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

PROPOSED AMENDMENT

20 CSR 2220-2.010 Pharmacy Standards of Operation. The board is amending sections (1) and (9), deleting sections (2)-(8) and (10), adding new sections (2)-(4) and (6)-(8) and renumbering as necessary.

PURPOSE: This amendment updates standards of operation requirements for all pharmacies permitted by the Board.

[*(1) The word medicine or medicines is a word similar or of like import to the words pharmacist, pharmacy, apothecary shop, chemist shop, drug store, druggist and drugs, and no person shall carry on, conduct or transact a business under a name which contains, as part of the name, the word medicine or medicines, unless the place of business is supervised by a licensed pharmacist.*

(A) At all times when prescriptions are compounded in a pharmacy or other establishments holding a Missouri pharmacy permit, there shall be on duty and present in that place of business a pharmacist licensed in Missouri as provided by law. In any Class J: Shared Service pharmacy where a permit is maintained at a location for the purpose of remote dispensing as defined in 20 CSR 2220-2.900 the pharmacist may be considered on duty and present as long as all required electronic connection requirements are maintained and the pharmacist is accessible at all times to respond to patient's or other health professionals' inquiries or requests pertaining to drugs dispensed through the use of the automated pharmacy system. When there is no pharmacist on duty, no prescription will be compounded, dispensed or otherwise provided and the public will be advised that no pharmacist is on duty by means of signs stating this fact. The signs will be displayed prominently on the doors of all entrances and the prescription counter of the pharmacy and the signs will be composed of letters of a minimum height of two inches (2").

(B) Whenever, in a pharmacy or other establishment holding a Missouri pharmacy permit, a person other than a licensed pharmacist does compound, dispense or in any way provide any drug, medicine or poison pursuant to a lawful prescription, a licensed pharmacist must be physically present within the confines of the dispensing area, able to render immediate assistance and able to determine and correct any errors in the compounding, preparation or labeling of that drug, medicine or poison before the drug, medicine or poison is dispensed or sold. In any Class J: Shared Service pharmacy where a permit is maintained at a location for the purpose of remote dispensing as defined in 20 CSR 2220-2.900 the pharmacist may be considered on duty and present as long as all required electronic

connection requirements are maintained and the pharmacist is accessible at all times to respond to patient's or other health professionals' inquiries or requests pertaining to drugs dispensed through the use of the automated pharmacy system. The pharmacist personally shall inspect and verify the accuracy of the contents of, and the label after it is affixed to, any prescribed drug, medicine or poison compounded or dispensed by a person other than a licensed pharmacist.

(C) No pharmacy shall be licensed under the provisions of this chapter unless it is equipped with proper pharmaceutical equipment and reference manuals. Requirements for proper equipment and references may vary between pharmacies and must insure accuracy and safety of all pharmaceutical activity.

1. Basic equipment recognized by the latest edition of the United States Pharmacopoeia (USP), the United States Pharmacopoeia/Drug Information (USP/DI) or Remington's Pharmaceutical Sciences shall be available for any procedures utilized in the dispensing, compounding or admixture of drugs and drug-related devices, and must maintain conformance with these publications.

2. A suitable machine or electronic data device for the numbering of all prescriptions must be maintained along with appropriate printing equipment for the production of prescription drug labels.

(D) Reference manuals may include any generally recognized pharmaceutical publication other than periodicals or journals. A pharmacy must maintain, at a minimum, the current or latest edition of a reference manual(s) which includes all Federal Drug Administration (FDA)-approved drugs. The following topics must be included in the reference(s) selected:

1. Pharmacology of drugs;

2. Dosages and clinical effects of drugs; and

3. Patient information.

(E) Pharmacies shall maintain at least one (1) current edition of statutes and rules governing the pharmacy's practice.

(F) All pharmacies shall be maintained in a clean and sanitary condition at all times. Any procedures used in the dispensing, compounding and admixture of drugs or drug-related devices must be completed under clean and, when recommended, aseptic conditions.

1. Appropriate sewage disposal and a hot and cold water supply within the pharmacy must be available.

2. Appropriate housekeeping and sanitation of all areas where drugs are stored or dispensed must be maintained.

3. Animals, except for service animals as defined by the Americans with Disabilities Act (ADA), are not allowed in pharmacies.

(G) The temperature of the facility where drugs are stored must be maintained thermostatically within temperature requirements as provided for by the manufacturer or the latest edition of the USP. Adequate refrigeration must be available to insure enough storage space for drugs requiring refrigeration

or freezing and under temperatures adequate to maintain the drug products as recommended by the manufacturer, the latest edition of the USP, or both. Drugs and drug-related devices must be stored separately from food and other items.

(H) Pharmacies must maintain adequate security in order to deter theft of drugs by personnel or the public. Sufficient alarm systems or locking mechanisms must be in place if the pharmacy is located in a facility into which the public has access and the pharmacy's hours of operation are different from those of the remainder of the facility.

(I) Pharmacies which maintain storage sites or warehouse facilities for the storage of pharmaceuticals at a separate address or premises from the main pharmacy that holds a pharmacy permit shall register those sites as storage facilities of the licensed pharmacy. Information required for proper registration of a storage facility shall include the address of the facility, hours of operation (if applicable), pharmacy permit numbers of the pharmacies that it services, and a certified statement that the facility is used for the sole purpose of distributing drugs only within its own pharmacy operations.

1. Records must be maintained at these facilities to guarantee security, storage and accountability of all drugs and drug-related devices under proper conditions.

2. All storage and warehouse locations will be considered facilities of a pharmacy pursuant to section 338.240, RSMo and shall be subject to inspection by the board as defined in section 338.150, RSMo.

3. No fee will be charged by the board for registering a facility as defined in subsection (1)(I) of this rule.

(J) Pharmacies that maintain storage sites or warehouse facilities for the storage of confidential pharmacy records at a separate address or premises from the main pharmacy that holds a pharmacy permit shall register those sites as storage facilities of the licensed pharmacy. Information required for proper registration of a storage facility shall include the address of the facility, hours of operation (if applicable), pharmacy permit numbers of the pharmacies that it services, and a statement that the facility is used for the sole purpose of storing records within its own pharmacy operations.

1. All storage and warehouse locations must maintain adequate security including an alarm system. Any breach in security must be documented and reported in writing via facsimile, email communication, or letter to the board within fifteen (15) days of the breach of confidentiality.

2. All storage and warehouse locations will be considered facilities of a pharmacy pursuant to section 338.240, RSMo and shall be subject to inspection by the board as defined in section 338.150, RSMo.

3. No fee will be charged by the board for registering a facility as defined in subsection (1)(J) of this rule.

4. All storage and warehouse locations must comply with 19 CSR 30-1.

5. No records less than two (2) years old may be stored offsite.

6. All storage and warehouse locations storing confidential pharmacy

records must make records retrievable within two (2) business days when requested by the board or its representatives.

(K) All pharmacists will be required to have a photo of themselves not smaller than two inches by two inches (2" × 2") in the upper right-hand corner of the current renewal licenses. This photo and license renewal shall be conspicuously exposed in the pharmacy or drug store or place of business in which the pharmacist is employed as required by law.

(L) Pharmacists regularly working as relief persons for more than one (1) store shall have in their possession proper identification of their pharmacy licensure.

(M) Pharmacy operations must be conducted at all times under the supervision of a properly designated pharmacist-in-charge. When a licensed pharmacist leaves the employment of a pharmacy where s/he has been pharmacist-in-charge, s/he immediately shall notify the executive director of the board of the termination of his/her services in the pharmacy. Likewise, the holder of the permit shall notify the executive director of the board of the termination of the services and give the name of the new licensed pharmacist-in-charge.

(N) Pharmacists are responsible to inform the executive director of the board in the case of changed address. Any mail or communications returned to the executive director's office marked Unknown, Incorrect Address, and the like, will not be sent out a second time until the correct address is sent in.]

(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 licensees/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 e-mail 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.

(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.

[*(P) When required by section 338.013(10), RSMo, to report technician disciplinary action, the pharmacy must notify the board in writing within fifteen (15) days of the action. The notification must include:*

1. The name and permit number of pharmacy;
2. Name of person making the notification;
3. Name of technician;
4. Technician registration number;
5. Date of action; and
6. Reason for action.

(Q) Pharmacists must 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 any effective change.

(2) Every pharmacy shall designate as its primary means of record keeping either a manual system which provides for the consecutive numbering of hard copy prescriptions and complies with the provisions of section (3) of this rule or an electronic system which complies with the provisions of 20 CSR 2220-2.080.

The designated record system shall be used to record the pharmacy's dispensing of all drugs, medicines and poisons.

(3) A pharmacy using a record keeping system other than an electronic system meeting the requirements of 20 CSR 2220-2.080 to record its dispensing of drugs, medicines and poisons shall provide a method of recording all of the following information concerning the refill of any prescription medication on the back or reverse side of every prescription order:

(A) The date the drug, medicine or poison was dispensed;

(B) The dispensing pharmacist's initials; and

(C) The amount of drug, medicine or poison dispensed to the patient if different from the amount on the face of the prescription order.

(4) Each licensed pharmacy shall maintain at least three (3) separate files of prescriptions and they shall be as follows:

(A) All prescriptions for controlled drugs listed in Schedules I and II shall be maintained in a separate prescription file;

(B) All prescriptions for controlled drugs listed in Schedules III, IV and V shall be maintained in a separate prescription file; and

(C) All other prescriptions for noncontrolled drugs shall be maintained in a separate prescription file(s).

(5) Pharmacies shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of legend drugs. Said records shall be maintained for two (2) years and be readily retrievable upon request by the board or its representatives.

(6) Drugs and devices that are maintained as part of the pharmacy inventory or are being processed for dispensing or other distribution purposes must be physically separated at all times from articles, supplies or other drugs that are for employee personal use or that are outdated, distressed, misbranded or adulterated. An area separate from drug storage must be used to store quarantined, nonusable substances. Areas used for this type of drug storage must be clearly identified. Any prescription drugs that are present in a licensed pharmacy but are for the personal use of pharmacy personnel must be labeled in accordance with section 338.059, RSMo.

(7) All records required by Chapters 195 and 338, RSMo or divisions 20 CSR 2220 and 19 CSR 30 shall be available for photocopying or electronic duplication by a board of pharmacy representative.

*(8) Except as provided for in section 21 U.S.C. section 353(d)(1)(A)–(C), (d)(2)(A)(i)–(ii), (d)(2)(B)(i)–(iv), and (d)(3)(A)(i)–(ii) of the Federal Food, Drug and Cosmetic Act, drug samples shall not be maintained in pharmacies.**]***

(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. Readily retrievable is defined as immediately providing records or within two (2) hours of a request by 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.

(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.

***[(9)]*(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 list of drugs that may be possessed by a home health or hospice*

agency without a license or permit, as defined in section (9), is as follows:] **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*[, such as influenza, pneumonia, hepatitis A and hepatitis B]*; and
6. Tuberculin test material.

(B) The agency shall have *[a policy and procedure that addresses at least the following]* **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 *[physicians' orders for administration of the drugs]* **orders from an authorized prescriber for drug administration**;
4. Leaving drugs with the patient for routine care procedures;
5. Conditions for *[storage and transport]* **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 *[a physician's authorization]* **authorization from an authorized prescriber**, such as an individual patient order, protocol or standing order, to administer the drugs.

(D) *[When the patient or the patient's representative has been instructed, verbally and in writing, in the performance of routine care procedures, u]*Up to a two (2)-week supply of sodium chloride, water, and heparin may be left with the patient *[for these procedures]* **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, *[R]*r**efrigerator units used by the agency for storing drugs shall not be used for storing non-drug items.

[(10) Class I: Consultant Pharmacies as defined in 20 CSR 2220-2.020(9)(I) and approved by the board to be located within a residence shall be required to address and comply with the following minimum standards of practice:

(A) Location Requirements—

1. The pharmacy must be located in a separate room that provides for a door with suitable lock;

2. Sufficient storage for securing confidential documents and any hardware used in accessing a central pharmacy by electronic connection must be provided;

3. Ceiling and walls must be constructed of plaster, drywall, brick or other substantial substance that affords a design that makes the room separate and distinct from the remainder of the domicile. Drop down ceilings that allow access into the room are not allowed;

4. All locations must be inspected and have approval by the board prior to the initiation of services; and

5. Patients are not allowed in the pharmacy.

(B) Documentation—

1. Maintain a current policy and procedure manual that is attested by the signature and date of review of the pharmacist-in-charge to its accuracy. All pharmacists working at the pharmacy shall be required to sign the manual attesting to their review and understanding of all policies and procedures in force;

2. Maintain documentation that the permit holder has provided training to all personnel on all operations associated with the pharmacy;

3. The permit holder must complete an audit to ensure compliance with pharmacy policy and procedures and this regulation at a minimum of twice per year, through physical visits by representatives of the permit holder. Audit results must be maintained by the permit holder for a period of three (3) years; and

4. If the pharmacist is working under a contract for the permit holder, a copy of the contract shall be available during an inspection.

(C) Security—Records and Internet—

1. All electronic data processing systems must meet all applicable state and federal confidentiality laws and regulations;

2. Data processing systems must utilize sufficient security software;

3. Any breach in the security of the system must be documented and reported to the board of pharmacy within seven (7) days of the breach of confidentiality. Such documentation shall be available during an inspection.

(D) Licensure and Inspection—

1. Each location must maintain and display a current Class I permit. The permit holder for this permit must be the pharmacy the individual pharmacist is employed by or contracted with;

2. Routine inspections for in-state pharmacies shall be arranged ahead of time. Notification by the inspector to the permit holder will be provided a minimum of seventy-two (72) hours ahead of the scheduled inspection. The permit holder must arrange for a designated representative to be present that is not a resident of the location under inspection;

3. A pharmacy located outside the state must maintain a pharmacist-in-charge with a current and active pharmacist license with the state of Missouri;

4. The audits required in paragraph (10)(B)3. shall be available for review during the inspection; and

5. The pharmacy shall provide copies of inspections completed by the state in which they are located if such inspections are required within seven (7) business days of the inspection date.]

(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 338.140, 338.240, and 338.280, RSMo 2000 and sections 338.010 and 338.210, RSMo Supp. 2007. This rule originally filed as 4 CSR 220-2.010. Original rule filed July 18, 1962, effective July 28, 1962. For intervening history, please consult the* ***Code of State Regulations****. Amended: filed January 20, 2022.*

PUBLIC COST: This proposed amendment will result in a fiscal impact to the Board of Pharmacy of three thousand seven hundred fifty-five dollars ($ 3,755) during the first year of implementation ($1,200 revenue increase/$2,555 revenue expenditure), three hundred six dollars and twenty-five cents ($306.25) annually for the life of the rule, and eight hundred dollars ($ 800) biennially for the life of the rule.

PRIVATE COST: This proposed amendment will cost private entities approximately two hundred seventy-eight thousand and nineteen dollars and thirty cents ($278,019.30) during the first year of implementation, two hundred twenty-five thousand, six hundred eighty dollars ($225,680) annually over the life of the rule, and eight hundred dollars ($800) biennially for the life of the rule. Costs may vary with inflation, and are expected to increase at the rate projected by the Legislative Oversight Committee.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Board of Pharmacy, PO Box 625, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 526-3464, or via email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this rule in the ***Missouri Register****. No public hearing is scheduled.*