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**Rules of**  
**Department of Economic**  
**Development**  
**Division 220—State Board of Pharmacy**  
**Chapter 2—General Rules**

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**Title 4—DEPARTMENT OF  
ECONOMIC DEVELOPMENT  
Division 220—State Board of Pharmacy  
Chapter 2—General Rules**

**4 CSR 220-2.010 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 physicians' 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. 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. 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.

(G) 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 as defined in section 338.240(2), 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) 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.

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

(L) 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.

(M) 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.

(N) 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.

(O) 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 4 CSR 220-2.080. 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 4 CSR 220-2.080 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 that distribute legend drugs separate from prescription services and the distributions fall below the threshold established for licensure as a drug distributor shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. Said records shall be maintained for two (2) years.

(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) Except as provided for in section 21 U.S.C. section 353(d)(1)(A)-(C), (d)(2)(A)(i)-(ii), (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.

(8) 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 (8), is as follows:

1. Injectable dosage forms of sodium chloride, water and heparin; heparin shall be possessed only in concentrations for maintaining venous access devices;

2. Irrigation dosage forms of sodium chloride and water that carry a federal prescription only restriction;

3. Injectable dosage forms of diphenhydramine and epinephrine;

4. Vaccines indicated for public health needs, such as influenza, pneumonia, hepatitis A and hepatitis B; and

5. 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 drugs listed in paragraphs (8)(A)1. and (8)(A)2., 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.

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

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

*Op. Atty. Gen. No. 1, Allen (12-8-61). Rule promulgated by board requiring the presence of registered pharmacist at all times that a drug store is open for business is invalid as unreasonable enlargement of statutory*



requirement that presence of pharmacist is necessary only when prescriptions are compounded or sold.

*Op. Atty. Gen. No. 90, Tracy (8-7-61). Missouri Board of Pharmacy may not pass a regulation prohibiting the truthful advertising of prescription drugs in pharmacies.*

*Op. Atty. Gen. No. 70, Missouri State Board of Pharmacy (10-6-52). Proprietor of wholesale drug business must be licensed pharmacist or have at least one in his/her employ.*

#### 4 CSR 220-2.015 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.\* Original rule filed May 4, 1995, effective Dec. 30, 1995.*

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

#### 4 CSR 220-2.016 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.\* Original rule filed May 4, 1995, effective Dec. 30, 1995.*

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

#### 4 CSR 220-2.018 Prescription Requirements

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

(1) In order for a prescription to be valid for purposes of dispensing a medication by a

pharmacy, it must conform to all requirements as outlined in sections 338.056 or 338.196, RSMo, and contain the following information:

- (A) The prescription date and a unique, readily retrievable identifier;
- (B) The name of the patient(s);
- (C) The prescriber's name, if an oral prescription, signature if a written prescription;
- (D) Any prescriber indication of name and dosage of drug, directions for use, name and dosage of drug dispensed;
- (E) The number of refills, when applicable;
- (F) The quantity dispensed in weight, volume or number of units;
- (G) The initials or name of the pharmacist responsible for processes in dispensing or compounding of the prescription;
- (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) 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 handwritten, telephone, oral and electronically produced prescriptions that are processed for dispensing by a pharmacist/pharmacy.

*AUTHORITY: sections 338.095, 338.100, 338.140, 338.240 and 338.280, RSMo 2000.\* 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.*

*\*Original authority: 338.095, RSMo 1939; 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999; 338.140, RSMo 1939; amended 1981, 1989, 1997; 338.240, RSMo 1951; and 338.280, RSMo 1951, amended 1971, 1981.*

**4 CSR 220-2.020 Pharmacy Permits**

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

(1) The fiscal year of the board shall be as provided by law. All permits for the operation of a pharmacy shall expire on the date specified by the director of the Division of Professional Registration by appropriate rule.

(2) A pharmacy permit may be issued on the application of the owners. If the owner is a corporation or partnership, an officer of the corporation or a partner 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.

(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. However, a grace period of thirty (30) days will be allowed after the change of ownership.

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

- 1. The business is sold and the sale becomes final;
- 2. The proprietor enters into a partnership with another individual or business entity; or
- 3. The proprietor dies; provided, however, that the proprietor's estate may continue to operate the pharmacy under the licensed pharmacist in good standing in this state, but in no case for a period of more than one (1) year and only so long as appropriate pharmacy permit fees are paid.

(B) A corporation is considered by law to be a separate person. If a corporation owns a pharmacy, it is not necessary to obtain a new license if the owners of the stock change. However, as a separate person, if the corporation begins ownership of a pharmacy or ceases ownership of that pharmacy, a new license must be obtained regardless of the relationship of the previous or subsequent owner to the corporation. It is not necessary to obtain a new license when ownership of the stock in the corporation changes. It is necessary to file written notice with the State Board of Pharmacy within ten (10) days after that change occurs. This notification must be in writing and certified.

(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 4 CSR 220-2.010(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 meets the requirements of 4 CSR 220-2.090.

(7) If the owner/applicant is not the licensed pharmacist-in-charge, then the pharmacist-in-charge must meet the requirements of 4 CSR 220-2.090 and complete the pharmacist-in-charge affidavit of the permit application and have it notarized.

(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:

(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 Outpatient Pharmacy. A pharmacy operated by and located within a hospital that provides services as defined in section 338.010, RSMo to patients other than to the hospital's inpatient population;

(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: Home Health. A pharmacy that provides services as defined in section 338.010, RSMo for patients in a public or private residence who are under the supervision of a home health or hospice agency;

(E) Class E: Radiopharmaceutical. A pharmacy that is not open to the general public and provides services as defined in section 338.010, RSMo limited to the preparation and dispensing of radioactive drugs as defined by the Food and Drug Administration (FDA) 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 4 CSR 220-2.200(1) and (15). Pharmacies providing sterile pharmaceuticals within the exemptions outlined in 4 CSR 220-2.200 shall not be considered a Class H pharmacy; and

(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 that provides services as defined in section 338.010, RSMo, and is involved 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.

(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. Whenever a change in service classification occurs at a pharmacy the permit must be sent to the board with a notarized statement explaining any additions or deletions of pharmacy classes that are to be made.

*AUTHORITY: sections 338.140, RSMo 2000 and 338.220, RSMo Supp. 2001 and Omnibus State Reorganization Act of 1974 (Appendix B). \*Original rule filed July 18, 1962, effective July 28, 1962. Amended: Filed Nov. 9, 1966, effective Nov. 19, 1966. Amended: Filed Oct. 27, 1970, effective Nov. 6, 1970. Amended: Filed Dec. 31, 1975, effective Jan. 10, 1976. Emergency amendment filed July 15, 1981, effective Sept. 28, 1981, expired Nov. 11, 1981. Amended: Filed Aug. 10, 1981, effective Nov. 12, 1981. Amended: Filed April 14, 1982, effective July 11, 1982. Amended: Filed March 14, 1983, effective June 11, 1983. Amended: Filed Feb. 11, 1985, effective May 11, 1985. Amended: Filed Dec. 16, 1985, effective May 11, 1986. Amended: Filed Aug. 1, 1986, effective Nov. 13, 1986. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed Jan. 6, 1998, effective Aug. 30, 1998. Amended: Filed June 29, 1999, effective Jan. 30, 2000. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed Nov. 30, 2001, effective June 30, 2002. Amended: Filed Dec. 3, 2002, effective June 30, 2003.*

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

*Op. Atty. Gen. No. 316, Tracy (9-16-64). Restrictions imposed by city zoning ordinance provide no basis for board to refuse to license a pharmacy where pharmacy is otherwise qualified for a license and where these restrictions in no way affect the actual filling of prescriptions.*

*Op. Atty. Gen. No. 1, Allen (12-8-61). Rule promulgated by board requiring the presence of registered pharmacist at all times that a drug store is open for business is invalid as unreasonable enlargement of statutory requirement that presence of pharmacist is necessary only when prescriptions are compounded or sold.*

*Op. Atty. Gen. No. 70, Missouri State Board of Pharmacy (10-6-52). Proprietor of wholesale drug business must be licensed pharmacist or have at least one in his/her employ.*

#### 4 CSR 220-2.025 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.\* Original rule filed Jan. 16, 1990, effective May 11, 1990. Amended: Filed June 28, 2002, effective Jan. 30, 2003.*

*\*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.*

#### 4 CSR 220-2.030 Educational and Licensure Requirements

*PURPOSE: This rule outlines requirements for internship standards and training, exam scoring procedures, procedures for examination score transfer and licensure transfer and defines accredited colleges.*

(1) An approved school or college of pharmacy means a school or college of pharmacy whose curriculum, physical equipment, course of instruction and teaching personnel conform to the standards and specifications or the equivalent required by the American Council on Pharmaceutical Education for accreditation and is approved annually by the board.

(2) All applicants for examination shall file an application for examination with the executive director at least twenty-one (21) days prior to the date of the examination. Application shall be made on forms provided by the executive director. The candidate shall furnish satisfactory evidence on the application that s/he has graduated from an approved school of pharmacy and present affidavits certifying the completion of fifteen hundred (1,500) hours of practical experience. An application will be considered filed if it is received by the deadline, even though it may have to be returned to the applicant for minor correction or completion. However, an application will not be considered filed if it has to be returned to the applicant for any one (1) or more of the following reasons:

(A) Incorrect or missing fee;

(B) Incomplete or missing college affidavit; or

(C) Incomplete or missing signature and notarization. In this instance, the application will be returned to the applicant and will not be considered filed until it has been returned with all corrections made. In addition, it must be postmarked on or before the appropriate deadline date. If an application is received with a postmark after the deadline date, it will be rejected and the candidate will be notified that s/he is not eligible to sit for that particular examination. The applicant must take the examination(s) within three hundred sixty-five (365) days of having been determined eligible, to avoid forfeiture of eligibility and fees.

(3) Requirements for Practical Experience.

(A) Requirements for Training as a Pharmacy Intern.

1. Every person who desires to gain practical experience in Missouri toward licensure as a pharmacist must apply for a license as an intern pharmacist. An application for licensure shall be made on forms provided by the Missouri Board of Pharmacy and must be accompanied by the appropriate licensure fee.

2. An applicant for licensure as a pharmacy intern shall be currently enrolled in or graduated from a college that is approved by the Missouri Board of Pharmacy and that applicant may apply for licensure after the completion of thirty (30) hours of college course work in an approved school of pharmacy.

3. The minimum practical experience shall be fifteen hundred (1,500) hours of training to qualify to take the examination for licensure as a pharmacist.

4. Not more than forty (40) hours' credit per week shall be given for experience obtained.

5. Practical experience may be gained within non-licensed programs, provided these programs have received prior approval by the board. The board shall approve the number of hours to be awarded to students within an approved non-licensed program on a case-by-case basis. The maximum number of hours that the board may approve for a program shall be set at one thousand (1,000) hours. The board shall make its determination concerning program approval and the number of hours to grant to an approved program through review of an application. The board may request additional information, interview program participants or complete site inspections before a decision on an application is made.

6. A maximum of seven hundred fifty (750) hours may be obtained in a structured

externship program which is part of the college curriculum.

7. A maximum of seven hundred fifty (750) hours may be obtained in a Class I: Consultant pharmacy that is licensed by the board of pharmacy.

(B) It shall be incumbent upon both the supervisor (preceptor) of a certified intern training pharmacy and the pharmacy intern to complete an accurate record of time spent by the intern in acquiring practical experience. The Missouri Board of Pharmacy may request to see the Social Security payment record of the intern to determine the exact time of employment. These records of time shall be kept current and open for inspection by any member of the Missouri Board of Pharmacy or its inspectors.

(C) Practical experience shall be computed from the date of licensure as a pharmacy intern and practical experience shall be credited only when it has been obtained in an approved intern training pharmacy.

(D) Pharmacy interns working under the direct supervision of a preceptor and expecting to qualify for the licensed pharmacist examination must notify the board of the beginning and end of their employment under the supervision of a preceptor within five (5) days of the beginning and ending of their employment.

1. The intern pharmacist must submit his/her employment information on a form supplied by the Missouri Board of Pharmacy and must identify the licensed pharmacist who will act as preceptor along with the certification number and permit number of the approved intern training pharmacy.

2. If a licensed intern has a change in employment, a change in preceptor, or both, the intern must complete the proper form to be furnished by the board, attach the intern license and return both documents to the board office. When board records have been updated, a corrected license will be mailed to the intern pharmacist.

(E) A pharmacy intern must file an affidavit for intern training experience executed by a pharmacy preceptor on a form furnished by the board. This form will include, at a minimum, a report of contract hours completed during the internship period.

(F) Reports must be filed by the intern with the board in order for any hours to be counted toward the required practical experience. The reports shall include, but not be limited to:

1. Application for registration as an intern;
2. Intern employment form; and
3. Intern evaluation of each training period or site.



(G) Practical experience in intern training given in a state other than Missouri may be allowed by the board if, in the opinion of the board, the requirements of the state of the applicant's residence and experience are equal in the minimum requirements of the board for intern training in Missouri. Intern hours earned in another state must be certified directly to the Missouri Board of Pharmacy from the board of pharmacy of the state in which the training occurred.

(H) Any intern pharmacist who has an intern registration number and provides all information as required for reporting employment and intern hours may submit hours toward practical experience requirements that were acquired through June 30, 1993, without obtaining a license as a pharmacy intern from the board.

(I) A pharmacy preceptor shall be a Missouri licensed pharmacist in good standing with the board employed full-time at a Certified Intern Training Pharmacy.

(J) Preceptors should designate what official written guides or references will be utilized for training interns while under their direction and supervision.

(K) The term supervision as used in connection with the intern training requirement shall mean that, in the pharmacy where intern training is being obtained, a preceptor shall be in personal contact with and actually giving instruction to the intern during the period of that training. The ratio of interns to the full-time employment preceptors where more than one (1) intern is employed must not be greater than one (1) intern to each preceptor.

(L) The preceptor in a Certified Intern Training Pharmacy must signify a willingness to cooperate with the Missouri Board of Pharmacy in developing intern training and to report to the board from time-to-time if requested on progress and aptitude of any intern under his/her supervision. Progress report forms are furnished by the board.

(M) In the management of a Certified Intern Training Pharmacy, the emphasis must be on activities connected with pharmaceutical care through the interpretation and evaluation of prescription orders; the compounding, dispensing and labeling of drugs and devices pursuant to prescription orders; the proper and safe storage of drugs and devices and the maintenance of proper records of them; and consultation with patients and other health care practitioners about the safe and effective use of drugs and devices.

(N) The provisions of this rule are not applicable to those students who gain their practical experience in another state. However, if any portion of the required fifteen hundred (1,500) hours are to be earned in Mis-

souri, the applicant must be licensed as an intern under the provisions of this rule.

(4) Requirements for a Certified Intern Training Pharmacy.

(A) A pharmacy certified to provide intern training for the purpose of gaining practical experience as required by sections 338.020 and 338.030, RSMo shall be known as a Certified Intern Training Pharmacy.

(B) An applicant to become a Certified Intern Training Pharmacy shall make application to the board and shall meet the following requirements:

1. It must be a pharmacy with a clear record with respect to the observance of all federal, state and municipal laws and ordinance governing any phase of activity in which the pharmacy is engaged;

2. It must be a pharmacy operating under a pharmacy permit issued by the board and must have signified a willingness to train interns;

3. It must maintain a satisfactory rating as per the Missouri Board of Pharmacy inspector's report;

4. It must reapply to be a Certified Intern Training Pharmacy at the end of each three (3)-year period; and

5. All interns will be under the direct supervision of a Missouri licensed pharmacist in good standing with the board.

(C) Certification granted an intern training pharmacy may be withdrawn if, in the opinion of the board, the pharmacy, at any time, fails to comply with these requirements in all respects.

(D) Institutional settings that are involved in training interns must maintain a pharmacy permit and comply with all other provisions of this rule. In addition, any inpatient areas of an institution used to train interns will be subject to regular inspection by the board.

(5) Examination.

(A) Each applicant for licensure by examination must pass the National Association Boards of Pharmacy Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE). The applicant is responsible for payment of any required fee for the NAPLEX and the MPJE examinations, as established by the National Association of Boards of Pharmacy.

(B) A minimum score of seventy-five (75) is required for each of the examinations listed in subsection (5)(A).

(C) All examinations are scored independently and may be retaken independently upon payment of the appropriate fee.

(D) The MPJE will consist of questions on Missouri and federal pharmacy laws and reg-

ulations and the Missouri and federal controlled substance laws and regulations.

(E) If a candidate fails to achieve a score of seventy-five (75) in any of the examinations listed in subsection (5)(A), it will be necessary to take that examination again and pass that examination before a license can be issued. The candidate must complete any required application(s) and pay any required fee(s) to reestablish eligibility to retake any of the examinations listed in subsection (5)(A).

(F) A candidate scheduled to write the NAPLEX may apply for licensure by completing the NAPLEX Score Transfer Form supplied by the National Association of Boards of Pharmacy. In addition to completion of the form, the candidate must fulfill all necessary requirements as set forth by the National Association of Boards of Pharmacy and the Missouri Board of Pharmacy. Any fees required to transfer scores must accompany the completed form. Transfer scores will be accepted by the board from any state which accords similar privileges to Missouri candidates. Scores transferred by the candidate to Missouri must meet all minimum grade requirements as set forth in section (5) of this rule. Once this has been determined, the board office will send an application form for Missouri licensure to the successful candidate. The candidate must return the completed form along with all appropriate fees to the board office. The candidate must successfully complete the Multistate Pharmacy Jurisprudence Examination (MPJE) at the next regular examination date. Any candidate who fails to achieve a passing score on any of the examinations required may retake the examination upon proper reapplication and upon payment of appropriate fees.

(G) When the applicant's examination application has been accepted, the board will notify the National Association of Boards of Pharmacy that the applicant is an eligible candidate for the NAPLEX automated examination and/or the MPJE automated examination. The applicant is responsible for completing any necessary application(s) and payment of fee(s) as required by the National Association of Boards of Pharmacy.

(H) The National Association of Boards of Pharmacy will then create an applicant database of eligible candidates for the NAPLEX and/or the MPJE which will be provided to the entity or entities which manages the testing centers. The National Association of Boards of Pharmacy will cause an Authorization to Test and instructions for scheduling a test appointment for either or both computerized examinations (NAPLEX and MPJE) to be mailed directly to the candidate. It will be the candidate's responsibility to schedule

his/her testing date, time and location for either or both computerized examinations (NAPLEX and MPJE).

(I) The score on the NAPLEX examination will be reported to the National Association of Boards of Pharmacy by the testing center(s) and subsequently to the board of pharmacy.

(6) Licensure Transfer.

(A) An applicant for licensure transfer must fully meet all the requirements in effect in Missouri on the date of registration in the state of original licensure.

(B) An applicant for licensure transfer shall meet all requirements of the state from which they are transferring including, but not limited to, that state's continuing education requirements.

(C) An applicant for licensure transfer must have attained the equivalent of fifteen hundred (1,500) practice hours, as set forth in section (3) of this rule, either as a pharmacy intern/extern or have maintained a pharmacist license in good standing for a period of not less than one (1) year in the state from which they are transferring.

(D) The board, in its discretion, may grant licensure transfer to an applicant when the applicant previously has taken and failed to pass an examination given by the Missouri board and who is eligible for licensure transfer, having later passed the examination for registry in another state.

(E) Applicants for licensure transfer must pass the Multistate Pharmacy Jurisprudence Examination (MPJE), a computerized examination provided through the National Association of Boards of Pharmacy. The applicant for licensure transfer is responsible for completing any necessary application(s) and payment of fee(s) as required by the National Association of Boards of Pharmacy. If the applicant fails the MPJE two (2) consecutive times, the application will be provided to the full board at its next regular meeting for appropriate review and action.

(F) No person shall be eligible for licensure transfer against whom there is pending any indictment or any alleged violation of the laws governing the practice of pharmacy, alcohol or other regulated law or who has been convicted of any crime within the past ten (10) years.

(G) All required fees must be paid prior to approval of a licensure transfer.

(H) The Missouri Board of Pharmacy reserves the right to reject any licensure transfer application for good and just reasons and, in the event of so doing, the fee paid to it will be refunded.

(I) No application for licensure transfer will remain valid if the applicant fails to complete the transfer process as outlined in this rule within six (6) months of receipt of the application by the board. Any failure by the applicant to complete the licensure transfer process will result in a forfeiture of all fees paid to the board.

(J) Any application for licensure transfer which is pending for three (3) months or more and is still a valid application may require an additional review by the board of licensure information from any state in which the applicant holds a license. Any applicant who provides a complete and truthful application to the board, completes the licensure process in less than three (3) months and is successful in passing the Multi-State Jurisprudence Examination on the first attempt, will not be required to register as a technician while working in a licensed pharmacy or acting in any capacity that would require licensure as a pharmacist as defined in section 338.010.1, RSMo. Direct supervision of an applicant by a licensed pharmacist is required at all times when any functions related to section 338.010, RSMo are performed. Any licensure transfer applicant who must subsequently apply for registration as a technician will not be required to provide fingerprints if all fingerprinting requirements have previously been fulfilled within the licensure transfer process.

(7) Licenses.

(A) No duplicate certificates or renewals for licenses or permits shall be issued except upon the return of the original or upon the sworn statement that the certificate has been lost or destroyed. The duplicate certificate or renewal fee shall accompany the affidavit.

(B) No assistant or apprentice-pharmacist license is recognized by the board inasmuch as the members of the State Missouri Board of Pharmacy in session in Kansas City, Missouri on January 24, 1938, ruled, and the adopted minutes so state, that March 1, 1938, would be the last day a license as a pharmacist could legally be issued to an assistant pharmacist as per Missouri statutes, section no. 13151 and the secretary was ordered at that time to accept no fees and to issue no license as a pharmacist to assistant pharmacists after that date. Furthermore, this portion of section no. 13151, relating to converting over of assistant pharmacists to registered pharmacists, was deleted by the 66th General Assembly, effective as of August 1, 1952.

*AUTHORITY: sections 338.020, 338.035, 338.040, 338.070, 338.140 and 338.280, RSMo 2000 and 338.030, RSMo Supp. 2001.\* 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.*

*\*Original authority: 338.020, RSMo 1939, amended 1947, 1949, 1981, 1990; 338.030, RSMo 1939, amended 1949, 1951, 1981, 1990, 2001; 338.035, RSMo 1990, amended 1993, 1995; 338.040, RSMo 1939, amended 1961, 1969, 1981, 1990; 338.070, RSMo 1939, amended 1947, 1953, 1961, 1969, 1981, 1985, 1997; 338.140, RSMo 1939, amended 1981, 1989, 1997; and 338.280, RSMo 1951, amended 1971, 1981.*

*Simon v. Missouri State Board of Pharmacy, 570 SW2d 334 (Mo. App. 1978). Respondent pleaded nolo contendere to a federal controlled substances distribution violation. The district court suspended imposition of sentence and the state board instituted a disciplinary action on the basis that respondent had been "convicted" under section 338.055.3, RSMo. A judgment which suspends imposition of sentence on a plea of nolo contendere is not a "conviction" subjecting respondent's license to suspension or revocation.*

*Missouri State Board of Pharmacy v. Kennedy*, 511 SW2d 913 (Mo. App. 1974). Where pharmacy board and Administrative Hearing Commission agreed on interpretation of rule on reciprocity, no controversy existed between the parties as to the validity of the rule on appeal.

*Op. Atty. Gen. No. 75, Riley (5-12-54)*. Ten-dollar fee required for issuance of permit to engage in pharmacy section 338.220, RSMo Supp. 1953 is not a tax and must be paid by a purely charitable organization engaging in pharmacy business.

#### 4 CSR 220-2.032 Licensure by Examination for Graduates of Nonapproved Foreign Pharmacy Schools

**PURPOSE:** This rule defines requirements for licensure by examination of applicants who are graduates of foreign colleges/schools of pharmacy not approved by the board as outlined in 4 CSR 220-2.030(1).

(1) An individual who is a graduate of a foreign college/school of pharmacy which is not currently accredited by the board may apply to write the examination for licensure, if current requirements for licensure in Missouri are met.

(2) The board shall consider an application only after the applicant submits all of the following required credentials:

(A) Photostatic copy of a certificate, stating name, date of birth and place of birth, by one (1) of the following methods:

1. Birth certificate;
2. Baptismal certificate; or
3. Notarized statement from an authorized agency;

(B) Documentation as required by the board showing proof of practical experience which is equal to the requirements of 4 CSR 220-2.030(2), (3) and (6)(C);

(C) Documentation of name change, if name on the credentials supplied for evaluation purposes is different than the present name appearing on the application;

(D) Copy of current visa, along with a copy of an employment authorization document such as an Alien Registration Receipt Card, Form I-551 or Employment Authorization Card Form I-688-B, or any other document approved or issued by the United States government permitting employment, if applicant is not a United States citizen, or proof of United States citizenship;

(E) One (1), two-inch by two-inch (2" × 2") frontal view portrait photograph of the applicant; and

(F) Foreign Pharmacy Graduate Equivalency Certification (FPGEC) as provided by the National Association of Boards of Pharmacy Foundation Foreign Pharmacy Graduate Examination Committee.

(3) An applicant who successfully completes all requirements as set forth in this rule will be considered eligible to apply and take the licensure examination as outlined in sections 338.020 and 338.030, RSMo and 4 CSR 220-2.030.

(4) An applicant who does not meet the current minimum requirements as set forth by the board for licensure shall be advised of the decision of the board. This decision may include recommendations as to what action the applicant can take to obtain licensure.

(5) Application pursuant to this rule should be submitted to the board's office six (6) months prior to the date for which the candidate wishes to sit for a regularly scheduled licensing examination.

(6) Documents in a foreign language shall be translated into English, notarized by an authorized individual and attached when submitted to the Missouri Board of Pharmacy.

(7) All fees are nonrefundable.

**AUTHORITY:** sections 338.020, 338.030 and 338.140, RSMo 2000.\* 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.

\*Original authority: 338.020, RSMo 1939, amended 1947, 1949, 1981, 1990; 338.030, RSMo 1939, amended 1949, 1951, 1981, 1990; 338.140, RSMo 1939, amended 1981, 1989, 1997.

#### 4 CSR 220-2.034 Licensure by Reciprocity for Graduates of Nonapproved Foreign Pharmacy Schools Who Have Been Licensed in Another State

**PURPOSE:** This rule defines requirements for licensure by reciprocity of applicants who are graduates of foreign colleges/schools of pharmacy not approved by the board as outlined in 4 CSR 220-2.030(1) who have been licensed in another state.

(1) An individual who is a graduate of a foreign college/school of pharmacy not approved by the Missouri Board of Pharmacy and is licensed as a pharmacist by another state may apply for licensure in this state by reciprocity, if the requirements for licensure by the other state are equivalent to those of this state.

(2) The applicant for reciprocal licensure must fulfill all requirements as set forth in 4 CSR 220-2.032.

(3) Appropriate fees must accompany all applications and are nonrefundable.

(4) Once the credentials of a candidate have been approved by the board, application to the National Association of Boards of Pharmacy for reciprocity to Missouri may begin. All reciprocal licensure requirements as set forth in 4 CSR 220-2.030(6) must then be satisfactorily completed.

**AUTHORITY:** sections 338.020 and 338.030, RSMo Supp. 1990.\* 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.

\*Original authority: 338.020, RSMo 1939, amended 1947, 1949, 1981, 1990 and 338.030, RSMo 1939, amended 1949, 1951, 1981, 1990.

#### 4 CSR 220-2.036 Temporary License

**PURPOSE:** This rule defines requirements to obtain a temporary license to practice pharmacy for persons completing residency programs.

(1) Temporary licenses issued under authority granted to the board in section 338.043, RSMo for purposes of completing a residency training or fellowship program shall limit the right of the licensee to practice only in locations approved by the board under the supervision of a pharmacist licensed to practice pharmacy in this state.

(A) The pharmacist license of the supervising pharmacist must be an active, unrestricted license and be in good standing with the board.

(B) All locations where the temporary licensee shall practice must be provided to the board when initially applying for a temporary license and must be updated when changes occur during the licensing period.

(2) An applicant for a temporary license for use in completing a postgraduate training program in pharmacy as recognized by the board



is required to make application upon a form supplied by the board.

(A) No application will be considered unless it is fully completed and properly attested.

(B) A frontal view portrait photograph which measures two inches by two inches (2" × 2") must accompany the application for a temporary license.

(C) The application shall be submitted along with the appropriate licensure fee as required by the board.

(D) The application must be accompanied by a protocol which will outline the duties of the temporary licensee as well as any documentation concerning affiliations with licensed pharmacies, other institutions or associations, or both. The protocol shall define and provide, at a minimum, the following:

1. Type of practice to be performed and a specific job description of professional duties and functions to be completed;
2. Identity of the supervising pharmacist which includes a statement attesting to the ability and understanding of responsibilities involved;
3. A complete listing of all affiliations to be utilized during the licensure period; and
4. A complete listing of all locations where professional services shall occur.

(3) In the event that an applicant for temporary licensure is not a graduate of a board approved school or college of pharmacy as outlined in 4 CSR 220-2.030(1), then all the requirements as outlined in 4 CSR 220-2.032 must be completed.

(4) A Missouri licensed pharmacist who agrees to supervise a temporary licensee shall conduct general supervision during his/her tenure.

(A) General supervision is defined as supervision required to fulfill the stated requirements of the practice protocol or may be required by the board and to insure appropriate outcomes as to training received or provided. In addition, general supervision requires that the supervisor be available for consultation with the licensee whenever necessary. Any proposed methods for supervising temporary licensees shall be stated in the practice protocol.

(B) General supervision also will include the timely submission of reports to the board as may be required through protocol or by the board in assessing outcomes or adherence to board requirements.

(5) The board may terminate a temporary license at its own discretion if, in the opinion

of the board, any of the requirements of the board or the approved protocol have not been adhered to. The licensee shall be notified in writing by personal service or certified mail when board action results in the termination of a temporary license.

(6) No applicant for a temporary license shall commence practicing until the temporary license is issued.

(7) The temporary licensing program is not intended to replace or conflict with any requirements or provisions of 4 CSR 220-2.030 as regards internship or externship. Students who rotate through a licensed pharmacy or other accredited internship site shall apply for a temporary license when the student is not currently licensed as an intern or registered as a technician. For purposes of this section to qualify for a temporary license the rotation shall be no more than six (6) weeks in length and the student cannot have been previously licensed as an intern by the board.

(8) If a temporary licensee desires to acquire a permanent license or desires to practice pharmacy outside of the provisions of this rule, then all provisions as outlined in 4 CSR 220-2.030 must be completed.

(9) A temporary license automatically expires at the end of the applicant's Missouri-based training program identified in the application and protocol. No temporary licensee shall continue to practice pharmacy beyond the expiration date of the license.

(10) Temporary licenses may be issued to licensure transfer candidates or licensure examination candidates who successfully complete the requirements for permanent licensure if background criminal checks are not complete.

(11) Any temporary license issued in lieu of a permanent license while a criminal background check is completed shall remain in effect until the permanent license is issued or denied. If a permanent license is denied, the board shall inform the applicant in writing of the denial. The temporary license will be considered invalid after notification is sent to the applicant by certified mail.

(12) All fees are nonrefundable.

*AUTHORITY: sections 338.043 and 338.140, RSMo Supp. 1999.\* 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.*

*\*Original authority: 338.043, RSMo 1990, amended 1997 and 338.140, RSMo 1939, amended 1981, 1989, 1997.*

**4 CSR 220-2.040 Wholesalers and Manufacturers and Violation Procedures**  
(Rescinded June 10, 1991)

*AUTHORITY: section 338.140, RSMo 1986. Original rule filed Nov. 9, 1966, effective Nov. 19, 1966. Amended: Filed Dec. 31, 1975, effective Jan. 10, 1976. Rescinded: Filed Feb. 4, 1991, effective June 10, 1991.*

**4 CSR 220-2.050 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 licensed pharmacist or pharmacy possessing a valid permit, 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., P.O. 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 logged in a book maintained by the board for that purpose. Complaints shall be logged in consecutive order as received. The logbook shall contain a record of each complainant's name and address; the name and address of the subject(s) of the complaint; the date each complaint is received by the board; a brief statement of the acts complained of, including the name of any person injured or victimized by the alleged acts or practices; a notation whether the complaint resulted in its dismissal by the board or in formal charges being filed with the Administrative Hearing Commission; and the ultimate disposition of the complaint. This logbook shall be a closed record of the board.

(5) Each complaint logged pursuant to this rule shall be acknowledged in writing. The acknowledgment shall state that the complaint is being investigated and shall be referred to the board or an appropriate board subcommittee for consideration following the investigation. The complainant subsequently shall be informed in writing as to whether the complaint 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 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. 2001.\* 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.*

*\*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.*

#### 4 CSR 220-2.060 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.\* Original rule filed March 14, 1983, effective June 11, 1983.*

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

#### 4 CSR 220-2.070 Hospital Pharmacy Services

(Invalidated by Court July 14, 1987)

#### 4 CSR 220-2.080 Electronic Data Processing

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

(1) All information concerning the compounding, dispensing or selling at retail of any drug, medicine or poison pursuant to a lawful prescription which is entered into an electronic data processing (EDP) system at any pharmacy shall be entered only by a licensed pharmacist or by an individual under the direct supervision and review of a licensed pharmacist. That pharmacist shall be personally responsible for the accuracy of the information.

(2) Any EDP system used by any pharmacy for record keeping shall comply with the requirements of section 338.100, RSMo, including the capability to store and retrieve the following information concerning the filling or refilling of any prescription:

(A) A prescription label number that is linked to the unique readily retrievable identifier;

(B) Date of original prescription, expiration date of the prescription or both;

(C) Date original prescription was filled;

(D) Patient's full name;

(E) Patient's address when a prescription prescribes a controlled substance;

(F) Prescriber's full name;

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

(H) Name of drug, medicine or poison dispensed;

(I) Quantity of drug, medicine or poison originally dispensed;

(J) Quantity of drug, medicine or poison dispensed on each refill;

(K) Initials or code of the pharmacist responsible for input or review of data on each original prescription and each refill;

(L) Date of each refill; and

(M) If a new prescription is transmitted by phone, a hard copy representation must be made and contain all of the information in subsections (2)(A)–(L) plus an indication of whether or not a generic substitution is permitted and made in accordance with 4 CSR 220-3.011.

(3) Prescription hard copies must be filed by either the prescription label number or by the unique readily retrievable identifier. Prescription hard copies must be retrievable at the time of inspection.

(4) Any pharmacy using an EDP system as described in section (1) shall provide documentation that the information concerning the refills of prescriptions entered into the system for all prescription drugs is accurate. This documentation shall include:

(A) The initials or code designation of the dispensing pharmacist for each refill;

(B) The date of the refill;

(C) The quantity of substances refilled;

(D) The number of authorized refills or dispensable units remaining;

(E) If additional refills are authorized and added to an existing 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; and

(F) If any other alteration is made in the original prescription record, a clear audit trail must be maintained. This shall include, but is not limited to, a change in authorizing physi-

cian, a change in total quantity ordered or a change in directions.

(5) Any pharmacy using an EDP system as described in section (1) shall maintain the following:

(A) A bound logbook or separate file in which each pharmacist involved in the pharmacy's record keeping system shall sign a statement each day attesting that information concerning the refill of prescriptions has been entered into the system for that day and that the pharmacist has reviewed the information for accuracy. The logbook or file shall be maintained at the pharmacy for at least five (5) years after the date the drugs, medicines or poisons are dispensed.

(6) Any hospital pharmacy using an EDP system, 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, as described in section (1), must be capable of producing the record required in subsections (2)(A)–(M) and said records shall be readily retrievable on-line. Readily retrievable is defined as providing EDP records within two (2) hours of time of 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 insure 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 pharmacist-in-charge or 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 twelve (12)-month period. Drug utilization information shall be available by 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.

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

*\*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.*

**4 CSR 220-2.085 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.\* 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.*

*\*Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990; 338.095, RSMo 1993; 338.140, RSMo 1939, amended 1981, 1989, 1997; and 338.280, RSMo 1951, amended 1971, 1981.*

#### 4 CSR 220-2.090 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. \* 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.*

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

**4 CSR 220-2.100 Continuing Pharmacy Education**

*PURPOSE: This rule defines continuing education requirements for relicensure of pharmacists in Missouri.*

(1) Commencing with the licensing period beginning November 1, 1985 and for each licensing period after that, no active pharmacist license will be renewed by the Missouri Board of Pharmacy unless the applicant has fulfilled the continuing education requirements as set forth in section 338.060, RSMo of the Pharmacy Practice Act.

(2) A continuing education program for pharmacists means postgraduate studies that have prior approval of the Missouri Board of Pharmacy to fulfill the requirements of continuing education for relicensure in Missouri. This may include institutes, seminars, lectures, conferences, workshops, extension study, correspondence courses, teaching, professional meetings, self-study courses and any other methods which may be approved by the board, but in any case, the studies must be pharmacy-related.

(A) Programs shall provide for evaluation methods or examinations to assure satisfactory completion by participants.

(B) The person(s) who is to instruct or who is responsible for the delivery or content of the program shall be qualified, as determined by the board, in the subject matter by education, experience or preparation in the preparation and methods of delivery.

(C) Continuing pharmacy education programs shall be approved by one (1) of the following methods:

1. All continuing pharmacy education programs offered by providers approved by the American Council on Pharmaceutical Education will be accepted as meeting the requirements of continuing education for relicensure as a pharmacist in Missouri;

2. The Missouri Board of Pharmacy may approve continuing education programs offered by providers who are not approved by the American Council on Pharmaceutical Education. Criteria for approval of those programs shall be based on the criteria promulgated by the American Council on Pharmaceutical Education in its publication "Accreditation Standards and Guidelines"

section on Approval of Providers of Pharmaceutical Education, Pages III-1 through III-C. Application to the board for this approval must be made at least thirty (30) days in advance of the program date to guarantee notification of certification status prior to the date of the program. Applications received less than thirty (30) days prior to the date of the program cannot be guaranteed to be certified prior to the date of the program. Application to the board for this approval shall be made on and in accordance with forms established by the board. The forms shall require detailed information relating to administration and organization, budget and resources, teaching staff, educational content and development, methods of delivery, facilities and evaluation. No applications for approval of continuing education programs will be accepted less than ten (10) business days from the date such program is offered for continuing education purposes. Applications returned due to errors or for purposes of requesting more information shall not be considered to be received by the office until the requested corrections or information are made and received by the board office. The executive director shall review applications for continuing education programs and may approve or deny such requests. Applicants shall be notified on a timely basis once the decision to approve or deny a program has been made. If an application was received by the board office sixty (60) days or more prior to the date it is scheduled to be offered and the program is denied, the applicant may request an appeal to further review the application by the continuing education committee. The request for appeal must be in writing. In no case shall an applicant be able to appeal a denial of an application if such application was initially received by the board office less than sixty (60) days prior to the date it is scheduled to be offered;

3. Any pharmacist whose primary responsibility is not the education of health professionals who leads, instructs or lectures to groups of nurses, physicians, pharmacists or others on pharmacy-related topics in organized continuing education or in-service programs shall be granted continuing education credit for the time expended during actual presentation upon adequate documentation to the Missouri Board of Pharmacy. Application for approval shall be made in accordance with procedures in section (2) of this rule. Credit for the same presentation or program will be allowed only once during a renewal period;

4. Any pharmacist whose responsibility is the education of health professionals shall be granted continuing education credit only for time expended in leading, instructing or

lecturing to groups of physicians, pharmacists, nurses or others on board-approved pharmacy-related topics in an organized continuing education or in-service program outside his/her formal responsibilities in a learning institution. Approval will be requested using procedures in section (2) and submitted to the Missouri Board of Pharmacy. Credit for the same presentation or program will be allowed only once during a renewal period;

5. Credit will be given for undergraduate or graduate studies in any regionally accredited pharmacy, medical or dental educational institution of higher learning. Satisfactory proof of course completion, as required by the board, must be submitted with the renewal notice. The following hourly equivalents will be used by the board in assessing credits:

3 hours college credit = 15 contact hours

2 hours college credit = 10 contact hours

1 hour college credit = 5 contact hours

6. One and one-half (1.5) continuing education unit (CEU) will be the equivalent of fifteen (15) clock hours of participation in programs approved by the Missouri Board of Pharmacy; and

7. Continuing education hours earned in another state will be accepted by the Missouri Board of Pharmacy provided the hours are acquired within the same renewal period and are certified by the other state board of pharmacy.

(D) No information or advertisements shall contain information that a continuing education program has been approved by the board of pharmacy unless the program is accredited by American Council on Pharmaceutical Education (ACPE) or notification has been received that the program has been approved by the board of pharmacy.

(3) Each licensed pharmacist, instead of submitting proof of the completion of the required continuing education courses, may apply for an inactive license at the time s/he makes application for the renewal of his/her license and pay the required renewal fee. An inactive license then shall be issued and may be renewed during the renewal period. While the inactive license is in effect, the pharmacist shall not practice pharmacy.

(4) The renewal fee will be the same for active and inactive licenses.

(5) Before any inactive license can be reactivated to active status, the licensee shall submit proper evidence that s/he has obtained at least fifteen (15) contact hours for each year that his/her license was inactive. It shall be permissible for the licensee to obtain the

required contact hours during any time period, while the license is on inactive status, as long as they are obtained prior to activation to active status.

(6) Any licensee who has a lapsed license and seeks to have it renewed pursuant to section 338.060.2, RSMo shall present proper evidence that s/he has obtained the required number of contact hours during the period that his/her license was lapsed.

(7) A pharmacist first licensed by the board within nine (9) months immediately preceding the biennial renewal date shall be exempt from the continuing pharmacy education requirements for that licensure period.

(8) The president of the board annually will select two (2) board members who will serve along with the executive director as the continuing education committee. The committee will review and decide on applications that have been denied approval and an appeal for further review has been submitted. In addition, the committee will report on its activities and continuing education at board meetings and make recommendations to the board concerning continuing education requirements.

(9) The proof of completion of continuing education requirements shall be submitted with the renewal notice and the appropriate fees by submitting—

(A) Completed certification from the American Council on Pharmaceutical Education;

(B) Completed certification from the Missouri Board of Pharmacy; or

(C) A letter from another state board of pharmacy stating the program, dates of attendance and number of contact hours that have been approved for relicensure by that state board.

(10) The Missouri Board of Pharmacy may elect to audit, with the appropriate accrediting body, any licensee to assess the authenticity and validity of contact hours submitted for relicensure.

*AUTHORITY: sections 338.060 and 338.140, RSMo 2000.\* Original rule filed Nov. 9, 1984, effective April 12, 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.*

*\*Original authority: 338.060, RSMo 1939, amended 1943, 1947, 1949, 1951, 1981, 1984, 1997, 1999 and 338.140, RSMo 1939, amended 1981, 1989, 1997.*

#### 4 CSR 220-2.110 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 prescriber's 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.\* Original rule filed Dec. 11, 1984, effective March 11, 1985.*

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

#### 4 CSR 220-2.120 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 may 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; and

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

(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 data base 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 4 CSR 220-2.300; 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.

*AUTHORITY: sections 338.100 and 338.140, RSMo Supp. 1999 and 338.280, RSMo 1994.\* 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.*

*\*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.*

#### 4 CSR 220-2.130 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 refer-

ence. 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.

(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, RSMo Supp. 1999 and 338.280, RSMo 1994.\* 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.*

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

#### 4 CSR 220-2.140 Prescription Services by Pharmacists/Pharmacies for Residents in Long-Term Care Facilities

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

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

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

(2) Medication Services.

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

1. Methods used to dispense medications in a timely fashion to the facility;
2. Proper notification to the facility when a medication is not readily available;
3. Proper labeling requirements to meet the needs of the facility and which are consistent with state and federal laws; and
4. Appropriate medication destruction, return of unused medication, or both, which is consistent with state and federal laws.

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

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

(3) Any drug, repackaged or prepacked that is dispensed into a long-term care facility, as defined in section (1) of this rule, in other

than the manufacturer's original container, shall bear the manufacturer's expiration date or twelve (12) months, whichever is less.

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

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

(B) Any products that are repackaged for use in a remote dispensing system must comply with all provisions of 4 CSR 220-2.130.

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

(5) A prescription drug order is defined for the purpose of this rule as an order originating from a long-term care facility that is initiated by a prescriber and entered into the patient's medical record by the prescriber or qualified personnel for the purpose of initiating or renewing an order for a medication or device. All prescription drug orders shall comply with 4 CSR 220-2.018.

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

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

(C) A pharmacy may elect to maintain a separate file system for prescription drug orders that are dispensed. When a separate file is utilized, it must comply with all applic-

able 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.\* 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.*

*\*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.*

#### 4 CSR 220-2.145 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 a series of containers and containing two (2) or more prescribed solid oral dosage

forms. The patient med pak is so designed or each container is so labeled as to indicate the day and time, or period of time that the contents within each container are to be taken.

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

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

(I) Multi-med packaging of controlled substances is prohibited.

*AUTHORITY: sections 338.010, RSMo 1994 and 338.059 and 338.140, RSMo Supp. 1999.\* Original rule filed March 15, 2000, effective Sept. 30, 2000.*

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

#### **4 CSR 220-2.150 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.\* Original rule filed Aug. 4, 1987, effective Jan. 29, 1988.*

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

#### 4 CSR 220-2.160 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 Mis-

souri 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.\* Original rule filed Oct. 1, 1987, effective March 11, 1988. Amended: Filed June 29, 1999, effective Jan. 30, 2000.*

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

#### 4 CSR 220-2.165 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.\* Original rule filed Jan. 3, 1990, effective May 11, 1990. Amended: Filed July 19, 1991, effective Jan. 13, 1992.*

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

#### 4 CSR 220-2.170 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.\* Original rule filed Oct. 1, 1987, effective Jan. 14, 1988. Amended: Filed Nov. 15, 1988, effective March 11, 1989.*

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

#### 4 CSR 220-2.180 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.\* Original rule filed Jan. 19, 1988, effective April 28, 1988. Amended: Filed June 26, 1995, effective Feb. 25, 1996.

\*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.

#### 4 CSR 220-2.190 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. 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 338.010.1 and 338.015.2, RSMo Supp. 1990, 338.140, RSMo Supp. 1989 and 338.280, RSMo 1986.\* Original rule filed May 1, 1992, effective Feb. 26, 1993. Amended: Filed March 4, 1993, effective Oct. 10, 1993.

\*Original authority: 338.010.1, RSMo 1939, amended 1951, 1989, 1990; 338.015.2, RSMo 1990; 338.140, RSMo 1939, amended 1981, 1989; and 338.280, RSMo 1951, amended 1971, 1981.

#### 4 CSR 220-2.200 Sterile Pharmaceuticals

**PURPOSE:** This rule establishes standards for the preparation, labeling and distribution of sterile pharmaceuticals by licensed pharmacies, pursuant to a physician's order or prescription.

(1) The provisions of sections (2)–(9) expire June 30, 2004.

(2) Definitions.

(A) Biological safety cabinet—containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel and environment, according to National Sanitation Foundation (NSF) Standard 49.

(B) Class 100 environment—an atmospheric environment which contains less than one hundred (100) particles 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209B.

(C) Compounded sterile drug—a sterile drug dosage form that has been prepared by a pharmacist, to include a commercially prepared sterile drug dosage form which has been altered by a pharmacist.

(D) Cytotoxic Therapeutic Class—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 the host's inflammatory response system.

(E) Parenteral—sterile preparation of drugs for injection through one (1) or more layers of skin.

(F) Sterile pharmaceutical—a dosage form free from living microorganisms (aseptic).

(3) Policy and Procedure Manual. A policy and procedure manual, as it relates to sterile products, shall be available for inspection at the pharmacy. The manual shall be reviewed and revised on an annual basis and shall include, but is not limited to, policies and procedures for any of the following services provided by the pharmacy:

(A) Clinical services;



(B) Cytotoxics handling, storage and disposal;

(C) Disposal of unused supplies and medications;

(D) Drug destruction and returns;

(E) Drug dispensing;

(F) Drug labeling/relabeling;

(G) Drug storage;

(H) Duties and qualifications for professional and nonprofessional staff;

(I) Equipment;

(J) Handling of infectious wastes;

(K) Infusion devices and drug delivery systems;

(L) Investigational drugs;

(M) Obtaining a protocol on investigational drugs from the principal investigator;

(N) Quality assurance procedures to include:

1. Recall procedures;

2. Storage and dating;

3. Educational procedures for professional staff, nonprofessional staff and patient;

4. Sterile procedures to include a log of the temperature of the refrigerator, routine maintenance and report of hood certification; and

5. Sterility testing;

(O) Record keeping;

(P) Reference material;

(Q) Sanitation;

(R) Security;

(S) Sterile product preparation procedures; and

(T) Transportation.

(4) Physical Requirements.

(A) Space. The licensed pharmacy shall have a designated area with entry restricted to designated personnel for preparing compounded, sterile products. This area shall be isolated from other areas and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled facility. It shall be used only for the preparation of sterile pharmaceutical products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation and security.

(B) Equipment. The licensed pharmacy preparing sterile products shall have—

1. Appropriate environmental control devices capable of maintaining at least Class 100 conditions in the work area where critical objects are exposed and critical activities are performed; furthermore, the devices are capable of maintaining Class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods

and zonal laminar flow systems of high efficiency particulate air filter (HEPA)-filtered air;

2. A sink with hot and cold running water and proper sewage disposal that is convenient to the compounding area for the purpose of hand scrubs prior to compounding;

3. Appropriate disposal containers for used needles, syringes, and if applicable, cytotoxic waste from the preparation of chemotherapy agents and infectious wastes from patients' homes;

4. When cytotoxic drug products are prepared, appropriate environmental control also includes appropriate biohazard cabinetry;

5. Refrigerator/freezer with a thermometer;

6. Temperature-controlled delivery container; and

7. Infusion devices, if appropriate.

(C) Supplies.

1. Disposable needles, syringes and other supplies needed for aseptic admixture;

2. Disinfectant cleaning solutions;

3. Hand washing agent with bactericidal action;

4. Disposable, lint free towels or wipes;

5. Appropriate filters and filtration equipment;

6. Oncology drug spill kit; and

7. Disposable masks, caps, gowns and sterile disposable gloves.

(D) Reference Library. The pharmacy shall have adequate current reference materials related to sterile products. Some suggested sources include: Handbook on Injectable Drugs, America Society for Hospital Pharmacists (ASHP); King's Guide to Parenteral Admixtures; United States Pharmacopeia (USP)/Negative Formulary (NF); American Hospital Formulary Service; Procedures for Handling Cytotoxic Drugs, American Society for Hospital Pharmacists (ASHP). In addition, the pharmacy shall maintain copies of current Occupational Safety and Health Administration (OSHA) requirements.

(5) Drug Distribution and Control.

(A) Medication Record System. A pharmacy generated medication record system must be separate from the prescription file. The patient medication record system shall be maintained under the control of the pharmacist-in-charge for a period of sixty (60) days after the last dispensing activity. The medication record system, at a minimum, shall contain:

1. Patient's full name;

2. Date of birth or age;

3. Weight;

4. Sex;

5. Sterile products dispensed;

6. Date dispensed;

7. Drug content and quantity;

8. Patient direction;

9. Identifying prescription number;

10. Identification of dispensing pharmacist;

11. Other drugs patient is receiving;

12. Known drug sensitivities and allergies to drugs and food; and

13. Primary diagnosis.

(B) Labeling (supplemental). Each sterile pharmaceutical dispensed to patients shall be labeled in accordance with section 338.059, RSMo and with the following supplemental information affixed to a permanent label:

1. Directions for administration including infusion rate, where applicable;

2. Date of compounding;

3. Expiration date and time;

4. Identity of pharmacist compounding and dispensing;

5. Storage requirements;

6. Auxiliary labels, where applicable; and

7. Cytotoxic drug auxiliary labels, where applicable.

(C) Records and Reports. The pharmacist-in-charge shall maintain access to, and submit as appropriate, records and reports required to insure the patient's health, safety and welfare. These reports shall be maintained for two (2) years and shall be readily retrievable, subject to inspections by the State Board of Pharmacy or its agents. Such shall include, at a minimum, the following:

1. Purchase records;

2. Policy and procedure manual;

3. Training manuals, where applicable;

4. Policies and procedures for cytotoxic waste, where applicable;

5. Other records and reports as may be required by law and the rules of the State Board of Pharmacy; and

6. Information regarding individual patients shall be maintained in a manner to assure confidentiality of the patient's record. Release of this information shall be in accordance with federal or state laws, or both.

(D) Delivery Service. The pharmacist-in-charge shall assure the environmental control of all products shipped. A sterile pharmaceutical product must be shipped or delivered to a patient in appropriate temperature controlled delivery containers (as defined by USP standards) and assurances must be made that appropriate storage facilities are available. Chain of possession for the delivery of Schedule II controlled substances via couriers must be documented and a receipt required.

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

(A) All cytotoxic drugs should be compounded in a vertical flow, Class II biological safety cabinet. If used for other products, the cabinet must be thoroughly cleaned;

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

(C) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products;

(D) Disposal of cytotoxic waste shall comply with all applicable local, state and federal requirements;

(E) Written procedures for handling both major and minor spills of cytotoxic agents must be developed and must be included in the policy and procedure manual; and

(F) 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.

(7) Quality Assurance.

(A) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment and facilities. Appropriate samples of finished products shall be examined to assure that the pharmacy is capable of consistently preparing sterile products meeting specifications. These examinations shall include: visual inspection under a direct light source in the preparation of products in order to determine the presence of inappropriate particulate matter or signs of deterioration; policies and procedures for monitoring of sterile products whereby any untoward effects exhibited by a patient that may be due to the product, are reported to the pharmacy; and appropriate samples are collected and microbial tests are completed to ascertain the presence of microbial contamination of suspect products. Quality assurance procedures shall include:

1. Recall procedures;

2. Storage and dating; and

3. Environmental procedures which include a log of the temperature of the refrigerator, routine maintenance and report of any hood certification.

(B) Clean Room and Hood Certification. All clean rooms and laminar flow hoods shall be certified by an independent contractor according to Federal Standard 209B or

National Sanitation Foundation Standard 49 for operational efficiency at a minimum of every twelve (12) months. Certification records shall be maintained as a part of the pharmacy record.

(C) Prefilters. Prefilters for the clean air source shall be replaced on a regular basis and the replacement date documented.

(D) Nonsterile Compounding. If bulk compounding is performed utilizing nonsterile chemicals, extensive end-product testing, as referenced in the Remington Reference Manual, must be documented prior to the release of the product from quarantine. This process must include appropriate tests for particulate matter and testing for pyrogens.

(E) Expiration Dates. There shall be written justification of the chosen expiration date for compounded products. If a written standard is not available, a maximum of twenty-four (24) hours expiration date shall be used.

(F) Quality Assurance Audits. There shall be documentation of quality assurance audits at regular, planned intervals and should include infection control and sterile technique audits.

(8) Pharmacists and pharmacies where sterile compounding is provided may be exempt from this rule when that compounding is restricted to the following:

(A) The method of compounding utilizes compounds or products that are contained only in a closed or sealed system and can be transferred or compounded within this self-contained system or topical products that require further transfer or combination in order to achieve a finished product without further modification of the product; or

(B) The amount of compounding provided by the pharmacy is for emergency situations. An emergency is defined as—

1. Situations where the sterile compound is needed and is unavailable from or inconvenient to obtain from other sources;

2. Compounding will be provided to the patient immediately and used within a twenty-four (24)-hour period; and

3. Products are provided to the patient as a single dosage unit and the drug is not intended to be provided beyond an immediate emergency period.

(9) This rule is not intended to include any pharmacy that provides sterile pharmaceuticals on a prescription order that has not been compounded by the pharmacy or had the packaging or labeling of the product altered by the pharmacy.

(10) The provisions of sections (11)–(26) become effective July 1, 2004.

(11) 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 product 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 product, personnel and environment, according to NSF International standards.

(E) Class 100 environment: an atmospheric environment which contains less than one hundred (100) particles 0.5 microns in diameter per cubic foot of air, according to federal standards.

(F) Class 10,000 environment: An atmospheric environment which contains less than ten thousand (10,000) particles 0.5 microns in diameter per cubic foot of air, according to federal standards.

(G) Clean room: A room—

1. In which the concentration of airborne particles is controlled;

2. That is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room; and

3. In which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary.

(H) Clean zone: Dedicated space—

1. In which the concentration of airborne particles is controlled;

2. That is constructed and used in a manner that minimizes the introduction, generation, and retention of particles inside the zone; and

3. In which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary.

This zone may be open or enclosed and may or may not be located within a clean room.

(I) Compounding: For the purposes of this regulation, compounding is defined as in 4 CSR 220-2.400(1). Compounded sterile medications may include, but are not limited

to, injectables, parenteral nutrition solutions, irrigation solutions, inhalation solutions, intravenous solutions and ophthalmic preparations.

(J) Controlled area: For purposes of these regulations, a controlled area is the area designated for preparing sterile products. This is referred to as the buffer zone (i.e., the clean room in which the laminar airflow workbench is located) by the *United States Pharmacopoeia* (USP).

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

(L) Critical site: An opening providing a direct pathway between a sterile product and the environment or any surface coming into contact with the product or environment.

(M) Critical surface: Any surface that comes into contact with previously sterilized products or containers.

(N) 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.

(O) Emergency dispensing: Is a situation where a Risk Level 3 product is necessary for immediate administration of the product and no alternative product is available and the prescriber is informed that the product is being dispensed prior to appropriate testing. Documentation of the dispensing of the product, 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.

(P) 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 a Class 100 clean room.

(Q) Isolator (or barrier isolator): 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 covering 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.

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

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

(T) 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 products lead to products that meet predetermined standards of quality.

(U) 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 products prepared meet predetermined requirements with respect to identity, purity, nonpyrogenicity and sterility.

(V) Repackaging: The subdivision or transfer of a compounded product from one container or device to a different container or device.

(W) Sterile pharmaceutical: A dosage form free from living microorganisms.

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

(Y) Temperatures:

1. Frozen means temperatures between twenty below zero and ten degrees Celsius ( $-20$  and  $10^{\circ}\text{C}$ ) (four below zero and fourteen degrees Fahrenheit ( $-4$  and  $14^{\circ}\text{F}$ )).

2. Refrigerated means temperatures between two and eight degrees Celsius ( $2$  and  $8^{\circ}\text{C}$ ) (thirty-six and forty-six degrees Fahrenheit ( $36$  and  $46^{\circ}\text{F}$ )).

3. Room temperatures means room temperatures between fifteen and thirty degrees Celsius ( $15$  and  $30^{\circ}\text{C}$ ) (fifty-nine and eighty-six degrees Fahrenheit ( $59$  and  $86^{\circ}\text{F}$ )).

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

(AA) Definitions of sterile compounded products by risk level:

1. Risk Level 1: Applies to compounded sterile products that exhibit characteristics A., B., and C., stated below. All Risk Level 1 products shall be prepared with sterile equipment, sterile ingredients and solutions and sterile contact surfaces for the final product. Risk Level 1 includes the following:

A. Products:

(I) Stored at room temperature and completely administered within forty-eight (48) hours after preparation; or

(II) Stored under refrigeration for seven (7) days or less before complete administration to a patient over a period not to exceed forty-eight (48) hours; or

(III) Frozen for thirty (30) days or less before complete administration to a patient over a period not to exceed forty-eight (48) hours.

B. Unpreserved sterile products prepared for administration to one (1) patient or batch-prepared products containing suitable preservatives prepared for administration to more than one (1) patient.

C. Products 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.

2. Risk Level 2: Sterile products exhibit characteristic A., B., or C., stated below. All Risk Level 2 products shall be prepared with sterile equipment, sterile ingredients and solutions and sterile contact surfaces for the final product and with closed-system transfer methods. Risk Level 2 includes the following:

A. Products stored beyond seven (7) days under refrigeration, stored beyond thirty (30) days frozen or administered beyond forty-eight (48) hours after preparation and storage at room temperature.

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

C. Products 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 products exhibit either characteristic A. or B.:

A. Products compounded from non-sterile ingredients or compounded with non-sterile components, containers or equipment before terminal sterilization.

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

(12) Policy and Procedure Manual.

(A) A manual, outlining policies and procedures encompassing all aspects of Risk Level 1, 2 and 3 products, shall be available



for inspection at the pharmacy. The manual shall be reviewed on an annual basis.

(13) Personnel Education, Training and Evaluation.

(A) Risk Level 1: All pharmacy personnel preparing sterile products must receive suitable didactic and experiential training.

(B) Risk Level 2: In addition to Risk Level 1 requirements, personnel training includes 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 products. The pharmacist knows principles of good compounding practice for risk level products, including—

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

(14) Storage and Handling in the Pharmacy.

(A) Risk Level 1 and 2: Solutions, drugs, supplies and equipment must be stored according to manufacturer or USP requirements. Refrigeration and freezer 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 products from boxes shall be done outside controlled areas. Removal of used supplies from the controlled area shall be done at least daily. Product recall procedures must permit retrieving affected products from specific involved patients.

(B) Risk Level 3: In addition to Risk Level 1 and 2 requirements, procedures include procurement, identification, storage, handling, testing, and recall of components and finished products. Finished but untested Risk Level 3 products must be quarantined under minimal risk for contamination.

(15) Facilities and Equipment.

(A) Risk Level 1: The controlled area shall be separated from other operations. The controlled area must be clean and well lit. 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 regularly. Sterile products must be prepared in at least a Class 100 environment (the critical area). Computer entry, order processing, label generation, and record keeping shall be performed outside the critical area. The critical area must be disin-

fectured prior to use. A workbench shall be recertified every six (6) months and when it is moved; 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, the controlled area must meet Class 10,000 clean room standards; cleaning supplies should be selected to meet clean room standards; critical area work surface must be cleaned between batches; floors should be disinfected daily; equipment surfaces weekly; and walls monthly; with applicable environmental monitoring of air and surfaces. Automated compounding devices must be calibrated and verified as to accuracy, according to manufacturer procedures. Clean rooms not utilized on a daily basis must be cleaned prior to use as stated above.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, products must be prepared in a Class 100 workbench in a Class 10,000 clean room, in a Class 100 clean room or within a positive pressure barrier isolator. Access to the clean room must be limited to those preparing the products and who are in appropriate garb. Equipment must be cleaned, prepared, sterilized, calibrated, and documented according to manufacturer's standards. Walls and ceilings must be disinfected weekly. All non-sterile equipment that is to come in contact with the sterilized final product must be sterilized before introduction in the clean room. Appropriate cleaning and disinfection of the environment and equipment are required.

(16) Apparel.

(A) Risk Level 2: In the controlled area, personnel wear low particulate, clean clothing covers. Head and facial hair is covered. Gloves, gowns, and masks are required. During sterile preparation gloves shall be rinsed frequently with a suitable agent and changed when integrity is compromised.

(B) Risk Level 3: In addition to Risk Level 2 requirements, clean room apparel must be worn inside the controlled area at all times during the preparation of Risk Level 3 sterile products except when positive pressure barrier isolation is utilized. Attire shall consist of a low-shedding coverall, head cover, face mask, and shoe covers.

(17) Aseptic Technique and Product Preparation.

(A) Risk Level 1: Sterile products must be prepared in a Class 100 environment. Per-

sonnel shall scrub their hands and forearms for an appropriate period at the beginning of each aseptic compounding process. 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 product 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 workbench. Surfaces of ampules and vials shall be disinfected before placement in the workbench. Sterile components shall be arranged in the workbench to allow uninterrupted laminar airflow over critical surfaces of needles, vials, ampules, etc. Automated devices and equipment shall be cleaned, disinfected and placed in the workbench 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. 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 formula, components, procedures, sample label, and final evaluation shall be made for each product batch. A separate work sheet and lot number for each batch shall be completed. When combining multiple sterile products, a second verification of calculations shall take place. The pharmacist shall verify data entered into any automatic compounder before processing and check the end product for accuracy.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, nonsterile components must meet standards if available, as 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 product integrity throughout the shelf life. Sterilization methods must be based on properties of the product.

(18) Process Validation.

(A) Risk Level 1: All pharmacy personnel who prepare sterile products shall pass a process validation of aseptic technique before compounding sterile products. Pharmacy personnel competency must be reevaluated by process validation at least annually, whenever

the quality assurance program yields an unacceptable result, or whenever unacceptable techniques are observed. If microbial growth is detected, the entire sterile process must be evaluated, corrective action taken, and the process simulation test performed again.

(B) Risk Level 2: In addition to Risk Level 1 requirements, process simulation procedures shall cover all types of manipulations, products and batch sizes.

(C) Risk Level 3: In addition to all Risk Level 1 and 2 requirements, written policies shall be maintained to validate all processes, procedures, components, equipment and techniques.

(19) Record Keeping.

(A) Risk Level 1: The following must be documented:

1. Training and competency evaluation of pharmacy personnel involved in sterile product preparation;

2. Refrigerator and freezer temperature logs;

3. Certification of workbenches;

4. Copies of any manufacturer standards that are relied upon to maintain compliance with this rule; and

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

(B) Risk Level 2: In addition to Risk Level 1 requirements, records of any end-product testing and batch preparation records must be maintained.

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

1. Preparation work sheet;

2. Sterilization records;

3. Quarantine records, if applicable;

4. End-product evaluation and testing records as required in section (22); and

5. Ingredient validation records as required in section (22).

(D) All records and reports shall be maintained for two (2) years and shall be readily retrievable, subject to inspections by the board of pharmacy or its agents.

(20) Labeling.

(A) Risk Level 1: Sterile products dispensed to patients shall be labeled in accordance with section 338.059, RSMo and with the following supplemental information affixed to a permanent label:

1. Beyond-use date;

2. Storage requirements;

3. Any device specific instructions; and

4. Auxiliary labels, when applicable.

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

(C) Risk Level 3: All requirements for Risk Level 1 must be met.

(21) Beyond-Use Dating.

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

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

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

(22) End-Product Evaluation.

(A) Risk Level 1: The final product must be inspected for container leaks, integrity, solution cloudiness or phase separation, particulates in solution, appropriate solution color, and solution volume. The pharmacist must verify that the product was compounded accurately as to the ingredients, quantities, containers, and reservoirs. Background light or other means for the visual inspection of products for any particulate and/or foreign matter must be used as part of the inspection process.

(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-product sterility testing according to a formal sampling plan. Samples shall be statistically valid to ensure that batches are sterile. A method for recalling batch products shall be established if end-product testing results are unacceptable. All sterile products must be tested for sterility. All parenteral sterile products must also be tested for pyrogenicity. Sterile products compounded from nonsterile components must be quarantined pending results of end-product 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 con-

ducted according to one (1) of the USP methods.

2. Pyrogen/Endotoxin testing: Each sterile parenteral product prepared from non-sterile drug components shall be tested for pyrogen or endotoxin according to recommended USP methods.

3. Potency: The pharmacy shall have a procedure for a pre-release check of the potency of the active ingredients in the compounded sterile product 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 products that have been assigned a beyond-use date of more than thirty (30) days.

(D) Emergency Dispensing of a Risk Level 3 Sterile Product: When a compounded Risk Level 3 product must be released prior to the completion of testing, the sterile product may be dispensed pending test results.

(23) Handling Sterile Products Outside the Pharmacy.

(A) Risk Level 1: The pharmacist-in-charge shall assure the environmental control of all sterile compounded products shipped. Sterile products 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 products. The pharmacy shall follow written procedures that specify packing techniques, configuration, and materials for groups of products with common storage characteristics and for specific products where unique storage conditions are required to retain adequate stability and product quality.

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

(C) Risk Level 3: All requirements for Risk Level 1 must be met.

(24) 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 an isolator. If used for other products, 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 products;

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;

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.

(25) Exemption: Pharmacists and pharmacies where sterile compounding is provided may be exempt from this rule when compounding is restricted to utilizing compounds or products that are contained only in a closed or sealed system and can be transferred or compounded within this self-contained system or topical products that require further transfer or combination in order to achieve a finished product without further modification of the product.

(26) In addition to the requirements outlined in this rule, all standards and requirements as outlined in 4 CSR 220-2.400 must be maintained.

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

*\*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.*

#### 4 CSR 220-2.300 Record Confidentiality and Disclosure

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

(1) Prescription records, physician orders and other records related to patient care 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) The authorized prescriber who issued the prescription order or a licensed health professional who is currently treating the patient;

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

(D) A person authorized by a court order;

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

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

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

(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.

*AUTHORITY: sections 338.100, 338.140 and 338.280, RSMo 2000. Original rule filed May 4, 1995, effective Dec. 30, 1995.\* Rescinded and readopted: Filed Nov. 1, 2000, effective June 30, 2001.*

*\*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.*

#### 4 CSR 220-2.400 Compounding Standards of Practice

*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 profes-

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

(C) Equipment used in 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 prod-

uct/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 manufactured 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.\* Original rule filed Aug. 25, 1995, effective April 30, 1996. Amended: Filed Dec. 3, 2002, effective July 30, 2003.*

*\*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.*

#### 4 CSR 220-2.450 Fingerprint Requirements

*PURPOSE: This rule establishes guidelines for the submission of fingerprint cards for applicants for licensure.*

(1) Applicants for licensure or registration that must provide fingerprints to the Board of Pharmacy shall include:

- (A) Pharmacist examination for licensure;
- (B) Pharmacist score transfer for licensure;
- (C) Pharmacist examination for licensure by graduates of nonapproved foreign pharmacy schools;
- (D) Pharmacist licensure by reciprocity (license transfer);
- (E) Drug distributor license manager-in-charge (unless currently licensed as a pharmacist in the state of Missouri); and
- (F) Pharmacy technician.

(2) No application shall be considered complete without two (2) sets of fingerprints and the required fingerprinting fee.

(3) Information collected under this background review will be held as confidential in accordance with state and federal laws governing the dissemination of criminal history information.

(4) Any application which is found to contain incomplete, inaccurate or false statements shall be deemed null and void. Any license or registration issued under such circumstances shall be considered a license or registration issued under the pretense of fraud, deception or misrepresentation and the board may file a complaint with the Administrative Hearing Commission to revoke or discipline the license or registration.

(5) The board may, in the course of an investigation of a licensee, require that two (2) sets of fingerprints be submitted for a background check as provided for in this rule.

*AUTHORITY: sections 338.185 and 338.280, RSMo 1994 and 338.013, 338.140 and 338.350, RSMo Supp. 1997.\* Original rule filed Jan. 6, 1997, effective July 30, 1997. Amended: Filed April 23, 1998, effective Nov. 30, 1998.*

*\*Original authority: 338.013, RSMo 1997; 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.185, RSMo 1990; 338.280, RSMo 1950, amended 1971, 1981; and 338.350, RSMo 1989, amended 1993, 1995.*

#### 4 CSR 220-2.500 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 pharma-

cy” 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.

(5) 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.

(6) 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.\* Original rule filed Sept. 2, 1997, effective April 30, 1998.*

*\*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.*

#### 4 CSR 220-2.600 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 prescribed.

(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.\* Original rule filed Jan. 20, 1998, effective Aug. 30, 1998.*

*\*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.*

**4 CSR 220-2.650 Standards of Operation for a Class J: Shared Services Pharmacy**

*PURPOSE: The purpose of this rule is to establish minimum standards of operation for Class J: Shared Services Pharmacy, in compliance with House Bill 567 of the 91st General Assembly.*

(1) Class J: Shared Services: Shared Service Pharmacy is defined as the processing by a pharmacy 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.

(A) A pharmacy may perform or outsource centralized prescription processing services provided the parties:

1. Have the same owner, or have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms

of said contract in compliance with federal and state laws and regulations;

2. Maintain separate licenses for each location involved in providing shared services; and

3. Share a common electronic file to allow access to sufficient information necessary or required to fill or refill a prescription drug order.

(B) There must be record keeping systems between shared service pharmacies with real time on-line access to shared services by both pharmacies. Transfer of prescription information between two (2) pharmacies that are accessing the same real-time, on-line database pursuant to the operation of a shared service pharmacy operation shall not be considered a prescription transfer and, therefore, is not subject to the requirements of 4 CSR 220-2.120.

(C) The parties performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the board for review upon request and that includes, but is not limited to, the following:

1. A description of how the parties will comply with federal and state laws and regulations;

2. The maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling processes;

3. The maintenance of a mechanism for tracking the prescription drug order during each step in the process;

4. The provision of adequate security to protect the confidentiality and integrity of patient information;

5. The maintenance of a quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care and resolve identified problems.

*AUTHORITY: sections 338.140, 338.240, and 338.280, RSMo 2000 and 338.210 and 338.220, RSMo Supp. 2001.\* Original rule filed Nov. 30, 2001, effective June 30, 2002. Amended: Filed Dec. 3, 2002, effective June 30, 2003.*

*\*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; 338.240, RSMo 1951 and 338.280, RSMo 1951, amended 1971, 1981.*

**4 CSR 220-2.700 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(s) are received by the board. Except that, persons already employed as a pharmacy technician at the time this rule becomes effective will have sixty (60) days to submit a completed application for registration and the required fee(s) to the board. The board will notify an applicant of the receipt of an application for registration and will later 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 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. Two (2) sets of fingerprint cards as required by 4 CSR 220-2.450.

(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 executive director of the board in the case of a changed residential 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 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. Any registered technician subject to restrictions or conditions who violates any portion thereof 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 pending litigation that pertains to the disqualification of any person from employment as a pharmacy technician.

*AUTHORITY: sections 338.013 and 338.140, RSMo 2000.\* Original rule filed Aug. 21, 1998, effective Feb. 28, 1999. Amended: Filed Nov. 13, 2002, effective June 30, 2003.*

*\*Original authority: 338.013, RSMo 1997 and 338.140, RSMo 1939, amended 1981, 1989, 1997.*

#### 4 CSR 220-2.800 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 to 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.\* Original rule filed Aug. 21, 1998, effective Feb. 28, 1999.*

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

#### 4 CSR 220-2.900 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) 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 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.

(C) 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.

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

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

(F) 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.

(G) 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.

(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 or first dose procedures, inspection of systems by pharmacy personnel, installation requirements, maintenance, medication security, quality assurance, inventory control, staff education and training and system set-up and malfunction.

(B) Documentation by the automated system for on-site patient administration 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 safeguards.

(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.

*AUTHORITY: sections 338.210 and 338.280, RSMo 2000.\* Original rule filed Nov. 1, 2000, effective June 30, 2001.*

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