of data on each original prescription;

(K) The identity of the pharmacist responsible for verifying the final product prior to dispensing on each original and refill prescription, if different;

(L) Whether generic substitution has been authorized by the prescriber;

(M) Any change or alteration made to the prescription dispensed based on contact with the prescriber to show a clear audit trail. This shall include, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug;

(N) The address of the prescriber and the patient when the prescription is for a controlled substance;

(O) The prescriber's Drug Enforcement Administration (DEA) number when the prescription is for a controlled substance; and

(P) 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, in such case the expiration date of the original prescription shall remain the same; and

(Q) Any prescription, when it is for a controlled substance, must comply with all requirements of federal and state controlled substance laws.

(2) The information specified in section (1) shall be required and recorded on all prescriptions prior to dispensing by a pharmacist/pharmacy.

(3) Prescription hard copies must be maintained and filed sequentially by the prescription label number or a unique readily retrievable identifier. Except as otherwise provided by 20 CSR 2220-2.010(1)(J), prescription hard copies shall be retrievable at the time of inspection.

AUTHORITY: sections 338.095, 338.100, 338.140, and 338.240, RSMo Supp. 2012, and section 338.280, RSMo 2000. Original rule filed Jan. 10, 2013, effective Aug. 30, 2013.*

**Original authority: 338.095, RSMo 1993, amended 2007; 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999, 2010; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; and 338.240, RSMo 1951, amended 2011.*

20 CSR 2220-2.018 Prescription Requirements

PURPOSE: This rule establishes requirements for information required on prescriptions.

(1) To be valid for purposes of dispensing, a prescription shall conform to all requirements of sections 338.056 or 338.196, RSMo, and shall contain the following information:

(A) The date of prescribing;

(B) The name of the patient(s), or if an animal, species and owner's name;

(C) The prescriber's name, if an oral prescription, or written or electronic signature if a written, faxed, or an electronically transmitted prescription. Electronic signatures shall comply with all applicable provisions of 20 CSR 2220-2.085;

(D) Name, strength and dosage of drug, device or poison prescribed and the directions for use;

(E) The number of refills, if applicable;

(F) The quantity prescribed in weight, volume, or number of units;

(G) An indication of whether generic substitution has been authorized by the prescriber, as required by section 338.056, RSMo;

(H) Any change or alteration made to the prescription dispensed based on contact with the prescriber to show a clear audit trail. This shall include, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug;

(I) The address of the prescriber and the patient when the prescription is for a controlled substance;

(J) The prescriber's Drug Enforcement Administration (DEA) number when the prescription is for a controlled substance; and

(K) Controlled substance prescriptions shall also comply with all requirements of federal and state controlled substance laws.

AUTHORITY: sections 338.095, 338.100, 338.140, and 338.240, RSMo Supp. 2012, and section 338.280, RSMo 2000. This rule originally filed as 4 CSR 220-2.018. Original rule filed May 4, 1995, effective Dec. 30, 1995. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed Nov. 1, 2000, effective June 30, 2001. Moved to 20 CSR 2220-2.018, effective Aug. 28, 2006. Amended: Filed Jan. 10, 2013, effective Aug. 30, 2013.*

**Original authority: 338.095, RSMo 1993, amended 2007; 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999, 2010; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; and 338.240, RSMo 1951, amended 2011.*

20 CSR 2220-2.020 Pharmacy Permits

PURPOSE: This rule outlines the requirements for obtaining and maintaining a pharmacy permit.

(1) All permits for the operation of a pharmacy shall expire on the date specified by the director of the Division of Professional Registration pursuant to 20 CSR 2231-2.010.

(2) A pharmacy permit may be issued on the application of the owners. If the owner is a corporation, an officer of the corporation must sign the application as the applicant. If the owner is a partnership, a partner must sign the application as the applicant. If the owner is a limited liability partnership, a general partner must sign the application as the applicant. If the owner is a limited liability company, a member must sign the application as the applicant. In the case where a pharmacy is owned and operated by a person(s) who is a licensed pharmacist and in active charge of the pharmacy, the application for permit can be made by either party. Alternatively, a pharmacy permit application may be signed by an attorney or other person lawfully granted power of attorney to sign the application on the applicant's behalf. In such case, a representative of the applicant shall review the application for truth and accuracy prior to submitting the application to the board. Proof of a power of attorney designation shall be submitted with the application.

(A) An application for a pharmacy permit will become null and void if the applicant fails to complete the process for licensure within six (6) months of receipt of the application by the board.

(3) When a pharmacy changes ownership, the original permit becomes void on the effective date of the change of ownership. Before any new business entity resulting from the change opens a pharmacy for business, it must obtain a new permit from the board. A temporary license shall be issued once a completed application and fee have been received by the board. The effective date of the temporary license may be the date the change of ownership is listed as effective on the application. Such license shall remain in effect until a permanent license is issued or denied by the board.

(A) A change of ownership of a pharmacy owned by a sole proprietor is deemed to have occurred when –

1. The business is sold and the sale becomes final;

2. The proprietor enters into a partnership with another individual or business entity; or

3. The proprietor dies; provided, however, that the proprietor's estate may continue to operate the pharmacy under the licensed pharmacist in good standing in this state, but in no case for a period of more than one (1) year and only so long as appropriate pharmacy permit fees are paid.

(B) If a corporation owns a pharmacy, it is not necessary to obtain a new license if the owners of the stock change. If a limited liability partnership or a limited liability company owns a pharmacy, it is not necessary to obtain a new license if the partners or members of the company change, as long as the partnership or company is not dissolved by that change. It is necessary to file written notice with the State Board of Pharmacy within ten (10) days after a change occurs in partners in a limited liability partnership, or in members in a limited liability company. This notification must be in writing and certified. However, when a corporation, limited liability partnership, or limited liability company begins ownership of a pharmacy or transfers ownership of a pharmacy, a new license must be obtained regardless of the relationship between the previous and subsequent owners.

(C) All individuals or business entities owning twenty-five percent (25%) or more of the ownership of any entity owning a pharmacy must notify the board within thirty (30) days of acquiring the percentage.

(4) If an individual or business entity operating a pharmacy changes the location of the pharmacy to a new facility (structure), the pharmacy shall not open for business at the new location until the board or its duly authorized agent has inspected the premises of the new location and approved it and the pharmacy as being in compliance with section 338.240, RSMo and all other provisions of the law. Upon the approval and receipt of a change of location fee, the board shall issue a permit authorizing operation of a pharmacy at the new location, and the permit shall bear the same number as the previous pharmacy permit. However, the permit remains valid if the pharmacy address changes, but not the location, and an amended permit will be issued without charge under these circumstances.

(A) Remodeling of a licensed pharmacy within an existing structure shall be deemed to have occurred when any change in the storage conditions of the Schedule II controlled substances is made or new connections to water/sewer resources are made or any changes in the overall physical security of drugs stored in the pharmacy as defined in 20 CSR 2220-2.010(1)(H) are made. Remodeling as defined within this section will not require the initiation of any change of location procedures. Satisfactory evidence of plans for any remodeling of a pharmacy must be provided to the board office thirty (30) days in advance of commencing such changes along with an affidavit showing any changes to the pharmacy physical plant and the projected completion date for any remodeling.

(5) Permits, when issued, will bear an original number. Permits must be posted in a conspicuous place in the pharmacy to which it is issued.

(6) No pharmacy permit will be issued unless the pharmacy area is under the direct supervision of a licensed pharmacist in good standing with the Missouri State Board of Pharmacy who is designated as the pharmacist-in-charge and meets the requirements of 20 CSR 2220-2.090.

(7) If the owner/applicant is not the licensed pharmacist-in-charge, then the pharmacist-in-charge must meet the requirements of 20 CSR 2220-2.090 and complete the pharmacist-in-charge affidavit of the permit application.

(8) The names of all pharmacists regularly working in a pharmacy shall be clearly displayed on the premises of every establishment having a pharmacy permit.

(9) The following classes of pharmacy permits or licenses are hereby established for entities providing services as defined in section 338.010, RSMo:

(A) Class A: Community/Ambulatory. A pharmacy that provides services as defined in section 338.010, RSMo to the general public;

(B) Class B: Hospital Pharmacy. A pharmacy owned, managed, or operated by a hospital as defined by section 197.020, RSMo, or a clinic or facility under common control, management, or ownership of the same hospital or hospital system. This section shall not be construed to require a Class B hospital pharmacy permit or license for hospitals solely providing services within the practice of pharmacy under the jurisdiction of, and the licensure granted by, the Department of Health and Senior Services under and pursuant to Chapter 197, RSMo;

(C) Class C: Long-Term Care. A pharmacy that provides services as defined in section 338.010, RSMo by the dispensing of drugs and devices to patients residing within long-term care facilities. A long-term care facility means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients;

(D) Class D: Non-Sterile Compounding. A pharmacy that provides services as defined in section 338.010, RSMo and provides a non-sterile compounded product as defined in 20 CSR 2220-2.400(1) and meets the following criteria:

1. Any product made from any bulk active ingredient in a batch quantity as defined in 20 CSR 2220-2.400(3);

(E) Class E: Radiopharmaceutical. A pharmacy that is not open to the general public and provides services as defined in section 338.010, RSMo that prepares and dispenses radioactive drugs as defined by the Food and Drug Administration (FDA) and drugs related to the use of radioactive drugs to health care providers for use in the treatment or diagnosis of disease and that maintains a qualified nuclear pharmacist as the pharmacist-in-charge;

(F) Class F: Renal Dialysis. A pharmacy that is not open to the general public that provides services as defined in section 338.010, RSMo limited to the dispensing of renal dialysis solutions and other drugs and devices associated with dialysis care;

(G) Class G: Medical Gas. A pharmacy that provides services as defined in section 338.010, RSMo through the provision of oxygen and other prescription gases for therapeutic uses;

(H) Class H: Sterile Product Compounding. A pharmacy that provides services as defined in section 338.010, RSMo, and provides a sterile pharmaceutical as defined in 20 CSR 2220-2.200;

(I) Class I: Consultant. A location where any activity defined in section 338.010, RSMo is conducted, but which does not include the procurement, storage, possession or ownership of any drugs from the location;

(J) Class J: Shared Service. A pharmacy engaged in the processing of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions;

(K) Class K: Internet. A pharmacy that provides services as defined in section 338.010, RSMo, and is involved in the receipt, review, preparation, compounding, dispensing, or offering for sale any drugs, chemicals, medicines, or poisons for any new prescriptions originating from the Internet for greater than ninety percent (90%) of the total new prescription volume on any day;

(L) Class L: Veterinary. A pharmacy engaged in the sale, dispensing, or filling of a legend drug for use in animals that must only be dispensed by prescription under state or federal law, provided that an additional Class L pharmacy permit shall not be required for pharmacies holding a Class A pharmacy permit that are also engaged in the sale, dispensing, or filling of a legend drug for animal use;

(M) Class M: Specialty (bleeding disorder). A pharmacy that provides blood-clotting products and ancillary infusion equipment or supplies to patients with bleeding disorders, as defined by 20 CSR 2220-6.100;

(N) Class N: Automated dispensing system (health care facility). An automated dispensing system as defined in 20 CSR 2220-2.900 that is located in a facility where medical services are provided to patients on the premises of or at the same physical location as such facility;

(O) Class O: Automated dispensing system (ambulatory care). An automated dispensing system as defined in 20 CSR 2220-2.900 that is not located in a healthcare facility identified in subsection (9)(N) of this rule; and

(P) Class P: Practitioner office/clinic. A pharmacy that is located in or on the premises of an office or clinic of a healthcare practitioner licensed in the United States who is authorized to prescribe medication by law and that provides pharmacy services as defined in section 338.010, RSMo, solely for patients of such practitioner or practitioners.

(10) Pharmacy applications for initial licensure or renewals of a license shall accurately note each class of pharmacy that is practiced at the location noted on the application or renewal thereof. The permit (license) issued by the board shall list each class of licensure that the pharmacy is approved to engage in. A Pharmacy Change of Classification Application shall be filed with the board prior to adding or deleting any pharmacy classes with the applicable fee.

(11) Prescriptions processed by any classification of licensed pharmacy must be provided by a practitioner licensed in the United States, authorized by law to prescribe drugs, and who has performed a medical evaluation of the patient as required by law. 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 pre-existing patient-practitioner relationship.

AUTHORITY: section 338.140, RSMo Supp. 2013, and section 338.280, RSMo 2000. This rule originally filed as 4 CSR 220-2.020. Original rule filed July 18, 1962, effective July 28, 1962. Amended: Filed Nov. 9, 1966, effective Nov. 19, 1966. Amended: Filed Oct. 27, 1970, effective Nov. 6, 1970. Amended: Filed Dec. 31, 1975, effective*

Jan. 10, 1976. Emergency amendment filed July 15, 1981, effective Sept. 28, 1981, expired Nov. 11, 1981. Amended: Filed Aug. 10, 1981, effective Nov. 12, 1981. Amended: Filed April 14, 1982, effective July 11, 1982. Amended: Filed March 14, 1983, effective June 11, 1983. Amended: Filed Feb. 11, 1985, effective May 11, 1985. Amended: Filed Dec. 16, 1985, effective May 11, 1986. Amended: Filed Aug. 1, 1986, effective Nov. 13, 1986. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed Jan. 6, 1998, effective Aug. 30, 1998. Amended: Filed June 29, 1999, effective Jan. 30, 2000. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed Nov. 30, 2001, effective June 30, 2002. Amended: Filed Dec. 3, 2002, effective June 30, 2003. Amended: Filed May 13, 2005, effective Oct. 30, 2005. Moved to 20 CSR 2220-2.020, effective Aug. 28, 2006. Amended: Filed Aug. 21, 2006, effective April 30, 2007. Emergency amendment filed Jan. 19, 2016, effective Feb. 2, 2016, expired July 30, 2016. Amended: Filed Jan. 19, 2016, effective July 30, 2016.

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011 and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.025 Nonresident Pharmacies

PURPOSE: This rule establishes licensure guidelines for nonresident pharmacies.

(1) Nonresident pharmacies shall not ship, mail, or deliver prescription drugs into Missouri without first obtaining a pharmacy license from the Missouri Board of Pharmacy. An exemption to licensure is allowed when a nonresident pharmacy provides a prescription drug in an emergency situation or supplies lawful refills to a patient from a prescription that was originally filled and delivered to a patient within the state in which the nonresident pharmacy is located.

(2) To obtain a Missouri pharmacy license, a nonresident pharmacy must –

(A) Maintain a pharmacy license in good standing from the state in which the nonresident pharmacy is located;

(B) Submit an application as provided by the Missouri Board of Pharmacy for licensure in compliance with 20 CSR 2220-2.020(2), (3), (9), and (10);

(C) Pay all appropriate licensing fees;

(D) Submit a copy of the state pharmacy license from the state in which the nonresident pharmacy is located;

(E) If controlled substances will be shipped into Missouri, submit a copy of the applicant's federal controlled substance registration and, if applicable, a copy of the applicant's state controlled substance registration from the state where the applicant is located;

(F) If the designated pharmacist-in-charge does not have a current and active Missouri pharmacist license issued by the board, submit an official verification from the state board of pharmacy or equivalent state pharmacist licensing agency verifying that the designated pharmacist-in-charge holds a current and active pharmacist license in the state in which the nonresident pharmacy is located; and

(G) Submit a copy of the applicant's most recent pharmacy inspection by the applicant's resident state board of pharmacy or its equivalent state regulatory body. The inspection must have occurred within the last eighteen (18) months for sterile compounding pharmacy applicants or within the last twenty-four (24) months for all other pharmacy applicants. If a state inspection is unavailable, an inspection by the Missouri Board of Pharmacy or from the Verified Pharmacy Program (VPP) of the National Association of State Boards of Pharmacy or a similar inspection by an entity approved by the board may be accepted.

(3) Each nonresident pharmacy shall supply any inspection reports, warning notices, notice of deficiency reports, or any other related reports requested by the board or the board's authorized designee to review compliance with state and federal drug laws.

(4) The Missouri Board of Pharmacy will extend reciprocal cooperation to any state that licenses and regulates nonresident pharmacies for the purpose of investigating complaints against pharmacies located in Missouri or the sharing of information and investigative reports, as long as the other state will extend the same reciprocal cooperation to the Missouri Board of Pharmacy.

AUTHORITY: sections 338.140, 338.210.4, 338.220, 338.240, and 338.280, RSMo 2016. This rule originally filed as 4 CSR 220-2.025. Original rule filed Jan. 16, 1990, effective May 11, 1990. Amended: Filed June 28, 2002, effective Jan. 30, 2003. Moved to 20 CSR 2220-2.025, effective Aug. 28, 2006. Amended: Filed Oct. 10, 2017, effective April 30, 2018.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.210, RSMo 1951, amended 2001, 2011; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014; 338.240, RSMo 1951, amended 2011; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.030 Educational and Licensing Requirements
(Rescinded August 30, 2013)

AUTHORITY: sections 338.020, 338.040, 338.070, 338.140, and 338.280, RSMo 2000, and sections 338.030 and 338.035, RSMo Supp. 2007. This rule originally filed as 4 CSR 220-2.030. This version of rule filed July 18, 1962, effective July 28, 1962. Amended: Filed Nov. 9, 1966, effective Nov. 19, 1966. Amended: Filed Nov. 27, 1967, effective Dec. 7, 1967. Amended: Filed Sept. 30, 1969, effective Oct. 10, 1969. Amended: Filed Dec. 31, 1975, effective Jan. 10, 1976. Emergency amendment filed July 15, 1981, effective Sept. 28, 1981, expired Nov. 11, 1981. Amended: Filed Aug. 10, 1981, effective Nov. 12, 1981. Amended: Filed April 14, 1982, effective July 11, 1982. Amended: Filed Dec. 12, 1983, effective May 11, 1984. Amended: Filed Dec. 11, 1984, effective March 11, 1985. Amended: Filed June 14, 1985, effective Aug. 26, 1985. Amended: Filed Feb. 25, 1986, effective June 12, 1986. Amended: Filed Oct. 1, 1987, effective Jan. 29, 1988. Amended: Filed Jan. 3, 1990, effective April 26, 1990. Amended: Filed Jan. 30, 1991, effective July 8, 1991. Amended: Filed Jan. 3, 1992, effective June 25, 1992. Amended: Filed Aug. 4, 1992, effective April 8, 1993. Amended: Filed Sept. 26, 1994, effective March 30, 1995. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed March 19, 1996, effective Oct. 30, 1996. Amended: Filed Dec. 9, 1996, effective July 30, 1997. Amended: Filed April 23, 1998, effective Nov. 30, 1998. Amended: Filed Nov. 1, 2000, effective June 30, 2001. Amended: Filed June 28, 2002, effective Jan. 30, 2003. Amended: Filed Nov. 13, 2002, effective June 30, 2003. Amended: Filed Dec. 1, 2004, effective June 30, 2005. Moved to 20 CSR 2220-2.030, effective Aug. 28, 2006. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008. Rescinded: Filed Jan. 10, 2013, effective Aug. 30, 2013.

20 CSR 2220-2.032 Licensure by Examination for Graduates of Nonapproved Foreign Pharmacy Schools
(Rescinded August 30, 2013)

AUTHORITY: sections 338.020, 338.030, and 338.140, RSMo 2000. This rule originally filed as 4 CSR 220-2.032. Original rule filed Oct. 16, 1985, effective Feb. 24, 1986. Amended: Filed Dec. 24, 1990, effective June 10, 1991. Amended: Filed Dec 15, 1995, effective July 30, 1996. Amended: Filed Nov. 21, 1997, effective June 30, 1998. Amended: Filed March 1, 2001, effective Sept. 30, 2001. Moved to 20 CSR 2220-2.032, effective Aug. 28, 2006. Rescinded: Filed Jan. 10, 2013, effective Aug. 30, 2013.

20 CSR 2220-2.034 Licensure by Reciprocity for Graduates of Nonapproved Foreign Pharmacy Schools Who Have Been Licensed in Another State
(Rescinded August 30, 2013)

AUTHORITY: sections 338.020 and 338.030, RSMo Supp. 1990. This rule originally filed as 4 CSR 220-2.034. Original rule filed Oct. 16, 1985, effective Feb. 24, 1986. Amended: Filed Aug. 29, 1986, effective Dec. 25, 1986. Amended: Filed Dec. 24, 1990, effective June 10, 1991. Moved to 20 CSR 2220-2.034, effective Aug. 28, 2006. Rescinded: Filed Jan. 10, 2013, effective Aug. 30, 2013.

20 CSR 2220-2.036 Temporary License
(Rescinded August 30, 2013)

AUTHORITY: section 338.140, RSMo 2000, and section 338.043, RSMo Supp. 2007. This rule originally filed as 4 CSR 220-2.036. Original rule filed May 24, 1993, effective Dec. 9, 1993. Amended: Filed Nov. 21, 1997, effective June 30, 1998. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Moved to 20 CSR 2220-2.036, effective Aug. 28, 2006. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008. Rescinded: Filed Jan. 10, 2013, effective Aug. 30, 2013.

20 CSR 2220-2.050 Public Complaint Handling and Disposition Procedure

PURPOSE: This rule establishes a procedure for the receipt, handling and disposition of public complaints by the board, pursuant to the mandate of section 620.010.16(6), RSMo.

(1) Any member of the public, the profession or any federal, state, or local official may make and file a complaint with the board. No member of the State Board of Pharmacy shall file a complaint with this board while s/he holds that office, unless that member excuses him/herself from further board deliberations or activity concerning the matters alleged within that complaint. Any staff member or employee of the board may file a complaint pursuant to this rule in the same manner as any member of the public.

(2) Complaints should be mailed or delivered to the following address: State Board of Pharmacy, 3605 Missouri Blvd., PO Box 625, Jefferson City, MO 65102. Complaints may be based upon personal knowledge or upon information and belief.

(3) Except as otherwise authorized by the board or executive director, all complaints shall be made in writing and identify their maker by name and address. Complaints may be made on forms provided by the board, which are available upon request. Complaints need not be made by affidavit, but oral or telephone communications will not be considered or processed as complaints unless otherwise authorized by the board or the executive director. Any staff member or employee of the board may make and file a complaint based upon information and belief, in reliance upon oral, telephone, or written but unsigned communications received by the board, unless those communications are believed by that staff member or employee to be false.

(4) Each complaint received under this rule shall be recorded by the board in consecutive order as received. The record shall contain each complainant's name and address; the name and address of the subject(s) of the complaint; the date each complaint is received by the board; a brief statement of the acts complained of, and the ultimate disposition of the complaint. This record shall be a closed record of the board.

(5) The complainant shall be informed in writing as to whether the complaint has been dismissed by the board or is being referred to legal counsel for legal action. The complainant may be notified of the ultimate disposition of the complaint, excluding judicial appeals and may be provided with a copy of the decisions (if any) of the Administrative Hearing Commission and the board. The provisions of this section do not apply to complaints filed by staff members or employees of the board, based upon information and belief, acting in reliance on third-party information received by the board.

(6) Both the complaint and any information obtained as a result of the complaint investigation are a closed record of the board and shall not be available for inspection by the public.

(7) This rule does not limit the board's authority to file a complaint with the Administrative Hearing Commission or with a court, charging a licensee, permittee, or other person or entity with any actionable conduct or violation, whether or not this complaint exceeds the scope of the acts charged in a preliminary public complaint filed with the board and whether or not any public complaint has been filed with the board.

(8) The board interprets this rule, which is required by law, to exist for the benefit of those members of the public who submit complaints to the board. This rule is not deemed to protect, or to inure to the benefit of those licensees, permit holders, registrants, or other persons or entities against whom the board has instituted or may institute administrative or judicial proceedings concerning possible violations of provisions of Chapter 338, RSMo.

(9) To facilitate the investigation, evaluation, and disposition of complaints, which involve violations of federal and state law governing controlled substances, the Board of Pharmacy may designate Bureau of Narcotics and Dangerous Drugs personnel and other state personnel as pharmacy inspectors. These inspectors shall be authorized pursuant to section 338.150, RSMo to enter and inspect various premises.

(10) Persons designated by the Board of Pharmacy as pharmacy inspectors and other Board of Pharmacy personnel may attend board meetings in order to assist the board in its deliberations.

AUTHORITY: section 338.280, RSMo 2016, and section 338.140, RSMo Supp. 2019. This rule originally filed as 4 CSR 220-2.050. riginal rule filed Jan. 11, 1982, effective June 1, 1982. Amended: Filed Aug. 27, 1985, effective Nov. 11, 1985. Amended: Filed Aug. 29, 1986, effective Dec. 25, 1986. Amended: Filed Sept. 26, 1994, effective March 30, 1995. Amended: Filed June 28, 2002, effective Jan. 30, 2003. Amended: Filed May 13, 2005, effective Oct. 30, 2005. Moved to 20 CSR 2220-2.050, effective Aug. 28, 2006. Amended:*

Filed May 13, 2019, effective Nov. 30, 2019.

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019 and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.060 Gold Certificates

PURPOSE: This rule sets requirements concerning the issuance of honorary gold certificates to pharmacists licensed in Missouri for fifty (50) years.

(1) The Missouri Board of Pharmacy shall issue gold certificates to all pharmacist licensees who have been regularly licensed as pharmacists in Missouri for fifty (50) years without charge to the recipient. Gold certificates are honorific in nature and confer no right to practice pharmacy upon the recipient.

AUTHORITY: section 338.140, RSMo Supp. 2019. This rule originally filed as 4 CSR 220-2.060. Original rule filed March 14, 1983, effective June 11, 1983. Moved to 20 CSR 2220-2.060, effective Aug. 28, 2006. Amended: Filed May 13, 2019, effective Nov. 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019.*

20 CSR 2220-2.080 Electronic Prescription Records

PURPOSE: This rule establishes requirements for utilizing an electronic data-processing system in a pharmacy.

(1) In lieu of a non-electronic (manual) record-keeping system, a pharmacy may elect to maintain an electronic data processing (EDP) record keeping-system. All information concerning the compounding, dispensing, or selling by a pharmacy of any drug, device, or poison pursuant to a lawful prescription which is entered into an EDP system at any pharmacy shall be entered only by a licensed pharmacist or by a technician or intern pharmacist under the direct supervision and review of a licensed pharmacist. Prior to dispensing, a pharmacist shall personally verify the accuracy of prescription data entered into the EDP for each original prescription. The EDP system shall comply with all applicable state and federal controlled substance laws and regulations.

(2) EDP systems shall comply with the requirements of section 338.100, RSMo, and capable of storing and retrieving the following information concerning the original filling or refilling of any prescription:

(A) A unique, sequential prescription label number;

(B) If applicable, a unique readily retrievable identifier;

(C) Date the prescription was prescribed;

(D) The date the prescription was initially filled and the date of each refill;

(E) Patient's full name, or if an animal, the species and owner's name;

(F) Patient's address or animal owner's address when a prescription prescribes a controlled substance;

(G) Prescriber's full name;

(H) Prescriber's address and Drug Enforcement Administration (DEA) number when a prescription specifies a controlled substance;

(I) Name, strength, and dosage of drug, device, or poison dispensed and any directions for use;

(J) Quantity originally dispensed;

(K) Quantity dispensed on each refill;

(L) Identity of the pharmacist responsible for verifying the accuracy of prescription data prior to dispensing on each original prescription;

(M) 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;

(N) The number of authorized refills and quantity remaining;

(O) Whether generic substitution has been authorized by the prescriber;

(P) The manner in which the prescription was received by the pharmacy (e.g., written, telephone, electronic, or faxed); and

(Q) Any other change or alteration made in the original prescription 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 authority to substitute a drug.

(3) The information specified in section (2) shall be required and recorded in the EDP system prior to dispensing by a pharmacist or pharmacy.

(4) Except as otherwise provided by 20 CSR 2220-2.083, prescription hard copies must be maintained and filed by either the sequential prescription label number or by a unique readily retrievable identifier. For verbal, telephone, or electronic prescriptions, a hard copy representation of the prescription shall be made and filed which contains all of the information in section (2). Prescription hard copies must be retrievable at the time of inspection, except as otherwise provided by 20 CSR 2220-2.010(1)(J). For purposes of this subsection an "electronic prescription" is defined as provided in 20 CSR 2220-2.085.

(5) If additional refills are authorized and added to a prescription, a notation indicating the method and source of the authorization must be a part of the EDP record or hard copy, in that case the expiration date of the original prescription shall remain the same.

(6) Any hospital pharmacy using an EDP system licensed by the board, as described in section (1), for outpatient prescriptions, employee prescriptions, and take-home prescriptions shall conform to all sections of this rule.

(7) Any EDP system must be capable of producing the record required by this rule and said records shall be readily retrievable online. Readily retrievable is defined as providing EDP records immediately or within two (2) hours of a request by an inspector or by making a computer terminal available to the inspector for immediate use.

(8) An auxiliary record-keeping system shall be established for the documentation of refills if the EDP system is inoperative for any reason. The auxiliary system shall ensure that all refills are authorized by the original prescription or prescriber. When this EDP system is restored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the EDP system within seven (7) working days. However, nothing in this section precludes the pharmacist from using his/her professional judgment for the benefit of a patient's health and safety.

(9) If a prescription is transferred from a pharmacy using an EDP 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 original

pharmacy, it shall be treated as a new record, showing the original date written and expiration date.

(10) Prior to or simultaneously with the purging of any EDP system, the permit holder shall make certain that a record of all prescription activity being erased exists in readable form, either on paper, microfiche, or electronic media storage. A pharmacy that desires to discard hard copy prescriptions that are more than three (3) years old must maintain all prescription information on microfiche or electronic media. Any process utilizing microfiche must ensure that all data is available and in readable form. Any pharmacy opting for the utilization of microfiche records must also maintain a microfiche reader so that records may be reviewed on-site by pharmacy personnel or board inspectors. Electronic media storage is defined as any medium such as a computer, floppy disk or diskette, compact disk (CD), or other electronic device that can reproduce all prescription information as required by section 338.100, RSMo, and this rule and is retrievable within three (3) working days.

(11) If coded information exists in the electronic EDP, the board inspector may request the definitions of the codes from the pharmacist on duty for immediate review.

(12) The EDP system shall be able to provide a listing of drug utilization by date for any drug for a minimum of the preceding twenty-four- (24-) month period that includes the specific drug product, patient name, or practitioner. If requested to do so, the pharmacy shall have three (3) working days to provide the report.

(13) The provisions of this rule do not preempt any federal laws or regulations. If any part of this rule is declared invalid by a court of law, that declaration shall not affect the other parts of the rule.

(14) Licensees shall also comply with all state and federal controlled substance record keeping requirements, including, any required daily log books or printouts.

AUTHORITY: sections 338.100 and 338.280, RSMo 2016, and section 338.140, RSMo Supp. 2019. This rule originally filed as 4 CSR 220-2.080. Original rule filed March 8, 1984, effective Aug. 11, 1984. Amended: Filed Nov. 4, 1985, effective Feb. 24, 1986. Rescinded and readopted: Filed Dec. 5, 1988, effective March 11, 1989. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed Nov. 1, 2000, effective June 30, 2001. Moved to 20 CSR 2220-2.080, effective Aug. 28, 2006. Amended: Filed Jan. 10, 2013, effective Aug. 30, 2013. Amended: Filed May 13, 2019, effective Nov. 30, 2019.*

**Original authority: 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999, 2010, 2016; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.083 Electronic Record-Keeping Systems

PURPOSE: The purpose of this rule is to establish requirements and guidelines for maintaining prescription hard copies in an electronic record-keeping system.

(1) In lieu of maintaining the original prescription hard copy or a hard copy representation as required by 20 CSR 2220-2.018 or 20 CSR 2220-2.080, a pharmacy shall be authorized to maintain an exact digitized image of the prescription in an electronic record-keeping system (ERS). For purposes of this rule, an electronic record-keeping system is defined as a system maintained by the pharmacy that provides input, storage, processing, communications, output, and control functions for digitized images of original prescriptions. Any alterations to the digitized original prescription shall be documented as required by 20 CSR 2220-2.018 or 20 CSR 2220-2.080, as applicable.

(2) Controlled substance hard copy prescriptions shall be maintained as required by applicable state and federal law.

(3) Digitized prescription images shall be readily retrievable by the pharmacy. Readily retrievable shall be defined as providing records immediately or within two (2) hours of a request of the inspector or by making a computer terminal available to the inspector for immediate use. An ERS system shall be capable of printing and retrieving the digitized prescription image at the time of inspection, including the reverse side of the prescription if applicable. Any printout of a digitized prescription image provided by a licensee/registrant to the patient or the patient's representative shall be conspicuously marked with the statement "Copy Only – Not Valid for Dispensing Purposes."

(4) Pharmacies maintaining an ERS shall establish written policies and procedures for the use of the ERS which shall include policies and procedures for reviewing compliance with the requirements of this rule and for storing, retrieving, and recovering digitized images. The policy and procedure manual shall be reviewed annually and shall be available to representatives of the board upon request.

(5) All digitized images in the ERS shall be stored, copied, or saved onto secure storage media on a regular basis in a manner that will allow image recovery in the event of a disaster, system interruption, or system failure.

AUTHORITY: sections 338.100 and 338.140, RSMo Supp. 2012. Original rule filed Jan. 10, 2013, effective Aug. 30, 2013.*

**Original authority: 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999, 2010 and 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011.*

20 CSR 2220-2.085 Electronic Prescriptions and Medication Orders

PURPOSE: This rule establishes guidelines for electronic prescriptions and medication orders.

(1) Definitions.

(A) Electronic image transmission – An exact visual image of a paper prescription or medication order that is electronically received by a pharmacy from a licensed prescriber or the prescriber's authorized agent (e.g., a facsimile/scan).

(B) Electronic prescription – Any prescription or medication order, other than an electronic image transmission, which is electronically transmitted from a licensed prescriber or the prescriber's authorized agent to a pharmacy.

(C) Electronic signature – An exact electronic replica of the prescriber's signature or a confidential digital key code, number, or other identifier attached to or logically associated with a record that is executed or adopted by a prescriber with the intent to sign the record.

(2) Prescriptions or medication orders may be transmitted to a pharmacy by the prescriber or the prescriber's authorized agent as an electronic image transmission or an electronic prescription.

(A) Electronic image transmissions and electronic prescriptions must contain all information required by state and federal law, including, designation of whether generic substitution is authorized. Electronic image transmissions must be formatted as required by section 338.056, RSMo, and bear the prescriber's manual or electronic signature.

(B) Controlled substance prescriptions and medication orders must comply with state and federal controlled substance laws and regulations and must be signed in accordance with state and federal law.

(C) A pharmacist shall be responsible for verifying the authenticity of any electronic image transmission or electronic prescription prior to dispensing by taking measures which, in his/her professional judgment, may be necessary to ensure the prescription or medication order was initiated or authorized by the prescriber.

(3) In lieu of a manually signed prescription or medication order, a pharmacist may accept a paper prescription or medication order with an electronic signature if the prescription/medication order is applied to paper that utilizes security features that will detect or otherwise identify if the prescription/medication order is subject to any form of copying and/or alteration.

AUTHORITY: sections 338.095, 338.140, and 338.280, RSMo 2016, and section 338.010, RSMo Supp. 2017. This rule originally filed as 4 CSR 220-2.085. Original rule filed Sept. 25, 1995, effective April 30, 1996. Amended: Filed July 28, 2000, effective Jan. 30, 2001. Amended: Filed April 16, 2001, effective Nov. 30, 2001. Moved to 20 CSR 2220-2.085, effective Aug. 28, 2006. Amended: Filed Dec. 15, 2017, effective June 30, 2018.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017; 338.095, RSMo 1993, 2007; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; and 328.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.090 Pharmacist-in-Charge

PURPOSE: This rule defines the term pharmacist-in-charge, sets the requirements and standards for this title, and defines the term full-time pharmacy.

(1) Except as otherwise authorized by law, each pharmacy shall designate a pharmacist-in-charge who is responsible for managing pharmacy compliance and supervising pharmacy staff. At a minimum, the pharmacist-in-charge shall assist the permit holder in ensuring pharmacy operations and clinical activities comply with the rules of the board and all applicable state and federal law governing pharmacy practice.

(A) The pharmacist-in-charge must be regularly involved in, and engaged with, pharmacy operations and monitoring pharmacy compliance. Except in the event of an emergency or other urgent need, the pharmacist-in-charge must be consulted and given an opportunity to provide input prior to implementation of any pharmacy policy, procedure, system, or practice that will modify or expand the delivery of pharmacy services.

(B) The pharmacist-in-charge must be physically present at the pharmacy for a sufficient amount of time as needed to effectively supervise pharmacy activities and ensure pharmacy compliance. Additionally, the permit holder must provide the pharmacist-in-charge designated time to review pharmacy compliance on a regular basis while not engaged in medication dispensing or providing patient services.

(C) The pharmacist-in-charge must have authority to temporarily suspend or restrict pharmacy operations or the activity of licensees/registrants, if deemed reasonably necessary or appropriate to ensure pharmacy compliance or the safe provision of pharmacy services, pending final direction or approval from the permit holder.

(D) The permit holder must have policies and procedures in place for regularly reviewing staffing and resource needs with the pharmacist-in-charge, including policies and procedures for requesting additional staff or staffing modifications.

(2) A pharmacist must immediately notify the board electronically or in writing on a form designated by the board if he/she stops serving as the designated pharmacist-in-charge. At or immediately prior to a pharmacist-in-charge change, a controlled substance inventory must be taken by a designee of the permit holder that complies with state and federal controlled substance inventory requirements, including 21 CFR 1304.11. The signature of the individual(s) taking the required inventory must be documented on the inventory.

(3) This rule does not exempt a permit holder from responsibility for compliance with applicable state or federal law.

AUTHORITY: sections 338.240 and 338.280, RSMo 2016, and section 338.140, RSMo Supp. 2021. This rule originally filed as 4 CSR 220-2.090. Emergency rule filed April 12, 1984, effective April 22, 1984, expired Aug. 20, 1984. Original rule filed April 12, 1984, effective Aug. 11, 1984. Amended: Filed Feb. 25, 1986, effective Aug. 11, 1986. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed Aug. 21, 1998, effective Feb. 28, 1999. Amended: Filed Dec. 30, 1998, effective June 30, 1999. Amended: Filed Nov. 1, 2000, effective June 30, 2001. Moved to 20 CSR 2220-2.090, effective Aug. 28, 2006. Amended: Filed Jan. 20, 2022, effective Aug. 30, 2022.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.240, RSMo 1951, amended 2011; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.095 Collection of Medication for Destruction

PURPOSE: The purpose of this rule is to authorize pharmacies to collect medication for purposes of destruction and to establish requirements for medication collection programs.

(1) Missouri licensed pharmacies may collect medication from the public for destruction in compliance with this rule. Pharmacies collecting controlled substances shall comply with all applicable state and federal controlled substance laws. Pharmacies collecting non-controlled substances shall comply with sections (2) to (9) of this rule. Participation in a medication return or destruction program is voluntary. This rule shall not be construed to require that a licensee or permit holder participate in or establish a return/destruction program.

(2) Definitions. The following definitions shall apply for purposes of this rule:

(A) "Mail"- Mail shall include mailing via the United States Postal Service or shipping via a common carrier; and

(B) "Nonretrievable"- For the purposes of destruction, a condition or state to which medication is rendered after

undergoing a process that permanently alters the medication's physical condition or state through irreversible means and thereby renders the medication unavailable and unusable for all practical purposes.

(3) Pharmacies may maintain a collection receptacle or establish an authorized mail-back program to collect non-controlled medication from the general public for destruction. Collection receptacles may not be used to dispose of unused/unwanted medication in the pharmacy's inventory (e.g., outdated drugs, medical waste). Collected medication shall not be resold or reused.

(A) Pharmacies collecting medication under this rule shall develop and implement written policies and procedures governing medication collection which must include, but not be limited to, authorized destruction procedures and methods.

(B) This rule does not preempt or modify return/reuse of medication as authorized by 20 CSR 2220-3.040, the provisions of Chapter 196, RSMo, governing the Prescription Drug Repository Program, or any provision of state or federal law governing controlled substances or the destruction, handling, or transporting of medical or pharmaceutical waste.

(4) Collection Receptacles. Pharmacies that maintain a collection receptacle to collect non-controlled medication for destruction must comply with the following:

(A) Collection receptacles must be securely placed and maintained inside the physical building of the pharmacy in a manner that prevents theft, diversion, or unauthorized removal. Receptacles must be securely fastened to a permanent structure. The receptacle must be visible to pharmacy staff at all times and shall not be located in or near exit doors;

(B) The receptacle must be a securely locked, substantially constructed container with a permanent outer container, and must contain an inner liner that complies with this rule. The receptacle must have an opening that allows medication to be added to the inner liner but does not allow the contents of the inner liner to be removed. The opening must be locked or otherwise made inaccessible to the public so that drugs cannot be deposited into the collection receptacle when the pharmacy is closed for business;

(C) A sign must be prominently displayed on the outer container of the receptacle indicating that only non-controlled substances may be deposited into the receptacle. If the receptacle is also used to collect controlled substances, the required sign must comply with state and federal controlled substance laws;

(D) Inner liners must be removable, waterproof, tamper-evident, and tear-resistant and must bear a permanent, unique identification number or identifier that enables the inner liner to be tracked. The contents of the inner liner shall not be viewable from the outside;

(E) Inner liners must be installed or removed from a collection receptacle by or under the supervision of at least two (2) board licensees or registrants. Inner liners must be immediately sealed once removed from the receptacle; the sealed inner liner shall not be opened, x-rayed, analyzed, or otherwise penetrated by the pharmacy or pharmacy staff. After removal, sealed inner liners pending destruction may be stored at the pharmacy in a securely locked, substantially constructed cabinet or in a securely locked room or area with controlled access for no more than thirty (30) business days; and

(F) Pharmacies must report any theft or diversion of or from a collection receptacle to the board in writing within fourteen (14) days in a manner designated by the board.

(5) Mail-Back Programs. Pharmacies may provide mail-back packages to the public for the purpose of mailing medication to a collector that is authorized by the Drug Enforcement Administration or federal law to receive prescription medication for destruction ("an authorized collector"). Packages may be provided directly by the pharmacy or the pharmacy's authorized designee, provided the pharmacy is responsible for ensuring compliance with this section.

(A) Mail-back packages must be preaddressed with the address of the authorized collector. The cost of shipping the package shall be postage or otherwise prepaid. Licensees/permit holders shall not accept any returned mail-back packages. Packages must be mailed directly to the authorized collector by the consumer or his/her agent.

(B) Mail-back packages must be nondescript and shall not include any markings or other information that might indicate that the package contains medication. Packages must be water-proof, spill-proof, tamper-evident, tear-resistant, and sealable.

(C) Mail-back packages must be provided with instructions for mailing, notice that packages may only be mailed from within the fifty (50) United States or US territories, and notice that only packages provided by or on behalf of the pharmacy may be used to mail medication.

(D) Senders shall not be required to provide any personally identifiable information when mailing back medication.

(E) Mail-back packages must include a unique identification number or other unique identifier that enables the package to be tracked.

(6) Long-Term Care Facilities. Pharmacies may provide and maintain a collection receptacle at a long-term care facility to collect medication from the public or facility residents for destruction. This section does not apply to medication collected for return and reuse as authorized by 20 CSR 2220-3.040.

(A) Collection receptacles must be securely placed and maintained inside the physical building of the long-term care facility in a manner that prevents theft, diversion, or unauthorized removal. Receptacles must be securely fastened to a permanent structure and must be visible to the facility's staff at all times. In lieu of fastening to a permanent structure, receptacles that are not accessible to the public or residents may be stored in a securely locked room or area with controlled access that is restricted to facility staff/personnel until transfer to the pharmacy. Collection receptacles shall not be located in or near exit doors.

(B) Collection receptacles must be a securely locked, substantially constructed container with a permanent outer container, and must contain an inner liner that complies with subsections (4)(D) and (E) of this rule. The receptacle must have an opening that allows medication to be added to the inner liner but does not allow the contents of the inner liner to be removed. The opening must be locked or otherwise made inaccessible to the public so that drugs cannot be deposited into the collection receptacle when the facility is closed for business.

(C) If the receptacle is accessible to the public or residents, a sign must be prominently displayed on the outer container of the receptacle indicating that only non-controlled substances may be deposited into the receptacle. The required sign must comply with state and federal controlled substance laws if the receptacle is also used to collect controlled substances.

(D) The pharmacy shall be responsible for installing, managing, and maintaining the receptacle and for the removal, sealing, transfer, and storage of inner liners and receptacle contents.

(E) Inner liners may only be installed, removed, and transferred either: 1) by or under the supervision of two (2) board licensees or registrants acting on behalf of the pharmacy; or 2) by or under the supervision of a board licensee/registrant and an employee/staff member of the long-term care facility designated by the pharmacy (e.g., a supervisory charge nurse).

(F) After removal, sealed inner liners may be stored at the facility in a securely locked, substantially constructed cabinet or in a securely locked room or area with controlled access for no more than three (3) business days.

(7) Destruction Methods. Medication collected for destruction shall be rendered nonretrievable and destroyed in compliance with all applicable federal and state laws. Medication shall be destroyed in one (1) of the following ways:

(A) On-site Destruction: Medication may be destroyed on the physical premises of the pharmacy, provided two (2) board licensees or registrants must personally witness the destruction of the medication and handle or observe the handling of the medication until the substance is rendered non-retrievable; or

(B) Transfer to an Authorized Entity: Collected medication may be mailed, shipped, or transferred to an entity authorized to destroy the medication off-site, provided two (2) board licensees or registrants must witness or observe the mailing, shipping, or transfer. If medication is transported by the pharmacy to the off-site location, the medication must be constantly moving towards its final location. Unnecessary and unrelated stops and stops of an extended duration shall not occur.

(8) Records. Except as otherwise provided herein, pharmacies shall maintain a complete and accurate record of the following for two (2) years:

(A) Inventories. Pharmacies shall conduct an inventory every twelve (12) months of inner-liners that are present at the pharmacy or at a long-term care facility that are unused or awaiting destruction. The inventory shall be documented in writing and must include:

1. The date of the inventory;

2. The number of inner liners present on the date of the inventory and the size of any inner liners (e.g., five (5) ten- (10-) gallon liners, etc.);

3. The unique identification number/identifier of each inner liner, whether unused or awaiting destruction;

(B) Inner Liners. The pharmacy must maintain the following written records for inner liners:

1. The unique identification number/identifier and the size of each unused inner liner (e.g., five- (5-) gallon, ten- (10-) gallon, etc.);

2. The date each inner liner is installed, the address of the location where each liner is installed, the unique identification number/identifier and size of each installed inner liner, and the names and signatures of the two (2) required witnesses for each installation; and

3. The date each inner liner is removed and sealed, the unique identification number/identifier of each removed inner liner, and the names and signatures of the two (2) required witnesses for each removal; and

(C) Destruction. The pharmacy must maintain the following written records:

1. For medication destroyed on-site of the pharmacy, the date and method of destruction, the unique identification number/identifier of each inner liner destroyed, and the names and signatures of the two (2) required witnesses of the destruction.

2. For medication destroyed off-site, the date each inner liner was transferred for destruction, the name and address of each entity to whom each sealed inner liner was transferred for destruction, the unique identification number/identifier of each inner liner transferred for destruction, and the name of the two (2) required witnesses for medication transfer or transport.

(9) Law Enforcement Return Programs. Licensees/permitholders shall be exempt from compliance with this rule when participating in medication collection programs conducted by local, state, or federal law enforcement agencies provided –

(A) Collected medication is placed into a collection container or area that is under the supervision of law enforcement personnel at all times;

(B) Law enforcement personnel are present whenever drugs are collected or on-site; and

(C) The licensee/permitholder does not take possession of the collected medications. Collected medications must remain under the control of, and must be removed by, law enforcement.

AUTHORITY: sections 338.140, 338.240, 338.280, and 338.315, RSMo 2016. Original rule filed Aug. 30, 2016, effective March 30, 2017.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.240, RSMo 1951, amended 2011; 338.280, RSMo 1951, amended 1971, 1981; and 338.315, RSMo 1989, amended 2011, 2012, 2014.*

20 CSR 2220-2.100 Continuing Pharmacy Education
(Rescinded August 30, 2013)

AUTHORITY: sections 338.060 and 338.140, RSMo 2000. This rule originally filed as 4 CSR 220-2.100. Original rule filed Nov. 9, 1984, effective April 11, 1985. Amended: Filed Nov. 21, 1997, effective June 30, 1998. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed June 28, 2002, effective Jan. 30, 2003. Amended: Filed April 1, 2004, effective Sept. 30, 2004. Amended: Filed June 15, 2005, effective Jan. 30, 2006. Moved to 20 CSR 2220-2.100, effective Aug. 28, 2006. Rescinded: Filed Jan. 10, 2013, effective Aug. 30, 2013.

20 CSR 2220-2.110 PRN Refills

PURPOSE: This rule clarifies the board's requirements for refills as needed so that the practicing pharmacists in Missouri will have adequate guidelines in this area.

(1) A pharmacist shall not fill or refill any prescription which was written more than one (1) year before being presented to the pharmacist, unless the pharmacist consults with the prescriber and confirms –

(A) That the person for whom the drugs or medicines were prescribed is still under the prescriber's care or treatment;

(B) That the prescriber desires for the person to continue receiving the drugs or medicines; or

(C) If the prescriber answers negatively in either case listed in subsection (1)(A) or (B), the pharmacist shall not fill or refill the prescription, even if the prescription authorizes refills as needed (PRN).

(2) If a pharmacist knows or has reason to believe that a person for whom a prescription has been written is not under the

prescribers care or treatment at the time the prescription is presented for filling or refilling, the pharmacist shall consult with their prescriber and ascertain that the prescriber intends for the person to receive the drugs or medicines. The pharmacist shall do this no matter when the prescription originally was written and even if the prescription authorizes refills PRN.

(3) After the pharmacist has confirmed the information required in sections (1) and (2) of this rule, s/he shall record it in his/her records in a uniform fashion so as to make it readily available for verification by the board or its authorized agents.

AUTHORITY: section 338.280, RSMo 1994. This rule originally filed as 4 CSR 220-2.110. Original rule filed Dec. 11, 1984, effective March 11, 1985. Moved to 20 CSR 2220-2.110, effective Aug. 28, 2006.*

**Original authority: 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.120 Transfer of Prescription or Medication Order Information

PURPOSE: This rule defines record-keeping required for transfer of prescription or medication order information.

(1) A valid new or refill prescription or medication order may be transferred to another pharmacy if –

(A) The prescription, medication order, and/or refills were authorized by the prescriber;

(B) The prescription or medication order and/or refills have not exceeded the maximum allowable time limit;

(C) If refills are involved, the number of lawfully allowable refills has not been exceeded;

(D) If the transfer involves a controlled substance, all information must be transferred directly between two (2) licensed pharmacists and comply with all applicable state and federal controlled substance laws and regulations; and

(E) The transfer of information for a controlled substance is permissible between pharmacies on a one- (1-) time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(2) The following record-keeping is required when a prescription, medication order, or refill is transferred:

(A) The prescription record at the transferring pharmacy must show –

1. The word void must appear on the face of the invalidated prescription for pharmacies using a manual record-keeping system. For pharmacies using an electronic data processing system, the prescription or medication order must be promptly voided within the system;

2. The name and location of the pharmacy to which it was transferred, the date of transfer, and the identity of the persons transferring and receiving information; and

3. If the transfer involves a controlled substance, the receiving pharmacy's address and Drug Enforcement Administration (DEA) registration number and the full name of the pharmacist(s) transferring and receiving the prescription information; and

(B) The record at the receiving pharmacy shall show all of the following, in addition to all other lawfully required information:

1. An indication that the prescription or medication order is a transfer;

2. Date of issuance;

3. Date of first dispensing;

4. Number of refills originally authorized and the number of remaining refills;

5. Date of last refill;

6. Prescription number or other unique identifier;

7. The name and location of the pharmacy that transferred the prescription or medication order;

8. The identity of the individuals transferring and receiving the information;

9. If the transfer involves a controlled substance, the transferring pharmacy's address and DEA registration number and the full names of the pharmacists transferring and receiving the prescription or medication order information; and

10. If the transfer involves information for a prescription or medication order that has never been dispensed, the date of first dispensing, the date of last refill, and the prescription number/unique identifier are not required.

(3) An electronic transfer of prescription or medication order between licensed pharmacies must meet all of the requirements of this rule. However, licensed pharmacies that share the same electronic database and are under the same ownership are not required to record the identities of the persons receiving and transferring non-controlled information.

(4) A Class-C Long Term Care pharmacy may transfer a non-controlled prescription or medication order to a second pharmacy for the purpose of the initial dispensing of up to a seventy-two- (72-) hour medication supply to a long-term care facility patient without voiding the remaining prescription. The transferring pharmacy must deduct this amount from the remaining prescription or medication order but is not required to void it.

(5) A prescription or medication order must be transferred within one (1) business day of receiving a transfer request directly from a patient or their caretaker. All other transfer requests must be completed in a timely manner, provided licensees/permit holders shall ensure no interruption in patient therapy.

AUTHORITY: sections 338.100 and 338.280, RSMo 2016, and section 338.140, RSMo Supp. 2020. This rule originally filed as 4 CSR 220-2.120. Original rule filed April 16, 1985, effective Aug. 11, 1985. Amended: Filed May 2, 1989, effective Aug. 24, 1989. Amended: Filed April 23, 1998, effective Nov. 30, 1998. Amended: Filed July 28, 2000, effective Jan. 30, 2001. Moved to 20 CSR 2220-2.120, effective Aug. 28, 2006. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008. Amended: Filed April 11, 2019, effective Nov. 30, 2019. Amended: Filed Oct. 29, 2020, effective May 30, 2021.*

**Original authority: 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999, 2010, 2016; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.130 Drug Repackaging

PURPOSE: This rule establishes requirements for drug repackaging.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome

or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.

(1) A pharmacist or pharmacy may prepackage drugs for other than immediate dispensing purposes provided that the following conditions are met:

(A) Only products which will be directly provided to the patient may be prepackaged;

(B) Containers utilized for prepackaging shall meet, as a minimum requirement, that of Class B container standards as referenced by the United States Pharmacopoeia (USP), which has been incorporated herein by reference. Where applicable, light sensitive containers shall be used;

(C) The maximum expiration date allowed for prepacked drugs shall be the manufacturer's expiration date or twelve (12) months, whichever is less; and

(D) Any prepacked drug must have a label affixed to it which contains, at a minimum, the name and strength of the drug, the name of the manufacturer or distributor, an expiration date as defined in subsection (1)(C) and lot number. Pharmacies that store drugs within an automated counting device may, in place of the required label, maintain records for lot numbers and expiration dates that are required on the label as long as it is fully traceable and is readily retrievable during an inspection.

(2) The term prepacked as used in this rule is defined as any drug which has been removed from the original manufacturer's container and is placed in a dispensing container for other than immediate dispensing to a patient.

AUTHORITY: sections 338.140 and 338.280, RSMo 2000. This rule originally filed as 4 CSR 220-2.130. Original rule filed Dec. 10, 1986, effective May 28, 1987. Amended: Filed Nov. 15, 1988, effective March 11, 1989. Emergency amendment filed July 1, 1991, effective July 26, 1991, expired Nov. 22, 1991. Amended: Filed July 1, 1991, effective Jan. 13, 1992. Amended: Filed July 28, 2000, effective Jan. 30, 2001. Amended: Filed Jan. 31, 2003, effective Aug. 30, 2003. Moved to 20 CSR 2220-2.130, effective Aug. 28, 2006.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997 and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.140 Prescription Services by Pharmacists/ Pharmacies for Residents in Long-Term Care Facilities

PURPOSE: This rule establishes standards for pharmacists providing prescription services to residents in long-term care facilities. The standards are directed to licensed pharmacists and pharmacies, and not to long-term care facilities.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.

(1) Licensure. A pharmacist who or pharmacy which provides prescription services to a long-term care facility must be licensed to practice pharmacy in this state. A long-term care facility means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

(2) Medication Services.

(A) Policies and procedures shall be formulated to cover all packaging and dispensing responsibilities of the pharmacist/ pharmacy to the residents of the long-term care facility and shall include, at a minimum:

1. Methods used to dispense medications in a timely fashion to the facility;

2. Proper notification to the facility when a medication is not readily available;

3. Proper labeling requirements to meet the needs of the facility and which are consistent with state and federal laws; and

4. Appropriate medication destruction, return of unused medication, or both, which is consistent with state and federal laws.

(B) Container labeling, at all times, shall conform to Chapter 338, RSMo. If a label change is required to reflect a change in directions, the pharmacist personally shall affix the correct label to the container. However, direction change labels which are defined as indicator labels that notify long-term care facility personnel that a change in directions for medication has taken place, may be used and affixed to the container by nursing home personnel in a way as not to deface the original label. Labeling of unit dose packages may be distinguished from the requirements as set forth in section 338.059, RSMo by insuring that the drug name and strength, control number and expiration date and manufacturer's name appear on the package itself. A patient's name and directions may not have to appear directly on the medication container but a mechanism should exist to identify for the personnel administering medications, what medications each patient is to receive and the directions for administration.

(C) All prescription containers, including, but not limited to, single unit, unit dose and unit-of-use containers utilized for distribution within a long-term care facility shall meet minimum requirements as referenced by the *United States Pharmacopoeia* (USP) which is incorporated herein by reference. Where applicable, light-sensitive packaging shall be used.

(3) Any drug, repackaged or prepacked that is dispensed into a long-term care facility, as defined in section (1) of this rule, in other than the manufacturer's original container, shall bear the manufacturer's expiration date or twelve (12) months, whichever is less.

(4) Remote dispensing systems are defined as any system of an automated or manual design that is used to provide doses of medication to patients for the immediate administration by authorized health care personnel and is not licensed under Chapter 338, RSMo as a pharmacy. Any medication obtained in excessive amounts shall constitute the practice of pharmacy and will require adherence to all applicable licensure and drug laws.

(A) If personnel other than a pharmacist restocks a remote dispensing system, then any drugs or other items that are to be placed within a remote dispensing system must be checked and approved by a licensed pharmacist.

(B) Any products that are repackaged for use in a remote

dispensing system must comply with all provisions of 4 CSR 220-2.130.

(C) Appropriate security must be maintained over any remote dispensing system and there must be policies and procedures utilized in the delivery and storage of drugs and devices that deter misuse or theft.

(5) A prescription drug order is defined for the purpose of this rule 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. All prescription drug orders shall comply with 4 CSR 220-2.018.

(A) A prescription drug order may be transferred to a licensed pharmacy for the purpose of providing an order to prepare, compound or dispense a medication or for the purpose of providing drug or medical information for use by the pharmacist in providing patient care services.

(B) In order for a generic substitution as defined in section 338.056, RSMo to take place, a prescription drug order must either comply with the prescription form as defined in section 338.056.2(1), RSMo or provide an alternate method for documenting whether a generic substitution has been authorized as determined by the long-term care medical staff. When a generic substitution is authorized and is executed by the pharmacist a clear documentation must be completed in accordance with 4 CSR 220-2.018(1)(H) and 4 CSR 220-2.080(2)(M).

(C) A pharmacy may elect to maintain a separate file system for prescription drug orders that are dispensed. When a separate file is utilized, it must comply with all applicable laws governing the maintenance and use of a prescription file by a pharmacy and the numbering system used to number prescription drug orders must be distinct from any other prescription file that is maintained.

(D) Packaging and labeling of containers shall comply with all applicable state and federal laws for any medications that leave the facility or are provided to the patient by the pharmacy for use outside the facility. Prescription drug orders issued for use within the long-term care facility are not valid for refill outside the facility.

(6) Nothing in this rule shall be deemed to constitute a waiver or abrogation of any of the provisions of Chapter 338, RSMo or other applicable provisions of state and federal laws and rules, nor should this rule be construed as authorizing or permitting any person not licensed as a pharmacist to engage in the practice of pharmacy.

(7) The provisions of this rule are declared severable. If any portion of this rule is held invalid by a court of competent jurisdiction, the remaining provisions of this rule shall remain in full force and effect unless otherwise determined by the court.

AUTHORITY: sections 338.010, 338.210, 338.240 and 338.280, RSMo 1994 and 338.140, RSMo Supp. 1999. This rule originally filed as 4 CSR 220-2.140. Original rule filed Oct. 16, 1987, effective March 25, 1988. Amended: Filed July 5, 1988, effective March 1, 1989. Amended: Filed July 19, 1991, effective Jan. 13, 1992. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed July 28, 2000, effective Jan. 30, 2001. Moved to 20 CSR 2220-2.140, effective Aug. 28, 2006.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990; 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.210, RSMo 1951; 338.240, RSMo 1951; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.145 Minimum Standards for Multi-Med Dispensing

PURPOSE: This rule establishes standards for multi-med dispensing.

(1) In lieu of dispensing two (2) or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or a prescriber, provide a customized patient medication package (patient med pak).

(2) A patient med pak is a package prepared by a pharmacist for a specific patient comprising one (1) or more containers and containing two (2) or more prescribed solid oral dosage forms. The patient med pak is so designed or each container is so labeled as to indicate the day and time, or period of time, that the contents within each container are to be taken.

(A) The patient med pak shall bear a label stating –

1. The name of the patient;
2. A serial number for the patient med pak itself and a separate identifying serial number for each of the prescription orders for each of the drug products contained therein;
3. The name, strength, physical description or identification and total quantity of each drug product contained therein;
4. The directions for use and cautionary statements if any, contained in the prescription order for each drug product therein;
5. Any storage instructions or cautionary statements required by the official compendia;
6. The name of the prescriber of each drug product;
7. The date of preparation of the patient med pak and the beyond-use date assigned to the patient med pak (such beyond-use date shall be not later than ninety (90) 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 of the drug products contained therein.

(B) If the patient med pak allows for the removal or separation of the intact containers therefrom, each individual container shall bear a label identifying each of the drug products contained therein.

(C) The patient med pak shall be accompanied by a patient package insert, in the event that any medication therein is required to be dispensed with such insert as accompanying labeling. Alternatively, such required information may be incorporated into a single, overall, educational insert provided by the pharmacist for the total patient med pak.

(D) In the absence of more stringent packaging requirements for any of the drug products contained therein, each container of the patient med pak shall comply with the moisture permeation requirements for a Class B single-unit or unit-dose container. Each container shall be either not reclosable or so designed as to show evidence of having been opened.

(E) It is the responsibility of the dispenser, when preparing a patient med pak, to take into account any applicable compendia requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container, as well as any therapeutic incompatibilities that may attend the simultaneous administration of the

medications. In this regard, pharmacists are encouraged to report to United States Pharmacopeia (USP) headquarters any observed or reported incompatibilities.

(F) In addition to any individual prescription filing requirements, a record of each patient med pak shall be made and filed. Each record shall contain, at a minimum:

1. The name and address of the patient;

2. The serial number of the prescription order for each drug product contained therein;

3. The name of the manufacturer or labeler and lot number for each drug product contained therein;

4. Information identifying or describing the design, characteristics, or specifications of the patient med pak sufficient to allow subsequent preparation of an identical patient med pak for the patient;

5. The date of preparation of the patient med pak and the beyond-use date that was assigned;

6. Any special labeling instructions; and

7. The name or initials of the pharmacist who prepared the patient med pak.

(G) There is no special exemption for patient med paks from the requirements of the Poison Prevention Packaging Act. Thus the patient med pak, if it does not meet child-resistant standards, shall be placed in an outer package that does comply, or the necessary consent of the purchaser or physician to dispense in a container not intended to be child-resistant, shall be obtained.

(H) Once a patient med pak has been delivered to an institution or to a patient it shall not be returned to the pharmacy, unless the following requirements are met:

1. The med pak is returned to the pharmacy from which it was originally dispensed;

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 labeled in compliance with the requirements of this rule, provided the med pak shall retain the original beyond-use date assigned to the med pak before modification/repackaging;

4. The med pak is assigned a new serial number;

5. The medications removed from the med pak are destroyed in compliance with state and federal law. In no event shall medication removed from a med pak be returned to stock/inventory or dispensed to another patient; and

6. Licensees shall comply with all applicable record-keeping requirements.

(I) Multi-med paks may include controlled substances as allowed by, and in accordance with, state and federal controlled substance laws and regulations.

(J) Except as otherwise allowed in subsection (H) of this section, once a drug has been commingled with other drugs in a med pak the drug may not be returned to stock, dispensed, or distributed except for destruction purposes.

AUTHORITY: section 338.140, RSMo Supp. 2019, and section 338.280, RSMo 2016. This rule originally filed as 4 CSR 220-2.145. Original rule filed March 15, 2000, effective Sept. 30, 2000. Moved to 20 CSR 2220-2.145, effective Aug. 28, 2006. Amended: Filed Jan. 3, 2012, effective June 30, 2012. Amended: Filed Nov. 6, 2019, effective May 30, 2020.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019 and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.150 Mandatory Reporting Rule

PURPOSE: This rule defines the responsibilities of a director of pharmacy or the pharmacist-in-charge, or both, in a hospital or ambulatory surgical center in reporting disciplinary actions against pharmacist employees to the chief executive officer of the employing institution.

(1) Reports to the board from a hospital or ambulatory surgical center concerning any disciplinary action against a licensed pharmacist or the voluntary resignation of any licensed pharmacist against whom any complaints or reports have been made which might have led to final disciplinary action shall comply with section 383.133, RSMo and this rule and include at a minimum:

(A) The name, address, and telephone number of the person making the report;

(B) The name, address, and telephone number of the person who is the subject of the report;

(C) A brief description of the facts which gave rise to the issuance of the report, including the dates of occurrence deemed to necessitate the filing of the report;

(D) If court action is involved and known to the reporting agent, the identity of the court, including the date of filing and the docket number of the action;

(E) A statement as to what final action was taken by the institution; and

(F) That the report is being submitted in order to comply with the reporting provisions of Chapter 383, RSMo.

(2) Any activity that is construed to be a cause for disciplinary action according to section 338.055, RSMo or results in potential or actual harm to the public shall be deemed reportable to the board. This rule does not limit or prohibit any pharmacist from reporting a violation of the Pharmacy Practice Act directly to the Missouri Board of Pharmacy.

(3) The provisions of this rule are declared severable. If any portion of this rule is held invalid by a court of competent jurisdiction, the remaining provisions of this rule shall remain in full force and effect, unless otherwise determined by a court of competent jurisdiction.

AUTHORITY: section 383.133, RSMo 2016, and section 383.140, RSMo Supp. 2019. This rule originally filed as 4 CSR 220-2.150. Original rule filed Aug. 4, 1987, effective Jan. 29, 1988. Moved to 20 CSR 2220-2.150, effective Aug. 28, 2006. Amended: Filed May 13, 2019, effective Nov. 30, 2019.*

**Original authority: 383.133, RSMo 1986 and 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019.*

20 CSR 2220-2.160 Definition of Disciplinary Actions

PURPOSE: This rule defines disciplinary actions which may be imposed by the Missouri Board of Pharmacy.

(1) The Missouri Board of Pharmacy may publish or cause to be published all disciplines of certificates of registration or licenses or both, including the name of the licensee, the license number, the terms of discipline and a summary of the Findings of Fact and Conclusions of Law of the Administrative Hearing Commission, in any professional journal or newsletter read by licensed pharmacists practicing in Missouri or in any newspaper of general circulation or both.

(2) The Missouri Board of Pharmacy may publicize the terms of disciplinary agreements, including the name of the licensee, the license number and a summary of the complaint, in any professional journal or newsletter read by licensed pharmacists practicing in Missouri or in any newspaper of general circulation.

(3) Any licensee whose certificate of registration, license to practice pharmacy, or both, has been revoked or suspended shall –

(A) Surrender his/her certificate of registration or license, or both, to the Missouri Board of Pharmacy to be held by the Missouri Board of Pharmacy for the duration of the suspension period;

(B) Refrain from misrepresenting the status of his/her license to practice pharmacy to any patient or to the general public; and

(C) Refrain from maintaining a physical presence in any location which is licensed as a pharmacy in Missouri during the period of suspension, except as a customer.

(4) The Missouri Board of Pharmacy may impose any other terms or requirements which, in its discretion, it may deem necessary to enforce an order of discipline.

(5) Any violation of a disciplinary order shall constitute grounds for the Missouri Board of Pharmacy to impose further discipline or terms on the licensee's certificate of registration, license to practice pharmacy, or both.

(6) Any violation of a disciplinary agreement shall constitute grounds for the Missouri Board of Pharmacy to impose a further period of discipline unless the disciplinary agreement provides otherwise.

(7) If at any time when any disciplinary sanctions have been imposed under section 338.055, RSMo or under any provision, the licensee removes him/herself from Missouri, ceases to be currently licensed under the provisions of sections 338.010–338.310, RSMo or fails to keep the Missouri Board of Pharmacy advised of his/her current place of employment and residence, the time of his/her absence or unlicensed status or unknown whereabouts may, at the discretion of the board, not be deemed or taken as any part of the time of discipline so imposed.

(8) The provisions of this rule are declared severable. If any portion of this rule is held invalid by a court of competent jurisdiction, the remaining provisions of this rule shall remain in full force and effect, unless otherwise determined by a court of competent jurisdiction.

AUTHORITY: sections 338.140, RSMo Supp. 1998 and 338.280, RSMo 1994. This rule originally filed as 4 CSR 220-2.160. Original rule filed Oct. 1, 1987, effective March 11, 1988. Amended: Filed June 29, 1999, effective Jan. 30, 2000. Moved to 20 CSR 2220-2.160, effective Aug. 28, 2006.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1986 and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.165 Licensure Disciplinary Agreements

PURPOSE: This rule establishes guidelines to be used by the board for licensure disciplinary agreements.

(1) The board may elect to enter into an agreement for discipline with the holder of a pharmacist or pharmacy license for the purpose of informally resolving a complaint which the board has prepared.

(2) The use of licensure disciplinary agreements shall be subject to the following:

(A) Agreements of this type will be used at the option of the board and shall not bar the board from filing any complaints with the Administrative Hearing Commission in order to seek disciplinary action for any violation of Chapter 338, RSMo;

(B) All licensure disciplinary agreements shall contain a public notice clause which provides that the board will publish the licensing action in its quarterly newsletter and shall treat the information contained in the agreement as public information;

(C) When entering into a licensure disciplinary agreement, the board and the licensee shall waive any rights attendant to a hearing before the Administrative Hearing Commission and will consent that the licensure disciplinary agreement is in lieu of proceedings before the Administrative Hearing Commission; and

(D) If the board determines that a licensee has violated a term or condition of the agreement, or has otherwise failed to comply with the provisions of Chapter 338, RSMo, which violation would be actionable in a proceeding before the State Board of Pharmacy, the Administrative Hearing Commission, or in a circuit court, the board may elect to pursue any lawful remedies or procedures afforded to it.

(3) The provisions of this rule are declared severable. If any portion of this rule is held invalid by a court of competent jurisdiction, the remaining provisions of this rule shall remain in full force and effect unless otherwise determined by a court of competent jurisdiction.

AUTHORITY: sections 338.140, RSMo Supp. 1989 and 338.280, RSMo 1986. This rule originally filed as 4 CSR 220-2.165. Original rule filed Jan. 3, 1990, effective May 11, 1990. Amended: Filed July 19, 1991, effective Jan. 13, 1992. Moved to 20 CSR 2220-2.165, effective Aug. 28, 2006.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989 and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.170 Procedure for Impaired Pharmacist

PURPOSE: This rule establishes an efficient and timely process for the disposition of information and tentative board action concerning impaired pharmacists to the attorney general's office for purposes of preparing a complaint and streamlines the procedure utilized in interviewing pharmacists who are chemically impaired.

(1) The executive director shall receive information concerning the impairment of licensees and coordinate any investigations that seek to substantiate information concerning a possible impairment.

(2) Investigations by board inspectors or division investigators concerning chemically impaired licensees will be collected and reviewed by the executive director. Cases will be divided into two (2) categories.

(A) Category A. Chemically impaired licensees where additional information is evident that known distribution of

controlled substances or legend drugs to other individuals has taken place.

(B) Category B. Chemical impairment of a licensee where controlled substances, legend drugs or alcohol have been acquired for personal use only.

(3) Cases which fall into Category A will be referred to the board for appropriate action.

(4) Cases which fall within Category B will be subject to administrative review as a preliminary action to facilitate any corrective actions deemed necessary by the board.

(5) The following shall constitute office procedures involving Category B cases:

(A) Normal procedures for completing field investigations and assimilating other pertinent information will be followed;

(B) If the director believes that a case falls into Category B of this policy, s/he shall consult with the president of the board concerning the appropriateness of an administrative review;

(C) If approval by the president is given, the director shall take actions necessary to set up a meeting with the licensee who is the subject of the investigation. In addition, other individuals such as legal counsel for the board may be asked to attend, along with any staff member, as necessary;

(D) A statement concerning due process procedures and the rights of the licensee will be read at the beginning of the review meeting. A complete record of the administrative review meeting shall be maintained by the board office. Notice that the president of the board has been notified and that s/he has given approval for an administrative fact-finding meeting shall be entered into the record;

(E) A format during the fact-finding meeting will be followed that allows the licensee to provide a statement of his/her own as well as a question/answer period allowed to discuss the aspects of the case centering on the chemical impairment issues or on any related concerns about the individual's ability to practice pharmacy;

(F) After the fact-finding meeting is concluded, a summary will be provided to each member of the board within the appropriate agenda, along with recommendations from the director as to any action to be taken. In addition, the president will be contacted and provided any follow-up information that could warrant changes in administrative procedures. The president, by executive order, may initiate an affidavit to the board attorney of an intent to file a complaint with the Administrative Hearing Commission. Once an order is executed, the information on the case shall be forwarded to the attorney for necessary legal preparation; and

(G) The entire board shall consider the case in closed session as to whether or not to file a complaint against the licensee and consider the recommendations made as to terms. Once the board authorizes a complaint, the attorney for the board shall assure that the appropriate filings take place.

(6) When an impaired pharmacist is disciplined by the board and a term of the discipline is that s/he participate in a chemical dependence treatment program, the impaired pharmacist shall select a program which meets the following guidelines:

(A) Persons who are involved in the treatment or counseling of a Missouri board-licensed pharmacist must submit written documentation of their credentials and qualifications to provide treatment or counseling;

(B) A written agreement or contract must be provided and executed between the counselor(s) and the licensee, outlining the responsibilities of each party for a successful treatment and monitoring program. The agreement must include a provision for sharing information concerning all aspects of therapy between the treatment facility or counselors, or both, and the Missouri Board of Pharmacy;

(C) An initial evaluation report must be completed and provided to the board outlining the licensee's present state of impairment, the recommended course(s) of treatment, the beginning date of treatment and an assessment of future prospects for recovery;

(D) A copy of the proposed treatment plan must be provided to the board and must include a provision outlining the method of referral to an appropriate after-care program;

(E) The counselor(s) must provide progress reports to the board as follows:

1. Inpatient therapy – monthly reports;
2. Outpatient therapy – quarterly reports; and
3. After-care programs – semiannual reports;

(F) The treatment program must include randomized and witnessed body fluid testing and analysis, with any drug presence not supported by a valid prescription to be reported to the Missouri Board of Pharmacy;

(G) The treatment program must include a provision for reporting any violation of the treatment contract or agreement by the licensee to the board; and

(H) All reports outlined in this protocol must be provided in writing to the board for a counselor or treatment facility, or both, to be approved for the treatment of a licensee undergoing disciplinary board action.

AUTHORITY: sections 338.140, RSMo Supp. 1989 and 338.240, RSMo 1986. This rule originally filed as 4 CSR 220-2.170. Original rule filed Oct. 1, 1987, effective Jan. 14, 1988. Amended: Filed Nov. 15, 1988, effective March 11, 1989. Moved to 20 CSR 2220-2.170, effective Aug. 28, 2006.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989 and 338.240, RSMo 1951.*

20 CSR 2220-2.175 Well-Being Program

PURPOSE: This rule establishes guidelines for the operation of the Well-Being Committee, pursuant to section 338.380, RSMo.

(1) Definitions.

(A) Board – State Board of Pharmacy.

(B) Impairment – An illness, substance abuse, or physical or mental condition suffered by a licensee that is reasonably related to the ability to practice pharmacy.

(C) Licensee – Pharmacist, intern pharmacist, or technician licensed or registered in the state of Missouri or who has applied for licensure or registration in the state of Missouri.

(D) Well-Being Committee – The committee established pursuant to section 338.380, RSMo, authorized to create, operate, and maintain the Well-Being Program.

(E) Well-Being Program – The program operated by the Well-Being Committee for purposes of early identification, intervention, treatment, and rehabilitation of pharmacists, intern pharmacists, and pharmacy technicians who may be impaired by reasons of illness, substance abuse, or as a result of any physical or mental condition.

(2) The board may contract with a contractor for purposes of creating and operating the Well-Being Program. Operational costs of the Well-Being Program may be paid by the board,

subject to available funding. All costs of drug screens and professional and administrative services provided to a participant shall be paid by the participant, unless otherwise provided by the board.

(3) A participant may enter the Well-Being Program voluntarily or by referral of the board pursuant to a settlement agreement or other disciplinary order. Participants entering the Well-Being Program voluntarily shall be subject to and comply with all requirements of this rule. Each participant shall be financially responsible for all drug screens and any other professional or administrative service rendered on behalf of the participant.

(4) Well-Being Committee Duties.

(A) The committee shall oversee all aspects of the Well-Being Program including, but not limited to, program administration, staffing, financial operations, and case management. The committee shall provide services as needed to carry out the functions of section 338.380, RSMo, including, but not limited to:

1. Referring participants for appropriate assessment or evaluation and ensuring that treatment recommendations based on the assessment are followed as deemed appropriate by the board or committee;
2. Assisting the participant in obtaining evaluation and treatment;
3. Monitoring participant compliance with the contract between the committee and participant;
4. Monitoring the participant's compliance with the terms of any board disciplinary order/agreement;
5. Monitoring treatment progress and re-entry contractual compliance;
6. Managing/monitoring random drug screens;
7. Assisting participants to re-enter practice from treatment;
8. Assisting with aftercare issues or recommendations;
9. Program development;
10. Outreach education, as requested by the board by contract;
11. Managing, ensuring, and monitoring random and scheduled drug screens; and
12. Other necessary services as agreed by the board and committee.

(B) The committee shall enter into written contracts with each participant. Unless otherwise approved by the board, the contract between the committee and the participant shall be a minimum of five (5) years or the time designated by the board, and shall include, but shall not be limited to, the following conditions/requirements:

1. Each participant shall comply with all terms, conditions, or treatment identified, required, or recommended by the committee or the board for the treatment, evaluation, monitoring, or assessment of the participant;
2. Each participant shall abstain from the possession or consumption of legend medication, except as prescribed by a treating prescriber or approved by the committee;
3. Each participant shall abstain from possession and the consumption of alcohol, and the possession or consumption of illegal drugs;
4. Each participant shall submit to random drug testing unless otherwise specified by the board or committee;
5. Each participant shall enter treatment within forty-eight (48) hours following the committee's or an approved evaluator's determination that the participant needs treatment, unless otherwise approved by the board or committee;
6. Each participant shall report to the committee all relapses or other breaches of the contractual terms;
7. Each participant shall report to or meet with the board or committee, or a board or committee appointed designee, as may be requested by the board/committee;
8. Each participant shall attend support meetings as requested by the committee or treatment providers;
9. Each participant referred to the Well-Being Program by the board shall authorize the committee to release any and all information regarding the participant to the board;
10. Each participant voluntarily enrolled in the Well-Being Program shall authorize the committee to release any and all information or documents regarding the participant to the board upon a violation of any state or federal drug law or if the participant breaches or fails to comply with any terms of a Well-Being contract; and
11. Each participant shall be financially responsible for all drug screens and any other professional or administrative service rendered on behalf of the participant.

(5) Committee Administrator Duties.

(A) The Well-Being Committee shall appoint and designate a committee administrator for approval by the board. The committee administrator shall oversee and manage the daily operations of the committee and assist with committee administrative duties.

(B) The committee administrator shall possess a combination of education and experience in the area of addiction counseling and be currently licensed in Missouri as a psychologist, psychiatrist, professional counselor, or clinical social worker. Upon request of the committee, the board may waive the licensure requirements of this subsection for qualified applicants that otherwise possess an equivalent combination of education and experience, as required by this rule.

(C) The committee administrator shall also be familiar with licensees suffering from impairment issues which include, but shall not be limited to, the following:

1. Dependency;
2. Alcohol addiction;
3. Drug addiction;
4. Other addictive diseases;
5. Physical issues; and
6. Mental health issues.

(6) Voluntary Participants.

(A) Except as otherwise provided in this subsection, the identity of participants who voluntarily submit to the Well-Being Program shall remain anonymous to the board.

(B) The contractor shall file a Notice of Non-Compliance with the board against any voluntary participant who breaches or fails to comply with the terms of any Well-Being Program contract or who violates any state or federal drug law. The Notice of Non-Compliance must include the participant's name, license number, and the factual basis for the alleged contractual breach/non-compliance. The committee shall also supply to the board any information or documentation that supports or evidences the alleged non-compliance.

(7) Reporting.

(A) The committee shall provide to the board in writing –

1. An annual action plan and budget as directed by the board. The committee shall report on progress with regard to preparing and implementing the action plan and budget as requested by the board;
2. Progress reports with regard to each participant in or

being assisted by the Well-Being Program, provided the identity of participants who voluntarily submit to the Well-Being Program shall remain anonymous to the board for purposes of these reports, except as otherwise provided by this rule;

3. Participant treatment, evaluation, and rehabilitation records as requested by the board, except as otherwise provided by this rule;

4. Quarterly income and expense reports for the Well-Being Program or other financial report requested by the board regarding the operation of the Well-Being Program; and

5. Any other report or information requested by the board, except as otherwise provided by this rule for voluntary participants.

(B) Violation reporting. In addition to the other requirements of this rule, the committee shall report to the board in writing –

1. All participant violations of a board disciplinary order/agreement, any provision of Chapter 338, RSMo, or the board regulations, or any state or federal drug law, which occurs after the date of the disciplinary order/agreement or the date the participant entered the Well-Being Program, whichever occurs first;

2. Any participant who fails to enter treatment within forty-eight (48) hours following the committee's or an evaluator's determination that the participant needs treatment;

3. Any participant who does not comply with the terms of a Well-Being Program contract or who resumes the practice of pharmacy before an approved treatment provider or committee has made a clear determination that the licensee is capable of practicing; and

4. Any breach of contract by the Well-Being Committee or committee administrator.

(8) Confidentiality.

(A) Except as otherwise provided by this rule, the committee shall provide the board access to all information pertaining to each participant referred to the committee by the board.

(B) The board and committee may exchange privileged and confidential information, interviews, reports, statements, memoranda, and other documents including information on investigations, findings, conclusions, interventions, treatment, rehabilitation, and other proceedings of the board and committee, and other information closed to the public, as needed to effectuate section 338.380, RSMo, or to promote the identification, intervention, treatment, rehabilitation, and discipline (accountability) of participants who may be impaired.

(C) All privileged and confidential information and other information not considered to be public records or information pursuant to Chapter 610, RSMo, shall remain privileged and confidential and closed to the public after such information is exchanged.

AUTHORITY: section 338.140.1, RSMo Supp. 2022, and section 338.380, RSMo 2016. Original rule filed Aug. 18, 2009, effective March 30, 2010. Amended: Filed Jan. 6, 2023, effective July 30, 2023.*

**Original authority: 338.140.1, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019, and 338.380, RSMo 2007.*

20 CSR 2220-2.180 Public Records

PURPOSE: This rule establishes standards for compliance with Chapter 610, RSMo as it relates to public records of the State Board of Pharmacy.

(1) All public records of the State Board of Pharmacy will be open for inspection and copying by any member of the general public during normal business hours, holidays excepted, except for those records closed pursuant to section 610.021, RSMo. All public meetings of the Board of Pharmacy not closed pursuant to the provisions of section 610.021, RSMo will be open to any member of the public.

(2) The Board of Pharmacy establishes the executive director of the board as the custodian of its records as required by section 610.023, RSMo. The executive director is responsible for the maintenance of the board's records and is responsible for responding to requests for access to public records.

(3) When a request for inspection of public records is made and the individual inspecting the records requests copies of the records, the board will collect the appropriate fee for costs for inspecting and copying of the records, as outlined in the board's fee rule, 20 CSR 2220-4.100. The board may require payment of the fees prior to making available any public records.

(4) Written requests for access to records and responses to the requests will be maintained by the board as a public record for two (2) years. Such records will be open for inspection by any member of the general public during regular business hours, as required by state law.

AUTHORITY: sections 338.140 and 338.280, RSMo 2016, and Chapters 610 and 620, RSMo 2016 and Supp 2019. This rule originally filed as 4 CSR 220-2.180. Original rule filed Jan. 19, 1988, effective April 28, 1988. Amended: Filed June 26, 1995, effective Feb. 25, 1996. Moved to 20 CSR 2220-2.180, effective Aug. 28, 2006. Amended: Filed May 13, 2019, effective Dec. 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989 and 338.280, RSMo 1951, amended 1971, 1981. For Chapters 610 and 620, please consult the Missouri Revised Statutes.*

20 CSR 2220-2.190 Patient Counseling

PURPOSE: This rule establishes minimum standards for patient counseling to comply with the federal Omnibus Budget Reconciliation Act of 1990 which requires that all states establish standards by January 1, 1993.

(1) Upon receipt of a prescription drug order and following a review of the available patient information, a pharmacist or his/her designee shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of each patient. Counseling shall be conducted by the pharmacist or a pharmacy extern under the pharmacist's immediate supervision to allow the patient to safely and appropriately utilize the medication so that maximum therapeutic outcomes can be obtained. If the patient or caregiver is not available, then a written offer to counsel with a telephone number of the dispensing pharmacy at no cost to the patient must be supplied with the medication so that the patient or caregiver may contact the pharmacist for counseling when necessary. In situations where automated pick-up systems are used for providing refill prescriptions to patients, the offer to counsel may be provided within the information provided by the kiosk to the patient during the processing phase prior to release of the medication to the patient. The elements of

counseling shall include matters which the pharmacist deems significant in the exercise of his/her professional judgment and is consistent with applicable state laws.

(2) Pharmacies shall maintain appropriate patient information to facilitate counseling. This may include, but shall not be limited to, the patient's name, address, telephone number, age, gender, clinical information, disease states, allergies and a listing of other drugs prescribed.

(3) Alternative forms of patient information shall be used to supplement patient counseling when appropriate. Examples may include, but shall not be limited to, written information leaflets, pictogram labels, video programs, and the like.

(4) Patient counseling, as described in this rule, shall not be required for inpatients of a hospital, institution or other setting where other licensed or certified health care professionals are authorized to administer medications.

(5) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses consultation.

AUTHORITY: sections 338.140 and 338.280, RSMo 2000. This rule originally filed as 4 CSR 220-2.190. Original rule filed May 1, 1992, effective Feb. 26, 1993. Amended: Filed March 4, 1993, effective Oct. 10, 1993. Moved to 20 CSR 2220-2.190, effective Aug. 28, 2006. Amended: Filed Aug. 21, 2006, effective April 30, 2007.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997 and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.195 Prospective Drug Utilization Review

PURPOSE: This rule establishes requirements for prospective drug utilization review prior to dispensing a prescription or medication order.

(1) Prospective Drug Review.

(A) Prior to dispensing or otherwise approving medication for patient use, pharmacists shall use their professional judgment to review available patient records to assess therapeutic appropriateness.

(B) The pharmacist shall take appropriate steps within their professional judgment to address or resolve identified therapeutic appropriateness issues. Prospective drug review may only be performed by a pharmacist or an intern pharmacist working under the supervision of a Missouri licensed pharmacist.

AUTHORITY: sections 338.100 and 338.280, RSMo 2016, and sections 338.035 and 338.140, RSMo Supp. 2020. Original rule filed Sept. 1, 2020, effective Feb. 28, 2021.*

**Original authority: 338.035, RSMo 1990, amended 1993, 1995, 2007, 2020; 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999, 2010, 2016; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.200 Sterile Compounding

PURPOSE: This rule establishes standards for the handling, labeling, distribution, and dispensing of compounded sterile preparations by licensed pharmacies, pursuant to a physician's order or prescription.

PUBLISHER'S NOTE: The secretary of state has determined that publication of the entire text of the material that is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) Except as otherwise provided by law or the board's rules, the *United States Pharmacopeia–NF* (2023), General Chapter 797 Pharmaceutical Compounding – Sterile Preparations (www.usp.org), is incorporated by reference (hereafter "USP Chapter 797") and available at 12601 Twinbrook Parkway, Rockville, MD 20852. This rule does not incorporate any subsequent amendments or additions to USP Chapter 797. In the event of a conflict between USP Chapter 797 and Missouri law or board rules, Missouri law and board rules shall control. Except as otherwise provided by law or rule, licensees shall comply with all provisions of USP Chapter 797 and the additional requirements of this rule.

(A) The use of technologies, techniques, materials, or procedures other than those described in USP Chapter 797 are prohibited, unless the technology, technique, material, or procedure is validated in accordance with applicable provisions of USP Chapter 1223 and USP Chapter 1225 and is approved by the board in advance after submission of scientific data evidencing the specific technology, technique, material, or procedure is safe, effective, and meets or exceeds USP Chapter 797 requirements.

(B) The permit holder and pharmacist-in-charge (PIC) are responsible for ensuring compliance with state and federal law and USP Chapter 797, including ensuring compliance for activities delegated to a designated person, as defined by Chapter 797. Identification of a designated person as defined by USP Chapter 797 shall not exempt or modify any duty or responsibility of the permit holder or PIC under the board's rules or state and federal law.

(C) For purposes of this rule, compounding shall be defined as provided in USP Chapter 797, provided that compounded sterile preparations (CSPs) also includes –

1. Docking of proprietary bag and vial systems; and

2. Mixing, reconstituting, or preparing an FDA-approved manufactured sterile product in accordance with the manufacturer's approved labeling recommendations.

(D) The pharmacy must have current reference material(s) related to CSPs available, as applicable to the pharmacy's compounding activities.

(E) Except as otherwise provided herein, sterile compounding must also comply with 20 CSR 2220-2.400.

(F) USP Chapter 797, Section 21, and the exemption in USP Chapter 797, Section 1.1.2, governing allergen extracts are not incorporated in this rule and shall not be applicable.

(G) USP Chapter 797, Section 1.3, and the exemption in USP Chapter 797, Section 1.3, governing immediate use CSPs is not incorporated in this rule and shall not be applicable. Preparation of a vaccine for immediate administration pursuant to 20 CSR 2220-6.050 is not considered sterile compounding.

(H) The board recommends but does not require compliance with USP Chapter 800. In the interim, pharmacies that compound sterile hazardous drugs, as defined by lists maintained by National Institute for Occupational Safety and Health (NIOSH), are required to establish policies and procedures that include all aspects of handling hazardous

drugs, including but not limited to personal protective equipment, use and maintenance of appropriate primary engineering controls, transport, storage, labeling, disposal, spill control, compounding procedures, personnel training, and deactivating, decontaminating, cleaning, and disinfecting.

(I) Class E radiopharmaceutical pharmacies must comply with USP Chapter 825, 20 CSR 2220-2.500, and all applicable rules of the board for radiopharmaceutical activities.

(J) Unless otherwise provided by law or court of competent jurisdiction, the provisions of this rule are only applicable to pharmacy services under the jurisdiction of the board and are not applicable to hospital pharmacy services under the jurisdiction of the Missouri Department of Health and Senior Services pursuant to Chapter 197, RSMo.

(2) Personnel Education, Training, and Evaluation. Licensees shall comply with all USP Chapter 797 personnel education, training, and evaluation requirements.

(A) Individuals who fail an aseptic manipulation competency evaluation or a garbing and hand hygiene competency evaluation must undergo requalification through additional training by competent compounding personnel. The pharmacy must investigate such failure and take appropriate corrective actions prior to the individual resuming compounding. Corrective actions must be documented in the pharmacy's records.

(B) Required competency evaluation results can be transferred between facilities under common ownership or control of the same pharmacy or healthcare facility, provided the competency evaluation captured the most difficult and challenging conditions the individual will be performing and was completed within USP Chapter 797's required time frames. Pharmacies accepting transferred competency evaluation results under this section must maintain current and written policies and procedures governing the transfer of results. Licensees or registrants with transferred competency evaluation results must be trained on applicable pharmacy operational procedures as needed to ensure proper compounding and must be skilled and trained to accurately and competently perform the duties assigned.

(C) If needed to prevent interruptions in patient care during an emergency, a pharmacy may also accept the required competency evaluations from another pharmacy or hospital in lieu of the required initial competency evaluations, provided –

1. A pharmacist verifies the applicable competency evaluation complies with USP Chapter 797;

2. The pharmacy maintains documentation of the other pharmacy's or hospital's completed competency evaluation(s), including the dates and results. Additionally, the receiving pharmacy must maintain a manual or electronic copy of the other pharmacy's or hospital's policies and procedures on aseptic manipulation competency evaluations for board licensees or registrants;

3. The board licensee or registrant has received training on applicable pharmacy operational procedures as needed to ensure proper compounding. The licensee or registrant must be skilled and trained to accurately and competently perform the duties; and

4. Individuals may not assist with compounding under the emergency allowance authorized by this subsection for more than forty-five (45) days without the required competency evaluation by the pharmacy that complies with USP Chapter 797.

(3) Facilities and Equipment. The pharmacy shall establish and follow proper controls to ensure environmental quality, prevent environmental contamination, and maintain air quality in all International Organization for Standardization (ISO) classified areas, in addition to compliance with USP Chapter 797.

(A) To minimize impact on patient care, Class H sterile compounding pharmacies licensed on the effective date of this rule may petition the board for a waiver of USP Chapter 797 facility and equipment requirements if immediate compliance with USP Chapter 797 requirements cannot be completed despite the permit holder's due diligence or would result in an undue hardship or adversely impact patient care. Waivers may be effective for a time period designated by the board, provided all Class H sterile compounding pharmacies must comply with USP Chapter 797 facility and equipment requirements within two (2) years of the effective date of this rule.

(B) Certification of primary engineering controls (PECs)/ISO classified areas must be conducted by competent staff/vendors in accordance with USP Chapter 797 using recognized and appropriate certification and testing equipment. Certification results must be reviewed by a designated person as defined by USP Chapter 797. The individual's identity and date of review must be documented in the pharmacy's records. Deficiencies or failures that may impact preparation sterility or quality must be investigated and corrected prior to further compounding, which may include recertification of the PEC/ISO classified area.

(C) PECs, cleanroom suites, and segregated compounding areas (SCA) must be designed and maintained to minimize microbial contamination and maintain air quality. Cleaning and disinfecting supplies must be low-lint, including tool handles and holders. Additionally, dust-collecting overhangs, such as utility pipes, and ledges, such as windowsills, must be minimized. The pharmacy's policies and procedures must address selecting, handling, and monitoring of cleaning, disinfecting, and sporicidal agents to prevent/minimize equipment damage and decay and to ensure environmental quality and preparation integrity. The pharmacy must also have policies/procedures for inspecting the PECs, cleanroom suite, SCA, and equipment and correcting/repairing any damage, rust, or corrosion.

(D) For SCAs, the area within one (1) meter of the PEC must be dedicated only for sterile compounding (e.g., not storage, hand hygiene, donning and doffing garb, or other highly particle-generating activities such as patient care).

(4) Garbing and Hand Hygiene. The following requirements apply in addition to USP Chapter 797:

(A) For restricted-access barrier systems (RABS) as defined by USP Chapter 797, the RABS and the pharmaceutical isolator sleeves and gloves must be changed per the manufacturer's recommendations and as defined in the pharmacy's policies/procedures; and

(B) Disposable gloves must be worn inside the gloves attached to the RABS sleeves. Sterile gloves must be worn over the gloves attached to the RABS sleeve.

(5) Record Keeping.

(A) In addition to USP Chapter 797 requirements, the following must be documented/maintained for all sterile compounding:

1. Manufacturer manuals relied on to properly operate equipment;

2. Other facility quality control logs, as appropriate, including all maintenance, cleaning, and calibration records;

3. Sterilization records, if applicable;

4. Quarantine records, if applicable;

5. End-preparation evaluation and testing records; and

6. Ingredient validation records, if applicable (e.g.,

Certificate of Analysis).

(B) All records, policies/procedures and reports required by USP Chapter 797 or this rule must be maintained electronically or as a hard-copy for two (2) years and must be readily retrievable and subject to inspection by the board of pharmacy or its agents. At a minimum, records shall be physically or electronically produced immediately or within two (2) hours of a request from the board.

(C) In lieu of a compounding log as required by 20 CSR 2220-2.400, Class H pharmacies must maintain a compounding record for each preparation that complies with USP Chapter 797. The compounding record must include a prescription number or other readily retrievable unique identifier assigned for which the compound was dispensed.

(6) End-Preparation Evaluation.

(A) In addition to USP Chapter 797 requirements, the pharmacy must have a procedure for a pre-release check of the potency of the active ingredients in a CSP prepared from non-sterile active ingredients. The procedure shall include at least the following verifications by a pharmacist:

1. The lot of the active ingredients used for compounding have the necessary labeling, potency, purity, certificate of analysis, and other relevant qualities;

2. All weighings, calculations, volumetric measurements, and additions of ingredients were carried out properly; and

3. The compounding or control records include documentation that the fill volumes of all units available for release were checked and were correct.

(B) A CSP may be released for emergency dispensing pending test results, if approved by the prescriber. A separate authorization from the prescriber is required for each emergency dispensing. For purposes of this rule, emergency dispensing is defined as a situation where a preparation is necessary for immediate administration and no alternative product or preparation is available. Documentation of the emergency dispensing, the prescriber's approval, and the need for the emergency must appear within the prescription record.

(7) Microbiological Air and Surface Monitoring. The pharmacy shall establish and follow proper controls to ensure environmental quality, prevent environmental contamination, and maintain air quality in all ISO classified areas. Applicable environmental monitoring of air and surfaces must be conducted as required by USP Chapter 797. In addition to USP Chapter 797 requirements, microbiological air and surface monitoring/testing results must be promptly reviewed by a designated person as defined by USP Chapter 797. The reviewer's identity and date of review must be documented in the pharmacy's records. When conducted, routine surface sampling must be performed under dynamic conditions, but before the area has been cleaned and disinfected.

(8) Remedial Investigations. A remedial investigation is required 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. The remedial investigation must be documented and include resampling of all affected areas to ensure a suitable state of microbial control. The pharmacy must ensure that no misbranded, contaminated, or adulterated CSP is administered or dispensed for patient use.

(A) If an environmental monitoring sample taken from a PEC exceeds USP Chapter 797 action levels, the pharmacy must cease compounding in the affected PEC until resampling shows a suitable state of microbial control has been achieved in the PEC. However, a pharmacy may continue to compound during the remedial investigation if –

1. The affected PEC is cleaned and disinfected by using an Environmental Protection Agency (EPA) registered sterile cleaning, disinfecting, and sporicidal agent, or a combination thereof, followed by sterile isopropyl alcohol;

2. The beyond-use date assigned to all preparations is no greater than twelve (12) hours; and

3. The affected PEC is resampled under dynamic conditions. If the resampling exceeds USP Chapter 797 action levels, compounding must cease until resampling shows a suitable state of microbial control has been achieved in the PEC, unless otherwise authorized by the board or board's authorized designee to continue compounding upon showing the facility can be operated in a manner not to endanger the public health or safety.

(B) If an environmental monitoring sample taken from a buffer room exceeds USP Chapter 797 action levels, the pharmacy must cease compounding in the affected buffer room until resampling shows a suitable state of microbial control has been achieved in the buffer room. However, a pharmacy may continue to compound during the remedial investigation if –

1. The affected buffer room is cleaned and disinfected by using an EPA registered cleaning, disinfection, and sporicidal agents, or a combination thereof;

2. The beyond-use date assigned to all preparations is no greater than twenty-four (24) hours; and

3. The affected buffer room is resampled under dynamic conditions. If two (2) consecutive resamplings exceed USP Chapter 797 action levels, compounding must cease until resampling shows a suitable state of microbial control has been achieved in the affected room, unless otherwise authorized by the board or board's authorized designee to continue compounding upon a showing that the facility can be operated in a manner not to endanger the public health or safety.

(C) Pharmacies must notify the board in writing within three (3) business days if a resample is collected as part of a remedial investigation that exceeds USP Chapter 797 action levels.

(9) Recalls. A recall must be initiated when a dispensed CSP is deemed to be misbranded, adulterated, or non-sterile or if end-preparation testing results are out of specification. The pharmacy shall notify the prescriber of the nature of the recall, the problem(s) identified, and any recommended actions to ensure public health and safety. In cases where the CSP has the potential to harm the patient, the same notification must be provided to all patients that received the recalled CSP(s). Any recall initiated by a pharmacy shall be reported, in writing, to the board within three (3) business days. The pharmacy shall document their activities related to the recall.

AUTHORITY: sections 338.240 and 338.280, RSMo 2016, and sections 338.010 and 338.140, RSMo Supp. 2025. This rule originally filed as 4 CSR 220-2.200. Original rule filed May 4, 1992, effective Feb. 26, 1993. Amended: Filed Oct. 28, 1994, effective May 28, 1995. Rescinded and readopted: Filed Dec. 3, 2002, effective July 30, 2003. Moved to 20 CSR 2220-2.200, effective Aug. 28, 2006. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008. Emergency amendment filed July 25, 2016, effective Aug. 4, 2016, expired Feb. 23, 2017. Amended: Filed July 25, 2016, effective Jan. 30, 2017. Emergency amendment filed Aug. 20, 2018, effective Aug. 30, 2018, expired Feb. 28, 2019. Amended: Filed Aug. 20, 2018, effective Feb. 28, 2019. ** Emergency amendment filed April 14, 2021, effective April 28, 2021, expired Feb. 7, 2022. Amended: Filed April 14, 2021,*

effective Oct. 30, 2021. Emergency amendment filed Feb. 8, 2022, effective Feb. 24, 2022, expired Aug. 22, 2022. Amended: Filed Feb. 8, 2022, effective Aug. 30, 2022. Amended: Filed Dec. 12, 2025, effective July 30, 2026.

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019, 2021, 2023; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.240, RSMo 1951, amended 2011; and 338.280, RSMo 1951, amended 1971, 1981.*

***Pursuant to Executive Order 21-09, 20 CSR 2220-2.200, subsection (10)(B) was suspended from March 20, 2020 through December 31, 2021.*

20 CSR 2220-2.300 Record Confidentiality and Disclosure

PURPOSE: This rule establishes requirements for the confidentiality and disclosure of records related to patient care.

(1) Prescription records, physician orders, and other records related to any patient care or medical condition(s) of a patient that are maintained by a pharmacy in accordance with section 338.100, RSMo shall be considered confidential. Adequate security shall be maintained over such records in order to prevent any indiscriminate or unauthorized use of any written, electronic or verbal communications of confidential information.

(2) Confidential records may only be released to –

(A) The patient;

(B) A health care provider involved in treatment activities of the patient;

(C) Lawful requests from a court or grand jury;

(D) A person authorized by a court order;

(E) Any other person or entity authorized by a patient to receive such information;

(F) For the transfer of medical or prescription information between pharmacists as provided by law;

(G) Government agencies acting within the scope of their statutory authority; or

(H) A person or entity to whom such information may be disclosed under 45 CFR Parts 160, 164, and 165 (the Privacy Standards of the Health Insurance Portability and Accountability Act of 1996) or other applicable state/federal law.

(3) This rule does not change or otherwise alter the authority of the board, its inspectors, or other authorized designees to review, inspect, copy, or take possession of any such records.

(4) Methods to access, transmit, store, analyze, or purge confidential information shall be implemented using procedures generally recognized as secure by experts qualified by training and experience. Procedures shall be in place to ensure that purged confidential information cannot be misused or placed into active operation without appropriate authorization as provided in this rule. Internet connectivity or remote access tied directly to systems containing confidential information must be secure.

AUTHORITY: sections 338.100 and 338.280, RSMo 2016, and section 338.140, RSMo Supp. 2019. This rule originally filed as 4 CSR 220-2.300. Original rule filed May 4, 1995, effective Dec. 30, 1995. Rescinded and readopted: Filed Nov. 1, 2000, effective June 30, 2001. Amended: Filed Dec. 15, 2003, effective July 30, 2004. Moved to 20 CSR 2220-2.300, effective Aug. 28, 2006. Amended: Filed May 13, 2019, effective Nov. 30, 2019.*

**Original authority: 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999, 2010, 2016; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.400 Compounding Standards of Practice

PURPOSE: This rule defines compounding and establishes guidelines for the compounding of drugs.

(1) Compounding is defined 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 may also be defined as 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.

(2) Manufacturing is defined as the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substance(s) or labeling or relabeling of its container, and the promotion and marketing of such drugs or devices.

(3) Batch compounded preparation is defined as a preparation compounded in advance of receipt of a prescription or a preparation compounded in a supply that will be used on more than one (1) dispensing to a patient or patients or any preparation compounded in excess of the filling of an individual prescription. A batch is a specific quantity of preparation compounded in a single, discrete process, by the same individuals, carried out during one (1) limited time period.

(4) Beyond-use date: A date after which a compounded preparation should not be used and is determined from the date the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their beyond-use dates must be assigned based on criteria different from those applied to assigning expiration dates to manufactured drug products.

(5) Compounding Area and Equipment Requirements.

(A) The area(s) used for compounding preparations shall be maintained in a sanitary condition and shall be free of infestation by insects, rodents, and other vermin. Trash shall be held and disposed of in a timely and sanitary manner.

(B) If drug products with special precautions for contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its return to inventory, must be utilized in order to prevent cross-contamination.

(C) Equipment used in compounding preparations shall be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in compounding preparations shall be of suitable composition so that surfaces that contact ingredients, in-process materials, or compounded preparations shall not be reactive, additive, or absorptive so as to alter the

safety, identity, strength, quality, or purity of the compounded preparation beyond that desired.

(6) Proper controls shall be maintained over drug products/ingredients, containers, and container closures.

(A) Bulk drugs and other materials used in compounding preparations must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.

(B) Pharmacists shall only receive, store, or use drug substances for compounding that have been made and/or distributed by Missouri licensed/registered drug distributors. A bulk drug substance for human use that is not the subject of an applicable United States Pharmacopeia or National Formulary monograph or is not a component of a Federal Drug Administration (FDA) approved drug cannot be used in compounding unless it appears on a list promulgated as a regulation pursuant to section 503A(b)(1)(A)(i)(III) of the Federal Food, Drug, and Cosmetic Act, except as otherwise allowed by the FDA.

(C) Pharmacists shall only use nondrug substances for compounding that are free of any contaminants and which maintain full potency.

(D) Drug products/ingredients, containers, and container closures used in compounding of preparations shall be handled and stored in a manner to prevent contamination.

(E) Drug products/ingredient containers and container closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded preparation beyond the desired result. Container systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded preparation.

(7) Appropriate quality control measures shall be maintained by the pharmacy and its staff over compounding methods.

(A) Such methods shall include the following and shall be followed in the execution of the compounding process. A separate log shall be maintained which includes –

1. Methods for compounding preparations to ensure that finished preparations have the identity, strength, quality, and purity they purport or are represented to possess;

2. Date of compounding;

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 the order of drug product/ingredient addition, if necessary for proper compounding;

6. The identity of 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. An identifying prescription number or a readily retrievable unique identifier for which the compound was dispensed.

(B) Information related to and the methods of compounding shall be available upon request.

(C) Pharmacists may compound preparations in limited quantities prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely with an established pharmacist/patient/prescriber relationship.

1. Except as otherwise provided by law, compounding preparations in anticipation of receiving prescriptions without an appropriate history of such prescriptions on file or a documented need shall be considered manufacturing instead of compounding of the drug(s) involved. Limited quantities, for purposes of this rule, are further defined as an amount of batched preparation that represents a three- (3-) month supply.

2. Creams, ointments, lotions, liniments, or other compounded preparations intended for external use may be batched in the same manner as provided for in paragraph (7)(C)1. of this rule that represents a one- (1-) year supply.

(D) Any excess compounded preparations shall be stored and accounted for under conditions dictated by its composition and stability characteristics to ensure its strength, quality, and purity. Excess preparations shall be labeled with the name of the drug(s), an in-house lot number, and beyond-use date.

(E) Records as outlined in this rule shall be retained and made readily retrievable for inspection for two (2) years from the date of compounding.

(F) The actual name of each active or therapeutic ingredient contained in a compound shall be listed on the container of any compounded preparation provided to a consumer.

(8) Management of Compounding.

(A) A pharmacist dispensing a compounded preparation is responsible for ensuring the preparation has been prepared, labeled, controlled, stored, dispensed, and distributed properly. The pharmacist is responsible for ensuring that quality is built into the preparation and ensuring –

1. Personnel are capable and qualified to perform their assigned duties;

2. Ingredients used in compounding have their expected identity, quality, and purity. Drug components must meet compendial standards or maintain a certificate of analysis on file when bulk drug substances are involved. Visual inspection of bulk drug substances must be performed;

3. Reasonable assurance that processes are always carried out as intended or specified;

4. Preparation conditions and procedures are adequate for preventing mix-ups or other errors; and

5. All finished preparations, as a condition of release, are individually inspected for evidence of visible particulates or other foreign matter and for container-closure integrity and any other apparent visual defects.

(B) The pharmacy is responsible for developing a drug monitoring system for compounded preparations. The outcome monitoring system shall provide readily retrievable information suitable for the evaluation of the quality of pharmaceutical services including but not limited to reported infection rates, incidence of adverse drug reactions, incidence of recalls, and complaints from prescribers or clients.

(C) A recall must be initiated when a compounded preparation is deemed to be misbranded or adulterated. The pharmacy shall notify the prescriber of the nature of the recall, the problem(s) identified, and any recommended actions to ensure public health and safety.

1. In cases where the compounded preparation has the potential to harm the patient, the same recall notification as provided for in this subsection shall be provided to all patients that have received the recalled compounded preparation(s).

2. Any recall initiated by a pharmacy shall be reported, in writing, to the board within three (3) business days.

(9) The compounding of a preparation that is a copy or essentially a copy of a commercially available product is prohibited except when there is a specific medical need for a particular variation of a commercially available compound for an individual patient as determined by the prescriber, or

when a change or modification for a specific patient would produce for that patient a clinically significant difference between the compounded preparation and the comparable commercially available drug product, as determined by the prescribing practitioner. Documentation from the prescriber of the specific medical need or clinically significant difference for a specific patient must be maintained in the pharmacy's records. A prescription that identifies only a patient name and compounded preparation formulation is insufficient documentation for a pharmacy to rely upon to conclude that the prescriber made a determination regarding a specific medical need or clinically significant difference. A different formulation without a documented specific medical need or clinically significant difference is not sufficient.

(A) For purposes of this rule, "essentially a copy of commercially available product" is a compounded preparation that has –

1. The same active pharmaceutical ingredient(s) as the commercially available drug product;
2. The same, similar, or an easily substitutable dosage strength; and
3. The same manner of administration as the commercially available drug product.

(B) For purposes of this rule, "easily substitutable" means the same or similar dosage strength can be achieved by administration of fractional or multiple doses of a commercially available drug product.

(C) When compounding an otherwise commercially available product due to a drug shortage, the pharmacy must confirm and document the commercially available product is not available despite due diligence.

(10) Any alteration, change, or modification to the contents of a commercially manufactured over-the-counter product shall require a prescription or prescription drug order from an authorized prescriber. The compounding of any preparation without a prescription or medication order is prohibited.

(11) Any person shown at any time, either by medical examination or pharmacist determination, to have an apparent illness or open lesion(s) that may adversely affect the safety or quality of a compounded preparation shall be excluded from direct contact with compounded preparations/ingredients, drug product containers, container closures, and in-process materials until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the compounded preparation.

(12) Except as provided by law, pharmacists shall not offer or provide compounded preparations to other pharmacies, practitioners, or entities for subsequent dispensing, distribution, resale, or administration, except in the course of professional practice for a prescriber to administer to an individual patient by a prescription dispensed by the pharmacy. A pharmacist or pharmacy may advertise or otherwise provide information concerning the provision of compounding services; however, no pharmacist or pharmacy shall attempt to solicit business by making specific claims about compounded preparations.

(13) Pharmacies may provide non-patient specific compounded preparations for veterinary use to a Missouri-licensed veterinarian to administer and dispense to the veterinarians's animal patients, provided the following:

(A) The preparation container is labeled with –

1. Pharmacy name, address, and telephone number;
2. Date of distribution;
3. Veterinarian's name;
4. Preparation name, strength, dosage form, and quantity;
5. Name of each active or therapeutic ingredient included in the preparation;
6. Preparation lot/batch number;
7. Preparation beyond-use date; and
8. Statement: "Office Stock Compounded Preparation";

(B) The pharmacy maintains a record of the distribution to the veterinarian;

(C) The pharmacy can retrieve distribution records by specific veterinarian, if requested;

(D) In lieu of paragraph (7)(A)7., the veterinarian's name may be recorded on the compounding log; and

(E) The pharmacy complies with all applicable controlled substance laws and regulations.

(14) In addition to the requirements outlined in this rule, all standards and requirements as outlined in 20 CSR 2220-2.200, Sterile Compounding, must be adhered to whenever compounding involves the need for asceptic procedures or requires the use of or results in an intended sterile pharmaceutical preparation.

AUTHORITY: sections 338.010 and 338.140, RSMo Supp. 2022, and sections 338.240 and 338.280, RSMo 2016. This rule originally filed as 4 CSR 220-2.400. Original rule filed Aug. 25, 1995, effective April 30, 1996. Amended: Filed Dec. 3, 2002, effective July 30, 2003. Moved to 20 CSR 2220-2.400, effective Aug. 28, 2006. Emergency amendment filed March 20, 2019, effective March 30, 2019, expired Jan. 8, 2020. Amended: Filed March 20, 2019, effective Sept. 30, 2019. Amended: Filed March 10, 2023, effective Sept. 30, 2023.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019, 2021; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.240, RSMo 1951, amended 2011; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.410 Class B Hospital Pharmacy Compounding for Drug Shortages

PURPOSE: This rule establishes requirements for Class B hospital pharmacies compounding medication in the event of a drug shortage.

(1) Class B hospital pharmacies may compound and provide medications that are in shortage to patients without a patient-specific prescription, provided –

(A) The pharmacy has confirmed and documented the product is not available despite due diligence;

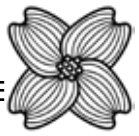
(B) The medication is compounded for administration to patients in a hospital clinic or facility or in another hospital that is under common control, management, or ownership of the same hospital or hospital system, as defined by section 338.165, RSMo;

(C) The preparation compounded is the same dosage form and strength that is in shortage;

(D) The quantity distributed at one time does not exceed the amount needed to meet the anticipated healthcare practitioner need for seven (7) days based on the hospital's or hospital clinic's/facility's usage;

(E) The pharmacy must stop compounding and distribution once the product is available;

(F) The pharmacy must label the preparation container with –



1. Pharmacy name, address, and telephone number;
2. Date of distribution;
3. Preparation name, strength, dosage form, and quantity;
4. Name of each active or therapeutic ingredient included in the preparation;
5. Preparation lot/batch number;
6. Preparation beyond-use date; and
7. Statement: "Pharmacy Compounded Preparation";

(G) The pharmacy maintains a record of the distribution that is readily available on request of the board or the board's authorized designee and can be retrieved by specific hospital or hospital clinic or facility, if requested;

(H) In lieu of recording an identifying prescription number or a readily retrievable unique identifier, the hospital or hospital clinic or facility name must be recorded on the compounding log;

(I) The pharmacy must comply with all applicable provisions of 20 CSR 2220-2.400. A Class H license and compliance with 20 CSR 2220-2.200 is required for any sterile preparation; and

(J) The pharmacy complies with all applicable controlled substance laws and regulations.

(2) Unless otherwise provided by law or court of competent jurisdiction, the provisions of this rule are only applicable to pharmacy services under the jurisdiction of the board and are not applicable to hospital pharmacy services under the jurisdiction of the Missouri Department of Health and Senior Services pursuant to Chapter 197, RSMo.

AUTHORITY: sections 338.140.1 and 338.210, RSMo Supp. 2022, and section 338.280, RSMo 2016. Original rule filed March 10, 2023, effective Sept. 30, 2023.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.210, RSMo 1951, amended 2001, 2011, 2020; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.425 Required Pharmacy Reporting

PURPOSE: The purpose of this rule is to establish requirements for reporting compounding information to the Missouri Board of Pharmacy to ensure compliance with state and federal law.

(1) Pharmacies located in Missouri that have distributed or dispensed compounded human drug preparations/products pursuant to prescriptions or medication orders in the previous calendar year, shall annually report the following information on a form provided by the board:

(A) The number of prescriptions or medication orders for compounded human drug preparations/products that the pharmacy distributed or dispensed interstate during the previous calendar year;

(B) The number of prescriptions or medication orders for compounded human drug preparations/products that the pharmacy dispensed (or caused to be dispensed) from the facility in which the drug preparations/products were compounded during the previous calendar year (e.g., not picked up on-site by the patient or the patient's designee);

(C) The number of prescription or medication orders for compounded human drug preparations/products dispensed on-site at the pharmacy during the previous calendar year (e.g., picked up by the patient or the patient's designee);

(D) The sum of the figures from subsections (1)(B) and (1)(C) above; and

(E) The quotient from dividing the figure in subsection (1)(A) by the figure from subsection (1)(D).

(2) If the figure in subsection (1)(E) is greater than five tenths (0.5), the pharmacy shall also report the following information:

(A) The total number of prescription or medication orders for sterile compounded human drugs distributed or dispensed interstate during the previous calendar year;

(B) A list of the states where the pharmacy was licensed during the previous calendar year; and

(C) A list of the states into which the pharmacy distributed compounded human drug preparations/products during the previous calendar year.

(3) The required information shall be reported no later than January 31, each calendar year.

(4) The term "prescription or medication orders for compounded human drug preparations/products" as used above, does not include veterinary drug products, and biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262).

(5) Notwithstanding the above, a pharmacy which participates in and reports all information required by this rule to the National Association of Boards of Pharmacy (NABP) Information Sharing Network shall not be required to also report to the board. Pharmacies reporting to NABP's Sharing Network shall notify the board no later than January 31 each calendar year that information required by this rule has been reported to NABP. A copy of information submitted to NABP pursuant to this rule shall be provided to the board or the board's authorized designee within five (5) business days of a request from the board or authorized board designee.

AUTHORITY: sections 338.010 and 338.140, RSMo Supp. 2020, and sections 338.240 and 338.280, RSMo 2016. Original rule filed Jan. 7, 2021, effective July 30, 2021.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.240, RSMo 1951, amended 2011; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.450 Fingerprint Requirements
(Rescinded August 30, 2013)

AUTHORITY: sections 338.140 and 338.280, RSMo 2000. This rule originally filed as 4 CSR 220-2.450. Original rule filed Jan. 6, 1997, effective July 30, 1997. Amended: Filed April 23, 1998, effective Nov. 30, 1998. Moved to 20 CSR 2220-2.450, effective Aug. 28, 2006. Amended: Filed Aug. 21, 2006, effective April 30, 2007. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008. Rescinded: Filed Jan. 10, 2013, effective Aug. 30, 2013.

20 CSR 2220-2.500 Nuclear Pharmacy – Minimum Standards for Operation

PURPOSE: This rule defines minimum standards for the operation of nuclear pharmacies and the preparation, labeling, dispensing, delivering, compounding, and repackaging of radiopharmaceuticals pursuant to a prescription drug or medication order. This regulation is intended to supplement other regulations of the Board of Pharmacy, as well as those of other state and/or federal agencies.

(1) Definitions.

(A) "Agreement state" (AS) means any state that has entered into an agreement under subsection 274b of the Atomic Energy Act of 1954, as amended, in which the United States Nuclear Regulatory Commission (NRC) has relinquished to such states the majority of its regulatory authority over source material, by-product, and special nuclear material in quantities not sufficient to form a critical mass.

(B) "Authorized address or location" means the building or buildings that are identified on the license and where by-product material may be received, prepared, used, or stored as defined by 10 CFR 35.2 or a temporary job site for providing mobile nuclear medicine services in accordance with 10 CFR 35.80.

(C) "Authorized nuclear pharmacist" (ANP) means an authorized nuclear pharmacist as defined by USP Chapter 825.

(D) "Class E: Radiopharmaceutical pharmacy" (also referenced herein as a "nuclear pharmacy") means the location where radiopharmaceuticals are prepared, compounded, repackaged, dispensed, distributed, or stored. A Class E pharmacy does not include the nuclear medicine facilities of hospitals or clinics where radiopharmaceuticals are compounded, dispensed, or administered to patients under the supervision of a licensed physician, authorized by the NRC/AS regulations. Nothing in this rule shall be construed as requiring a licensed clinical laboratory, which is also licensed by the NRC/AS to handle radioactive materials, to obtain the services of an ANP, or to have a Class E pharmacy permit, unless the laboratory is engaged in the commercial sale or resale of radiopharmaceuticals.

(E) "Contingency prescription drug order" means a radiopharmaceutical prescription drug order issued for contingency material for a diagnostic purpose.

(F) "Designated person" means a designated person as defined by USP Chapter 825.

(G) "NRC" means the United States Nuclear Regulatory Commission.

(H) "Nuclear pharmacy technician" means a person who has successfully completed a nuclear pharmacy technician training program provided by an accredited college program or meets the American Pharmacist's Association's (APhA) Guidelines for Nuclear Pharmacy Technician Training Program or an equivalent company sponsored program that meets APhA guidelines for nuclear pharmacy technician training.

(I) "Prescription drug order" means an order issued by an authorized prescriber for a specific patient for a diagnostic or therapeutic purpose.

(J) "Radiopharmaceutical" means a radiopharmaceutical as defined by USP Chapter 825.

(K) "Segregated radiopharmaceutical processing area" (SRPA) means a segregated radiopharmaceutical processing area as defined by USP Chapter 825.

(L) "Therapeutic prescription drug order" means a radioactive prescription drug order issued for a specific patient for a therapeutic purpose.

(M) "USP Chapter 825" means the United States Pharmacopeia–NF (2023), General Chapter 825 Radiopharmaceuticals — Preparation, Compounding, Dispensing, and Repackaging (Jan. 1, 2024; DOI: https://doi.org/10.31003/USPNF_M11915_05_01), which is incorporated by reference, except as otherwise provided by law or the board's rules, and available at 12601 Twinbrook Parkway, Rockville, MD 20852 or at www.usp.org. This rule does not incorporate any subsequent amendments or additions to USP Chapter 825. In the event of a conflict between USP Chapter 825 and Missouri law or board rules, Missouri law and board rules shall control.

(2) Except as otherwise provided by law or rule, licensees shall comply with all provisions of USP Chapter 825 and the additional requirements of this rule.

(A) No person may receive, acquire, possess, prepare, compound, dispense, repackage, store, distribute, dispose of, or manufacture for sale or resale any radiopharmaceutical except in accordance with accepted standards of nuclear pharmacy practice and applicable state/federal law, USP Chapter 825, and the rules/regulations promulgated by the NRC or applicable AS. Only an ANP or nuclear pharmacy technician, or a licensed pharmacist, intern pharmacist, or pharmacy technician in training under the supervision of an ANP may prepare, compound, repackage, or dispense radiopharmaceuticals.

(B) Unless otherwise provided by law or court of competent jurisdiction, the provisions of this rule are only applicable to pharmacy services under the jurisdiction of the board and are not applicable to hospital pharmacy services under the jurisdiction of the Missouri Department of Health and Senior Services pursuant to Chapter 197, RSMo.

(C) Unless otherwise required by federal law, Class E pharmacies are exempt from the required pharmacy reporting requirements in 20 CSR 2220-2.425 for dispensing/preparation of radiopharmaceuticals.

(D) The use of technologies, techniques, materials, or procedures other than those described in USP Chapter 825 and Chapter 71 are prohibited, unless the technology, technique, material, or procedure is validated in accordance with applicable provisions of USP Chapter 1223 and USP Chapter 1225 and is approved by the board in advance after submission of scientific data evidencing the specific technology, technique, material, or procedure is safe, effective, and meets or exceeds USP Chapter 825 and Chapter 71 requirements.

(E) A Class E pharmacy must have on file a copy of the active NRC/AS radioactive materials license for the licensed facility requesting any radiopharmaceutical prior to dispensing to that facility. The radiopharmaceutical may only be delivered to the authorized addresses or locations listed in, or temporary job sites as authorized by, the NRC/AS license. The authorized physician ordering radiopharmaceuticals is hereby recognized as the patient's authorized designee for delivery purposes.

(F) Compounding of sterile radiopharmaceutical preparations involving one (1) or more non-sterile components must comply with USP Chapter 797, Section 10 (Sterilization and Depyrogenation).

(G) The immediate use exemptions/modifications in USP Chapter 825, Section 3 (Immediate Use of Sterile Radiopharmaceuticals), Section 4.4. (Hand Hygiene and Garbing for Immediate Use Preparations), and Section 10.4 (Preparation of Radiolabeled Red Blood Cells for Immediate Use) are not adopted or incorporated in this rule.

(H) Preparation/compounding of positron emission tomography (PET) drugs that are not manufactured as United States Food and Drug Administration (FDA) approved drug products must comply with USP Chapter 823.

(I) Class E pharmacies shall comply with any applicable local, state, and federal requirements regarding its daily operations and the disposal of any biohazardous medical waste. Appropriately labeled and, when required, shielded disposal containers shall be used for radioactive and biohazardous waste from the preparation or the return of radiopharmaceuticals.

(J) Any reusable outer shielding container that is returned shall be considered to be contaminated. No pharmacy shall use reusable outer shielding containers for radioactive doses without either an effective process to decontaminate the container of biohazardous and radioactive substances or an effective mechanism to avoid contamination of the container.

No pharmacy may reuse an outer shielding container that remains contaminated with blood, radiation, or other biohazardous substances.

(K) A Class E pharmacy may accept returns and waste as authorized by NRC/AS regulations.

(3) Permits. All Class E pharmacies must hold a Class E radiopharmaceutical permit issued by the board. The appropriate pharmacy permit classification is required for any pharmacy activities that occur at the Class E site other than Class E services. An additional Class D permit is not required to compound non-sterile radiopharmaceuticals. An additional Class H permit is not required to compound sterile radiopharmaceuticals.

(A) The pharmacist-in-charge (PIC) of a Class E pharmacy must be an ANP. The permit holder and PIC are responsible for ensuring compliance with state and federal law and USP Chapter 825, including ensuring compliance for activities delegated to a designated person. Identification of a designated person shall not exempt or modify any duty or responsibility of the permit holder or PIC under the board's rules or state and federal law.

(B) A permit to operate a Class E pharmacy shall only be issued to a person who is, or who employs/contracts with, an ANP. All personnel performing tasks in the preparation, compounding, dispensing, repackaging, or distribution of radiopharmaceuticals and ancillary drugs/materials must be under the direct supervision of an ANP.

(C) The permit to operate a Class E pharmacy is effective only if the pharmacy also holds a current NRC and/or AS radioactive materials license. Copies of the most recent regulatory inspection reports must be made available upon request to the board for inspection.

(D) Class E pharmacies shall post in a conspicuous area of the pharmacy a copy of its Class E permit and a copy of the most current NRC or applicable AS license. A reference to the specific location of the NRC/AS license within the pharmacy is acceptable.

(E) The PIC shall notify the Board of Pharmacy of the outcome of any hearings under state or federal laws or regulations governing radiopharmaceuticals involving or against the pharmacy location licensed by the board. Notification must be made electronically or in writing within thirty (30) calendar days of the date of the outcome.

(4) Space, Security, Recordkeeping, and Equipment. Class E pharmacies must establish and follow proper controls to ensure environmental quality and prevent environmental contamination, including maintaining air quality in all primary engineering controls (PEC) and ISO classified areas. In addition to USP Chapter 825 requirements, microbiological air and surface monitoring/testing results must be promptly reviewed by a designated person. The reviewer's identity and date of review must be documented in the pharmacy's records.

(A) Class E pharmacies shall have adequate space and equipment for the scope of services provided consistent with USP Chapter 825 and as required by the NRC/AS license.

(B) Certification of PECs/ISO classified areas must be conducted by competent staff/vendors using recognized and appropriate certification and testing equipment. Certification results must be reviewed by a designated person. The individual's identity and date of review must be documented in the pharmacy's records. Deficiencies or failures that may impact preparation sterility or quality must be investigated and corrected prior to further preparation/compounding in the affected PEC/ISO classified areas, which may include recertification of the PEC/ISO classified area.

(C) PECs, secondary engineering controls (SECs), and SRPAs must be designed and maintained to minimize microbial contamination and maintain air quality. Cleaning and disinfecting supplies must be low-lint, including tool handles and holders. Additionally, dust-collecting overhangs, such as utility pipes, and ledges, such as windowsills, must be minimized. The pharmacy's policies and procedures must address selecting, handling, and monitoring of cleaning, disinfecting, and sporicidal agents to prevent/minimize equipment damage and decay, and to ensure environmental quality and preparation integrity. The pharmacy must also have policies/procedures for inspecting the PEC, SEC, SRPA, and equipment and correcting/repairing any damage, rust, or corrosion.

(D) Cleaning and disinfecting of surfaces in the PECs, ISO classified areas, and the SRPA must occur at the minimum frequencies specified in USP Chapter 825, Table 5 (Minimum Frequency for Cleaning and Disinfecting Surfaces in Classified Areas and within the Perimeter of the SRPA) or, if activities are not performed daily, cleaning and disinfecting must be completed before use. The walls, bars, torso shield, and any exposed surface of equipment inside the PEC must be cleaned to the extent possible, in accordance with manufacturer recommendations. All cleaning, disinfecting, and sporicidal agents used in the PEC must be sterile.

(E) For non-sterile radiopharmaceutical preparations under USP Chapter 825, Section 10.1 (Preparation Following Manufacturer Instructions), the preparation area must be suitably cleaned and uncluttered to ensure the overall integrity and quality of prepared radiopharmaceutical(s).

(F) Class E pharmacies must maintain records of acquisition, inventory, preparing, compounding, repackaging, dispensing, and distribution of all radioactive and non-radioactive drugs/materials in accordance with State Board of Pharmacy and NRC/AS rules/requirements. In addition to USP Chapter 825 requirements, the following must also be documented/maintained:

1. Manufacturer manuals relied on to properly operate equipment;
2. Other facility quality control logs, as appropriate, including all maintenance, cleaning, and calibration records;
3. Sterilization records, if applicable;
4. Quarantine records, if applicable;
5. End-preparation evaluation and testing records, if applicable;
6. Ingredient validation records, if applicable (e.g., Certificate of Analysis); and
7. Documentation of aseptic competency qualification(s) and required media fills, including the name of the person evaluated, qualification/testing dates and results, media and components used, including manufacturer, expiration date and lot number, monitoring of incubation temperatures, and dates of incubation. For temperature monitoring, a continuous temperature monitoring system may be used if the system maintains ongoing documentation of temperature recordings and alerts a pharmacist when temperatures are outside of the required range and provides the amount of variance.

(G) Class E pharmacies must maintain a compounding record that complies with USP Chapter 825, Section 9.2 (Records for Preparation with Minor Deviations/Compounding), for all radiopharmaceuticals prepared, prepared with minor deviations, dispensed, repackaged, or compounded. A compounding record is not required for FDA-approved radiopharmaceuticals dispensed in an unopened manufacturer container if the Class

E pharmacy does not manipulate the radiopharmaceutical in any manner.

(H) Unless required by other rule or applicable law, all records, policies/procedures, and reports required by this rule or USP Chapter 825 must be maintained electronically or as a hard copy for two (2) years and must be readily retrievable and made available to the board or its representative upon request. At a minimum, records must be physically or electronically produced immediately or within two (2) hours of a board request.

(5) Personnel Training and Competency. Licensees/registrants must comply with all USP Chapter 825 education, training, and qualification requirements. The required aseptic competency qualification program must include all elements required by USP Chapter 825, Section 4.1 (Aseptic Qualifications), and must include cleaning and disinfecting the PEC and, if applicable to the individual's duties, cleaning and disinfection of SEC and the SRPA.

(A) Required aseptic competency qualification results can be transferred between facilities under common ownership or control of the same pharmacy or healthcare facility, provided the competency qualification captured the most difficult and challenging conditions the individual will be performing using similar equipment and was completed within USP Chapter 825's required time frames. Pharmacies accepting transferred aseptic competency qualification results under this section must maintain current and written policies and procedures governing the transfer of results. Licensees or registrants with transferred competency evaluation results must be trained on applicable pharmacy operational procedures as needed to ensure proper compounding and must be skilled and trained to accurately and competently perform the duties assigned.

(B) If needed to prevent interruptions in patient care during an emergency, a pharmacy may also accept the required competency evaluations from another pharmacy or hospital in lieu of the required initial competency evaluations, provided –

1. A pharmacist verifies the applicable competency evaluation complies with USP Chapter 825;

2. The pharmacy maintains documentation of the other pharmacy or hospital's completed competency evaluation(s), including the dates and results. Additionally, the receiving pharmacy must maintain a manual or electronic copy of the other pharmacy's or hospital's policies and procedures on aseptic competency qualifications for board licensees or registrants;

3. The board licensee or registrant has received training on applicable pharmacy operational procedures as needed to ensure proper compounding. The licensee or registrant must be skilled and trained to accurately and competently perform the duties; and

4. Individuals may not assist with compounding under the emergency allowance authorized by this subsection for more than forty-five (45) days without the required competency evaluation by the pharmacy that complies with USP Chapter 825.

(6) Preparation/Compounding. All sterile and non-sterile radiopharmaceuticals must be prepared, compounded, repackaged, and dispensed in accordance with accepted standards of nuclear pharmacy practice and in compliance with applicable state/federal law. Additionally, Class E pharmacies must comply with all applicable rules for compounding sterile and non-sterile non-radioactive preparations, including but not limited to 20 CSR 2220-2.200 (Sterile Compounding) and 20 CSR 2220-2.400 (Compounding Standards of Practice).

(A) Appropriate safety and containment techniques must be used in conjunction with the aseptic techniques required for sterile radiopharmaceutical preparations.

(B) Materials, equipment, and supplies must be placed in an ISO Class 5 PEC in a manner that minimizes disruption of airflow in the direct preparation area. Furniture, equipment, and other materials in the ISO classified area or SRPA must be low-shedding and easily cleaned/disinfected.

(7) Dispensing, Packaging, Labeling.

(A) A radiopharmaceutical shall only be dispensed or transferred to a practitioner or facility authorized by the NRC or an AS to possess, use, and administer such radiopharmaceutical drug. A radiopharmaceutical shall not be dispensed directly to a patient. A Class E pharmacy may distribute radionuclide elutions to other authorized licensees to meet a radiopharmaceutical drug shortage.

(B) Radiopharmaceuticals shall only be dispensed pursuant to a prescription drug order or a contingency prescription drug order from a practitioner or facility authorized by the NRC/AS to possess, use, and administer radiopharmaceuticals or the practitioner's/facility's designated agent. Only ANPs may receive verbal therapeutic prescription drug orders or an order for radio-labeled blood components. Except as otherwise provided herein, prescriptions must contain all information required by 20 CSR 2220-2.018 (Prescription Requirements), as applicable. The pharmacy's prescription record shall also include –

1. The date of dispensing and the calibration time of the radiopharmaceutical; and

2. The patient's name for therapeutic prescription drug orders and radio-labeled blood components or, if an animal, species and owner's name.

(C) In addition to USP Chapter 825 requirements, the outer shielding container of a radiopharmaceutical to be dispensed 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 date of dispensing and a prescription or unique identification number;

4. The name of the procedure, if known;

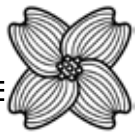
5. If applicable, molybdenum-99 content to *United States Pharmacopoeia* (USP) limits of <0.15uCi Mo-99 per 1mCi Tc-99m at time of administration or product expiration; and

6. The patient name or, if an animal, the species and owner's name or the words "Physician's Use Only," "Contingency Prescription Drug Order," "Per Physician's Order," or similar wording in the absence of a patient/owner name. If no patient/owner name is used, the pharmacy must have a policy/procedure in place for retrieving the name of the patient/owner from the authorized prescriber/facility within three (3) days if requested. The patient/owner name must appear on the label if the prescription is for a therapeutic radiopharmaceutical or radio-labeled blood component.

(D) In addition to USP Chapter 825 requirements, the immediate inner container label of a radiopharmaceutical to be dispensed shall be labeled with –

1. The unique, readily retrievable identifier of the radiopharmaceutical; and

2. If known, the patient's name or, if an animal, the species and owner's name or the words "Physician's Use Only," "Contingency Prescription Drug Order," "Per Physician's Order,"



or similar wording in the absence of a patient/owner name.

(E) Radiopharmaceuticals approved by the United States Food and Drug Administration are not subject to the inner shielding labeling requirements in subsection (D) if the Class E pharmacy does not manipulate the radiopharmaceutical in any manner nor violate the original manufacturer product packaging/labeling.

(F) Beyond-use dating (BUD) must comply with USP Chapter 825, Table 7 (Preparation Conditions for Sterile Radiopharmaceuticals). The assigned BUD shall not exceed the sterility-related times listed in Table 7, unless a longer time is justified by USP Chapter 71 (Sterility Tests). The use of non-radioactive conventionally manufactured products in preparing, preparing with minor deviations, dispensing, or compounding must follow USP Chapter 797 Section 15 (Use of Conventionally Manufactured Products as Components).

(8) Reference Manuals. Each Class E pharmacy shall have a current copy of, or electronic access to –

(A) Applicable reference materials commensurate with the scope of services provided;

(B) A current print or electronic edition of statutes and rules governing the pharmacy's practice, including but not limited to Chapters 338 and 195, RSMo, 20 CSR 2220 and, if applicable, 19 CSR 30 governing controlled substances;

(C) NRC or AS regulations governing the safe storage, handling, use, dispensing, transport, and disposal of radioactive material, including but not limited to Title 10 and Title 49 of the *United States Code of Federal Regulations*; and

(D) USP Chapter 825 (Radiopharmaceuticals) and, if applicable, USP Chapter 795 (Pharmaceutical Compounding – Non-sterile Preparations), Chapter 797 (Pharmaceutical Compounding – Sterile Preparations), Chapter 823 (Positron Emission Tomography Drugs for Compounding, Investigational, and Research Uses), Chapter 1223 (Validation of Alternative Microbiological Methods), and Chapter 1225 (Validation of Compendial Procedures).

(9) Special Conditions.

(A) To comply with NRC exposure guidelines of keeping radiation exposure as low as reasonably achievable (ALARA), the required pharmacist verification of the preparation shall be deemed satisfied if an ANP has previously verified the correct components and intended radioactivity. Additionally, an ANP must verify the accuracy of the prescription/contingency drug order information used.

(B) At its discretion, the board may grant an exemption for a Class E pharmacy from regulation requirements that do not pertain to the practice of a Class E pharmacy for a time period designated by the board, if such exemption is not contrary to any other law and the exemption will provide equal or greater protection of the public safety, health, or welfare. Exemption requests must be submitted in writing and identify the specific exemption requested, the grounds for exemption, the requested exemption length, and any proposed procedures or safeguards for protecting the public safety, health, or welfare if the exemption is approved. If deemed appropriate, the board may grant an exemption to all nuclear pharmacies based on one (1) pharmacy's request.

(C) To minimize impact on patient care, Class E pharmacies licensed on the effective date of this rule may also petition the board for a waiver of USP Chapter 825 facility and equipment requirements if immediate compliance with USP Chapter 825 requirements cannot be completed despite the permit holder's due diligence or would result in an undue hardship or adversely impact patient care. Waivers may be effective for a time period designated by the board.

(10) Remedial Investigations. A remedial investigation is required if any environmental monitoring sample demonstrates a colony forming unit (CFU) count that exceeds USP Chapter 825 recommended action levels for the type of sampling. The remedial investigation must be documented and include resampling of all affected areas to ensure a suitable state of microbial control. The pharmacy must ensure that no misbranded, contaminated, or adulterated compounded sterile radiopharmaceutical is administered or dispensed for patient use.

(A) If an environmental monitoring sample taken from a PEC exceeds USP Chapter 825 action levels, the pharmacy must cease compounding in the affected PEC until resampling shows a suitable state of microbial control has been achieved in the PEC. However, a pharmacy may continue to compound during the remedial investigation if –

1. The affected PEC is cleaned and disinfected by using an EPA-registered sterile cleaning, disinfecting, and sporicidal agent, or a combination thereof, followed by sterile isopropyl alcohol;

2. The beyond-use date assigned to all preparations is no greater than twelve (12) hours; and

3. The affected PEC is resampled under dynamic conditions. If the resampling exceeds USP Chapter 825 action levels, compounding must cease until resampling shows a suitable state of microbial control has been achieved in the PEC, unless otherwise authorized by the board or board's authorized designee to continue compounding upon showing the facility can be operated in a manner not to endanger the public health or safety.

(B) If an environmental monitoring sample taken from a buffer room exceeds USP Chapter 825 action levels, the pharmacy must cease compounding in the affected buffer room until resampling shows a suitable state of microbial control has been achieved in the affected buffer room. However, a pharmacy may continue to compound during the remedial investigation if –

1. The affected buffer room is cleaned and disinfected by using an EPA-registered cleaning, disinfecting, and sporicidal agent, or a combination thereof;

2. The beyond-use date assigned to all preparations is not greater than twenty-four (24) hours; and

3. The affected buffer room is resampled under dynamic conditions. If two (2) consecutive resamplings exceed USP Chapter 825 action levels, compounding must cease until resampling shows a suitable state of microbial control has been achieved in the affected room, unless otherwise authorized by the board or board's authorized designee to continue compounding upon showing the facility can be operated in a manner not to endanger the public health or safety.

(C) Pharmacies must notify the board in writing within three (3) business days if a resample is collected as part of a remedial investigation and it exceeds USP Chapter 825 action levels.

AUTHORITY: sections 338.240, 338.250, 338.280, and 338.350, RSMo 2016, and sections 338.210, 338.220, and 338.330(3), RSMo Supp. 2025. This rule originally filed as 4 CSR 220-2.500. Original rule filed Sept. 2, 1997, effective April 30, 1998. Moved to 20 CSR 2220-2.500, effective Aug. 28, 2006. Amended: Filed April 23, 2019, effective Nov. 30, 2019. Amended: Filed Dec. 12, 2025, effective July 30, 2026.*

**Original authority: 338.210, RSMo 1951, amended 2001, 2011, 2020; 338.220, RSMo*

1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014, 2020; 338.240, RSMo 1951, amended 2011; 338.250, RSMo 1951, amended 1990, 1998; 338.280, RSMo 1951, amended 1971, 1981; 338.330, RSMo 1989, amended 1993, 1998, 2011, 2018; and 338.350, RSMo 1989, amended 1993, 1995.

20 CSR 2220-2.600 Standards of Operation for a Class F: Renal Dialysis Pharmacy

PURPOSE: This rule defines minimum standards for a Class F: Renal Dialysis Pharmacy.

(1) A Class F pharmacy (renal dialysis) shall be limited in scope to the provision of dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address. Pharmacy services and dialysis supplies and products provided by a Class F pharmacy shall be limited to the distribution and delivery of drugs and devices as provided within this rule. All drugs and devices must be ordered by an authorized prescriber for administration or delivery to a person with chronic kidney failure for self-administration at the person's home or specified address. All dialysis supplies and products provided by a Class F pharmacy shall be prepackaged and covered by an approved New Drug Application (NDA) or 510(k) application issued by the Food and Drug Administration (FDA).

(2) A Class F pharmacy shall maintain a pharmacist-in-charge on a consultant basis who shall review pharmacy operations at least weekly. Class F pharmacies shall ensure:

(A) Use of legend drugs and devices that are provided to a person for the treatment of chronic kidney disease for self-administration at the person's home or specified address are under the professional supervision of an appropriate practitioner licensed under Missouri law;

(B) Only drugs and devices that have been ordered by an authorized prescriber and are included on the list of approved formulary drugs and devices are provided to patients;

(C) No drugs or devices are dispensed to a patient until adequate training in the proper use and administration of such products has been completed;

(D) Proper documentation of drug and device distributions and deliveries are maintained by the Class F pharmacy and are made available upon request to practitioners involved in the care of the patient and to board of pharmacy representatives;

(E) A policy and procedure manual is maintained that is available for inspection by board of pharmacy personnel. The manual shall include a quality assurance program with which to monitor the qualifications, training and performance of personnel; and

(F) The pharmacist-in-charge is responsible for the drug/device delivery system and for establishing a written protocol for the implementation of the delivery system including methods for supervising drug/device deliveries to patients of the pharmacy.

1. Any written protocols shall be available for inspection by board of pharmacy personnel.

2. Any changes to the policy and procedure manual or to written protocols must be approved by the pharmacist-in-charge.

(3) A Class F pharmacy may deliver products to a person with chronic kidney failure only upon the receipt of a valid prescription from an authorized prescriber specifying or including:

(A) Documents that the intended recipient will require such products for the appropriate treatment of the disease and that the intended recipient has been trained in home dialysis therapy;

(B) The duration of the prescriber's order, not to exceed one (1) year, including all authorized refills; and

(C) The name and product code of each product prescribed and the quantity prescribed.

(4) Personnel of the pharmacy shall assemble the products to be delivered pursuant to the prescriber's order(s). In assembling such products for delivery, the pharmacy shall take steps necessary to assure the following:

(A) The code numbers and quantities of the products assembled match the code numbers identified in the prescriber's order(s);

(B) Any products bearing an expiration date have a minimum of three (3) full months of shelf-life remaining;

(C) A visual inspection is completed of all drugs and devices for compliance with the prescriber's order(s) and with all labeling requirements as set forth in 338.059, RSMo. Manufacturer sealed case lots shall be labeled with the name of the patient, date, and a control number that serves as a unique patient identifier number; and

(D) Products ordered by a prescriber and provided to patients of the pharmacy shall be delivered either by personnel of the pharmacy or by a carrier authorized by the pharmacy.

1. Upon the delivery to patients of any drugs/devices, pharmacy personnel or the approved carrier shall confirm receipt by the patient or the patient's designee and that the number of units delivered equals the number of units identified by documentation supplied by the pharmacy.

(5) Class F pharmacies shall ensure:

(A) The license of the pharmacy is displayed in plain view at the pharmacy location;

(B) The pharmacy is open such hours as are necessary to safely and effectively dispense and deliver supplies to those persons designated by the applicable prescriber;

(C) The pharmacy maintains sufficient space and storage capabilities as necessary to carry out its operations; and

(D) All drugs and/or devices shall be properly identified and any outdated, misbranded or adulterated items shall be segregated from the active inventory within a clearly separate and defined area and held separately until the item is destroyed or returned to a licensed drug distributor.

AUTHORITY: sections 338.220 and 338.280, RSMo 2016, and section 338.140, RSMo Supp. 2019. This rule originally filed as 4 CSR 220-2.600. Original rule filed Jan. 20, 1998, effective Aug. 30, 1998. Moved to 20 CSR 220-2.600, effective Aug. 28, 2006. Amended: Filed May 13, 2019, effective Nov. 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.650 Standards of Operation for a Class J: Shared Services Pharmacy

PURPOSE: The purpose of this rule is to establish standards for Class J: Shared Services pharmacies.

(1) Class J Shared Services. A Class J Shared Services 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. These functions may include, but are not limited to, prescription/order receipt, 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 (DUR), and obtaining refill authorization. All pharmacies participating in the shared services arrangement must have a Class J permit.

(A) Pharmacies may perform Class J Shared Services provided the parties –

1. Have the same owner or have a written contract outlining the services to be provided and the responsibilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations;

2. Maintain a separate Class J classification for each location involved in providing shared services; and

3. Either share a common database or have access to each pharmacy's prescription records and patient profiles and records, as needed to safely and properly perform the shared services activities.

(B) Class-J pharmacies operating in compliance with this section are exempt from the requirements of 20 CSR 2220-2.120 and 20 CSR 2220-6.030(4) when transferring prescription information between themselves. A Class-J permit is not required to transfer an individual prescription as authorized by 20 CSR 2220-2.120 pursuant to a request by the patient or the patient's authorized designee.

(C) The parties performing Class J Shared Services shall maintain a detailed written description of authorized shared services that includes the name, address, and permit number(s) of all pharmacies involved. The parties must maintain a current and accurate policy and procedure manual that includes, but is not limited to, the following:

1. Policies and procedures that identify the duties and responsibilities of each pharmacy including any functions identified in section (1). The required policies and procedures must also identify the pharmacy responsible for –

A. Verifying prescription/medication order accuracy and validity;

B. Data entry verification;

C. Drug utilization review as required by 20 CSR 2220-2.195;

D. Final product verification; and

E. Patient counseling;

2. A mechanism for tracking the prescription or medication order during each step in the process;

3. Security provisions for protecting the confidentiality and integrity of patient information;

4. Policies and procedures to ensure the safe and appropriate delivery of prescription drugs 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 and federal law. For purposes of section 338.059, RSMo, the name and address of either the pharmacy 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.

(D) Each pharmacy involved in a Class-J arrangement must maintain a quality assurance program that is designed to objectively and systematically monitor and evaluate the quality and appropriateness of pharmacy services and resolve identified problems.

(E) Compounding may only be performed pursuant to a Class-J pharmacy arrangement pursuant to a patient-specific prescription or in anticipation of a patient-specific prescription as authorized by 20 CSR 2220-2.200 and the rules of the board.

(F) A Class-J permit is not required for pharmacists performing non-dispensing activities authorized by 20 CSR 2220-6.050 outside of a licensed pharmacy.

(2) A Class J Shared Services permit shall not be required if a completed and labeled prescription is delivered from a Missouri licensed pharmacy to another Missouri licensed pharmacy for administration by a pharmacist or other licensed health care professional to the patient on the same premises or physical location as the pharmacy.

(A) The exemption recognized in this subsection only applies if a completed and labeled prescription is delivered to the receiving pharmacy.

(B) If additional manipulation or compounding is required by the receiving pharmacy, receipt of a prescription or order is required and the receiving pharmacy must dispense the product as their own prescription/order. All prescription requirements, record keeping, compounding, and labeling requirements must be met.

(C) The receiving pharmacy must maintain documentation of the medication received, the name and address of the pharmacy providing the medication, the date of receipt, and the patient's name.

(D) The receiving pharmacy is responsible for ensuring compliance with all applicable patient counseling requirements.

(E) For purposes of this rule, administration is defined as applying or introducing medication to the body of a patient, whether by injection, infusion, inhalation, ingestion, or other means.

(F) Medication administered by a pharmacist must be performed in compliance with all applicable provisions of law.

(G) Notwithstanding any other provision of this rule, licensees shall comply with all applicable controlled substance laws and regulations, including, but not limited to, all applicable security and record keeping requirements.

(3) A Class J Shared Services permit is not required for pharmacies that have an arrangement to provide only initial dispensing services for a Class C pharmacy, as allowed under 20 CSR 2220-2.120(4).

(4) A pharmacy participating in Class J Shared Services with a pharmacy that is not under common ownership must notify patients that his/her prescription or medication order may be filled or compounded by another pharmacy.

(5) All records required by this rule including all policy and procedure manuals, contracts, quality assurance documentation, or other agreements must be maintained for two (2) years and must be made available to the board or its representative upon request.

AUTHORITY: sections 338.240 and 338.280, RSMo 2016, and sections 338.140, 338.210, and 338.220, RSMo Supp. 2021. This rule originally filed as 4 CSR 220-2.650. Original rule filed Nov. 30, 2001, effective June 30, 2002. Amended: Filed Dec. 3, 2002, effective June 30, 2003. Moved to 20 CSR 2220-2.650, effective Aug. 28, 2006. Emergency amendment filed July 27, 2017, effective Aug. 6, 2017, expired Feb. 22, 2018. Amended: Filed July 27, 2017, effective Jan. 30, 2018. ** Amended: Filed Aug. 23, 2021, effective Feb. 28, 2022.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.210, RSMo 1951, amended 2001, 2011, 2020; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014, 2020; 338.240, RSMo 1951, amended 2011; and 338.280, RSMo 1951, amended 1971, 1981.*

***Pursuant to Executive Order 21-09, 20 CSR 2220-2.650 was suspended from March 20, 2020 through December 31, 2021.*

20 CSR 2220-2.675 Standards of Operation/Licensure for Class L Veterinary Pharmacies

PURPOSE: This rule defines standards for a Class L veterinary pharmacy.

(1) A Class A or a Class L pharmacy permit shall be required for any entity engaged in the sale, dispensing, or filling of a legend drug for use in animals that must only be dispensed by prescription under state or federal law. For purposes of this rule, a legend drug shall be defined as provided by 21 USC section 353.

(2) Class A Pharmacies. Class A permit holders shall comply with all laws/rules applicable to Class A pharmacies, provided a Class A pharmacy shall comply with sections (7) and (8) of this rule when legend drugs are dispensed for animal use.

(3) Class L Pharmacies. A Class L pharmacy shall dispense, sell, or provide legend drugs only for animal use. Except as otherwise provided in this rule, a Class L pharmacy shall comply with all applicable state and federal pharmacy and controlled substance laws/rules including, but not limited to, all applicable provisions of Chapter 338, RSMo, and the rules of the board.

(4) Pharmacy Operations. A Class L pharmacy shall comply with 20 CSR 2220-2.010, with the following allowed modifications:

(A) The pharmacy permit shall be displayed in plain view at the pharmacy location;

(B) The pharmacy shall maintain sufficient space, equipment, and storage capabilities as necessary to carry out its operations;

(C) Legend drugs shall be properly identified and stored in a defined area within the pharmacy;

(D) Legend drugs shall be stored in a clean and sanitary designated area and within temperature requirements as provided for by the manufacturer or the latest edition of the United States Pharmacopoeia (USP);

(E) The pharmacy shall maintain a current reference manual related to veterinary drugs that complies with 20 CSR 2220-2.010(1)(D);

(F) Appropriate sewage disposal must be available within the pharmacy and a hot and cold water supply shall be accessible to pharmacy staff. If compounding is performed, the hot and cold water supply shall be located within the pharmacy;

(G) Pharmacy compounding shall comply with 20 CSR 2220-2.200, 20 CSR 2220-2.400, and all other applicable provisions of state/federal law;

(H) All dispensing errors shall be documented in the pharmacy's records;

(I) Animals shall not be allowed in the designated area where legend drugs are stored or maintained; and

(J) The pharmacist-in-charge shall be notified within twenty-four (24) hours after a dispensing error is learned by pharmacy staff. Documentation of notification shall be maintained in the pharmacy's prescription records.

(5) A Class L pharmacy shall designate a pharmacist-in-charge as required by 20 CSR 2220-2.010(1)(M). The pharmacist-in-charge shall be responsible for supervising pharmacy operations and ensuring compliance with the provisions of this rule and all applicable state/federal laws. Except as otherwise provided in this rule, the pharmacist-in-charge shall also –

(A) Ensure legend drugs are only sold, dispensed, or filled by the pharmacy for animal use;

(B) Ensure legend drugs have been ordered/prescribed by an authorized prescriber; and

(C) Maintain a policy and procedure manual for pharmacy operations. The policy and procedure manual shall be reviewed annually by the pharmacist-in-charge. The manual shall be available for inspection by board personnel and shall include policies and procedures for:

1. Accepting, compounding, dispensing, or filling prescriptions;
2. Accepting, dispensing, or filling prescriptions in the pharmacist's absence;
3. Drug storage and security;
4. Handling drug recalls;
5. Procedures for offering patient/client counseling;
6. If applicable, procedures for dispensing or providing prescriptions in a pharmacist's absence pursuant to section (8) of this rule;
7. Contacting the pharmacist-in-charge for consultation during the pharmacy's business operations or in the event of an emergency; and
8. Reporting and handling dispensing errors. The pharmacist-in-charge shall be notified of a dispensing error within twenty-four (24) hours after the error is learned by pharmacy staff. Policies/procedures shall include the manner of notification.

(6) A pharmacist shall not be required to be physically present on-site during the business operations of a Class L pharmacy if the pharmacist-in-charge reviews the activities and records of the pharmacy operations on a monthly basis to ensure compliance with this rule. This exemption shall not apply if the pharmacy sells, dispenses, or otherwise provides controlled substances. The date of the pharmacist-in-charge review shall be documented and maintained at the pharmacy.

(7) To be valid for purposes of dispensing, legend drug prescriptions for animal use shall conform to all requirements of sections 338.056 and 338.196, RSMo, and shall contain the following:

(A) The date issued;

(B) The client's/owner's name and the class, species, or identification of the animal, herd, flock, pen, lot, or other group being treated;

(C) The prescriber's name, if an oral prescription, or signature, if a written prescription;

(D) Name, strength, and dosage form of drug and directions for use;

(E) The number of refills, when applicable;

(F) The quantity prescribed in weight, volume, or number of units;

(G) The address of the prescriber and the patient when the prescription is for a controlled substance;

(H) Whether generic substitution has been authorized;

(I) The prescriber's Drug Enforcement Administration (DEA) number when the prescription is for a controlled substance; and

(J) Controlled substance prescriptions shall comply with all

requirements of federal and state controlled substance laws.

(8) Dispensing. A Class L pharmacy may accept, fill, enter, dispense, or otherwise provide non-controlled legend drugs for animal use in the absence of a pharmacist, provided the pharmacist-in-charge shall review the prescription record for each such prescription on a monthly basis. The review shall be documented as provided in section (6) of this rule. For purposes of 20 CSR 2220-2.010(3), the dispensing pharmacist shall be identified as the pharmacist-in-charge unless dispensed by another licensed pharmacist.

(A) Legend drugs may only be compounded for use in animals when a pharmacist is present on site.

(B) Clients must be offered an opportunity to consult with a pharmacist as required by 20 CSR 2220-2.190. If the pharmacist is not present on site, a written offer to counsel with a contact telephone number for a pharmacist shall be supplied with the medication.

(9) Labeling. Prescriptions must be labeled as required by section 338.059, RSMo. Prescription labels may be manually written and numbered and shall include:

(A) The class, species, or identification of the animal, herd, flock, pen, lot, or other group being treated; and

(B) 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).

(10) Records. Class L pharmacy records shall be maintained as required by Chapter 338, RSMo, and the rules of the board, including, 20 CSR 2220-2.018 and 20 CSR 2220-2.080.

(A) The information specified in section (7) of this rule shall be required and recorded on all handwritten, telephone, oral, and electronically produced prescriptions that are processed for dispensing by a pharmacist/pharmacy. If applicable, prescription records shall also include the veterinarian's specified withdrawal, withholding, or discard time identified in section (9) of this rule.

(B) Any change or alteration made to the prescription dispensed based on contact with the prescriber shall be documented in the pharmacy's prescription records. This shall include, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug.

(C) The pharmacy's prescription records shall identify any prescription dispensed in a pharmacist's absence pursuant to section (8) of this rule.

(11) A Class L pharmacy shall comply with all applicable state or federal controlled substance laws.

(12) The provisions of this rule shall not be applicable to the sale of medication for use in animals that may lawfully be dispensed without a prescription nor shall this rule be construed to require licensure for entities solely engaged in selling, dispensing, or providing medications authorized for dispensing without a prescription.

(13) The provisions of this rule shall not prohibit or interfere with any legally registered practitioner of veterinary medicine in the compounding, administering, prescribing, or dispensing of their own prescriptions, medicine, drug, or pharmaceutical product to be used for animals.

AUTHORITY: sections 338.056, 338.059, 338.196, 338.250, 338.280, and 338.343, RSMo 2000, and sections 338.010, 338.055, 338.140, 338.150, 338.210, 338.220, and 338.240, RSMo Supp. 2011. Emergency rule filed Aug. 29, 2011, effective Sept. 8, 2011, expired March 5, 2012. Original rule filed Aug. 29, 2011, effective March 30, 2012.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011; 338.055, RSMo 1971, amended 1978, 1981, 1986, 1998, 2001, 2004, 2011; 338.056, RSMo 1978, amended 1996; 338.059, RSMo 1971, amended 1973, 1978, 1997; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.150, RSMo 1939, amended 1951, 1961, 1980, 1981, 2011; 338.196, RSMo 1991; 338.210, RSMo 1951, amended 2001, 2011; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2011; 338.240, RSMo 1951, amended 2011; 338.250, RSMo 1951, amended 1990, 1998; 338.280, RSMo 1951, amended 1971, 1981; and 338.343, RSMo 1989, amended 1993.*

20 CSR 2220-2.680 Class R-Remote Dispensing Site Pharmacy

PURPOSE: This rule defines licensing requirements and compliance standards for Class-R Remote Dispensing Site pharmacies.

(1) Definitions.

(A) "Community Mental Health Center" – A community mental health center as defined by 42 CFR section 410.2, section 205.975, RSMo, or the Missouri Department of Mental Health.

(B) "Federally qualified health center" – A federally qualified health center as defined by 42 U.S.C. section 1396d(l)(2)(B), as amended.

(C) "Intern Pharmacist" – An individual who holds a current and active Missouri intern pharmacist license and has completed employer approved training in the activities to be performed at the Class R pharmacy and has an initial and annual documented assessment of competency.

(D) "Outpatient Clinic" – A facility where healthcare services are provided by a licensed healthcare provider on the facility's premises to patients who are not hospitalized or admitted to the outpatient clinic for greater than twenty-three (23) hours.

(E) "Qualified Pharmacy Technician" – A currently registered Missouri pharmacy technician who –

1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies;

2. Has completed employer approved training in the activities to be performed at the Class R pharmacy and has an initial and annual documented assessment of competency; and

3. Has assisted in the practice of pharmacy as a registered pharmacy technician in the state of Missouri for a minimum of one (1) year.

(F) "Remote Dispensing Site Pharmacy" – Any location in this state where the practice of pharmacy occurs that is staffed by one (1) or more qualified pharmacy technicians or intern pharmacists whose activities are supervised by a pharmacist at a supervising pharmacy that is under common ownership through a continuous real-time audio and video link. A remote dispensing site pharmacy does not include a dispensing prescriber's office or an automated device.

(G) "Retail Pharmacy" – A pharmacy licensed by the board that is open to, and offers pharmacy services to, the general public.

(H) "Rural Health Clinic" – A rural health clinic as defined by the federal Rural Health Clinic Services Act, PL. 95-210, as amended.

(I) "Supervising pharmacy" – A Missouri licensed pharmacy located in this state or approved by the board that oversees the dispensing activities of a Class R pharmacy.

(2) A Class R pharmacy permit is required for any Missouri

location operating, or offering to operate, as a remote dispensing site pharmacy in Missouri. Applications for a Class R permit must be submitted on a form approved by the board with the pharmacy permit fee, in accordance with 20 CSR 2220-2.020.

(A) Class R pharmacy permits expire and must be renewed, as provided by Chapter 338, RSMo and 20 CSR 2220-2 for pharmacy permits. Renewal applications must be submitted on a form approved by the board with the applicable renewal fee.

(B) Class R pharmacies must be located at least ten (10) miles away from an existing retail pharmacy unless the Class R pharmacy is part of a community mental health center, federally qualified health center, rural health clinic, or outpatient clinic setting. Requests to waive the mileage requirement may be submitted to the board in writing along with documentation demonstrating how the proposed remote dispensing site pharmacy will promote public health. The board will consider the following factors when determining whether to grant a waiver request:

1. The availability of pharmacy services in the proposed pharmacy area;
2. The nature of proposed Class R pharmacy services;
3. Benefits or risks to patient care;
4. The applicant's and supervising pharmacy's experience and compliance history; and
5. Any other factor that may benefit or adversely impact public health.

(C) Class R pharmacies shall be authorized to provide Class A, Class B, and Class C pharmacy services with a Class R permit. Class R pharmacies must apply for and hold the applicable pharmacy permit classification identified in section 338.220, RSMo, for any additional pharmacy services provided by the pharmacy. A Class J Shared services permit is not required for Class R pharmacies engaged in shared pharmacy services with the supervising pharmacy. If the Class R pharmacy is engaged in Class J shared services with another pharmacy, or has an arrangement to provide or receive Class J shared services with another pharmacy, the supervising pharmacy, the remote dispensing site, and all involved pharmacies must have a Class J shared services permit and comply with 20 CSR 2220-2.650.

(D) By the tenth day following each calendar quarter, Class R pharmacies must calculate the average number of prescriptions dispensed by the pharmacy per day during the previous calendar quarter, excluding immunizations given by protocol (e.g., January 10, April 10, July 10, October 10).

1. If the average number of prescriptions or medication orders dispensed by the pharmacy during the previous quarter exceeds one hundred fifty (150) prescriptions/medication orders per day, excluding immunizations given by protocol, the pharmacy must apply for a change of classification to add a Class A, B, or C permit classification within ten (10) days of discovery. Change of classification requests must be submitted on a form approved by the board with the applicable fee. Class R operations must cease once a Class A, B, or C permit is issued by the board.

2. Class R operations may resume if the daily average number of prescriptions dispensed by the pharmacy does not exceed one hundred fifty (150) prescriptions/medications orders during a calendar quarter (January 1–March 31, April 1–June 30, July 1-September 30, or October 1–December 31). The pharmacy's Class A, B, or C pharmacy classification must be surrendered to the board within five (5) days of resuming Class R operations.

(3) Supervising Pharmacies. Class R pharmacies must be under the supervision of a supervising pharmacy, as required by section 338.215, RSMo. The supervising pharmacy must ensure the Class R pharmacy is properly and safely operated in compliance with applicable state and federal law. Effective policies and procedures must be in place to ensure appropriate oversight of a Class R pharmacy at all times.

(A) The supervising pharmacy and Class R pharmacy must manually or electronically maintain a current and accurate written policy and procedure manual that complies with section 338.215, RSMo.

(B) The supervising pharmacy and Class R pharmacy must share a common database or have access to each other's prescription record-keeping system. The common database or shared system must allow real-time, online access to the patient's complete profile for both the supervising pharmacy and the Class R pharmacy.

(C) Supervising pharmacies must be located in Missouri and within fifty (50) miles of the supervised Class R pharmacy site, unless otherwise approved by the board. Requests to waive the location and mileage requirements must be submitted to the board in writing along with proof the Class R pharmacy will be sufficiently supported by the supervising pharmacy and that necessary personnel or supplies can be delivered to the Class R pharmacy within a reasonable period of time of an identifiable need. The board will also consider the factors identified in subsection (2)(B) of this rule when reviewing a waiver request.

(D) A Class R pharmacy must immediately cease operations if the supervising pharmacy and Class R pharmacy are no longer under common ownership, the supervising pharmacy is no longer eligible to supervise the Class R pharmacy, or the supervising pharmacy's Missouri pharmacy permit is not current and active. Class R operations may resume once the supervising pharmacy's permit returns to active or eligible status or common ownership is reestablished.

(4) Class R Standards of Operation. Except as otherwise authorized by law, Class R pharmacies must comply with all laws and regulations applicable to the pharmacy services provided by the Class R pharmacy, including, 20 CSR 2220-2.010.

(A) Class R pharmacies must be staffed by a current and active Missouri licensed pharmacist at least eight (8) hours a month. At a minimum, the pharmacist-in-charge (PIC) of the Class R pharmacy must visit the remote dispensing site weekly during the first month of operation to verify compliance and monthly thereafter. The date of the monthly PIC compliance visit must be documented in the pharmacy's records.

(B) Class R pharmacies must maintain a perpetual inventory for all controlled substances that is reconciled twice per month. The PIC must review the reconciliation for accuracy/discrepancies during the compliance visits required by subsection (4)(A).

(C) A prominent sign must be posted at the Class R pharmacy notifying patients that the remote dispensing site is supervised by the supervising pharmacy along with the supervising pharmacy's name, address, and telephone number.

(D) Intern pharmacists and qualified pharmacy technicians activities must be supervised by a Missouri-licensed pharmacist present at the Class R pharmacy or remotely supervised by a Missouri-licensed pharmacist located at the supervising pharmacy using technology that provides a continuous real-time audio and video link. The required technology must allow the supervising pharmacist to provide the personal assistance, direction, and approval needed to verify and ensure remote

tasks are safely and properly performed. The supervising pharmacist must be employed by the supervising pharmacy, as required by section 338.215, RSMo, and must be competent to perform the services being supervised. A pharmacist cannot supervise more than two (2) Class R pharmacies at the same time.

(E) A Class R pharmacy may not be operated if the required supervision technology is unavailable or not in working order unless a pharmacist is onsite. The no pharmacist on duty sign required by 20 CSR 2220-2.010 must be posted in the event of a technology or system malfunction that requires the Class R pharmacy to cease operations.

(5) Medication Dispensing. Prescriptions/Medication orders may be prepared, dispensed, or compounded at a Class R pharmacy, as authorized by section 338.215, RSMo, and the rules of the board.

(A) The final contents and label of a prescription/medication order must be verified by a Missouri licensed pharmacist at the Class R pharmacy, or remotely verified by a Missouri licensed pharmacist located at the supervising pharmacy through the use of technology that includes bar coding and visual review of the medication contents and affixed label via remote video. The verifying pharmacist must be employed by the supervising pharmacy, as required by section 338.215, RSMo.

(B) Patient counseling must be provided for all new and refill prescriptions, unless refused by the patient. The required patient counseling must be provided by a Missouri licensed pharmacist at the Class R pharmacy or remotely provided by a Missouri licensed pharmacist at the supervising pharmacy via a HIPAA-compliant continuous real-time video and audio link, as authorized by section 338.215, RSMo. Medication may not be dispensed without a pharmacist physically present at the Class R pharmacy if the required counseling technology is not available or in working order. Remote patient counseling via technology may not be delegated to an intern pharmacist.

(C) Policies and procedures must be established to ensure appropriate pharmacist review of verbal prescription orders received by an intern pharmacist or qualified pharmacy technician at a Class R pharmacy when a pharmacist is not present.

(6) Adequate security and supervision must be maintained at all times to prevent unauthorized access to a Class R pharmacy and prevent medication theft and diversion.

(A) An alarm mechanism must be maintained that alerts the supervising pharmacy or the Class R pharmacist-in-charge in the event of unauthorized access to the remote dispensing site. Unauthorized access to a Class R pharmacy must be documented and reported to the board in writing within seven (7) days of discovery.

(B) Confidential records must be securely maintained to prevent unauthorized access and ensure secure data access and storage at all times.

(7) Record-Keeping.

(A) Except as otherwise provided by law, Class R pharmacies shall comply with all applicable record-keeping and documentation requirements of Chapter 338, RSMo, and the board's rules.

(B) Class R pharmacies must also maintain documentation of –

1. The number of prescriptions dispensed by the Class R pharmacy each calendar quarter; and

2. Proof that qualified pharmacy technicians and intern pharmacists assisting at a Class R pharmacy have completed the experience, training, and competency assessment required by this rule.

(C) Records required by this rule must be manually or electronically maintained for two (2) years at the Class R pharmacy, or at the supervising pharmacy if the Class R pharmacy is no longer operating, and must be readily retrievable on request of the board or the board's authorized designee.

AUTHORITY: section 338.280, RSMo 2016, and sections 338.140 and 338.215, RSMo Supp. 2020. Original rule filed Sept. 3, 2020, effective March 30, 2021.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.215, RSMo 2020; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.685 Standards of Operation for a Class Q: Charitable Pharmacy

PURPOSE: This rule establishes licensing requirements and standards of operation for a Class Q Charitable Pharmacy.

(1) Definitions.

(A) "Charitable organization" – An organization qualified as a charitable organization pursuant to section 501(c)(3) of the *Internal Revenue Code*.

(B) "Charitable pharmacy" – A site in Missouri that is owned or operated by a charitable organization for purposes of providing pharmacy services to appropriately screened and qualified indigent patients. Class Q pharmacies may only provide services to or for qualified indigent patients.

(C) "Health care entity" – A hospital owned by the state of Missouri or any entity or organization that is licensed or certified by the state or federal government as a hospital, hospice facility, ambulatory surgical center, nursing home, long-term care facility, residential care facility, skilled nursing facility, mental/behavioral health care facility, or a habilitation center as defined by Chapter 630, RSMo, and that is required to maintain patient records by state or federal law.

(D) "Qualified indigent patient" – A patient of a charitable pharmacy that has been screened and approved by a charitable organization and deemed not to have sufficient funds to obtain needed medication based on the charitable organization's pre-established criteria.

(E) "Qualified intern pharmacist" – A currently licensed Missouri intern pharmacist who has completed employer approved training in the activities to be performed at a Class Q pharmacy and has an initial and, if applicable, annual documented assessment of competency.

(F) "Qualified pharmacy technician" – A currently registered Missouri pharmacy technician who –

1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies;

2. Has completed employer approved training in the activities to be performed at a Class Q pharmacy and has an initial and, if applicable, annual documented assessment of competency; and

3. Has assisted in the practice of pharmacy as a registered pharmacy technician in the state of Missouri for a minimum of one (1) year.

(2) Applications for a Class Q pharmacy must be submitted on a

form approved by the board and must be renewed as provided by Chapter 338, RSMo, and 20 CSR 2220-2. No application fee is required (initial or renewal).

(3) Except as otherwise authorized by the board, Class Q pharmacies must comply with all laws and regulations applicable to the pharmacy services provided, including but not limited to 20 CSR 2220-2.010. Class Q pharmacies/applicants may petition the board to waive designated facility or pharmacy operational requirements not applicable to the Class Q pharmacy's operations. Waiver requests must be submitted in writing and must demonstrate how the permit holder will maintain patient safety and ensure appropriate patient care and pharmacy security, if approved. Controlled substances must be handled and dispensed in accordance with state and federal law.

(4) Class Q pharmacy services must be safely and accurately provided at all times, in compliance with state and federal law. If authorized by the pharmacist-in-charge, a qualified pharmacy technician or qualified intern pharmacist may assist in the practice of pharmacy at a Class Q pharmacy when a pharmacist is absent, with the exception of sterile compounding activities.

(A) Non-controlled medication may be dispensed or provided by a Class Q pharmacy when a pharmacist is absent if –

1. A pharmacist has previously verified the prescription/medication order contents and affixed label; or

2. Medication is provided to a healthcare provider for administration or delivery to the ultimate user as authorized by the healthcare provider's scope of practice, and bar code technology is used to verify the correct medication has been provided for the applicable patient. The healthcare provider must be notified that the medication has not been verified by a pharmacist prior to or on delivery.

(B) Patients or the patient's designee must be offered an opportunity to consult with a pharmacist as required by 20 CSR 2220-2.190. If the pharmacist is not present on site or unavailable to provide remote patient counseling, a written offer to counsel with a contact telephone number for a pharmacist must be supplied with the medication.

(C) If medication is dispensed or provided without a pharmacist present, a Missouri-licensed pharmacist designated by the pharmacist-in-charge must visit the Class Q pharmacy on a weekly basis to review the pharmacy's activities and records to ensure proper dispensing and compliance with this rule. The name of the reviewing pharmacist and review date must be documented and maintained in the pharmacy's records.

(D) The pharmacy's prescription records must identify any prescription/medication order dispensed without a pharmacist present.

(5) If authorized by the pharmacist-in-charge, a Missouri-licensed physician, dentist, physician assistant, or registered nurse may remove non-controlled medication from the pharmacy when a pharmacist is not at the Class Q location in an amount or volume needed to provide or administer to patients on the premises. Medication may only be removed pursuant to a valid order from a healthcare provider authorized to prescribe. The Class Q pharmacy must maintain a record of the distribution that includes the identity of the person removing the medication, the date removed, and the medication's identity, quantity, strength, and dosage form. A Missouri-licensed pharmacist must review the required documentation on a weekly basis to ensure compliance with this rule. Controlled substances may not be removed or dispensed by a Class Q pharmacy unless a Missouri-licensed pharmacist is present and supervising.

(6) Donated Medication. A Class Q pharmacy may accept and dispense donated medication if –

(A) The medication is a non-controlled substance and is donated by a pharmacy, drug distributor, healthcare entity, or a healthcare provider who is licensed to prescribe. Donated medication cannot be accepted from a patient or a member of the public;

(B) The medication has not been previously dispensed to a patient and is donated in the original, sealed, and unopened manufacturer or unit of use packaging/container;

(C) The medication is not adulterated, misbranded, expired, outdated, subject to a recall, or otherwise not appropriate for patient use. A pharmacist must visually inspect all donated medication prior to placing the medication in active inventory to ensure the medication complies with the requirements of this rule;

(D) The donating entity/healthcare provider attests in writing that the medication has been stored in accordance with manufacturer or United States Pharmacopeia requirements/guidelines and all applicable state and federal law;

(E) The Class Q pharmacy maintains a record of donated medication that identifies the medication received, the donating entity/healthcare provider, the date received, and the medication's quantity, strength, lot number, dosage form, and expiration date; and

(F) The parties comply with all applicable state and federal laws.

(7) Policies and Procedures. Class Q pharmacies must maintain current and accurate policies and procedures governing pharmacy operations, including, but not limited to, policies/procedures for the following, if applicable:

(A) Accepting, dispensing, or filling prescriptions;

(B) Training pharmacy staff;

(C) Drug storage and security;

(D) Offering patient counseling;

(E) Contacting a pharmacist for consultation during the pharmacy's business operations or in the event of an emergency;

(F) If applicable, procedures for dispensing or providing medication in a pharmacist's absence pursuant to section (4) of this rule; including, documenting medication dispensed in the pharmacist's absence, reconciling medication inventory, notifying healthcare providers as required by subsection (4)(A), and documenting required healthcare provider notifications;

(G) Receiving, storing, dispensing, and disposal of donated medication;

(H) Granting, terminating, and monitoring authorized pharmacy access when a pharmacist is not present; and

(I) Reporting and handling of dispensing errors. The pharmacist-in-charge must be notified of a dispensing error within twenty-four (24) hours after the error is learned by pharmacy staff. Policies/procedures must include the manner of notification.

(8) Records. Records required by this rule must be maintained at the pharmacy for a minimum of two (2) years and must be readily retrievable and made available to the board or the board's authorized designee upon request.

(9) A Class Q pharmacy receiving a completed and labeled prescription from another pharmacy to provide to a qualified indigent patient is not considered to be shared services under

20 CSR 2220-2.650. For prescriptions received from another pharmacy –

(A) The Class Q pharmacy must maintain documentation of the prescription received, the name and address of the pharmacy providing the prescription, the date of receipt, the prescription number or unique identifier, and the patient's name;

(B) The Class Q pharmacy is responsible for ensuring compliance with all applicable patient counseling requirements;

(C) Prior to dispensing a prescription received from another pharmacy, a pharmacist must perform a drug utilization review with the patient information available at the Class Q pharmacy in compliance with 20 CSR 2220-2.195;

(D) If additional manipulation or compounding is required by the Class Q pharmacy, receipt of a prescription or medication order is required and the receiving pharmacy must dispense the product as their own prescription/order. All prescription, record keeping, compounding, and labeling requirements must be met; and

(E) Licensees shall comply with all applicable controlled substance laws and regulations, including but not limited to all applicable security and record keeping requirements.

AUTHORITY: sections 338.140, 338.210, 338.220, and 338.333, RSMo Supp. 2022, and sections 338.280 and 338.350, RSMo 2016. Original rule filed Jan. 26, 2021, effective July 30, 2021. Amended: Filed May 13, 2022, effective Nov. 30, 2022.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.210, RSMo 1951, amended 2001, 2011, 2020; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014, 2020; 338.280, RSMo 1951, amended 1971, 1981; 338.333, RSMo 1989, amended 2010, 2012, 2018; and 338.350, RSMo 1989, amended 1993, 1995.*

20 CSR 2220-2.700 Pharmacy Technician Registration

PURPOSE: This rule defines the requirements for pharmacy technician registration.

(1) A pharmacy technician is defined as any person who assumes a supportive role under the direct supervision and responsibility of a pharmacist and who is utilized according to written standards of the employer or the pharmacist-in-charge to perform routine functions that do not require the use of professional judgement in connection with the receiving, preparing, compounding, distribution, or dispensing of medications.

(A) No person shall assume the role of a pharmacy technician without first registering with the board in accordance with the requirements in section 338.013, RSMo and this rule. Nothing in this rule shall preclude the use of persons as pharmacy technicians on a temporary basis as long as the individual(s) is registered as or has applied to the board for registration as a technician in accordance with 338.013.1 and .2, RSMo.

(B) A person may be employed as a technician once a completed application and the required fee is received by the board. The board will provide either a registration certificate that shall be conspicuously displayed or a letter of disqualification preventing the applicant's employment within a pharmacy.

(C) Information required on the application shall include, but is not limited to –

1. The name, phone number, and residential address of the applicant;

2. Full-time and part-time addresses where the applicant will be employed as a technician;

3. Information concerning the applicant's compliance with state and federal laws, as well as any violations that could be considered grounds for discipline as outlined in section 338.013.5, RSMo;

4. One (1) two-inch by two-inch (2" × 2") frontal view portrait photograph of applicant; and

5. Proof of fingerprinting as required by 20 CSR 2220-2.450.

(D) A copy of the application must be maintained by the applicant at the site(s) of employment during and until notice of registration or disqualification is received by the applicant and must be readily retrievable for review by the board of pharmacy or the board's representatives.

(2) Registered technicians as well as applicants for registration as a technician are responsible for informing the board in the case of a changed residential address. Any mail or communications returned to the board office marked unknown, incorrect address, and the like will not be mailed a second time until the correct address is provided.

(3) Registered technicians as well as applicants for registration as a technician shall inform the executive director of the board of any change in their employment address. The notification of an employment change must be provided in writing to the board no later than fifteen (15) days following the effective date of the change.

(4) Any person whose name appears on the board of pharmacy employment disqualification list shall be barred from employment as a pharmacy technician except as provided in section (5) of this rule.

(A) Information on the disqualification list shall include, at a minimum, the name and last known residential address of the person disqualified, as well as any previous registration number, the date on which the person's name was entered on the list and the date at which time the person will again become eligible for employment in a pharmacy. The board may place a person on the disqualification list for an indefinite period of time if the disqualified person fails to maintain a current mailing address with the board or fails to communicate with the board on a timely basis when contacted in writing by the board.

(B) Once the board has made a determination to place a person's name on the disqualification list, the board shall notify the person in writing by mailing the notification to the person's last known address. The disqualification notice shall include:

1. The name, address of residence and, if already registered as a technician, the registration number;

2. The reasons for being placed on the disqualification list;

3. The consequences of the person's name appearing on the list;

4. The time period of disqualification;

5. Any alternative restrictions or provisions for conditional employment, if provided by the board; and

6. The right to appeal the decision of the board as provided in Chapter 621, RSMo.

(5) Any person whose name appears on the disqualification list may be employed as a pharmacy technician subject to any restrictions or conditions ordered by the board. As an alternative to barring an individual from employment in a pharmacy, the board may consider restricted forms of employment or

employment under special conditions for any person who has applied for or holds a registration as a pharmacy technician. Special conditions may include participation in the board's Well-Being Program, as provided in 20 CSR 2220-2.175. Any registered technician subject to restrictions or conditions who violates any portion of the restrictions or conditions may be further restricted in employment or have additional conditions placed on their registration. The board may also implement full disqualification on a registrant who has violated any restrictions or conditions.

(6) The letter of notice of intent to disqualify and the disqualification list shall be considered an open record of the board as well as any notice of appeal or litigation that pertains to the disqualification and/or conditional registration as a pharmacy technician.

AUTHORITY: sections 338.013 and 338.380, RSMo Supp. 2009, and section 338.140, RSMo 2000. This rule originally filed as 4 CSR 220-2.700. Original rule filed Aug. 21, 1998, effective Feb. 28, 1999. Amended: Filed Nov. 13, 2002, effective June 30, 2003. Moved to 20 CSR 2220-2.700, effective Aug. 28, 2006. Amended: Filed Aug. 18, 2009, effective March 30, 2010. ***

**Original authority: 338.013, RSMo 1997, 2004, 2009; 338.140, RSMo 1939, amended 1981, 1989, 1997; and 338.380, RSMo 2007.*

***Pursuant to Executive Order 21-09, 20 CSR 2220-2.700, section (1) was suspended from March 20, 2020 through December 31, 2021.*

20 CSR 2220-2.710 Pharmacy Technician and Intern Pharmacist Supervision

PURPOSE: This rule defines the required supervision for pharmacy technicians and intern pharmacists.

(1) Pharmacy technicians and intern pharmacists may assist a pharmacist in the practice of pharmacy as authorized by Chapter 338, RSMo, and the rules of the board, provided delegated tasks are performed under the direct supervision of a pharmacist. Direct supervision means supervision by a Missouri licensed pharmacist who is readily and immediately available at all times the delegated tasks are being performed and who provides personal assistance, direction, and approval throughout the time the delegated tasks are being performed. "Readily and immediately available" means the pharmacist and pharmacy technician(s) or intern pharmacists are on the same physical premises, or if not, technology is used to communicate with and monitor the pharmacy technician and intern pharmacist, as authorized in section (2).

(2) Use of Technology. Except as otherwise provided by law or regulation, technology may be used to directly supervise a pharmacy technician and intern pharmacist, provided:

(A) Sufficient technology is available to allow communication between the pharmacist and the pharmacy technician or intern pharmacist in a manner that is sufficient to provide the personal assistance, direction, and approval required to verify and ensure delegated tasks are safely and properly performed. Technicians and intern pharmacists may not be supervised as authorized by this subsection if the required technology is not operating or available;

(B) All applicable state and federal laws are fully observed, including, but not limited to, all applicable privacy and confidentiality laws;

(C) The pharmacy technician or intern pharmacist has completed employer approved training in the activities performed and has an initial and annual documented assessment of competency. Documentation of the completed training and competency assessment must be maintained in the pharmacy's records for a minimum of two (2) years and provided to the board or the board's designee upon request; and

(D) The supervising pharmacist and the permit holder must maintain a sufficient audit trail of prescription/medication order data entry and modifications to a patient record performed by a pharmacy technician or intern pharmacist being supervised as authorized by this subsection. The record must include the identity of the pharmacy technician or intern pharmacist performing the data entry or modification and must be maintained in the pharmacy's records for a minimum of five (5) years.

(3) The supervising pharmacist and permit holder shall retain responsibility for activities delegated to a pharmacy technician or intern pharmacist.

(4) Nothing in this rule shall override the provisions of 20 CSR 2220-2.010.

(5) Unless otherwise provided by law or court of competent jurisdiction, the provisions of this rule are only applicable to pharmacy services under the jurisdiction of the board and are not applicable to hospital pharmacy services under the jurisdiction of the Missouri Department of Health and Senior Services pursuant to Chapter 197, RSMo.

AUTHORITY: sections 338.010 and 338.140, RSMo Supp. 2019, and sections 338.013, 338.035, and 338.280, RSMo 2016. Original rule filed Feb. 7, 2020, effective Aug. 30, 2020. Emergency rule filed June 5, 2020, effective June 19, 2020, expired Sept. 1, 2020.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019; 338.013, RSMo 1997, amended 2004, 2009; 338.035, RSMo 1990, amended 1993, 1995, 2007; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.715 Authorized Pharmacy Technician Duties

PURPOSE: This rule clarifies authorized duties that may be delegated to a Missouri registered pharmacy technician.

(1) A pharmacist may delegate tasks to a registered pharmacy technician within the practice of pharmacy, as defined in the pharmacy's policies and procedures. Pharmacy technicians must be competent and properly trained to perform delegated duties. Pharmacy technicians must be under the direct supervision of a pharmacist when assisting in the practice of pharmacy, as required by Chapter 338, RSMo, and the board's rules.

(2) Except as otherwise authorized by law/rule or section (3) of this rule, pharmacy technicians shall not perform any activity that requires the professional judgment of a pharmacist, including but not limited to –

(A) Patient counseling on medication or medical therapy, provided a pharmacy technician may read directions or information exactly as printed on a prescription label, medication container, or other pharmacist-approved written communication, if authorized by the delegating pharmacist

and the pharmacy has a written policy and procedure detailing allowed activities;

(B) Prospective drug use review required by 20 CSR 2220-2.195;

(C) Advising on therapeutic duplications, drug-disease contraindications, drug interactions, drug-allergy interactions, or prescription and non-prescription drug recommendations;

(D) Recommending any prescription, non-prescription, or homeopathic medication, provided a technician may inform patients of available vaccine services, vaccine eligibility, or past patient vaccine dates if authorized by a pharmacist;

(E) Final prescription verification, except as otherwise authorized for technicians using technology-assisted medication verification under 20 CSR 2220-2.012;

(F) Any activity required by law or rule to be performed by a pharmacist; and

(G) Any other activity prohibited by law or board rule.

(3) Dually Licensed Pharmacy Technicians/Intern Pharmacists. This rule does not prohibit Missouri registered pharmacy technicians or intern pharmacists who also hold a Missouri professional license or registration issued by another Missouri state board or agency from providing services authorized by such other license or registration. The pharmacy must develop and maintain current written policies and procedures governing the use of dually licensed licensees/registrants when assisting in the practice of pharmacy, including but not limited to ensuring appropriate supervision.

(4) Community Health Workers. This rule does not prohibit Missouri registered pharmacy technicians or intern pharmacists who hold a community health worker (CHW) certification issued by a CHW training provider approved/recognized by the Missouri Department of Health and Senior Services from providing services authorized by their CHW certification.

(A) Pharmacies/pharmacists must establish and maintain written policies and procedures governing pharmacy technicians/intern pharmacists providing CHW activities for or on behalf of a pharmacy or pharmacist. At a minimum, required policies/procedures must include but are not limited to pharmacy technician/intern pharmacist supervision and training, and communicating with a pharmacist when appropriate or necessary.

(B) Pharmacies or pharmacists engaging a pharmacy technician or intern pharmacists to provide CHW activities must ensure compliance with all applicable state and federal pharmacy and drug laws/regulations. For purpose of 20 CSR 2220-6.055(6), pharmacy technicians/intern pharmacists providing CHW activities must be appropriately supervised to ensure activities are safely and properly performed. A pharmacist must be available to respond to pharmacy technician/intern pharmacist questions regarding CHW activities, as defined in the engaging pharmacy's or pharmacist's written policies/procedures.

(C) Pharmacy technicians/intern pharmacists must wear an identification badge or similar identifying article that identifies their name and title when practicing or assisting in the practice of pharmacy as a CHW for or on behalf of a pharmacy.

AUTHORITY: sections 338.013, 338.240, and 338.280, RSMo 2016, and sections 338.140, 338.210, and 338.215, RSMo Supp. 2024. Original rule filed June 20, 2024, effective Jan. 30, 2025.*

**Original authority: 338.013, RSMo 1997, amended 2004, 2009; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.210, RSMo 1951, amended 2001, 2011, 2020; 338.215, RSMo 2020; 338.240, RSMo 1951, amended 2011; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.725 Remote Data Entry

PURPOSE: This rule authorizes and establishes requirements for remote data entry sites.

(1) Definitions.

(A) "Remote Data Entry Sites" – A remote site located in a U.S. state or territory that is operated by a Missouri licensed pharmacy and used by a Missouri licensed or registered pharmacy technician or intern pharmacist to electronically perform non-dispensing data entry functions, including, but not limited to, obtaining, entering, validating, or processing patient information or data.

(B) "Supervising Pharmacy" – A Missouri licensed pharmacy that is physically located in Missouri and responsible for operating a remote data entry site.

(2) Licensing.

(A) "Remote Data Entry Sites" – A permit is not required for a remote data entry site. The site shall be deemed part of and operating under the supervising pharmacy's permit. The supervising pharmacy must maintain an address listing of all remote data entry sites in operation which must be made immediately available upon request of the board or the board's authorized designee.

(3) Remote data entry sites must be safely operated in compliance with applicable state and federal law. The supervising pharmacy is responsible for all pharmacy operations at the remote data entry site. No medication or medical device may be located at or dispensed from a remote data entry site.

(A) Adequate security and supervision must be maintained at all times to prevent unauthorized access to the remote data entry site and equipment. Confidential records must be securely maintained to prevent unauthorized access to, and unauthorized storage/transfer of, confidential information. Any breach in the security of the remote data entry site equipment or confidential records must be documented and reported to the board in writing within seven (7) days of the breach. Paper patient or prescription records may not be generated, located, or maintained at a remote data entry site.

(B) Except as otherwise provided by state and federal requirements, the remote data entry site and the supervising pharmacy must share a common database or prescription record-keeping system that allows real-time, online access to relevant patient profile information by both the supervising pharmacy and the remote site. The identity of the pharmacy technician or intern pharmacist responsible for remotely entering, validating, or modifying data at a remote data entry site must be electronically documented/recorded in the pharmacy's records and maintained for a minimum of five (5) years.

(C) Pharmacy technicians and intern pharmacists operating at a remote data entry site must be competent in the duties performed. At a minimum, technicians and intern pharmacists must have completed employer approved training in the activities performed remotely and must have an initial and, if applicable, annual documented assessment of competency. Documentation of the completed training and competency assessment must be maintained in the pharmacy's records for

a minimum of two (2) years and provided to the board or the board's designee upon request.

(D) A sufficient mechanism must be in place to allow communication between the supervising pharmacist and pharmacy technician or intern pharmacist when needed. A pharmacist must be available to respond to technician/intern pharmacist questions at all times a remote data entry site is in operation and must provide the personal assistance, direction, and approval required to verify and ensure delegated tasks are safely and properly performed. Non-dispensing data entry functions may not be performed by a pharmacy technician or intern pharmacist at a remote data entry site if the required real-time communication mechanism is not operating or available.

(E) Remote data entry sites may be inspected by the board as authorized by law. Notification by the inspector will be provided to the supervising pharmacy a minimum of seventy-two (72) hours ahead of the scheduled inspection. The supervising pharmacy permit holder must arrange for a designated representative to be present that is not a resident of the location under inspection.

(4) Policies and Procedures. The supervising pharmacy must establish written policies and procedures governing all aspects of operation of a remote data entry site that are reviewed annually by the pharmacist-in-charge. At a minimum, policies and procedures must include authorized technician and intern pharmacist activities, site security procedures and requirements, reporting security breaches, quality assurance review procedures, and staff education/training. The annual policy and procedure review date must be documented in the pharmacy's records.

AUTHORITY: sections 338.010, 338.035, and 338.140, RSMo Supp. 2021, and sections 338.013 and 338.280, RSMo 2016. Original rule filed Feb. 7, 2020, effective Aug. 30, 2020. Emergency rule filed June 5, 2020, effective June 19, 2020, expired Sept. 1, 2020. Amended: Filed Nov. 2, 2021, effective May 30, 2022.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019, 2021; 338.013, RSMo 1997, amended 2004, 2009; 338.035, RSMo 1990, amended 1993, 1995, 2007, 2020; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.800 Vacuum Tube Drug Delivery System

PURPOSE: This rule defines the minimum standards for a vacuum tube drug delivery system utilized in licensed pharmacies.

(1) Vacuum tube systems are for use in the delivery of drugs to the patient or his/her agent.

(A) Any drug delivery system that utilizes a vacuum tube to deliver drugs outside of a licensed pharmacy must be designed and engineered in such a way as to ensure security of all drugs and that drugs are delivered correctly and efficiently to the intended recipient.

(B) Only systems that are dedicated for the delivery of drugs from a location within a licensed pharmacy to another location specific for drug delivery and are not connected, combined or attached to other systems shall be used. Multiple or switchable stations where the delivery of drugs could occur at more than one destination outside of the pharmacy are prohibited.

1. When the pharmacy is closed or there is no pharmacist on duty, the vacuum tube system must be turned off and no drugs shall be delivered to consumers during these time periods.

(C) Any pharmacy, which cannot maintain a direct and identifiable line of sight with the consumer, must maintain a video camera and audio system to provide for effective communication between pharmacy personnel and consumers. It must be a system that will allow for the appropriate exchange of oral as well as written communications to facilitate patient counseling and other matters involved in the correct transaction or provision of drugs.

1. Video monitors used for the proper identification of persons receiving prescription drugs shall be a minimum of twelve inches (12") wide.

2. Both the video monitor and the audio system must be in good working order or operations utilizing the vacuum tube system shall cease until appropriate corrections or repairs are made to the system(s).

3. Backlighting or other factors that may inhibit video or audio performance must be taken into account when using such systems to identify recipients of prescription drugs. Positive identification of recipients must be made before any drug is delivered.

(2) Any vacuum tube delivery system already installed in a pharmacy prior to September 1, 1998, will not be required to comply with this rule; except that, should the vacuum tube delivery system or any part thereof require replacement, change, or upgrading after September 1, 1998, the system or any part of the system being replaced, changed, or upgraded shall comply with the minimum standards set forth in this rule. This exemption does not relieve a pharmacy of its duty to maintain adequate security measures as required by Chapter 195, RSMo, 19 CSR 30-1, or the rules of the board; nor does it relieve pharmacists from their duty to provide patient counseling as required by 20 CSR 2220-2.190.

AUTHORITY: section 338.280, RSMo 2016, and section 338.140, RSMo Supp. 2019. This rule originally filed as 4 CSR 220-2.800. Original rule filed Aug. 21, 1998, effective Feb. 28, 1999. Moved to 20 CSR 2220-2.800, effective Aug. 28, 2006. Amended: Filed May 13, 2019, effective Nov. 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019 and 338.280, RSMo 1951, amended 1971, 1981.*

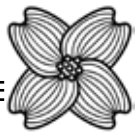
20 CSR 2220-2.900 Class N: Health Care Facility Automated Dispensing Systems

PURPOSE: This rule establishes licensing standards and requirements for the use of Class N automated dispensing systems (Health Care Facility).

(1) Definitions.

(A) "Class N: Automated dispensing system" (ADS) – An automated system located within a licensed health care facility used to dispense medication for resident patients of the facility pursuant to a patient-specific prescription or a medication order as defined by Chapter 338, RSMo, or a prescription drug order as defined by 20 CSR 2220-2.140. An automated dispensing system does not include an automated system used for compounding medication, a Class O automated dispensing system, or an automated filling system governed by 20 CSR 2220-2.950.

(B) "Electronic verification system" – An electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process



or system process used to verify and ensure medication has been properly stocked, restocked, loaded, filled, dispensed, or labeled.

(C) "Licensed health care facility" — A health care facility licensed by or operated by the state of Missouri, or otherwise authorized by the state, to administer health care to resident patients in the ordinary course of business or professional practice.

(D) "Med pak" — A patient med pak as defined by 20 CSR 2220-2.145.

(2) Licensing. Applicants for a Class N (ADS) permit classification must file an application on a form approved by the board with the applicable fee, and submit proof that the proposed Class N ADS location qualifies as a licensed health care facility, as defined by this rule.

(A) A Class N ADS permit will be issued for the health care facility address designated on the application, and may be used to operate all Class N ADSs located at the board approved address. A Class N ADS must be located indoors at the permitted health care facility address and may not be located outside of the health care facility.

(B) The appropriate pharmacy permit classification is required for any pharmacy activities under the board's jurisdiction that occur at the Class N ADS site other than dispensing from an automated dispensing system. Class N ADS pharmacies must comply with all requirements applicable to any additional pharmacy permit classifications held by the pharmacy, including but not limited to all applicable security and staff supervision requirements. A Class J pharmacy permit is required for shared service activities, as provided in 20 CSR 2220-2.650.

(C) A Class N ADS permit is not required for automated dispensing systems used solely to provide medication for immediate administration by health care facility staff to resident patients in an emergency situation, as allowed by law or the health care facility's licensing agency.

(3) System requirements. A Class N ADS must be maintained in good working order and in a clean and sanitary manner. If applicable, a Class N ADS must be cleaned and disinfected on a regular basis using appropriate materials and agents.

(A) A Class N ADS must be validated by a properly qualified board licensee or appropriately supervised board registrant designated by the pharmacy to ensure the system is functioning properly prior to first use and prior to restarting the system after an unanticipated system shutdown or interruption. Additional validation must occur if any modification to the automated dispensing system occurs that changes or alters the dispensing or electronic verification process.

(B) Medication must be stored and maintained in a thermostatically controlled area within temperature and humidity requirements as provided in the Food and Drug Administration approved drug product labeling or the United States Pharmacopeia (USP).

(C) At a minimum, temperatures in drug storage areas of the ADS must be recorded and reviewed daily. Alternatively, a continuous temperature monitoring system may be used if the system maintains ongoing documentation of temperature recordings that promptly alerts pharmacy staff when temperatures are outside of the required range and provides the amount of variance.

(D) An ongoing and documented quality assurance program must be established to monitor the performance of the automated dispensing system. The quality assurance program must include procedures for handling and reporting dispensing errors, system malfunctions, and other compliance concerns.

(E) A pharmacist must reconcile a sample size of medication dispensed/removed from a Class N ADS on a quarterly basis to verify authorization for dispensing. The required sample size must be identified in the pharmacy's policies and procedures. Proof of compliance with this subsection and the review date(s) must be maintained and documented in the pharmacy's records.

(4) Standards of operation. A Class N ADS must be safely and properly operated at all times in compliance with applicable state and federal laws, including but not limited to all applicable controlled substance laws.

(A) A Class N ADS may only be used in settings that ensure prescriptions and medication/drug orders are reviewed by a pharmacist. Only staff of the licensed health care facility may remove or obtain medications from a Class N ADS for patient use. Patients may not obtain medication directly from the automated dispensing system.

(B) Medication may only be dispensed by a Class N ADS pursuant to a valid prescription or medication/drug order. A prospective drug utilization review must be conducted for initial and changed prescriptions and medication/drug orders, as required by 20 CSR 2220-2.195. Policies and procedures must be in place for reviewing medication dispensing for compliance with this subsection, including but not limited to policies and procedures for terminating discontinued prescriptions and medication/drug orders and as needed prescriptions and medication/drug orders to prevent unauthorized dispensing.

(C) A pharmacist must control all operations of the ADS and approve the release of the initial dose, except in cases of emergency dispensing for immediate administration to a patient as authorized by law. Subsequent doses from an approved prescription or medication/drug order may be removed from the ADS by health care staff in accordance with the pharmacy's policies and procedures, provided a pharmacist must approve the release of subsequent dose(s) if any change in the prescription or medication/drug order occurs. Subsequent doses of patient-specific labeled prescriptions must comply with subsection (4)(D) of this rule.

(D) For ADSs that dispense a patient-specific labeled prescription or medication/drug order, pharmacist verification of the final drug product and label may be satisfied if —

1. A pharmacist reviews and verifies the prescription or medication/drug order and the patient information used to initiate the dispensing process prior to dispensing;

2. The entire dispensing process is fully automated from the time the process is initiated until a completed, sealed, and properly labeled medication container is produced that is ready for dispensing. Required labels must be affixed to the container prior to release of the medication from the automated dispensing system. No manual manipulation of the prescription container or label may occur after the medication is released; and

3. An electronic verification system is used to ensure the correct label has been affixed and the correct medication and medication strength, dosage form, and quantity have been dispensed.

(E) Labeled prescription containers provided to patients must be labeled in accordance with applicable statutory and regulatory requirements, and must contain the name, address, and telephone number of the Class N ADS permit holder. Med paks dispensed by a Class N ADS must comply with all applicable provisions of 20 CSR 2220-2.145, regardless if given

to the patient.

(F) In addition to 20 CSR 2220-2.080 and other prescription record-keeping requirements, the following information must be documented and readily retrievable for all prescriptions and medication/drug orders removed from the system:

1. The patient's name or other unique identifier;
2. The date and time the medication is removed;
3. The medication, dosage strength, and quantity removed; and
4. The identity or other unique identifier of the authorized health care staff member removing the medication.

(5) Supervision. A Class N ADS must be supervised by a Missouri-licensed pharmacist who is readily accessible physically or electronically to monitor system activities and respond to inquiries or requests (e.g., on call). Electronic technology must allow the pharmacist to adequately monitor and supervise Class N ADS operations. The pharmacist supervision required by this section may not be delegated to an intern pharmacist.

(A) If applicable, a two- (2-) way audio communication system must be in place to allow pharmacy technicians or intern pharmacists present at the Class N ADS pharmacy to effectively communicate with the supervising pharmacist. The Class N ADS may not be operated if the electronic or communication technology required by this section is unavailable or not in working order unless a pharmacist is on-site.

(6) Stocking/restocking. Medication must be securely stocked, loaded, and reloaded in a Class N ADS in a manner that protects against theft and diversion, and in compliance with 20 CSR 2220-2.010.

(A) Only board licensees or registrants may stock, load, or restock a Class N ADS, as authorized by the pharmacy's policies and procedures.

(B) A pharmacist must physically verify that medication has been properly stocked, restocked, and loaded into a Class N ADS. Alternatively, an electronic verification system may be used to verify that medication or medication containers have been properly stocked, restocked, and loaded into the device, if no manual intervention with the medication or medication container after the electronic verification occurs other than health care staff retrieving medication or medication being removed by authorized pharmacy staff for return/destruction.

(C) If authorized by a pharmacist, intern pharmacists, or pharmacy technicians may stock, restock, or load manufacturer unit of use packages and repacked containers previously verified by a pharmacist into a Class N ADS without a pharmacist present or additional pharmacist verification if an electronic verification system is used to verify the manufacturer unit of use packages and repacked containers have been correctly stocked, restocked, or loaded. No manual intervention with the manufacturer unit of use package or repacked container may occur after the electronic verification required by this subsection, other than removing the manufacturer unit of use package or repacked containers by authorized health care facility staff for dispensing or return/destruction.

(D) Return-to-stock medication may be returned and reused as authorized by 20 CSR 2220-3.040 or 20 CSR 2220-2.145 governing multi-med dispensing. No medication shall be returned directly to the Class N ADS for reissue or reuse by a person not licensed or registered by the Board of Pharmacy.

(E) The following documentation must be maintained and readily retrievable:

1. The name, strength, and quantity of the medication stocked, loaded, restocked, or removed from the ADS system;
2. The date and time medication is stocked, loaded, restocked, or removed from the ADS system;
3. The identity of individuals stocking, loading, restocking, or removing medication in the ADS system; and
4. The identity of the pharmacist responsible for verifying the contents of any repacked containers stocked, restocked, or loaded into the ADS system, if applicable.

(7) Security. Adequate security and supervision must be maintained at all times to prevent medication theft and diversion and unauthorized access to or use of the Class N ADS. A Class N ADS must also comply with all security provisions of 20 CSR 2220-2.010. Confidential records and Class N data must be securely maintained to prevent unauthorized access to, and unauthorized storage/transfer of, confidential information.

(A) A Class N ADS must be securely placed, locked, and maintained inside the physical building of the licensed health care facility in a manner that prevents theft, diversion, and unauthorized access or medication removal.

(B) A Class N ADS must have an alarm mechanism that promptly alerts a designated member of the pharmacy's staff in the event of a security breach or unauthorized access to the system.

(C) Authorized access to the Class N ADS must be defined in the pharmacy's policies and procedures. The permit holder must be able to stop or change access to the Class N ADS as deemed necessary or appropriate.

(D) A perpetual inventory must be maintained for each Class N ADS that stocks controlled substances that is reconciled by pharmacy staff on a monthly basis.

(E) Class N ADS permit holders must maintain current policies and procedures for handling and investigating confirmed or suspected security breaches and medication losses or diversion, including but not limited to an escalation policy/procedure for addressing inventory discrepancies and policies/procedures for terminating system operations in the event of a security breach, inventory discrepancy, suspected loss/diversion, or unauthorized access to or loss of patient confidential information.

(F) Security breaches of the Class N ADS must be immediately investigated. Use/operation of the Class N ADS must immediately cease until the security breach has been rectified and proper security is restored. Any security breach of the Class N ADS must be documented and reported to the board in writing within three (3) business days of discovery.

(G) Any confirmed or suspected medication diversion/theft must be immediately investigated. Medication diversion/theft must be reported to the board in writing within three (3) business days of discovery.

(8) Policies and procedures. Class N ADS permit holders must maintain current and accurate written policies and procedures governing all aspects of Class N ADS activities, including but not limited to –

(A) Staff education and training;

(B) Maintaining the Class N ADS and the accompanying electronic verification process in good working order;

(C) Maintaining and protecting system data and confidential information;

(D) Granting, restricting, or terminating Class N ADS system access;

(E) Filling, stocking, restocking, and loading the Class N ADS;

(F) Removing expired, adulterated, misbranded, or recalled medication;

(G) Temperature monitoring and documentation;

(H) Prescription processing, verification, and recordkeeping, including handling/termination of discontinued prescriptions and medication/drug orders and as-needed prescriptions and medication/drug orders to prevent unauthorized dispensing;
(I) Patient counseling, if applicable;
(J) Ensuring cleanliness and sanitary operation of the device and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;
(K) Emergency response procedures, including but not limited to addressing power outages and terminating system operations;
(L) Monitoring medication inventory to prevent diversion, theft, or loss, including an escalation policy/procedure for addressing inventory discrepancies;
(M) Security requirements, including policies/procedures for authorizing Class N ADS system access and terminating Class N ADS system operations in the event of a security breach;
(N) Handling and investigating inventory discrepancies, suspected loss/diversion, or unauthorized access to or loss of patient confidential information;
(O) Receiving, handling, documenting, and investigating alarm notifications/alerts in the event of a security breach or unauthorized access to the Class N ADS, as referenced in section (7);
(P) Conducting routine and preventive system validation and maintenance;
(Q) Quality assurance;
(R) Handling, investigation, and reporting dispensing errors;
(S) Recordkeeping; and
(T) Data retention and retrieval.

(9) Records.
(A) Class N permit holders must maintain readily retrievable records of all Class N ADS transactions, including but not limited to all prescriptions and medication/drug orders processed and/or dispensed by the Class N ADS and records of all medication stocked in or removed from the Class N ADS.
(B) Prescriptions and medication/drug orders dispensed from a Class N ADS must be separately identifiable in the pharmacy's prescription records and individually retrievable from other prescriptions and medication/drug orders dispensed by the pharmacy. This requirement also applies to any Class J pharmacy dispensing prescriptions or medication/drug orders via a Class N ADS.
(C) Except as otherwise provided by this rule or other applicable law, all records required by this rule must be maintained a minimum of two (2) years and readily retrievable on request of the board or a board-authorized designee. Records maintained at a pharmacy must be produced immediately or within two (2) hours of a request from the board or the board's authorized designee, or by making a computer terminal available to the inspector for immediate use to review the records requested. Records not maintained at a pharmacy must be produced within three (3) business days of a board request.

AUTHORITY: sections 338.140, 338.210, and 338.220, RSMo Supp. 2023, and section 338.280, RSMo 2016. This rule originally filed as 4 CSR 220-2.900. Original rule filed Nov. 1, 2000, effective June 30, 2001. Amended: Filed Feb. 18, 2003, effective Sept. 30, 2003. Moved to 20 CSR 2220-2.900, effective Aug. 28, 2006. Amended: Filed Aug. 21, 2006, effective April 30, 2007. Amended: Filed Sept. 6, 2023, effective March 30, 2024.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.210, RSMo 1951, amended 2001, 2011, 2020; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014, 2020; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.910 Class O: Automated Dispensing Systems (Ambulatory Care)

PURPOSE: This rule establishes licensing standards and requirements for Class O: Automated Dispensing Systems (Ambulatory Care).

(1) Definitions.
(A) "Ambulatory prescription dispensing system" — A Class O automated dispensing system (Class O ADS) used to process, verify, fill, label, and dispense a completed prescription/medication order for patient retrieval from the system using an electronic verification system.
(B) "Class O automated dispensing system" — A pharmacy license classification which allows the use of an ambulatory prescription dispensing system or a prescription pick-up system as defined by this rule at a specific location. A Class O ADS does not include an automated system used for compounding medication, a Class N automated dispensing system, or an automated filling system governed by 20 CSR 2220-2.950.
(C) "Electronic verification system" — An electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system process used to verify and ensure medication/prescriptions have been properly stocked, restocked, loaded, filled, dispensed, or labeled.
(D) "Prescription pick-up system" — A Class O ADS that allows a patient to obtain a filled, labeled, and pharmacist-verified prescription/medication order placed in the system by or on behalf of a Missouri-licensed pharmacy for patient retrieval. A prescription pick-up system does not include a vacuum tube drug delivery system identified in 20 CSR 2220-2.800.
(E) "Supervising pharmacist" — A Missouri-licensed pharmacist designated to supervise a Class O ADS while the system is in operation.

(2) Licensing. Applicants for a Class O ADS pharmacy permit classification must file an application on a form approved by the board and pay the applicable fee. A pharmacy Change of Classification application is required for currently licensed Missouri pharmacies opting to add a Class O ADS classification to their existing Missouri pharmacy permit. Application fees to add or obtain a Class O ADS pharmacy permit shall be waived for Class N ADS permit holders licensed on the effective date of this rule for a period of six (6) months from this rule's effective date.
(A) A Class O ADS permit may be used to operate all Class O ADSs located at the address designated on the permit. A Class O ADS may only be used by the permit holder, and may not be used to dispense prescriptions/medication orders for multiple pharmacies.
(B) The appropriate pharmacy permit classification is required for any pharmacy activities under the board's jurisdiction that occur at the Class O ADS site other than operating the Class O ADS. Class O ADS pharmacies must comply with all requirements applicable to any additional pharmacy permit classifications held by the pharmacy, including but not limited to all applicable security and staff supervision requirements. A Class J pharmacy permit is required for shared service activities, as provided in 20 CSR 2220-2.650.
(C) To be eligible for licensure, a Class O ADS must be located within the permitted address of a Missouri-licensed pharmacy

where pharmacy services other than Class J Shared services, Class I Consultant services, or Class O ADS services are provided, or at an indoor location where health care services are regularly provided by a licensed health care provider at the same location. A Class O ADS must be located at an address recognized by the United States Postal Service and may not be located outside of a physical structure.

(D) Applicants may petition the board in writing to approve a Class O ADS at an alternative location to increase patient access to medication in an area where access to an ambulatory/community pharmacy is limited. Petition requests must include documentation or evidence demonstrating how the proposed Class O ADS location will expand patient access to medication and promote public health. The board will consider the following factors when determining petition requests:

1. The availability of pharmacy services in the proposed Class O ADS pharmacy area;
2. Benefits or risks to patient care;
3. Policies/procedures for ensuring adequate security;
4. The permit holder's ability to promptly access the Class O ADS in the event of an emergency, which shall be no more than thirty (30) minutes;
5. The applicant's experience and compliance history; and
6. Any other factor that may benefit or adversely impact public health.

(3) System requirements. A Class O ADS must be maintained in good working order and in a clean and sanitary manner. If applicable, a Class O ADS must be cleaned and disinfected on a regular basis using appropriate materials and agents.

(A) A sign must be conspicuously posted or electronically displayed on the Class O ADS that clearly identifies the permit holder's name, address, the system's hours of operation, and a telephone number for contacting the pharmacy during operational hours.

(B) A Missouri-licensed pharmacist must be capable of being physically present at the approved Class O ADS location within thirty (30) minutes in the event of an emergency or other system malfunction.

(C) A video surveillance system must be in place that allows the pharmacy to physically view the Class O ADS and the Class O ADS site at all times. A video surveillance system is not required if a pharmacist is present on-site and able to view the Class O ADS at all times the system is accessible to the public.

(D) Medication must be stored and maintained in a thermostatically controlled area within temperature and humidity requirements as provided in the Food and Drug Administration approved drug product labeling or the United States Pharmacopeia (USP).

(E) At a minimum, temperatures in drug storage areas of the Class O ADS must be recorded and reviewed daily. Alternatively, a continuous temperature monitoring system may be used to comply with this subsection, if the system maintains ongoing documentation of temperature recordings that promptly alerts pharmacy staff when temperatures are outside of the required range and provides the amount of variance.

(F) The Class O ADS system must use an electronic verification system to electronically verify and ensure prescriptions/medication orders are properly dispensed to the correct patient. The electronic verification system(s) must be validated by a properly qualified board licensee or appropriately supervised board registrant designated by the pharmacy to ensure the system is functioning properly prior to first use and prior to restarting the system after an unanticipated system shutdown or interruption. Additional validation must occur if any modification to the Class O ADS occurs that changes or alters the dispensing or electronic verification process. Validation dates and results must be documented in writing and readily retrievable.

(G) The Class O ADS permit holder must regularly review system operations to ensure proper functioning. At a minimum, a Missouri-licensed pharmacist must visit and review Class O ADS operations weekly during the first month of system operations and monthly thereafter. The dates of the required weekly and monthly visits/reviews and the identity of the designated pharmacist must be documented and readily retrievable at the request of the board or the board's authorized designee. The permit holder shall remain responsible for Class O ADS services and ensuring proper functioning.

(H) An ongoing and documented quality assurance program must be established to monitor the performance of the Class O ADS. The quality assurance program must include procedures for handling and reporting dispensing errors, system malfunctions, and other compliance concerns.

(I) Notification of any dispensing error involving a Class O ADS that is dispensed to the patient must be submitted electronically or in writing to the board within ten (10) days of discovery. The required notification must include the date of the incident, patient name, description of the error, the applicable prescription/medication order number or unique identifier, and any corrective action taken.

(4) Standards of operation. A Class O ADS must be safely and properly operated at all times in compliance with applicable state and federal laws, including but not limited to all applicable controlled substance laws. Medication must be accurately dispensed and labeled.

(A) Medication may only be dispensed by a Class O ADS pursuant to a valid patient-specific prescription or medication order. A Class O ADS may not be used to dispense prescriptions/medication for multiple pharmacies.

(B) The Class O ADS must be supervised at all times it is in operation by a Missouri-licensed pharmacist who is either physically present at the Class O ADS site or who is supervising via an electronic system that allows the pharmacist to adequately view the Class O ADS and supervise all Class O ADS activities. The required pharmacist supervision may not be delegated to an intern pharmacist.

1. The supervising pharmacist must maintain full operational control over the Class O ADS whenever the Class O ADS is in operation, and must be able to terminate or suspend Class O ADS operations when deemed necessary or appropriate.
2. The required electronic system must provide a continuous real-time video link to allow the supervising pharmacist to see the entire Class O ADS site. A two- (2-) way communication mechanism must also be available that allows communication between the supervising pharmacist and any technicians or intern pharmacists present on-site. Medication may not be dispensed and the Class O ADS may not be operated if the required video link and audio communication are not fully functioning.
3. A supervising pharmacist may not supervise more than two (2) Class O ADSs at a time. The identity of the supervising pharmacist must be documented and maintained in the supervising pharmacy's records. Licensees may request a waiver of the supervision limit. The board will consider the factors in subsection (2)(D) when determining waiver requests.

(C) For Class O ADS prescription pick-up systems, only filled and labeled prescriptions that have been verified by a pharmacist may be loaded in or dispensed from the Class O ADS prescription pick-up system, except as otherwise authorized

by law. The entire dispensing process must be fully automated after the prescription/medication order is loaded into the Class O prescription pick-up system. No manual manipulation of the prescription/medication order or the affixed label may occur after the prescription/medication order is stocked, restocked, or loaded in the Class O ADS prescription pick-up system.

(D) For Class O ADS ambulatory prescription dispensing systems, the entire prescription/medication order filling, dispensing, and labeling process must be automated and the required prescription/medication label must be affixed by the Class O ADS ambulatory prescription dispensing system prior to dispensing from the Class O ADS ambulatory prescription dispensing system. No manual manipulation of the prescription/medication order or the affixed label may occur after the automated filling process is initiated.

(E) Medication may not be dispensed via a Class O ADS if the patient or the patient's authorized designee requests not to use the Class O ADS.

(5) Patient counseling. An offer to counsel must be made to the patient or the patient's authorized representative prior to a prescription or medication order being dispensed from a Class O ADS, except as otherwise required by law for Class R remote dispensing site pharmacies. The offer to counsel may be made verbally by authorized pharmacy staff or made electronically via the Class O ADS.

(A) Adequate space and equipment must be available to confidentially counsel patients. Live, real-time patient counseling must be provided if counseling is requested by the patient or otherwise required. If a pharmacist is not present on-site, two-(2-) way video and audio technology must be available that allows the pharmacist and patient to both view and communicate with each other. Medication may not be dispensed if the required video and audio technology is not fully functioning.

(B) Video monitors/screens used for patient counseling or communication must be a minimum of twelve inch (12") wide diagonally. Backlighting or other factors that may inhibit video performance must be taken into account when using video technology to counsel/communicate with patients.

(C) A sign must be conspicuously posted or continuously displayed electronically on the Class O ADS informing patients that a pharmacist will provide counseling either in-person or via the video/audio system on request. The sign must include clear instructions for requesting counseling and must be easily viewed and readable by the public.

(6) Stocking/restocking. Medication must be securely stocked, loaded, and reloaded in a Class O ADS in a manner that protects against theft or diversion, and in compliance with 20 CSR 2220-2.010.

(A) Only board licensees or registrants may stock, load, or restock a Class O ADS, as authorized by the supervising pharmacy's policies and procedures.

(B) For Class O ADS prescription pick-up systems, a pharmacist must physically verify that prescriptions/medication orders have been properly loaded into the Class O ADS prescription pick-up system. The identity of the verifying pharmacist must be documented and maintained in the pharmacy's records. Alternatively, an electronic verification system may be used to verify that prescriptions/medication orders have been properly loaded into the Class O ADS prescription pick-up system, if no manual intervention with the prescription/medication order occurs after the electronic verification is completed. If authorized by a pharmacist, intern pharmacists or pharmacy technicians may load a Class O ADS prescription pick-up system without a pharmacist present or additional pharmacist verification if –

1. An electronic verification system is used to verify the prescription/medication order has been properly loaded into the ADS system;

2. No manual intervention with the prescription/medication order occurs after the electronic verification required by this subsection, other than removing the prescription/medication order by authorized pharmacy staff for return/destruction; and

3. The electronic verification system has been validated and revalidated as required by subsection (3)(F). Validation dates and results must be documented in writing and readily retrievable.

(C) For Class O ADS ambulatory prescription dispensing systems, an electronic verification system must be used to verify that medication or medication containers have been properly stocked, restocked, and loaded into the Class O ADS ambulatory prescription dispensing system. If authorized by a pharmacist, intern pharmacists or pharmacy technicians may stock, restock, or load manufacturer unit of use packages and repacked containers previously verified by a pharmacist into a Class O ADS ambulatory prescription dispensing system without a pharmacist present or additional pharmacist verification if –

1. An electronic verification system is used to verify the medication has been correctly stocked, restocked, or loaded;

2. No manual intervention with the manufacturer unit of use package or repacked container occurs after the required electronic verification required by this subsection occurs, other than removing the manufacturer unit of use package or repacked container by authorized pharmacy staff for return/destruction; and

3. The electronic verification system has been validated and revalidated as required by subsection (3)(F). Validation dates and results must be documented in writing and readily retrievable.

(D) Return-to-stock medication may be returned and reused as authorized by 20 CSR 2220-3.040 or 20 CSR 2220-2.145 governing multi-med dispensing. No medication shall be returned directly to a Class O ADS for reissue or reuse by a person not licensed or registered by the Board of Pharmacy.

(E) The following documentation must be maintained and readily retrievable:

1. The date and time prescriptions/medication orders are stocked, loaded, restocked, and removed from the Class O ADS system;

2. The date and time medications are stocked, loaded, restocked, and removed from the Class O ADS system;

3. The identity of individuals stocking, loading, restocking, or removing prescriptions/medication orders and medication in the system; and

4. For Class O ADS ambulatory prescription dispensing systems, the identity of the pharmacist responsible for verifying the contents of any manufacturer unit of use packages and repacked containers stocked, restocked, or loaded into the Class O ADS ambulatory prescription dispensing system by an intern pharmacist or pharmacy technician without a pharmacist present.

(7) Security. Adequate security and supervision must be maintained to prevent medication theft and diversion and unauthorized access to or use of the Class O ADS. Class O ADS permit holders must comply with all security provisions of this rule and 20 CSR 2220-2.010. Confidential records must be securely maintained to prevent unauthorized access to, and

unauthorized storage/transfer of, confidential information.

(A) A Class O ADS must be securely placed, locked, and maintained at the address licensed by the board in a manner that prevents theft, diversion, or unauthorized access, or medication removal. Authorized access to the Class O ADS must be defined in the permit holder's policy and procedures.

(B) In addition to the requirements of section (8), written policies and procedures must be in place to immediately access, secure, remove, and store medication in the event of an emergency or security breach.

(C) The Class O ADS must have an alarm mechanism that promptly alerts a designated member(s) of the pharmacy's staff in the event of a security breach or unauthorized access to the Class O ADS. For Class O ADSs located outside of a Missouri-licensed pharmacy, the alarm must also alert local law enforcement in the event of a security breach or unauthorized access to the Class O ADS, if available. Additionally, a board licensee or registrant located in Missouri must have the authority to access and suspend operations of the Class O ADS if necessary.

(D) Confirmed or suspected security breaches of the Class O ADS must be immediately investigated. If confirmed, use/operation of the Class O ADS must immediately cease until the security breach has been rectified and proper security is restored. All security breaches of the Class O ADS must be documented and reported to the board in writing within three (3) business days of discovery.

(E) Any confirmed or suspected medication diversion/theft must be immediately investigated. Medication diversion/theft must be reported to the board in writing within three (3) business days of discovery.

(F) A perpetual inventory must be maintained for each Class O ambulatory prescription dispensing system stocking controlled substances that is reconciled by pharmacy staff on a monthly basis.

(8) Policies and procedures. Class O permit holders must maintain current and accurate written policies and procedures governing all aspects of Class O ADS activities, including but not limited to –

(A) Staff education and training;

(B) Maintaining the Class O ADS and the accompanying electronic verification process in good working order;

(C) Maintaining and protecting system data and confidential information;

(D) Granting, restricting, or terminating Class O ADS system access;

(E) Filling, stocking, restocking, and loading the Class O ADS;

(F) Removing expired, adulterated, misbranded, or recalled medication;

(G) Temperature monitoring and documentation;

(H) Prescription processing, verification, and recordkeeping;

(I) Patient counseling;

(J) Ensuring cleanliness and sanitary operation of the Class O ADS and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;

(K) Emergency response procedures, including but not limited to addressing power outages and terminating and restarting Class O ADS operations;

(L) Monitoring medication inventory to prevent diversion, theft, or loss, including an escalation policy/procedure for addressing inventory discrepancies;

(M) Security requirements, including policies/procedures for authorizing Class O ADS access and terminating Class O ADS operations in the event of a confirmed or suspected security breach, inventory discrepancy, suspected loss/diversion, loss of patient confidential information, and unauthorized access to the Class O ADS;

(N) Receiving, handling, documenting, and investigating alarm notifications/alerts in the event of a security breach of the Class O ADS;

(O) Conducting routine and preventive system validation and maintenance of the Class O ADS;

(P) Quality assurance;

(Q) Handling, investigating, and reporting dispensing errors;

(R) Recordkeeping; and

(S) Data retention and retrieval.

(9) Records.

(A) Class O permit holders must maintain readily retrievable records of all Class O ADS transactions, including but not limited to all prescriptions and medication orders processed and/or dispensed by the Class O ADS and records of all medication stocked in or removed from the Class O ADS.

(B) Prescriptions and medication orders dispensed from a Class O ADS must be separately identifiable in the pharmacy's prescription records and individually retrievable from other prescriptions/medication orders maintained by the pharmacy. This requirement also applies to any Class J pharmacy dispensing prescriptions via a Class O ADS.

(C) Except as otherwise provided by this rule or other applicable law, all records required by this rule must be maintained for a minimum of two (2) years and readily retrievable on request of the board or a board-authorized designee. Records maintained at a pharmacy must be produced immediately or within two (2) hours of a request from the board or the board's authorized designee, or by making a computer terminal available to the inspector for immediate use to review the records requested. Records not maintained at a pharmacy must be produced within three (3) business days of a board request.

AUTHORITY: sections 338.140, 338.210, and 338.220, RSMo Supp. 2023, and section 338.280, RSMo 2016. Original rule filed Sept. 6, 2023, effective March 30, 2024.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.210, RSMo 1951, amended 2001, 2011, 2020; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014, 2020; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.950 Automated Filling Systems

PURPOSE: This rule establishes standards for automated filling systems.

(1) Definitions. The following definitions shall be applicable for purposes of this rule:

(A) "Automated filling system" – 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 "automated filling system" shall not include automated devices used solely to count medication, vacuum tube drug delivery systems governed by 20 CSR 2220-2.800, or automated dispensing and storage systems governed by 20 CSR 2220-2.900 used to dispense medication directly to a patient or to an authorized health care practitioner for immediate distribution or administration to the patient;

(B) "Electronic verification system" – An electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or

system that accurately verifies medication has been properly dispensed and labeled by, or loaded into, an automated filling system;

(C) "Manufacturer unit of use package" – A drug dispensed in the manufacturer's original and sealed packaging, or in the original and sealed packaging of a repackager, without additional manipulation or preparation by the pharmacy, except for application of the pharmacy label;

(D) "Repackager" – A repackager registered with the United States Food and Drug Administration; and

(E) "Repacked" – Any drug that has been removed from the original packaging of the manufacturer or a repackager's packaging and is placed in a container for use in an automated filling system.

(2) Medication Stocking. Automated filling systems (hereinafter "system") may be stocked or loaded by a pharmacist or by an intern pharmacist or pharmacy technician under the direct supervision of a pharmacist. Pharmacy repacked medication, cartridges, or containers shall comply with 20 CSR 2220-2.130.

(3) Verification. Except as provided herein, a licensed pharmacist shall inspect and verify the accuracy of the final contents of any medication filled or packaged by an automated filling system, and any label affixed thereto, prior to dispensing, as required by 20 CSR 2220-2.010(1)(B).

(4) The pharmacist verification requirements of section (3) shall be deemed satisfied if –

(A) The pharmacy establishes and follows a policy and procedure manual that complies with section (5) of this rule;

(B) The filling process is fully automated from the time the filling process is initiated until a completed, labeled, and sealed prescription is produced by the automated filling system that is ready for dispensing to the patient. No manual intervention with the medication or prescription may occur after the medication is loaded into the automated filling system. For purposes of this section, manual intervention shall not include preparing a finished prescription for mailing, delivery, or storage;

(C) A pharmacist verifies the accuracy of the prescription information used by or entered into the automatic filling system for a specific patient prior to initiation of the automatic fill process. The name, initials, or identification code(s) of the verifying pharmacist shall be recorded in the pharmacy's records and maintained for five (5) years after dispensing;

(D) A pharmacist verifies the correct medication, repacked container, or manufacturer unit of use package was properly stocked, filled, and loaded in the automated filling system prior to initiating the fill process. Alternatively, an electronic verification system may be used for verification of manufacturer unit of use packages or repacked medication previously verified by a pharmacist;

(E) The medication to be dispensed is filled, labeled, and sealed in the prescription container by the automated filling system or dispensed by the system in a manufacturer's unit of use package or a repacked pharmacy container;

(F) 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; and

(G) Daily random quality testing is conducted by a pharmacist on a sample size of prescriptions filled by the automated filling system. The required sample size shall not be less than two percent (2%) of the prescriptions filled by the automated system on the date tested or two percent (2%) of the prescriptions filled by the automated system on the last day of system operation, as designated in writing by the pharmacist-in-charge. Proof of compliance with this subsection and random quality testing date(s) and results shall be documented and maintained in the pharmacy's records.

(5) Policies and Procedures. Pharmacies verifying prescriptions pursuant to section (4) of this rule shall establish and follow written policies and procedures to ensure the proper, safe, and secure functioning of the system. Policies and procedures shall be reviewed annually by the pharmacist-in-charge and shall be maintained in the pharmacy's records for a minimum of two (2) years. The required annual review shall be documented in the pharmacy's records and made available upon request. At a minimum, the pharmacy shall establish and follow policies and procedures for –

(A) Maintaining the automated filling system and any accompanying electronic verification system in good working order;

(B) Ensuring accurate filling, loading, and stocking of the system;

(C) Ensuring sanitary operations of the system and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;

(D) Reporting, investigating, and addressing filling errors and system malfunctions;

(E) Testing the accuracy of the automated filling system and any accompanying electronic verification system. At a minimum, the automated filling system and electronic verification system shall be tested before the first use of the system or restarting the system and upon any modification to the automated filling system or electronic verification system that changes or alters the filling or electronic verification process;

(F) Training persons authorized to access, stock, restock, or load the automated filling system in equipment use and operations;

(G) Tracking and documenting prescription errors related to the automated filling system that are not corrected prior to dispensing to the patient. Such documentation shall be maintained for two (2) years and produced to the board upon request;

(H) Conducting routine and preventive maintenance and, if applicable, calibration;

(I) Removing expired, adulterated, misbranded, or recalled drugs;

(J) Preventing unauthorized access to the system, including, assigning, discontinuing, or changing security access;

(K) Identifying and recording persons responsible for stocking, loading, and filling the system;

(L) Ensuring compliance with state and federal law, including, all applicable labeling, storage, and security requirements; and

(M) Maintaining an ongoing quality assurance program that monitors performance of the automatic fill system and any electronic verification system to ensure proper and accurate functioning.

(6) Recordkeeping. Except as otherwise provided herein, records required by this rule shall be maintained in the pharmacy's records electronically or in writing for a minimum of two (2) years. When the verification requirements of subsection (4)(D) of this rule are completed by a pharmacist, the name, initials, or identification code(s) of the verifying pharmacist shall be recorded in the pharmacy's records and maintained for five

(5) years after dispensing. Records shall be made available for inspection and produced to the board or the board's authorized designee upon request.

AUTHORITY: sections 338.250 and 338.280, RSMo 2000, and sections 338.140 and 338.210.4, RSMo Supp. 2013. Original rule filed July 1, 2013, effective Jan. 30, 2014.*

**Original authority: 338.140, RSMo 1939, amended 1989, 1997, 2011; 338.210, RSMo 1951, amended 2001, 2011; 338.250, RSMo 1951, amended 1990, 1998; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.990 Rx Cares For Missouri Program

PURPOSE: This rule establishes the Missouri Board of Pharmacy's medication disposal program as part of the Rx Cares for Missouri Program created by section 338.710, RSMo and establishes standards/criteria for Program operation and participation.

(1) Section 338.710, RSMo, established the "Rx Cares for Missouri Program" within the Board of Pharmacy to promote medication safety and to prevent prescription drug abuse, misuse, and diversion in Missouri. As part of the Rx Cares for Missouri Program, the board is hereby establishing a medication destruction and disposal program (the "Program") for the purposes of collecting unused or unwanted medication from the public for disposal in accordance with state and federal law. Operation of the Program may be delegated to a board approved vendor or third-party.

(2) Eligible Participants. To be eligible for participation, applicants must be physically located in Missouri and currently registered to collect unwanted controlled substances with the United States Drug Enforcement Administration ("DEA") and the Missouri Bureau of Narcotics and Dangerous Drugs ("BNDD") unless exempt from registration by state or federal law. Additionally, the applicant must be –

(A) A licensed Missouri pharmacy or drug distributor;

(B) A licensed healthcare provider authorized to prescribe controlled substances;

(C) A hospital, office, clinic, or other medical institution that provides health care services;

(D) A federal, state, local, or municipal public health, law enforcement, or other governmental agency, or

(E) A higher education institution located in Missouri that is accredited by a national or regional accrediting body recognized by the United States Secretary of Education.

(3) Participant Requirements. Approved participants must establish and operate a public medication collection program in compliance with Program requirements, including, but not limited to, all applicable board or vendor requirements for collecting, submitting, or forwarding medication for destruction and disposal. Participants must promptly enroll in the program after notification of approval is received from the board.

(A) Subject to appropriation, approved Program participants will be provided a collection receptacle and inner liners to be used for collecting medication pursuant to the Program. Participants may alternatively use an existing collection receptacle if approved by the board or the Program vendor. Program participants are responsible for installation of the collection receptacle in accordance with vendor requirements.

(B) Collection receptacles must be physically located in the state of Missouri at an address approved by the board. A board approved sign must be located on or near the receptacle indicating that the collection program has been funded by the Missouri Board of Pharmacy as part of the Rx Cares for Missouri Program. Collection receptacles may not be used to dispose of medication from the pharmacy's inventory.

(C) Medication must be collected and handled in compliance with all state and federal controlled substance laws. Program participants may submit collected medication to the vendor or the vendor's authorized designee for disposal at no cost to the participant up to twelve (12) times per participation year. Program participants may arrange for additional medication disposal at the participant's cost.

(D) Program participants shall notify the board in writing within ten (10) days after ceasing or terminating Program participation. Unless otherwise agreed by the board for good cause, Program participants shall reimburse the board for the cost of the collection receptacle if the participant fails to actively maintain and operate a collection program during the participation year. Collection receptacle costs must be remitted to the board within sixty (60) days after notification from the board.

(4) Application Procedures. Applications to participate in the Program must be submitted to the board on a board approved form and include –

(A) The applicant's name, address, contact telephone number, and e-mail address;

(B) The Missouri address where the collection receptacle will be located;

(C) A copy of the applicant's DEA and BNDD controlled substance collector registrations;

(D) A description of how the medication collection program will be operated, including operational times and how the program will be advertised to the public;

(E) A designation of whether the applicant will be using a board approved collection receptacle or supplying their own collection receptacle subject to vendor approval; and

(F) A description of the need for a medication collection program in the proposed collection site area along with any supporting data or evidence.

(5) Approval Criteria. At the discretion of the board, applicants will be approved for Program participation subject to funding availability. Participation approval shall be valid for one (1) calendar year. The following criteria will be considered by the board when reviewing applications:

(A) The need for a medication collection program in the proposed collection site area, including, but not limited to, any alternative collection programs/opportunities available;

(B) Relevant evidence or data regarding drug use, abuse, fatalities, or trends;

(C) The number of applications submitted or previously approved by the board for the applicant regardless of collection site;

(D) The nature and structure of the proposed collection program, including, but not limited to, operational times and any public restrictions;

(E) Available staff, resources, or expertise;

(F) Any state, federal, or local disciplinary action, including any pending board complaints or investigations;

(G) The applicant's compliance with state and federal drug and controlled substance laws;

(H) The applicant's financial need and available resources; and

(I) Any other factor that may be relevant to the applicant's

ability to participate in or comply with the Program.

(6) Information Sharing. As a condition of participation, applicants must agree that program information collected or maintained by the vendor or the vendor's designee may be disclosed to –

(A) The board or the board's authorized designee on request; and

(B) The Missouri Governor and the Missouri General Assembly pursuant to section 338.710, RSMo.

AUTHORITY: sections 338.140 and 338.280, RSMo 2016, and sections 338.142 and 338.710, RSMo Supp. 2019. Emergency rule filed July 18, 2019, effective July 28, 2019, expired Feb. 27, 2020. Original rule filed July 18, 2019, effective Feb. 29, 2020.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.142, RSMo 2017; 338.280, RSMo 1951, amended 1971, 1981; and 338.710, RSMo 2017.*

20 CSR 2220-2.995 Board Approved Pilot and Research Projects

PURPOSE: This rule establishes application requirements and criteria for pilot projects authorized by section 338.143, RSMo.

(1) This rule establishes requirements for the approval and operation of pharmacy pilot or demonstration research projects related to technology assisted verification or remote medication dispensing that are designed to enhance patient care or safety, improve patient outcomes, or expand access to pharmacy services, as authorized by section 338.143, RSMo.

(2) Applicants to operate a pilot program pursuant to this rule shall file an application on a form provided by the board. To be eligible, the applicant must hold a current and active license, registration, or permit from the board that is not under discipline.

(3) Proposal Requirements. Proposed pilot projects must be submitted to the board in writing and include –

(A) A one (1) page abstract of the project that includes the project's goals, purpose, scope, and proposed timelines;

(B) A narrative description of the following:

1. Activities that will be undertaken as part of the pilot project, including, the intended audience;

2. The goals and objectives of the project. Services and anticipated outcomes must be clearly described and align with section 338.143, RSMo;

3. A description of the capacity and structure the applicant has in place to operate the proposed pilot program, including, staff and personnel who will be monitoring, supervising, or participating in the pilot project and their relevant education, experience, or qualifications;

4. Procedures for training staff on project operations;

5. An explanation of how the proposal will enhance patient care or safety, improve patient outcomes, or expand access to pharmacy services for Missouri citizens;

6. A projected timeline for implementation and completion of the proposed pilot project. The proposed pilot project must be eligible for completion within eighteen (18) months of approval, unless otherwise authorized by the board;

7. Evaluation measures for assessing impact and effectiveness; and

8. A plan for pilot project termination.

(4) Pilot Projects shall be awarded at the discretion of the board with due consideration to public protection, patient safety, feasibility, the needs of the state, and the impact on pharmacy practice. Approved pilot projects shall report on program activities, as requested by the board. Approval of a pilot project may be withdrawn or rescinded by the board for the following:

(A) Any grounds authorized for discipline under section 338.055.2, RSMo;

(B) Failure to report on project operations, as requested by the board;

(C) To prevent or avoid patient harm or undue patient risk;

(D) To protect the public health, safety, or welfare; or

(E) Exceeding/Failure to comply with approved project guidelines. Deviations from approved pilot project operations must be reported to the board within five (5) business days.

AUTHORITY: sections 338.140 and 338.143, RSMo Supp. 2019. Emergency rule filed Sept. 13, 2019, effective Sept. 27, 2019, expired March 24, 2020. Original rule filed Sept. 13, 2019, effective March 30, 2020.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019 and 338.143, RSMo 2019.*