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**Rules of**  
**Department of Insurance,**  
**Financial Institutions and**  
**Professional Registration**  
**Division 2220—State Board of Pharmacy**  
**Chapter 2—General Rules**

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**Title 20—DEPARTMENT OF  
INSURANCE, FINANCIAL  
INSTITUTIONS AND  
PROFESSIONAL REGISTRATION**  
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”;

3. “Rx Only”;

(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) 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.

(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.

(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.

(9) 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:

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:

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;

4. Leaving drugs with the patient for routine care procedures;

5. Conditions for storage and transport 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, 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, up to a two (2)-week supply of sodium chloride, water, and heparin may be left with the patient for these procedures. 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. 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.

(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 pharmacist 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.

*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. 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.*

*\*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007; 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.210, RSMo 1951, amended 2001; 338.240, RSMo 1951; and 338.280, RSMo 1951, amended 1971, 1981.*

**20 CSR 2220-2.013 Prescription Delivery Requirements**

*PURPOSE: This rule establishes requirements for authorized prescription delivery sites.*

(1) Every pharmacy delivering prescription drugs shall develop and implement written

policies and procedures to ensure the safe and appropriate delivery of prescription drugs within the temperature requirements recommended by the manufacturer or the *United States Pharmacopeia* (USP). Except as otherwise provided herein, prescriptions 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 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 for veterinary use may be delivered 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) 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.

*AUTHORITY: section 338.280, RSMo 2000, and sections 338.095, 338.100, 338.140, and 338.240, RSMo Supp. 2011.\* Original rule filed May 14, 2012, effective Nov. 30, 2012.*

*\*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; 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 Operating Procedures During Declared Disasters

*PURPOSE: This rule is to establish guidelines for the operation and temporary relocation of a pharmacy during a declared disaster.*

(1) Declared disaster areas are defined as specified geographical counties within the state that have been designated by the governor or federal authorities as counties that have been adversely affected by a natural or man-made disaster and requires extraordinary measures to provide adequate, safe and effective health care for the affected population.

(2) In cases where a disaster as defined in section (1) has been declared, any pharmacy located within the disaster area may arrange to move to a temporary location to better serve the public or provide pharmacy services from a mobile unit that is under the control and management of the pharmacist-in-charge.

(A) The following constitutes requirements for maintaining temporary or mobile facilities:

1. Temporary or mobile pharmacy facilities shall only be located within the disaster area or adjacent county;

2. Temporary facilities may be maintained by a pharmacy operation for a period of up to six (6) months without applying for a change of location. Any pharmacy wishing to maintain a temporary site for more than six (6) months or desires to remain permanently at the temporary site, must apply for a change of location as outlined in 4 CSR 220-2.020(4);

3. Mobile pharmacy operations must cease services once the immediate disaster is over;

4. Temporary or mobile pharmacy facilities must inform the board of their location and provide an estimate of the time period for

which the temporary or mobile pharmacy operation will be needed; and

5. The executive director shall have the authority to approve or disapprove temporary or mobile pharmacy facilities and shall make arrangements for appropriate monitoring and inspection of the pharmacy on a case by case basis.

A. Approval of this type of operation will be based on the need, type and scope of disaster, as well as the ability of the pharmacy to comply with state and federal drug laws in addition to section 338.240, RSMo.

B. Temporary or mobile pharmacy facilities shall cease operations under the provisions of this rule if any previous approval is withdrawn.

C. Any decision made concerning the approval of a temporary or mobile pharmacy shall not interfere with any rights or privileges of a pharmacy permit holder at the original location of operation or prevent a permit holder from applying for a change of location as outlined in 4 CSR 220-2.020(4).

*AUTHORITY: sections 338.210 and 338.280, RSMo 1994.\* 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.*

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

### 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, how-

ever, 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 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*



II, 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 or provides medications upon receipt of a prescription or physician order for patients in institutional settings and the nonresident pharmacy is not recognized as a primary provider.

(2) To obtain a license as a pharmacy, a nonresident pharmacy must comply with each of the following:

(A) Maintain a 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 4 CSR 220-2.020(2) and (3);

(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; and

(E) Submit a copy of the state and federal controlled substance registrations from the state in which it is located, if controlled substances are to be shipped into Missouri.

(3) When requested to do so by the Missouri

Board of Pharmacy, each nonresident pharmacy shall supply any inspection reports, warning notices, notice of deficiency reports or any other related reports from the state in which it is located concerning the operation of a nonresident pharmacy for review of 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 and 338.280, RSMo 2000 and 338.220, RSMo Supp. 2001. \* 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.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001; and 338.280, RSMo 1951, amended 1971, 1981.*

#### **20 CSR 2220-2.030 Educational and Licensure 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) The State Board of Pharmacy shall receive and process each complaint made against any licensee or registrant or other person or entity, which complaint alleges certain acts or practices which may constitute one (1) or more violations of the provisions of Chapter 338, RSMo. Any member of the public, the profession or any federal, state or local official may make and file a complaint with the board. Complaints shall be received from sources outside Missouri and will be processed in the same manner as those originating within Missouri. 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. However, actual receipt of the complaint by the board at its administrative offices in any manner shall be sufficient. Complaints may be based upon personal knowledge or upon information and belief, reciting information received from other sources.

(3) All complaints shall be made in writing and shall fully identify their maker by name and address. Complaints may be made on forms provided by the board, which shall be available upon request. Complaints need not be made by affidavit, but oral or telephone communications will not be considered or processed as complaints. Any person attempting to make an oral or telephone complaint against an individual will be provided with a complaint form and requested to complete it and return it to the board. 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. Complaints shall be logged in consecutive order as received. The record shall contain each com-

plainant'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 shall 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 shall be considered a closed record of the board and shall not be available for inspection by the public.

(7) This rule shall not be deemed to 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: sections 338.140 and 338.280, RSMo 2000 and 620.010.15(6), RSMo Supp. 2004.\* This rule originally filed as 4 CSR 220-2.050. Original 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.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.280, RSMo 1951, amended 1971, 1981; and 620.010.15(6), RSMo 1973, amended 1981, 1983, 1986, 1989, 1990, 1993, 1994, 1995, 1999, 2001.*

### 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 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. These gold certificates shall be distinctive in coloration and text from other documentary licenses issued by the board and shall be designed to appropriately recognize each recipient pharmacist for his/her half century of professional practice. Gold certificates are honorific in nature and confer no right to practice pharmacy upon the recipient.

(2) The awarding of gold certificates shall be made by the Missouri Board of Pharmacy routinely and without charge to the recipient.

*AUTHORITY: section 338.140, RSMo Supp. 1989.\* 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.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989.*

### 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 shall be 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. This

shall include, but is 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 data transmission 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 data transmission prescription" shall be 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 shall preclude 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 for any drug for a minimum of the preceding twenty-four- (24-) month period. Drug utilization information shall be available by date(s), 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 shall not conflict with 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 338.140, RSMo Supp. 2012, and section 338.280, RSMo 2000.\* 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.

*\*Original authority: 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999, 2010; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 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 Transmission of Prescription Data

**PURPOSE:** *This rule establishes basic guidelines to address new technology for the transmission of prescription data utilizing electronic mediums.*

(1) Definitions.

(A) Electronic transmission prescription—Includes transmission of both image and data prescriptions.

(B) Electronic image transmission prescription—Any prescription order for which an exact visual image of the order is received by a pharmacy from a licensed prescriber.

(C) Electronic data transmission prescription—Any prescription order, other than an electronic image transmission prescription, which is electronically transmitted from a licensed prescriber to a pharmacy.

(D) Electronic signature—Means a confidential personalized digital key, code, number or other identifier used for secure electronic data transmissions which identifies and authenticates the signatory. Electronic signatures may be sent as part of an electronic transmission prescription to a pharmacy or it may be applied to a hard copy to be provided to the patient.

(2) When a prescription is transmitted to a pharmacy electronically, the following requirements must be met:

(A) The original electronic facsimile transmission (FAX) document or all information from an electronic source must be readily

retrievable through the pharmacy computer system;

(B) To maintain the confidentiality of patient records, the system shall have adequate security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. Once the drug has been dispensed, any alterations in prescription drug order data shall be documented including the identification of the pharmacist responsible for the alteration;

(C) In verifying the authenticity of a transmitted prescription, the pharmacist shall ensure the validity of the prescription as to its source of origin. Measures to be considered in authenticating prescription drug orders received via electronic transmission include:

1. Maintenance of a practitioner's facsimile number reference or other electronic signature file;

2. Verification of the telephone number of the originating facsimile equipment;

3. Telephone verification with the practitioner's office that the prescription as both written by the practitioner and transmitted by the practitioner or the practitioner's authorized agent;

4. Other efforts which, in the professional judgment of the pharmacist, may be necessary to ensure the transmission was initiated by the prescriber;

(D) At the option of the patient, an electronically produced prescription may be sent to a pharmacy electronically or provided as a hard copy generated from the prescriber's electronic prescribing system;

(E) Hard copy prescriptions presented to the patient generated from electronic media shall be applied to paper that utilizes security features that will ensure that the prescription is not subject to any form of copying and/or alteration; and

(F) Electronic transmission technology utilized by pharmacy personnel shall not be used to circumvent or violate any provision of state and federal drug laws or the Pharmacy Practice Act and accompanying regulations.

**AUTHORITY:** *sections 338.010, 338.095 338.140 and 338.280, RSMo 2000.\* 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.*

*\*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990; 338.095, RSMo 1993; 338.140, RSMo 1939, amended 1981, 1989, 1997; 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) A pharmacist may be a pharmacist-in-charge of a licensed pharmacy; provided, that s/he complies with all provisions of this rule.

(2) The responsibilities of a pharmacist-in-charge, at a minimum, will include:

(A) The management of the pharmacy must be under the supervision of a Missouri-licensed pharmacist at all times when prescriptions are being compounded, dispensed or sold;

(B) The traffic in the prescription area must be restricted to authorized personnel only so that proper control over the drugs can be maintained at all times;

(C) All the required signs are displayed in the appropriate places when there is no pharmacist on duty;

(D) The licenses of all pharmacists employed are conspicuously displayed in the pharmacy;

(E) Assurance that all procedures of the pharmacy in the handling, dispensing and recordkeeping of controlled substances are in compliance with state and federal laws;

(F) Any excessive or suspicious requests, or both, for the dispensing of controlled substances be verified prior to dispensing;

(G) All labeling requirements are complied with according to section 338.059, RSMo, federal laws where required and board regulations governing auxiliary labeling of drugs and devices;

(H) The prescription files are maintained according to the requirements of this board and the other state and federal controlled substance laws and regulations;

(I) The Missouri Revised Negative Drug Formulary and state laws governing drug substitution be complied with when generic substitution takes place;

(J) If exempt narcotics are sold, complete records be kept of all exempt narcotics in a bound exempt narcotic register;

(K) If poisons are sold, the pharmacy maintain a poison register;

(L) The pharmacy maintain and have on file at all times the required reference library;

(M) The pharmacy be kept in a clean and sanitary condition;

(N) The pharmacist-in-charge will be responsible for the supervision of all pharmacy personnel, to assure full compliance with the pharmacy laws of Missouri;

(O) All Missouri and federal licenses are kept up-to-date;

(P) Policies and procedures are in force to insure safety for the public concerning any action by pharmacy staff members or within the pharmacy physical plant;

(Q) All equipment, as prescribed through regulation, is available and in good working order;

(R) Security is sufficient to insure the safety and integrity of all legend drugs located in the pharmacy;

(S) Any changes of the following are appropriately carried out:

1. Pharmacy permit transfer of any type or manner;

2. Regulation requirements completed satisfactorily when a change of pharmacist-in-charge occurs;

3. Change of pharmacist's own address as it appears on his/her license;

(T) When the board-recognized pharmacist-in-charge is changed at that licensed facility, an appropriate documented inventory of controlled substances must be taken;

(U) Assure that the appropriate handling and disposal of controlled substances is done and verified through appropriate documentation and when necessary that controlled substances be disposed of through appropriate procedures involving the Missouri Board of Pharmacy or the Bureau of Narcotics and Dangerous Drugs;

(V) No outdated drugs are dispensed or maintained within the active inventory of the pharmacy, including prescription and related nonprescription items;

(W) Assure full compliance with all state and federal drug laws and rules;

(X) Compliance with state and federal requirements concerning drug samples;

(Y) Assure that all state and federal laws concerning drug distribution and control are complied with and that no violations occur that would cause a drug or device or any component thereof to become adulterated or misbranded;

(Z) Maintain compliance with all state and federal laws governing drug distributor activities and assure that appropriate licensure as a drug distributor is secured if lawful thresholds for unlicensed drug distributions are exceeded;

(AA) Assure overall compliance with state and federal patient counseling requirements;

(BB) Maintain a current list of all personnel employed by the pharmacy as pharmacy technicians. The list shall include the name, registration number or a copy of an application for registration that has been submitted to the board and a description of duties to be

performed by each person contained on the list;

(CC) Maintain written standards setting out the responsibilities of registered pharmacy technicians as well as the procedures and policies for supervision of registered pharmacy technicians, as required by 4 CSR 220-2.700(1). Said standards shall be available to the board and its designated personnel for inspection and/or approvals;

(DD) Any person other than a pharmacist or permit holder who has independent access to legend drug stock on a routine basis in a pharmacy shall be required to register with the board as a pharmacy technician. The determination of whether or not an individual must register as a pharmacy technician will be the responsibility of the pharmacist-in-charge; and

(EE) Maintain compliance of automated dispensing and storage systems with applicable board rules and regulations.

*AUTHORITY: sections 338.140, 338.240 and 338.280, RSMo 2000.\* 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.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.240, RSMo 1951; 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, water-proof, 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 pre-addressed 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 non-retrievable 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 Information for the Purpose of Refill

**PURPOSE:** *This rule defines record keeping required for transfer of prescription information for the purpose of refill.*

(1) Prescription information shall be transferred for the purposes of refill between licensed pharmacies, provided the prescription information to be transferred meets all of the following criteria:

(A) The prescription information indicates authorization by the prescriber for refilling;

(B) The drug on the prescription information is not a Schedule II controlled substance;

(C) The number of lawfully allowable refills has not been exceeded or the maximum allowable time limit has not been exceeded;

(D) If the transfer involves a controlled substance, all information must be transferred directly between two (2) licensed pharmacists; and

(E) The transfer of original prescription information for a controlled substance listed in Schedules III, IV or V for the purpose of refill dispensing 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) When a prescription on record is transferred, the following record keeping is required:

(A) The prescription record at the transferring pharmacy shall show all of the following:

1. The word void must appear on the face of the invalidated prescription or be immediately voided within the electronic system when the prescription is transferred;

2. The prescription record shall provide the name of the pharmacy to which it was transferred, the date of transfer and the identity of the transferring pharmacist; and

3. If the transfer involves a controlled substance, the address and Drug Enforcement Administration (DEA) registration number of the pharmacy to which it was transferred and the full name of the pharmacist receiving the prescription information must be recorded;

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

information of an original prescription:

1. The prescription record is a transferred prescription record from another licensed location;

2. Date of original issuance;

3. Date of original filling, if different from original issuance date;

4. Original number of refills authorized on the original prescription and the number of remaining authorized refills;

5. Date of last refill;

6. Prescription label number;

7. Identity of licensed pharmacy from which the record was transferred;

8. The identity of the transferring pharmacist provided that pharmacies that share the same database and are under the same ownership may, instead of transferring prescriptions directly between two (2) pharmacists, transfer a prescription electronically by generating a computer-based report at the transferring pharmacy of any prescriptions that have been transferred out. This record shall be readily retrievable to the transferring pharmacy and board representatives and comply with all of the requirements of this rule, except that the requirement to document pharmacist identity shall not be required unless otherwise required by federal law;

9. If the transfer involves a controlled substance, the address and DEA registration number from the transferring pharmacy must be recorded; and

10. Any electronic transfer must maintain patient confidentiality in accordance with 20 CSR 2220-2.300; and

(C) A computerized transfer of prescription information between licensed pharmacies for the purpose of refill shall meet all the requirements stated in sections (1) and (2) of this rule.

(3) A pharmacy shall complete the transfer within one (1) business day of receiving the request.

**AUTHORITY:** *sections 338.100, 338.140, and 338.280, RSMo 2000.\* 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.*

*\*Original authority: 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999; 338.140, RSMo 1939, amended 1981, 1989, 1997; 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 consis-

tent 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 caution-

ary 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 sixty (60) days from the date of preparation);

8. The name, address, and telephone number of the dispenser; and

9. Any other information, statements, or warnings required for any 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 packaging of controlled substances is prohibited.

(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: sections 338.010 and 338.140, RSMo Supp. 2011, and section 338.059, RSMo 2000.\* 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.*

*\*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011; 338.059, RSMo 1971, amended 1973, 1978, 1997; and 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011.*



**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) The board of pharmacy shall receive and process any report from a hospital or ambulatory surgical center concerning any disciplining 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.

(2) Reports to the board shall comply with the minimum requirements as set forth in section 383.133, RSMo and this rule. This information shall include, but not be limited to:

(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.

(3) The director of pharmacy or pharmacist-in-charge shall report any actions as described in section (1) to the chief executive officer (CEO) or his/her designee. 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. Nothing in this rule shall be construed as limiting or prohibiting any pharmacist from reporting a violation of the Pharmacy Practice Act directly to the Missouri Board of Pharmacy.

(4) In response to an inquiry from a hospital or ambulatory surgical center regarding reports received by the board on a specific pharmacist, the board shall provide the following information:

(A) Whether any reports have been received;

(B) The nature of each report; and

(C) The action which the board took on each report or if the board has taken action on the report.

(5) Each report received shall be acknowledged in writing. The acknowledgment shall state that the report is being reviewed by the board or is being investigated and shall be referred to the board or an appropriate board subcommittee for consideration. The institution subsequently shall be informed in writing as to whether the report has been dismissed by the board or is being referred to legal counsel for filing with the Administrative Hearing Commission or for other legal action. The institution may be notified of the ultimate disposition of the report excluding judicial appeals and may be provided with a copy of the decisions (if any) of the Administrative Hearing Commission and the board.

(6) 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 383.133, RSMo 1986.\* 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.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989 and 383.133, RSMo 1986.*

**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) Committee administrator—The person who is hired by the contractor or the committee to oversee and manage the Well-Being Program.

(C) Contractor—An entity with whom the board contracts for the purpose of creating, supporting, and maintaining the Well-Being Program.

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

(E) 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 Mis-

souri.

(F) Well-Being Committee—The committee established pursuant to section 338.380, RSMo, for the purpose of promoting the early identification, intervention, treatment, and rehabilitation of pharmacists, intern pharmacists, and technicians who may be impaired by reasons of illness, substance abuse, or as a result of any physical or mental condition.

(G) Well-Being Program—The activities and functions of the Well-Being Committee.

(2) The board may contract with a contractor for purposes of creating, supporting, and maintaining the Well-Being Program. The Well-Being Committee may assist the board in the identification, selection, and evaluation of the contractor, as requested by the board. 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 licensee shall be paid by the licensee.

(3) Membership and Organization.

(A) The Well-Being Committee (hereinafter committee) shall be composed of the committee administrator and three (3) appointed members as follows:

1. One (1) member designated by the Missouri Pharmacy Association;

2. One (1) member designated by the Missouri Society of Health-System Pharmacists; and

3. One (1) member designated by the State Board of Pharmacy.

(B) The appointed committee members shall serve staggered three (3)-year terms and may serve as many terms as their respective organizations deem appropriate. The entity designating a member to the committee shall designate a person to finish the three (3)-year term of any member of the committee who becomes unable to serve.

(C) The committee shall annually elect a chairperson.

(D) The committee shall meet at least two (2) times annually.

(E) The appointed committee members shall serve without compensation other than that allowed by law for service as a board member. Each appointed committee member shall be entitled to reimbursement for travel expenses as deemed appropriate by the board.

(F) The committee administrator shall be a nonvoting member of the committee.

(4) An impaired licensee may enter the Well-Being Program voluntarily or by referral of the board pursuant to a settlement agreement or other disciplinary order. Licensees entering the Well-Being Program voluntarily shall be subject to and shall comply with all requirements of this rule.

(5) Well-Being Committee Duties.

(A) The committee shall oversee all aspects of the general operation of the contractor including, but not limited to, oversight of the administration, staffing, financial operations, and case management of the Well-Being Program.

(B) The committee shall assist the board in monitoring the impaired licensee's compliance with the terms of any disciplinary order/agreement.

(C) The committee shall provide the board access to all information and documents pertaining to impaired licensees referred to the Well-Being Program by the board.

(D) The committee shall enter into written contracts with each impaired licensee. The contract between the committee and the impaired licensee shall be a minimum of five (5) years in duration, or the time designated by the board. The contract between the committee and impaired licensee shall include, but shall not be limited to, the following conditions/requirements:

1. Each impaired licensee shall comply with all terms, conditions, or treatment identified, required, or recommended by the contractor or the board for the treatment, evaluation, monitoring, or assessment of the impaired licensee;

2. Each impaired licensee shall abstain from the possession or consumption of legend medication, except as prescribed by a treating prescriber;

3. Each impaired licensee shall abstain from illegal possession of alcohol, the consumption of alcohol, and the possession or consumption of illegal drugs;

4. Each impaired licensee shall submit to random drug testing unless otherwise specified by the board, committee, or contractor;

5. Each impaired licensee shall report to the committee or the contractor all relapses or other breaches of the contractual terms;

6. Each impaired licensee shall report to or meet with the board, committee, contractor, or the contractor's appointed designee as may be requested by the board, committee, or contractor;

7. Each impaired licensee shall attend support meetings as requested by the committee, contractor, or treatment providers;

8. Each impaired licensee referred to the Well-Being Program by the board shall authorize the committee to release any and all information regarding the impaired licensee to the board;

9. Each impaired licensee voluntarily enrolled in the Well-Being Program shall authorize the committee to release any and all information regarding the impaired licensee to the board upon a violation of any state or



federal drug law or if the licensee breaches or fails to comply with any terms of a Well-Being contract; and

10. Each impaired licensee shall be financially responsible for all drug screens and any other professional or administrative service rendered on behalf of the impaired licensee.

(E) The committee shall provide to the board in writing:

1. An annual action plan and budget to be approved 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 or committee;

2. Progress reports with regard to each licensee participating in or being assisted by the Well-Being Program. The identity of licensees 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. Progress reports shall be provided to the board at board meetings or upon request of the board;

3. Except as otherwise provided by this rule for voluntary participants, any and all information or documentation with regard to the identification, intervention, treatment, and rehabilitation of any licensee who participates in, or is assisted by, the Well-Being Program;

4. Quarterly income and expense reports. These reports must be itemized and account for all income from any and every source and each expense to any and every vendor that relates to the Well-Being Program in any way; and

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

(F) In addition to the other requirements of this rule, the committee shall also report, in writing, to the board:

1. All licensee violations of board disciplinary orders/agreements, board statutes or regulations, or other state or federal drug laws which occur after the date of the disciplinary order/agreement or the date the licensee entered the Well-Being Program, whichever occurs first;

2. Any licensee who fails to enter treatment within forty-eight (48) hours following the provider's determination that the licensee needs treatment;

3. Any licensee who does not comply with the terms of a Well-Being Program contract or who resumes the practice of pharmacy before the treatment provider has made a clear determination that the licensee is capa-

ble of practicing; and

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

(G) The identity of licensees who voluntarily submit to the Well-Being Program shall remain anonymous to the board, provided that upon receipt of a Notice of Non-Compliance from the contractor, the committee shall promptly file a complaint with the board against the licensee identified in the notice. The complaint required by this subsection shall include the impaired licensee's name, license number, and the factual basis for the alleged contractual breach/non-compliance. Upon the filing of a complaint, the committee shall require the committee administrator to supply to the board any information or documentation with regard to the licensee's identification, intervention, treatment, compliance, and rehabilitation, as requested by the board or their designated representative.

(H) The committee shall require the costs of drug screens and professional and administrative services to be paid by the impaired licensee.

#### (6) Committee Administrator Duties.

(A) The committee administrator shall oversee and manage the daily operations of the committee and assist with the administrative duties of the committee.

(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.

(D) Upon referral, the duties of the committee administrator shall also include, but are not limited to, assisting the committee with the following:

1. Organizing and carrying out interventions;
2. Referring licensees for appropriate assessment or evaluation and seeing that treatment recommendations based on the

assessment are followed;

3. Monitoring treatment progress and re-entry contractual compliance;

4. Managing/monitoring random drug screens;

5. Assisting licensees to re-enter practice from treatment;

6. Assisting with aftercare issues;

7. Any and all reporting to appropriate agencies, as requested by the board or the committee;

8. Program development;

9. Outreach education, as requested by the committee; and

10. Other necessary services as determined by the committee.

(E) Upon request by the committee, the committee administrator shall supply to the committee in writing:

1. Any information or documentation regarding the operation of the Well-Being Program;

2. All information or documentation with regard to the identification, intervention, treatment, and rehabilitation of any licensee that is participating in or being assisted by the Well-Being Program or who has participated in or been assisted by the Well-Being Program;

3. Progress reports to the committee with regard to each licensee participating in the Well-Being Program; and

4. Any reports provided to the board.

(F) Upon request, the committee administrator shall supply to the board in writing:

1. Any information requested by the board regarding the Well-Being Program or any licensee participating in or being assisted by the Well-Being Program, except as otherwise provided herein for voluntary participants; and

2. Any information or documentation with regard to the identification, intervention, treatment, rehabilitation, and compliance of any voluntary participant who breaches or fails to comply with the terms of any Well-Being Program contract or violates any state or federal law.

#### (7) Contractor Duties.

(A) Upon referral, the contractor shall be responsible for requiring evaluators to provide written reports which address whether a participant of the Well-Being Program suffers from an impairment, identifies the impairment, provides recommendations for treatment of the impairment, and whether the participant's practice of pharmacy should be restricted due to the impairment; and

(B) The contractor shall provide services when appropriate to impaired licensees which include, but are not limited to, the following:



1. Monitoring compliance of the contractor between the committee and the impaired licensee;

2. Assisting the impaired licensee in obtaining evaluation and treatment;

3. Ensuring that treatment recommendations based on the assessment of the licensee are followed;

4. Monitoring treatment progress and re-entry contractual compliance;

5. Managing/monitoring random drug screens;

6. Assisting licensees to re-enter practice from treatment;

7. Assisting with aftercare issues;

8. Any and all reporting to appropriate agencies, as requested by the board or the committee;

9. Program development;

10. Outreach education, as requested by the committee;

11. Managing, ensuring, and monitoring random and scheduled drug screens; and

12. Other necessary services as determined by the committee.

(C) The contractor shall assist the board in monitoring the impaired licensee's compliance with the terms of any disciplinary order/agreement.

(D) The contractor shall obtain a written release from all licensees referred to the Well-Being Program that authorizes the contractor to release to the board, the committee, or the committee administrator all information and documents pertaining to a licensee referred by the board.

(E) Voluntary Participants.

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

2. The contractor shall file with the committee a Notice of Non-Compliance 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. If a complaint is filed by the committee against the licensee, the contractor shall require the committee administrator to supply to the board any information or documentation with regard to the licensee's identification, intervention, treatment, compliance, and rehabilitation, as requested by the board.

3. The contractor shall obtain a written release from all licensees who voluntarily enter the Well-Being Program that authorizes the contractor to release any and all information or documents pertaining to the licensee to the board or the committee in the event the licensee breaches or fails to comply with the terms of any Well-Being Program contract or

violates any state or federal drug law.

(F) General Reporting.

1. The contractor shall provide to the committee in writing:

A. An annual action plan and budget to be approved by the board. The contractor shall report on progress with regard to preparing and implementing the action plan and budget as requested by the board or committee;

B. Quarterly income and expense reports for the Well-Being Program and any other financial report requested by the board or the committee;

C. Progress reports with regard to each licensee participating in or being assisted by the Well-Being Program;

D. Any reports provided to the board;

E. Any and all information or documentation with regard to the identification, intervention, treatment, and rehabilitation of any licensee who participates in, or is assisted by, the Well-Being Program;

F. Any other report or information requested by the committee; and

G. The information and documentation required by this subsection shall only be released to the board pursuant to Chapter 338, RSMo, and the rules promulgated there-to.

2. The contractor shall provide to the board in writing:

A. An annual action plan and budget as directed by the board. The contractor shall report on progress with regard to preparing and implementing the action plan and budget as requested by the board or committee;

B. Progress reports with regard to each licensee participating in or being assisted by the Well-Being Program, provided the identity of licensees 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; and

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

(G) Violation Reporting. In addition to the other requirements of this rule, the contractor shall report, in writing, to the committee:

1. All licensee 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 licensee entered the Well-Being Program, whichever occurs first;

2. Any licensee who fails to enter treatment within forty-eight (48) hours following

the provider's determination that the licensee needs treatment; and

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

(H) The contractor shall require the costs of drug screens and professional and administrative services to be paid by the impaired licensee.

(8) Confidentiality.

(A) The committee and contractor shall provide the board access to all information pertaining to each impaired licensee referred to the committee by the board.

(B) In regards to participants referred by the board and the voluntary participants who have violated or breached their Well-Being Program contracts, 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 to promote the identification, interventions, treatment, rehabilitation, and discipline (accountability) of licensees 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 2000 and section 338.380, RSMo Supp. 2009.\* Original rule filed Aug. 18, 2009, effective March 30, 2010.*

*\*Original authority: 338.140.1, RSMo 1939, amended 1981, 1989, 1997 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 shall 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, 4 CSR 220-4.020. The board may require payment of the fees prior to making available any public records.

(4) When a request for access to public records is made and the custodian believes that access is not required under the provisions of Chapter 610, RSMo, the custodian shall inform the individual or entity making the request that compliance with the request cannot be made, specifying in particular what sections of Chapter 610, RSMo require that the record remain closed. Any such correspondence or documentation of the denial made for access to records shall be copied to the Board of Pharmacy general counsel. Whenever the custodian denies access to the records, the custodian also shall inform the individual requesting the records that s/he may appeal directly to the Board of Pharmacy for access to the records requested. The appeal and all information pertaining to the appeal shall be placed on the meeting agenda of the Board of Pharmacy for its next regularly scheduled meeting. In the event that the board decides to reverse the decision of the custodian, the board shall direct the custodian to so advise the person requesting access to the information and supply the access to the information during regular business hours at the convenience of the requesting party.

(5) The custodian shall maintain a file which will contain copies of all written requests for access to records and responses to the requests. These requests shall be maintained on file with the board for a period of one (1) year and will be maintained as a public record of the board open for inspection by any member of the general public during regular business hours.

(6) Pursuant to section 620.111, RSMo any complaints, investigation reports and accompanying documents or exhibits that are considered closed documents under Chapter 610 or 620, RSMo, and are possessed by the

board or any of its agents shall not be disclosed to any member of the public or to a licensee until the investigation is completed.

(A) Federal or state agency documents shall not be released without the written consent of the federal or state agency involved.

*AUTHORITY: sections 338.140, 338.280, Chapters 610 and 620, RSMo 1994.\* 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.*

*\*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 2220-2.200 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 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. 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) Definitions.

(A) Aseptic processing: The technique involving procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during processing.

(B) Batch: Compounding of multiple sterile preparation units in a single discrete process, by the same individuals, carried out



during one (1) limited time period.

(C) 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.

(D) Biological safety cabinet: Containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the preparation, personnel, and environment, according to National Sanitation Foundation (NSF) International standards.

(E) Buffer area: An ISO Class 7 or better area where the primary engineering control is physically located that is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room and in which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary.

(F) Compounding: For the purposes of this regulation, compounding is defined as in 20 CSR 2220-2.400(1). Compounded sterile medications may include, but are not limited to:

1. Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that must or are required to be sterile when they are administered to patients, including, but not limited to, the following dosage forms: bronchial and inhaled nasal preparations intended for deposition in the lung(s), baths and soaks for live organs and tissues, epidural and intrathecal solutions, bladder/wound solutions, injectables, implantable devices and dosage forms, inhalation solutions, intravenous solutions, irrigation solutions, ophthalmic preparations, parenteral nutrition solutions, and repackaged sterile preparations. Nasal sprays and irrigations intended for deposit in the nasal passages may be prepared as nonsterile compounds;

2. An FDA approved manufactured sterile product that is either prepared according to the manufacturers' approved labeling/recommendations or prepared differently than published in such labeling; and

3. Assembling point-of-care assembled systems.

(G) Compounding aseptic containment isolator (CACI): A restricted access barrier system (RABS) that is designed for compounding sterile hazardous drugs and designed to provide worker protection from exposure to undesirable levels of airborne drugs throughout the compounding and material transfer

processes and to provide an aseptic environment for Compounded Sterile Preparation (CSPs).

(H) Compounding aseptic isolator (CAI): A RABS specifically designed for compounding sterile non-hazardous pharmaceutical ingredients or CSPs and designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes.

(I) Controlled area: For purposes of these regulations, a controlled area is a separate room designated for preparing sterile preparations or an area designated for preparing sterile preparations that is separated from other activities/operations by a line of demarcation that clearly separates the area from other operations.

(J) Critical area: Any area in the controlled area where preparations or containers are exposed to the environment.

(K) Critical site: Any surface, pathway, or opening (e.g., vial septa, injection ports, beakers, needle hubs) that provides a direct pathway between a compounded sterile preparation or other ingredient used to compound a sterile preparation and the air, environment or moisture, or that poses a risk of touch contamination.

(L) CSP: Compounded sterile preparation.

(M) Cytotoxic drugs: A pharmaceutical product that has the capability of direct toxic action on living tissue that can result in severe leukopenia and thrombocytopenia, depression of the immune system, and the alteration of a host's inflammatory response system.

(N) Emergency dispensing: Is a situation where a Risk Level 3 preparation is necessary for immediate administration of the preparation and no alternative product or preparation is available and the prescriber is informed that the preparation is being dispensed prior to appropriate testing. Documentation of the dispensing of the preparation, the prescriber's approval for dispensing prior to the receipt of test results and the need for the emergency must appear within the prescription record. A separate authorization from the prescriber is required for each emergency dispensing.

(O) High-Efficiency Particulate Air (HEPA) filter: A filter composed of pleats of filter medium separated by rigid sheets of corrugated paper or aluminum foil that direct the flow of air forced through the filter in a uniform parallel flow. HEPA filters remove ninety-nine point ninety-seven percent (99.97%) of all particles three-tenths (0.3) microns or larger. When HEPA filters are used as a component of a horizontal- or vertical-laminar-airflow workbench, an environment can be created consistent with standards for an ISO Class 5 environment.

(P) In-use time/date: The time/date before which a conventionally manufactured product or a CSP must be used after it has been opened or needle-punctured.

(Q) ISO Class 5: An area with less than three thousand five hundred twenty (3,520) particles (0.5  $\mu\text{m}$  and larger in size) per cubic meter.

(R) ISO Class 7: An area with less than three hundred fifty-two thousand (352,000) particles (0.5  $\mu\text{m}$  and larger in size) per cubic meter.

(S) Multiple-dose container: A multiple unit container for articles or compounded sterile preparations that contains more than one (1) dose of medication and usually contains an antimicrobial preservative.

(T) Parenteral: A sterile preparation of drugs for injection through one (1) or more layers of skin.

(U) Point-of-care assembled system: A closed system device that creates a physical barrier between diluents, fluids, or other drug components and is designed to be activated by the end user by allowing the components to mix prior to administration.

(V) Primary engineering control (PEC): A system that provides an ISO 5 environment for the exposure of critical sites when compounding sterile preparations. PECs include, but may not be limited to, horizontal/vertical laminar airflow hoods, biological safety cabinets, and a RABS such as compounding aseptic isolators (CAIs), or compounding aseptic containment isolators (CACIs).

(W) Process validation or simulation: Microbiological simulation of an aseptic process with growth medium processed in a manner similar to the processing of the preparation and with the same container or closure system.

(X) Quality assurance: For purposes of these regulations, quality assurance is the set of activities used to ensure that the processes used in the preparation of sterile drug preparations lead to preparations that meet predetermined standards of quality.

(Y) Quality control: For the purposes of these regulations, quality control is the set of testing activities used to determine that the ingredients, components, and final sterile preparations prepared meet predetermined requirements with respect to identity, purity, nonpyrogenicity, and sterility.

(Z) Restricted access barrier system (RABS): A primary engineering control that is comprised of a closed system made up of four (4) solid walls, an air-handling system, and transfer and interaction devices. The walls are constructed so as to provide surfaces that are cleanable with coving between wall junctures. The air-handling system provides



HEPA filtration of inlet air. Transfer of materials is accomplished through air locks, glove rings, or ports. Transfers are designed to minimize the entry of contamination. Manipulations can take place through either glove ports or half suits. Examples of a RABS may include, but is not limited to, a CAI or CACI.

(AA) Repackaging: The subdivision or transfer of a compounded preparation from one (1) container or device to a different container or device.

(BB) Single-dose/single-unit container/vial: A container/vial of medication intended for administration that is meant for use in a single patient for a single case, procedure, or injection.

(CC) Sterilization: A validated process used to render a preparation free of viable organisms.

(DD) Temperatures:

1. Frozen means temperatures between twenty-five degrees below zero and ten degrees below zero Celsius (-25 and -10°C) (thirteen degrees below zero and fourteen degrees Fahrenheit (-13 and 14°F));

2. Refrigerated means temperatures between two and eight degrees Celsius (2 and 8°C) (thirty-six and forty-six degrees Fahrenheit (36 and 46°F)); and

3. Controlled room temperature means a temperature maintained thermostatically that encompasses the usual and customary working environment 20° to 25° Celsius (68° to 78° F). Excursions between 15° and 30° Celsius (59° to 86° F) as commonly experienced in pharmacies and other facilities shall be deemed compliant.

(EE) USP: *The United States Pharmacopeia and the National Formulary* (USP-NF) as adopted and published by the United States Pharmacopoeial Convention, effective May 2013. Copies of the USP-NF are published by, and available from, USP, 12601 Twinbrook Parkway, Rockville, MD 20852-1790 or online at <http://www.usp.org/>. The USP-NF is incorporated herein by reference. This rule does not include any later amendments or additions to the USP-NF.

(FF) Validation: Documented evidence providing a high degree of assurance that specific processes will consistently produce a preparation meeting predetermined specifications and quality attributes.

(GG) Definitions of sterile compounded preparations by risk level:

1. Risk Level 1: Applies to compounded sterile preparations that exhibit characteristics A., B., or C., stated below. All Risk Level 1 preparations shall be prepared with sterile equipment and sterile ingredients and solutions in an ISO Class 5 environment. Risk Level 1 includes the following:

A. Preparations:

(I) Stored at controlled room temperature and assigned a beyond-use date of forty-eight (48) hours or less; or

(II) Stored under refrigeration and assigned a beyond-use date of seven (7) days or less; or

(III) Stored frozen and assigned a beyond-use date of thirty (30) days or less;

B. Unpreserved sterile preparations prepared for administration to one (1) patient or batch-prepared preparations containing suitable preservatives prepared for administration to more than one (1) patient with an assigned beyond-use date that does not exceed the beyond-use date allowed under subparagraph (1)(GG)1.A. of this rule;

C. Preparations prepared by closed-system aseptic transfer of sterile, nonpyrogenic, finished pharmaceuticals (e.g., from vials or ampules) obtained from licensed manufacturers into sterile final containers obtained from licensed manufacturers with an assigned beyond-use date that does not exceed the beyond-use date allowed under subparagraph (1)(GG)1.A. of this rule;

2. Risk Level 2: Sterile preparations exhibit characteristic A., B., or C., stated below. All Risk Level 2 preparations shall be prepared with sterile equipment and sterile ingredients in an ISO Class 5 environment and with closed-system transfer methods. Risk Level 2 includes the following:

A. Preparations stored under refrigeration and assigned a beyond-use date greater than seven (7) days, or preparations stored frozen and assigned a beyond-use date greater than thirty (30) days, or preparations stored at controlled room temperature and assigned a beyond-use date greater than forty-eight (48) hours;

B. Batch-prepared preparations without preservatives that are intended for use by more than one (1) patient;

C. Preparations compounded by complex or numerous manipulations of sterile ingredients obtained from licensed manufacturers in a sterile container or reservoir obtained from a licensed manufacturer by using closed-system aseptic transfer (e.g., automated compounding);

3. Risk Level 3: Sterile preparations exhibit either characteristic A. or B.:

A. Preparations compounded from nonsterile ingredients or compounded with nonsterile components, containers, or equipment before terminal sterilization;

B. Preparations prepared by combining multiple ingredients (sterile or nonsterile) by using an open-system transfer or open reservoir before terminal sterilization.

(2) Policy and Procedure Manual/Reference Manuals.

(A) A manual, outlining policies and procedures encompassing all aspects of Risk Level 1, 2, and 3 compounding performed, shall be available for inspection at the pharmacy. The manual shall be reviewed on an annual basis. The pharmacy shall have current reference materials related to sterile preparations.

(3) Personnel Education, Training, and Evaluation.

(A) Risk Level 1: All pharmacy personnel preparing sterile preparations must receive suitable didactic and experiential training in aseptic technique and procedures and shall be skilled and trained to accurately and competently perform the duties assigned. Additional training must be provided if the risk level of sterile activity conducted by the individual changes or if there is a change in compounding methods performed. To ensure competency, individuals preparing sterile preparations must successfully pass an Aseptic Technique Skill Assessment that complies with section (10) of this rule. The pharmacy shall establish policies and procedures for staff training and assessment.

(B) Risk Level 2: In addition to Risk Level 1 requirements, personnel training must include assessment of competency in all Risk Level 2 procedures via process simulation.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, operators have specific education, training, and experience to prepare Risk Level 3 preparations. The pharmacist knows principles of good compounding practice for risk level preparations, including—

1. Aseptic processing;
2. Quality assurance of environmental, component, and end-preparation testing;
3. Sterilization; and
4. Selection and use of containers, equipment, and closures.

(4) Storage and Handling in the Pharmacy.

(A) Risk Level 1 and 2: Solutions, drugs, supplies, and compounding equipment must be stored and maintained in a manner that will maintain the chemical and microbiological stability of CSPs. Refrigeration, freezer and, if applicable, incubator temperatures shall be documented daily. Other storage areas shall be inspected regularly to ensure that temperature and lighting meet requirements. Drugs and supplies shall be shelved above the floor. Removal of drugs and supplies from boxes shall be done outside the controlled and buffer areas. Removal of used supplies from the controlled area shall be



done at least daily. Preparation recall procedures must comply with section (21) of this rule and must permit retrieving affected preparations from specific involved patients.

(B) Risk Level 3: In addition to Risk Level 1 and 2 requirements, the pharmacy must establish procedures for procurement, identification, storage, handling, testing, and recall of components and finished preparations. Finished Risk Level 3 preparations awaiting test results must be quarantined under minimal risk for contamination in a manner that will maintain chemical and microbiological stability.

(5) Facilities and Equipment. The pharmacy shall establish and follow proper controls to ensure environmental quality, prevent environmental contamination, and maintain air quality in all ISO classified areas. The identity of the pharmacist conducting the required review and the review date shall be documented in the pharmacy's records.

(A) Risk Level 1: Risk Level 1 preparations must be prepared in a PEC located in a controlled area that meets the requirements of this rule. A sink with hot and cold water must be near, but not in, the controlled area. The controlled area and inside equipment must be cleaned and disinfected as provided in section (17) of this rule. Activities within the critical area shall be kept to a minimum to maintain the ISO classified environment. Primary engineering controls shall meet the requirements of section (6) of this rule; prefilters must be visually inspected on a regularly scheduled basis and replaced according to manufacturer's specifications. Pumps utilized in the compounding process shall be recalibrated and documented according to manufacturer procedures.

(B) Risk Level 2: In addition to all Risk Level 1 requirements, Risk Level 2 preparations must be prepared in a PEC located in a buffer area or prepared in a RABS located within a controlled area. Applicable environmental monitoring of air and surfaces must be conducted. Risk Level 2 preparations shall at a minimum remain a Risk Level 2 for the life of the preparation.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, Risk Level 3 preparations must be prepared in a PEC located in a buffer area or prepared in a RABS located within a controlled area. All non-sterile equipment that is to come in contact with the sterilized final preparation must be sterilized before introduction in the buffer area or into the RABS. Once compounded, Risk Level 3 preparations shall at a minimum remain Risk Level 3 for the life of the preparation.

(D) Automated compounding devices shall

be calibrated according to manufacturer procedures for content, volume, weight, and accuracy prior to initial use and prior to compounding each day the device is in use or more frequently as recommended by manufacturer guidelines. Calibration results shall be reviewed by a pharmacist to ensure compliance. The identity of the reviewing pharmacist and the review date shall be documented in the pharmacy's records.

(E) All PECs and ISO classified areas shall be certified to ensure compliance with the requirements of this rule prior to beginning sterile compounding activities and every six (6) months thereafter. Certification shall be conducted by competent staff/vendors using recognized and appropriate certification and testing equipment. Certification results shall be reviewed by a pharmacist once received. Deficiencies or failures shall be investigated and corrected prior to further compounding which may include recertification of the PEC/ISO classified area.

1. The PEC and ISO classified areas must be recertified when— 1) any changes or major service occurs that may affect airflow or environmental conditions or 2) the PEC or room is relocated or the physical structure of the ISO classified area has been altered.

2. Corrections may include, but are not limited to, changes in the use of the affected PEC or ISO classified area or initiating a recall.

(F) Pressure differential: If the sterile compounding area is equipped with a device to monitor pressure differential between ISO classified air spaces, pressure differential results must be recorded and documented each day that the pharmacy is open for pharmacy activities. Alternatively, a continuous monitoring system may be used to record pressure differential results if the system maintains ongoing documentation of pressure recordings or maintains pressure alerts that are reviewed daily.

(6) Primary Engineering Controls (PECs).

(A) PECs must be properly used, operated, and maintained and must be located out of traffic patterns and away from conditions that could adversely affect their operation or disrupt intended airflow patterns (e.g., ventilation systems or cross-drafts).

(B) PECs shall maintain ISO Class 5 or better conditions during dynamic operating conditions and while compounding sterile preparations, including, when transferring ingredients into and out of the PEC and during exposure of critical sites.

(C) PECs shall provide unidirectional (laminar flow) HEPA air at a velocity sufficient to prevent airborne particles from con-

tacting critical sites.

(D) The recovery time to achieve ISO Class 5 air quality in any PEC shall be identified in the pharmacy's policies and procedures. Procedures must be developed to ensure adequate recovery time is allowed before or during compounding operations and after material transfer.

(7) Controlled Areas. The controlled area shall be designed, maintained, and controlled to allow effective cleaning and disinfection and to minimize the risk of contamination and the introduction, generation, and retention of particles inside the PEC.

(A) Controlled areas must be clean and well-lit and shall be free of insects, rodents, and/or other vermin. Trash shall be disposed of in a timely and sanitary manner and at least daily. Tacky mats or similar articles are prohibited in the controlled area or any ISO classified environment.

(B) Traffic flow in or around the controlled area shall be minimized and controlled. Food items, chewing gum, eating, drinking, and smoking are prohibited in the area.

(C) Non-essential objects that shed particles shall not be brought into the controlled area, including, but not limited to, pencils, cardboard cartons, paper towels, and cotton items (e.g., gauze pads). Furniture, carts, supplies, and equipment shall be removed from shipping cartons/containers and properly cleaned and disinfected with sterile alcohol or an equivalently effective non-residue generating disinfectant before entering any ISO classified area. No shipping or other external cartons may be taken into the controlled area or an ISO classified area.

(D) Only supplies essential for compounding shall be stored in the controlled area. Supplies or other non-essential equipment shall not be stored in or on the PEC.

(8) Garbing and Hand Hygiene. Individuals engaged in, or assisting with, CSPs shall be trained and demonstrate competence in proper personal garbing, gloving, and hand hygiene. Competence must be documented and assessed through direct visual observation as part of the aseptic technique skill assessment required by this rule.

(A) Risk Level 1: Low-particulate and non-shedding gowns, hair covers, gloves, face masks, and, if applicable, beard covers must be worn during compounding and cleaning. All head and facial hair must be covered. During sterile preparation, gloves shall be disinfected before use and frequently thereafter with a suitable agent and changed when integrity is compromised. All personnel in the controlled area must be appropriately



garbed as required by this section.

(B) Risk Level 2 and Risk Level 3: In addition to Risk Level 1 requirements, shoe covers and sterile gloves must be worn while compounding and cleaning, including, over RABS gloves. All personnel in the controlled or buffer area must garb as required by this section.

(9) Aseptic Technique and Preparation. Appropriate quality control methods shall be maintained over compounding methods at all times to ensure proper aseptic technique.

(A) Risk Level 1: Sterile preparations must be prepared in an ISO Class 5 environment. Personnel shall scrub their hands and forearms a minimum of thirty (30) seconds and remove debris from underneath fingernails under warm running water before donning the required gloves. Eating, drinking, and smoking are prohibited in the controlled area. Talking shall be minimized to reduce airborne particles. Ingredients shall be determined to be stable, compatible, and appropriate for the preparation to be prepared, according to manufacturer, USP, or scientific references. Ingredients and containers shall be inspected for defects, expiration, and integrity before use. Only materials essential for aseptic compounding shall be placed in the PEC. Supplies, equipment, and the surfaces of ampules and vials shall be disinfected before entering the PEC by wiping the outer surface with sterile alcohol or an equivalently effective non-residue generating disinfectant. Sterile components shall be arranged in the PEC to allow a clear, uninterrupted path of HEPA-filtered air over critical sites. Automated devices and equipment shall be cleaned, disinfected, and placed in the PEC to enable laminar airflow. Aseptic technique shall be used to avoid touch contamination of critical sites of containers and ingredients. Particles shall be filtered from solutions, if applicable. Needle cores shall be avoided. The pharmacist shall check before, during, and after preparation to verify the identity and amount of ingredients before release.

(B) Risk Level 2: In addition to Risk Level 1 requirements, a file containing the formula, components, procedures, sample label, and final evaluation shall be made for each preparation batch. A separate work sheet and lot number for each batch shall be completed. When combining multiple sterile preparations, a second verification of calculations shall take place. The pharmacist shall verify data entered into any automatic compounder before processing and check the end preparation for accuracy.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, nonsterile components

must meet compendial standards or must be verified by a pharmacist and a certificate of analysis. Batch preparation files shall also include comparisons of actual with anticipated yields, sterilization methods, and quarantine specifications. Presterilized containers shall be used when feasible. Final containers must be sterile and capable of maintaining preparation integrity throughout the shelf life. Sterilization methods must be based on properties of the preparation, and must be conducted in a method recognized by USP for the preparation and confirmed through sterility testing using a testing method recognized by USP for the preparation.

(D) Single-dose vials/containers and pharmacy bulk vial/containers exposed to ISO Class 5 or cleaner air may be used in compounding until the assigned in-use time which shall not exceed six (6) hours after initial needle puncture, unless otherwise specified by the manufacturer. Opened single-dose ampules shall not be stored for any time period. The in-use time must be placed on the vial/container.

(E) Unless otherwise specified by the manufacturer, multiple-dose vials/containers with an antimicrobial preservative may be used in compounding until the assigned in-use date which shall not exceed twenty-eight (28) days after initially entering or opening the vial/container (e.g., needle-puncture). The in-use date must be placed on the vial/container.

(10) Aseptic Technique Skill Assessment. Individuals engaged in sterile compounding must take and successfully pass an aseptic technique skill assessment to verify aseptic competency. The assessment must include a direct visual observation of the individual's aseptic competency during a process simulation that represents the most challenging or stressful conditions encountered or performed by the person being evaluated. The assessment must include media-fill testing for all risk levels performed. Self-observation is not allowed.

(A) The required visual observation shall assess:

1. Proper aseptic technique, manipulations, and work practices, including, but not limited to, avoiding touch contamination, proper use of first air, and if applicable, sterilizing high risk CSPs;
2. Cleaning and disinfection;
3. Hand hygiene, gloving, and garbing;
4. Identifying, weighing, and measuring of ingredients;
5. Maintaining sterility in ISO Class 5 areas;
6. Labeling and inspecting CSPs for quality.

(B) Media-Fill Testing. Pharmacies shall establish and follow policies and procedures for media-fill testing. Media-fill testing shall comply with USP Chapter 797's recommended procedures and methods and must be conducted using the most challenging or stressful conditions/compounding actually encountered or performed by the person being evaluated using the same container or closure. A minimum of three (3) media-fill tests must be completed during initial media-fill testing and one (1) media-fill test completed for ongoing testing.

(C) Frequency: The required Aseptic Technique Skill Assessment must be conducted prior to initial compounding and every twelve (12) months thereafter for Risk Levels 1 and 2 compounding and every (6) months thereafter for Risk Level 3 compounding. Additionally, an Aseptic Technique Skill Assessment must be conducted whenever unacceptable techniques are observed or discovered, if the risk level of sterile activity conducted by the individual changes, or if there is a change in compounding methods performed.

(D) Individuals who fail written tests; visual observation of hand hygiene, garbing, or aseptic technique; or media-fill tests must undergo immediate requalification through additional training by competent compounding personnel. Individuals who fail visual observation of hand hygiene, garbing, or aseptic technique; or media-fill tests must pass a reevaluation in the deficient area before they can resume compounding of sterile preparations. Individuals who fail media-fill testing must pass three (3) successive media-fill tests prior to resuming sterile compounding.

(11) Record Keeping.

(A) Risk Level 1 and 2: The following must be documented/maintained:

1. Training and competency evaluation of pharmacy personnel involved in sterile compounding, including, the dates and results of the required aseptic technique training, aseptic technique skill assessment, and media-fill testing;
2. Refrigerator, freezer and, if applicable, incubator temperature logs;
3. Certification dates and results for any PEC or ISO classified area;
4. Manufacturer manuals that are relied upon to maintain compliance with this rule;
5. Other facility quality control logs, as appropriate, including all maintenance, cleaning, and calibration records;
6. If applicable, pressure recordings including documentation of the review of continuous monitoring system results as required by subsection (5)(F);



7. Any end-preparation testing records; and

8. Single preparation and batch preparation records.

(B) Risk Level 3: In addition to Risk Level 1 and 2 requirements, record requirements for Risk Level 3 preparations must include:

1. Preparation work sheet;
2. Sterilization records;
3. Quarantine records, if applicable;
4. End-preparation evaluation and testing records as required in section (14); and
5. Ingredient validation records as required in section (14).

(C) All records and reports shall be maintained either electronically or physically for two (2) years and shall 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 or the board's authorized designee.

(12) Labeling.

(A) Sterile preparations shall be labeled in accordance with section 338.059, RSMo and with the following supplemental information:

1. Beyond-use date;
2. Storage requirements if stored at other than controlled room temperature;
3. Any device specific instructions;
4. Auxiliary labels, when applicable; and
5. If applicable, a designation indicating the preparation is hazardous.

(13) Beyond-Use Dating.

(A) Risk Level 1 and Risk Level 2: All sterile preparations must bear a beyond-use date. Beyond-use dates must be assigned based on current drug and microbiological stability information and sterility considerations.

(B) Risk Level 3: In addition to all Risk Level 1 requirements, there must be a reliable method for establishing all beyond-use dates, including laboratory testing of preparation stability, pyrogenicity, particulate contamination, and potency. Beyond-use dating not specifically referenced in the products approved labeling or not established by preparation specific instrumental analysis shall be limited to thirty (30) days. There must be a reliable method for establishing all beyond-use dating. Preparations assigned a beyond-use date of greater than thirty (30) days shall have laboratory validation of preparation stability and potency.

(14) End-preparation Evaluation.

(A) Risk Level 1: The final preparation

must be inspected for clarity, container leaks, integrity and appropriate solution cloudiness or phase separation, solution color, and solution volume. The pharmacist must verify that the preparation was compounded accurately as to the ingredients, quantities, containers, and reservoirs. Background light or other means for the visual inspection of preparations for any particulate and/or foreign matter must be used as part of the inspection process, provided an alternate means of inspection shall be used if a visual inspection or exposure to the preparation may pose a health hazard.

(B) Risk Level 2: All Risk Level 1 requirements must be met.

(C) Risk Level 3: In addition to all Risk Level 1 requirements, the process validation procedure shall be supplemented with a program of end-preparation sterility testing according to a formal sampling plan. Samples shall be statistically valid to ensure that batches are sterile. A method for recalling batch preparations shall be established if preparation testing results are unacceptable. A sample from each sterile preparation/batch must be tested for sterility. A sample from each parenteral sterile preparation/batch must also be tested for pyrogenicity. Risk Level 3 preparations must be quarantined and stored to maintain chemical and microbiological stability pending results of end-preparation testing.

1. Sterility testing: Sampling for the sterility test shall occur promptly upon the completion of preparation. The sterility test, including the sampling scheme, shall be conducted according to a method recognized for the preparation by USP Chapter 71.

2. Pyrogen/Endotoxin testing: Sterile parenteral preparations prepared from non-sterile drug components shall be tested for pyrogen or endotoxin according to a method recognized by USP Chapter 151 for pyrogen testing and recognized by USP Chapter 85 for endotoxin testing.

3. Potency: The pharmacy shall have a procedure for a pre-release check of the potency of the active ingredients in the compounded sterile preparation prepared from non-sterile bulk active ingredients. The procedure shall include at least the following verifications by a pharmacist:

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

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

C. The compounding or control records include documentation that the fill volumes of all units available for release were

checked and were correct; and

D. The final potency is confirmed by instrumental analysis for sterile preparations that have been assigned a beyond-use date of more than thirty (30) days.

(D) Emergency Dispensing of a Risk Level 3 Sterile Preparation: When a compounded Risk Level 3 preparation must be released prior to the completion of testing, the sterile preparation may be dispensed pending test results. Emergency dispensing shall be defined as, and comply with, subsection (1)(N) of this rule.

(15) Storage, Handling, and Transport. Sterile preparations shall be packaged, stored, dispensed, and distributed in a manner that will maintain the preparation's chemical and microbiological stability until the assigned beyond-use date or until delivery to the patient or intended recipient. The pharmacist-in-charge shall assure the environmental control of all sterile compounded preparations shipped. Sterile preparations shall be transported so as to be protected from excesses of temperatures and light within appropriate packaging or delivery containers that maintain necessary storage conditions to preserve the quality and integrity of sterile preparations. The pharmacy shall follow written procedures that specify packing techniques, configuration, and materials for groups of preparations with common storage characteristics and for specific preparations where unique storage conditions are required to retain adequate stability and preparation quality.

(16) Point-of-Care Assembled Systems. Assembly of point-of-care assembled systems shall be considered Risk Level 1 compounding. Point-of-care assembled systems shall be assigned a beyond-use date which may exceed the beyond-use date authorized for Risk Level 1 preparations provided the date is assigned in accordance with the manufacturer's recommendations or labeling.

(A) When dispensed, an assembled non-activated system shall be labeled with beyond-use dates for both activated and non-activated states. The compounding record must document both dates. The beyond-use date of an assembled non-activated system shall be limited to a maximum of fifteen (15) days unless the pharmacy has documentation from the system's manufacturer that a longer date is acceptable.

(B) Point-of-care assembled systems shall be assembled and stored in accordance with the manufacturer's labeling and recommendations.

(17) General Cleaning and Disinfection



Requirements. Except as otherwise provided herein, cleaning and disinfection of controlled and buffer areas, supplies, and equipment shall be performed and conducted in accordance with USP Chapter 797 timeframes and procedures. Controlled areas that do not meet ISO air classifications shall be cleaned and disinfected as required by USP Chapter 797 for segregated compounding areas. If compounding is done less frequently than the cleaning and disinfection timeframes specified in USP Chapter 797, cleaning and disinfection must occur before each compounding session begins.

(A) The pharmacy shall establish and follow written policies and procedures governing all aspects of cleaning and disinfection, including approved cleaning/disinfecting agents and materials, schedules of use, and methods of application.

(B) Individuals shall be trained in proper cleaning and disinfection procedures prior to performing such activities. Training shall include direct visual observation of the individual's cleaning and disinfecting process by qualified staff. The individual shall be annually reassessed for competency through direct visual observation. Documentation of the required training and training dates shall be maintained in the pharmacy's records. Individuals who fail to demonstrate competency shall be reinstructed and successfully reevaluated prior to any further cleaning or disinfection.

(C) Cleaning and disinfection activities shall be performed using approved cleaning/disinfection agents and procedures described in the pharmacy's written policies and procedures. Manufacturers' directions for minimum contact time shall be followed.

(D) All cleaning tools (e.g., wipes, sponges, and mop heads) must be low-lint and dedicated for use in the controlled area and ISO classified areas.

(E) Primary engineering controls shall be cleaned with a germicidal agent followed by sterile alcohol. Sterile water for irrigation shall be used to dilute germicidal agents used inside the PEC that require dilution.

(F) At a minimum, the critical area shall be cleaned and disinfected prior to compounding, between batches, and whenever contamination is suspected using sterile alcohol which is allowed to dry immediately prior to compounding.

(18) Environmental Sampling/Testing. 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. Air monitoring must be conducted prior to initial compounding and every six (6) months thereafter. Surface sampling/monitoring must be conducted every six (6) months for Risk Level 2 and every thirty (30) days for Risk Level 3 compounding.

(19) Cytotoxic Drugs.

(A) The following additional requirements are necessary for those licensed pharmacies that prepare cytotoxic drugs to insure the protection of the personnel involved:

1. Cytotoxic drugs shall be compounded in a vertical flow, Class II biological safety cabinet or a CACI. If used for other preparations, the cabinet must be thoroughly cleaned;

2. Protective apparel shall be worn by personnel compounding cytotoxic drugs which shall include disposable masks, gloves, and gowns with tight cuffs;

3. Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile preparations. Chemotherapy preparations should be compounded using a closed system transfer device;

4. Appropriate disposal containers for used needles, syringes, and if applicable, cytotoxic waste from the preparation of chemotherapy agents and infectious waste from patients' homes. Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements;

5. Written procedures for handling major and minor spills and generated waste of cytotoxic agents must be developed and must be included in the policy and procedure manual; and

6. Prepared doses of cytotoxic drugs must be labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

(20) Remedial Investigations: A remedial investigation shall be required if: 1) any sampling or testing required by this rule demonstrates a colony forming unit (CFU) count that exceeds USP Chapter 797 recommended action levels for the type of sampling/testing and/or 2) if a highly pathogenic microorganism is detected in any preparation or ISO classified area (e.g., Gram-negative rods, coagulase positive staphylococcus, molds, fungus, or yeasts).

(A) CSPs and any ingredients used within the compounding process that are part of the remedial investigation shall be quarantined until the results of the investigation are known. All affected areas shall be resampled

to ensure a suitable state of microbial control as part of the remedial investigation. If a highly pathogenic microorganism is detected, or if the CFU count exceeds USP 797 action levels in any ISO-5 or ISO-7 classified area, no further compounding shall be performed until resampling shows a suitable state of microbial control. The pharmacy shall ensure that no misbranded, contaminated, or adulterated CSP is administered or dispensed for patient use.

(B) The pharmacy shall notify the board in writing within seven (7) days if any preparation or environmental monitoring/testing detects a highly pathogenic microorganism, regardless of CFU count.

(21) 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 shall 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 338.010, 338.140, 338.240, and 338.280, RSMo Supp. 2016.\* 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.*

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

**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 shall not be released to anyone except—

(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).

(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 as provided for in 4 CSR 220-2.085(2)(B).

*AUTHORITY: sections 338.100, 338.140 and 338.280, RSMo 2000.\* 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.*

*\*Original authority: 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999; 338.140, RSMo 1939, amended 1981, 1989, 1997; 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 product is defined as a product compounded in advance of receipt of a prescription or a product compounded in a supply that will be used on more than one (1) dispensing to a patient or patients or any product compounded in excess of the filling of an individual prescription. A batch is a specific quantity of product 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 the compounding of drugs 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 precau-

tions 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 the compounding of drug products 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 the compounding of drug products shall be of suitable composition so that surfaces that contact ingredients, in-process materials or drug products shall not be reactive, additive or absorptive so as to alter the safety, identity, strength, quality or purity of the drug product 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 the compounding of drugs 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.

(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 the compounding of drugs shall be handled and stored in a manner to prevent contamination.

(E) Drug product/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 drug 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 drug product.

(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 drug compounding process. A separate log shall be maintained which includes:

1. Methods for the compounding of drug products to insure that the finished products 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 products; 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 drugs 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. The compounding of drug products 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 product that represents a three (3)-month supply.

2. Creams, ointments, lotions, liniments or other compounded products intended for external use may be batched in the same manner as provided for in paragraph (5)(C)1. of this rule that represents a one (1)-year supply.

(D) Any excess compounded products shall be stored and accounted for under conditions dictated by its composition and stability characteristics to insure its strength, quality and purity. Excess product 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 product provided to a consumer.

#### (8) Management of Compounding.

(A) A pharmacist dispensing any compounded drug is responsible for ensuring that the product has been prepared, labeled, controlled, stored, dispensed and distributed

properly. The pharmacist is responsible for ensuring that quality is built into the preparation of products, with key factors including at least the following general principles:

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 products, as a condition of release, must be 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 products. The outcome monitoring system shall provide readily retrievable information suitable for the evaluation of the quality of pharmaceutical services. This shall include but not be 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 product 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 product 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 product(s).

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

(9) Compounding of drug products that are commercially available in the marketplace or that are essentially copies of commercially available Federal Drug Administration (FDA) approved drug products is prohibited. There shall be sufficient documentation within the prescription record of the pharmacy of the specific medical need for a particular variation of a commercially available compound.

(10) Any alteration, change or modification to the contents of a commercially manufac-

ured over-the-counter product shall require a prescription or prescription drug order from an authorized prescriber. The compounding of any drug product to be sold without a prescription 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 drug product being compounded shall be excluded from direct contact with drug products/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 products being compounded.

(12) Pharmacists shall not offer compounded drug products to other pharmacies, practitioners or commercial entities for subsequent resale or administration, except in the course of professional practice for a prescriber to administer to an individual patient by prescription. 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 products.

(13) In addition to the requirements outlined in this rule, all standards and requirements as outlined in 4 CSR 220-2.200 Sterile Pharmaceuticals must be adhered to whenever compounding involves the need for aseptic procedures or requires the use of or results in an intended sterile pharmaceutical product.

*AUTHORITY: sections 338.010, 338.140, 338.240 and 338.280, RSMo 2000.\* 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.*

*\*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990; 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.240, RSMo 1951; 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, a specialty of pharmacy practice. 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) The “practice of nuclear pharmacy” means a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs.

(B) The term “nuclear pharmacy” means the location where radioactive drugs, and chemicals within the classification of legend drugs, are compounded, dispensed, stored, or sold. The term “nuclear pharmacy” does not include the nuclear medicine facilities of hospitals or clinics where radiopharmaceuticals are compounded or dispensed to patients under the supervision of a licensed physician, authorized by the Nuclear Regulatory Commission and/or the Missouri Department of Health.

(C) A “qualified nuclear pharmacist” means a pharmacist who holds a current license issued by the board and who is either certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties, a pharmacist who meets minimal standards of training for status as an authorized nuclear pharmacist or an authorized user of radioactive material, as specified by the Nuclear Regulatory Commission or by agencies of states that maintain certification agreements with the Nuclear Regulatory Commission.

(D) “Radiopharmaceutical services” means the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, distribution, transfer, record keeping and disposal of radiochemicals, radiopharmaceuticals and ancillary drugs, and also includes quality assurance procedures, radiological health activities, any consulting activities associated with the use of radiopharmaceuticals, health physics, and any other activities required for provision of pharmaceutical care.

(E) “Quality control testing” means the performance of appropriate chemical,

biological and physical tests on compounded radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.

(F) “Quality assurance procedures” means all activities necessary to assure the quality of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by pertinent regulatory agencies.

(G) “Authentication of product history” means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

(H) “Radiopharmaceutical” means any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term “radiopharmaceutical” also includes any biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

### (2) General Requirements for Pharmacies Providing Radiopharmaceutical Services.

(A) No person may receive, acquire, possess, compound or dispense any radiopharmaceutical except in accordance with the provisions of this rule and the conditions of rules and regulations promulgated by the Nuclear Regulatory Commission and/or the Missouri Department of Health. The requirements of this rule are in addition to and not in substitution of, other applicable statutes and regulations administered by the State Board of Pharmacy or the Missouri Department of Health.

(B) Nothing in this rule shall be construed as requiring a licensed physician to obtain a separate license as a nuclear pharmacist, when the use of radiopharmaceuticals is limited to the diagnosis and treatment of patients under the supervision of the physician.

(C) Nothing in this rule shall be construed as requiring a licensed clinical laboratory, which is also licensed by the Nuclear Regulatory Commission and/or the Missouri Department of Health to handle radioactive materials, to obtain the services of a nuclear pharmacist, or to have a pharmacy permit, unless the laboratory is engaged in the commercial sale or resale of radiopharmaceuticals.

(D) Nothing in this rule shall be construed to require a department of nuclear medicine which is located in a hospital, which has a

physician board certified in his/her specialty and which is licensed by the Nuclear Regulatory Commission and/or the Missouri Department of Health to handle radioactive materials, to obtain the services of a pharmacist or to have a nuclear pharmacy license for radiopharmaceutical preparation and distribution to patients within that institution.

### (3) Permits.

(A) A permit to operate a nuclear pharmacy shall only be issued to a person who is, or who employs, a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of a qualified nuclear pharmacist, who shall be in personal attendance. The pharmacist-in-charge shall be responsible for all operations of the pharmacy.

(B) The permit to operate a nuclear pharmacy is effective only so long as the pharmacy also holds a current Nuclear Regulatory Commission and/or Missouri Department of Health license. Copies of inspection reports shall be made available upon request to the board for inspection.

(C) Any nuclear pharmacy which provides (transfers) product outside of a patient specific prescription service must be licensed as a drug distributor in order to provide a product for a prescriber’s use.

### (4) Space, Security, Record Keeping and Equipment.

(A) Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided and as required by the Nuclear Regulatory Commission. All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas:

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

(B) The nuclear pharmacy professional service area shall be secured against unauthorized personnel and must be totally enclosed and lockable.

(C) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radioactive drugs and other radioactive materials in accordance with State Board of Pharmacy, Nuclear Regulatory Commission and/or Missouri Department of Health statutes and regulations.

(D) Nuclear pharmacies shall compound and dispense radiopharmaceuticals in accordance with accepted standards of radiopharmaceutical quality assurance. The State



Board of Pharmacy recognizes that the preparation of radiopharmaceuticals involves the compounding skills of the nuclear pharmacist to assure that the final drug product meets accepted professional standards of purity and quality.

(E) A nuclear pharmacy shall have available the following resources:

1. A vertical laminar airflow hood that is annually certified to assure aseptic conditions within the working areas;

2. A sanitary work area that is designed to avoid outside traffic and outside airflow and that is ventilated so that it does not interfere with sanitary conditions. The sanitary work area shall not be used for bulk storage of supplies or other materials;

3. A sink located nearby that is suitable for cleaning purposes;

4. A current policy and procedure manual that includes the following subjects:

A. Sanitation;

B. Storage;

C. Dispensing;

D. Labeling;

E. Record keeping;

F. Recall procedures;

G. Responsibilities and duties of supportive personnel;

H. Training and education in aseptic technique; and

I. Compounding procedures.

(5) Dispensing, Packaging, Labeling.

(A) A radiopharmaceutical shall be dispensed only to a licensed physician authorized by the Nuclear Regulatory Commission and/or the Missouri Department of Health to possess, use and administer such drug. A radiopharmaceutical shall be dispensed only upon receipt of a prescription or medication order from such licensed physician. Except that a radiopharmaceutical may be transferred to a person who is authorized to possess and use the drug for nonclinical applications.

(B) Radioactive drugs are to be dispensed only upon a non-refillable prescription order from a licensed physician or the physician's designated agent. Upon receiving an oral prescription order for a radiopharmaceutical, the nuclear pharmacy shall immediately have the prescription order reduced to writing or recorded in a data processing system. The order must be taken by a pharmacist, intern pharmacist, nuclear medicine technologist or designated agents. Nuclear medicine technologists may only receive prescription orders for diagnostic radiopharmaceuticals, and all such prescriptions must be reviewed and initialed by the pharmacist. The prescription record shall contain all information as required in 4 CSR

220-2.018 Prescription Requirements and shall also include:

1. The date of dispensing and the calibration time of the radiopharmaceutical; and  
2. The name of the procedure.

(C) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with—

1. The name and address of the pharmacy;

2. The name of the prescriber;

3. The date of dispensing;

4. The serial number assigned to the order for the radiopharmaceutical;

5. The standard radiation symbol;

6. The words "Caution Radioactive Material";

7. The name of the procedure;

8. The radionuclide and chemical form;

9. The amount of radioactivity and the calibration date and time;

10. If a liquid, the volume;

11. If a solid, the number of items or weight;

12. If a gas, the number of ampules or vials;

13. Molybdenum-99 content to *United States Pharmacopoeia* (USP) limits; and

14. The patient name or the words "Physician's Use Only" in the absence of a patient name. When the prescription is for a therapeutic or blood-product pharmaceutical, the patient name shall appear on the label. The requirements of this paragraph shall be met when the name of the patient is readily retrievable from the physician upon demand.

(D) The immediate inner container label of a radiopharmaceutical to be dispensed shall be labeled with—

1. The standard radiation symbol;

2. The words "Caution Radioactive Material";

3. The identity of the radionuclide; and

4. The serial number of the radiopharmaceutical.

(E) When a radiopharmaceutical is dispensed under the authority of an Investigational New Drug Application (IND), the nuclear pharmacy records shall include an investigator's protocol for the preparation of the radiopharmaceutical, a copy of the Institutional Review Board approval form (or letter) and a letter from the manufacturer (sponsor) indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

(6) Reference Manuals.

(A) Each nuclear pharmacy shall have a copy of the Missouri Pharmacy Practice Act and current regulations under the act; one recognized text in nuclear pharmacy, and a

current copy of state and federal regulations governing the safe storage, handling, use, dispensing, transport and disposal of radioactive material.

(7) Any preparation of Positron Emission Tomographic (PET) radiopharmaceuticals shall comply with 4 CSR 220-2.200 Sterile Pharmaceuticals and with applicable USP standards.

*AUTHORITY: sections 338.210, 338.240, 338.250, 338.280, 338.330(3), RSMo 1994 and 338.220 and 338.350, RSMo Supp. 1997.\* 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.*

*\*Original authority: 338.210, RSMo 1951; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997; 338.240, RSMo 1951; 338.250, RSMo 1951, amended 1990; 338.280, RSMo 1951, amended 1971, 1981; 338.330, RSMo 1989, amended 1993; 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 incorporates the provisions of SB 141 and 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 shall be 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. The pharmacist-in-charge of a Class F pharmacy will be responsible for the following requirements:



(A) Ensure that the 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 shall be under the professional supervision of an appropriate practitioner licensed under Missouri law.

(B) Ensure that 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) Ensure that no drugs or devices shall be dispensed to a patient until adequate training in the proper use and administration of such products has been completed;

(D) Ensure that 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) Maintain a policy and procedure manual that shall be 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 shall be responsible for the drug/device delivery system and shall establish 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) Drug Formulary List/Device List. The pharmacy shall submit a list of drugs and/or devices which must be approved by the board of pharmacy.

(4) A Class F pharmacy shall 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 pre-

scribed.

(5) 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 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.

(6) Class F pharmacies shall comply with all of the following:

(A) The license of the pharmacy shall be displayed in plain view at the pharmacy location;

(B) The pharmacy shall be 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 must maintain 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 shall be held separately until the item is destroyed or returned to a licensed drug distributor.

*AUTHORITY: sections 338.140 and 338.220, RSMo Supp. 1997 and 338.280, RSMo 1994.\* 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.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997; 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. Both 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 allow access to each pharmacy's electronic medication or prescription records. The access must provide real-time, online access to the patient's complete profile for the pharmacies involved.

(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 of each pharmacy including any functions identified in section (1);



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, either the name and address of 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 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.

(4) 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 338.140, 338.210, 338.220, 338.240, and 338.280, RSMo 2016.\* 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.*

*\*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 2220-2.675 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 2220-2.700 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.*

## **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) All vacuum tube delivery systems installed after September 1, 1998, shall comply with the minimum standards set forth in this rule. 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 4 CSR 220-2.010(1)(H); nor does it relieve pharmacists from their duty to provide patient counseling as required by 4 CSR 220-2.190.

*AUTHORITY: sections 338.140, RSMo Supp. 1997 and 338.280, RSMo 1994.\* 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.*

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

## 20 CSR 2220-2.900 Automated Dispensing and Storage Systems

*PURPOSE: This rule establishes guidelines for the use of automated dispensing and storage systems.*

(1) Automated dispensing and storage systems (hereafter referred to as automated system or system) are hereby defined to include, but are not limited to, mechanical systems that perform operations or activities, relative to the storage, packaging or dispensing of medications, and which collect, control, and maintain all transaction information. Such systems may be used in pharmacies and where a pharmacy permit exists, for maintaining patient care unit medication inventories or for a patient profile dispensing system, provided the utilization of such devices is under the supervision of a pharmacist. A pharmacist is not required to be physically present at the site of the automated pharmacy system if the system is supervised electronically by a pharmacist. In order to supervise the system within an ambulatory care setting, the pharmacist must maintain constant visual and auditory communication with the site and full control of the automated system must be maintained by the pharmacist and shall not be delegated to any other person or entity. Supervision of an automated refill patient self-service device requires that a pharmacist employed by the pharmacy by which the device is owned and operated be available at all times during operating hours of the pharmacy.

(A) Documentation shall be maintained by the owner/operator of an automated system for the type of equipment, locations where all systems are located, identification of all persons accessing the automated system, the identity of persons stocking or restocking the system and the pharmacist responsible for checking the accuracy of medications stocked.

(B) Automated systems that are used within licensed health care facilities shall be used only in settings that ensure medication orders are reviewed by a pharmacist in accordance with established policies and procedures and laws governing the practice of pharmacy. A pharmacist shall control all operations of the automated system and approve the release of the initial dose of a prescription drug order. Subsequent doses from an approved prescription drug order may be removed from the automated system after this initial approval. Any change made in the prescription drug order shall require a new approval by a pharmacist to release the drug.

(C) In ambulatory care settings, a pharmacist must input all information from a prescription or prescription drug order into the electronic data system utilized for the initiation of the dispensing of a drug at a remote site and maintain proper oversight over the entire dispensing process. A pharmacist shall be 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. No prescription shall be prepared or dispensed from a remote automated system unless it is from a prescriber providing clinical services at the same location. Labeling of drug containers must be in accordance with section 338.059, RSMo, and application of labels to containers must occur prior to release of the prepared prescription drug from the automated system. Labels shall contain both the name, address and phone number of the supervising pharmacy and the remote dispensing site.

(D) When automated systems are located at remote sites the central pharmacy responsible for the operation and supervision of a remote site must maintain separate and readily retrievable records of all transactions and prescriptions processed by each remote automated system. Remote automated sites must provide the name, address and toll free telephone number of the supervising pharmacy displayed on the automated dispensing system in a prominent location.

(E) Automated systems shall maintain adequate security systems and procedures to prevent unauthorized access or use and shall at all times maintain compliance with all state and federal drug laws including all controlled substance requirements and patient confidentiality laws.

1. Any remote automated system that stocks controlled substances must maintain a perpetual inventory from each site.

2. Automated systems in ambulatory care settings must be located in an area that will provide adequate space for private consultations to occur and must only be installed within the same area utilized by the prescriber for the provision of clinical services.

3. Automated refill patient self-service devices must be physically attached to the pharmacy so that access to areas used to restock the device are only accessible through the pharmacy physical plant by pharmacy personnel.

(F) Restocking of automated systems shall be done by registered technicians under the supervision of a pharmacist or by a pharmacist.

(G) All events involving access to the contents of the automated system must be recorded electronically.

(H) No medication or device shall be returned directly to the system for reissue or reuse by a person not licensed or registered by the board of pharmacy.

(I) Quality assurance documentation for the use and performance of the automated systems shall be maintained for a minimum





period of two (2) years and shall include at a minimum the following:

1. Breach of security of the automated system;
2. Failure of the system to operate correctly along with the frequency of any failures and the necessary repairs completed;
3. Tests completed to measure the effectiveness and accuracy of the system. every six (6) months and whenever any upgrade or change is made to the system.

(J) Drugs that are repackaged for use in automated systems at remote locations must comply with 20 CSR 2220-2.130 Drug Repackaging requirements. Automated refill patient self-service devices must comply with all labeling and dispensing laws governing the provision of medication refills to patients. Products that are considered temperature sensitive or products that require further manipulation in order to be ready for use by a patient shall not be provided through patient self-service devices, unless the device has the capability to provide storage conditions in compliance with Food and Drug Administration (FDA) requirements.

(K) If an automated system uses removable cartridges or containers to hold drugs, the repackaging of the cartridges or containers must occur at the pharmacy where the original inventory is maintained unless provided by a FDA approved repackager and who is licensed as a drug distributor. The prepackaged cartridges or containers may be sent to the automated system at remote locations to be loaded into the machine by registered technicians under the supervision of a pharmacist or by a pharmacist provided that—

1. A pharmacist has verified the container has been properly filled and labeled;
2. The individual containers are transported to the automated system in a secure, tamper-evident container; and
3. The automated system utilizes technologies to ensure that the containers are accurately loaded in the automated system.

(L) Any pharmacy that maintains an automated system for remote dispensing to ambulatory patients 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 as provided in 20 CSR 2220-2.190 and other matters involved in the correct transaction or provision of drugs.

1. Video monitors used for the proper identification and communication with persons receiving prescription drugs shall be a minimum of twelve inches (12") wide and provided at both the pharmacy and remote

location for direct visual contact between pharmacist and patient.

2. Both the video monitor and the audio system must be in good working order or operations utilizing the automated 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) Each automated system shall maintain a manual of policies and procedures that, at a minimum, shall include the following:

(A) System operations that include specific and measurable accountability for safety, security, accuracy, patient confidentiality, access, data retention and retrieval, downtime procedures, emergency first dose or refill patient self-service procedures, inspection of systems by pharmacy personnel, installation requirements, maintenance, medication security, quality assurance, inventory levels and control, staff education and training and system set-up and malfunction.

(B) Documentation by the automated system at remote locations for on-site patient administration and remote dispensing of medications that includes specific identification of patients, medications used along with dates and times the system is utilized.

(C) Effective procedures for securing and accounting for wasted medications or discarded medications.

(D) Access to and limits on access (security levels) to the automated system must be defined and must comply with applicable state and federal laws and regulations.

(3) The pharmacist-in-charge is responsible for the overall compliance of the automated system in the same manner as other pharmacy operations as outlined in 4 CSR 220-2.090. In addition, responsibilities will also include:

(A) Establishment of a quality assurance program prior to implementation of an automated system and the supervision of an ongoing quality assurance program that monitors appropriate use and performance of the automated system, which is evidenced by written policies and procedures developed by the pharmacy;

(B) Assign, discontinue or change access to the automated system;

(C) Assure that the automated system is in good working order and accurately provides the correct strength, dosage form and quantity of a drug prescribed while maintaining appropriate record keeping and security safe-

guards.

(D) Procedures used for notifying the board on a timely basis and other state and federal agencies, when warranted, of any breach of security which results in the unauthorized removal of drugs.

(4) Except where otherwise noted in this rule, all records specified must be retained as a part of the dispensing record of the pharmacy and in accordance with section 338.100, RSMo and board regulations governing the proper maintenance and retrieval of records.

(5) Pharmacies that maintain automated sites for dispensing drugs to ambulatory patients shall maintain a Class J: Shared Service classification on each pharmacy permit involved in such activity.

(6) The supervising pharmacy shall have sufficient pharmacists on duty such that each pharmacist may supervise no more than three (3) remote sites that are simultaneously open to provide services. An exception to the supervision limit may be granted by the board in situations where the provider has documented a need for a pharmacist to supervise additional remote sites and has demonstrated that appropriate safeguards are in place to assure proper supervision of each remote site.

*AUTHORITY: sections 338.210 and 338.220, RSMo Supp. 2006 and 338.140 and 338.280, RSMo 2000.\* 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.*

*\*Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.210, RSMo 1951, amended 2001; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004; 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.*