RECENT CHANGES TO REGULATIONS

The following regulations have recently been added or amended. Only the portions of the rules that were revised, added (shown in bold), or deleted (shown in brackets [ ]) are provided here. The entire rule is available from our website, www.pr.mo.gov/pharmacists.asp, click Rules & Statutes, then click Rules and Regulations, Division 2220.

20 CSR 2220-2.010 Pharmacy Standards of Operation – Effective 8/30/08 – Amends subsections (1)(A) and (1)(B), adds paragraph (1)(F)3., amends subsection (1)(G) and paragraph (1)(I)2., adds a new subsection (J), renumbers the remaining subsections, amends sections (3) and (5), adds a new section (7), renumbers the sections thereafter, and amends new paragraphs (10)(B)2., (10)(C)2., and (10)(D)4.
PURPOSE: Pursuant to Executive Order 06-04, the Division of Professional Registration was transferred from the Department of Economic Development (Title 4), to the Department of Insurance, Financial Institutions and Professional Registration (Title 20); therefore, references to 4 CSR 220 are being amended throughout the rule. This amendment also clarifies the conditions necessary for the operation of a pharmacy as well as corrects grammatical errors.

(1) The word medicine or medicines is a word similar or of like import to the words pharmacist, pharmacy, apothecary shop, chemist shop, drug store, druggist and drugs, and no person shall carry on, conduct or transact a business under a name which contains, as part of the name, the word medicine or medicines, unless the place of business is supervised by a licensed pharmacist.
(A) At all times when prescriptions are compounded in a pharmacy or other establishments holding a Missouri pharmacy permit, there shall be on duty and present in that place of business a pharmacist licensed in Missouri as provided by law. In any Class J: Shared Service pharmacy where a permit is maintained at a location for the purpose of remote dispensing as defined in *[4 CSR 220-2.900]* **20 CSR 2220-2.900** the pharmacist may be considered on duty and present as long as all required electronic connection requirements are maintained and the pharmacist is accessible at all times to respond to patient's or other health professionals' inquiries or requests pertaining to drugs dispensed through the use of the automated pharmacy system. When there is no pharmacist on duty, no prescription will be compounded, dispensed or otherwise provided and the public will be advised that no pharmacist is on duty by means of signs stating this fact. The signs will be displayed prominently on the doors of all entrances and the prescription counter of the pharmacy and the signs will be composed of letters of a minimum height of two inches (2").

(B) Whenever, in a pharmacy or other establishment holding a Missouri pharmacy permit, a person other than a licensed pharmacist does compound, dispense or in any way provide any drug, medicine or poison pursuant to a lawful prescription, a licensed pharmacist must be physically present within the confines of the dispensing area, able to render immediate assistance and able to determine and correct any errors in the compounding, preparation or labeling of that drug, medicine or poison before the drug, medicine or poison is dispensed or sold. In any Class J: Shared Service pharmacy where a permit is maintained at a location for the purpose of remote dispensing as defined in *[4 CSR 220-2.900]* **20 CSR 2220-2.900** the pharmacist may be considered on duty and present as long as all required electronic connection requirements are maintained and the pharmacist is accessible at all times to respond to patient's or other health professionals' inquiries or requests pertaining to drugs dispensed through the use of the automated pharmacy system. The pharmacist personally shall inspect and verify the accuracy of the contents of, and the label after it is affixed to, any prescribed drug, medicine or poison compounded or dispensed by a person other than a licensed pharmacist.

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

(G) **The temperature of the facility where drugs are stored must be maintained thermostatically within temperature requirements as provided for by the manufacturer or the latest edition of the USP.** Adequate refrigeration must be available to insure enough storage space for drugs requiring refrigeration or freezing and under temperatures adequate to maintain the drug products as recommended by the manufacturer, the latest edition of the USP, or both. Drugs and drug-related devices must be stored separately from food and other items.

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

(J) Pharmacies that maintain storage sites or warehouse facilities for the storage of confidential pharmacy records at a separate address or premises from the main pharmacy that holds a pharmacy permit shall register those sites as storage facilities of the licensed pharmacy. Information required for proper registration of a storage facility shall include the address of the facility, hours of operation (if applicable), pharmacy permit numbers of the pharmacies that it services, and a statement that the facility is used for the sole purpose of storing records within its own pharmacy operations.
1. All storage and warehouse locations must maintain adequate security including an alarm system. Any breach in security must be documented and reported in writing via facsimile, e-mail communication, or letter to the board within fifteen (15) days of the breach of confidentiality.
2. All storage and warehouse locations will be considered facilities of a pharmacy pursuant to section 338.240, RSMo and shall be subject to inspection by the board as defined in section 338.150, RSMo.
3. No fee will be charged by the board for registering a facility as defined in subsection (1)(J) of this rule.
4. All storage and warehouse locations must comply with 19 CSR 30-1.
5. No records less than two (2) years old may be stored offsite.
6. All storage and warehouse locations storing confidential pharmacy records must make records retrievable within two (2) business days when requested by the board or its representatives.

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

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

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

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

is sent in.

*[(N)]***(O)** When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

(P) When required by section 338.013(10), RSMo, to report technician disciplinary action, the pharmacy must notify the board in writing within fifteen (15) days of the action. The notification must include:
1. The name and permit number of pharmacy;
2. Name of person making the notification;
3. Name of technician;
4. Technician registration number;
5. Date of action; and
6. Reason for action.

[(O)](**Q)** Pharmacists must inform the executive director of the board of any change in their employment address. The notification of an employment change must be provided in writing to the board no later than fifteen (15) days following any effective change.

(3) A pharmacy using a record keeping system other than an electronic system meeting the requirements of *[4 CSR 220-2.080]* **20 CSR 2220-2.080** to record its dispensing of drugs, medicines and poisons shall provide a method of recording all of the following information concerning the refill of any prescription medication on the back or reverse side of every prescription order:

(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]* **legend** drugs. Said records shall be maintained for two (2) years **and be readily retrievable upon request by the board or its representatives.**

(7) All records required by chapters 195 and 338, RSMo or divisions 20 CSR 2220 and 19 CSR 30 shall be available for photocopying or electronic duplication by a board of pharmacy representative.
[(7)]**(8)** 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)]***(9)** A home health or hospice agency licensed or certified according to Chapter 197, RSMo, or any licensed nurses of such agency, may possess drugs in the usual course of business of such agency without being licensed as a pharmacist or a pharmacy.

[(9)](**10)** Class I: Consultant Pharmacies as defined in 20 CSR 2220-2.020(9)(I) and *[are]* approved by the board to be located within a residence shall be required to address and comply with the following minimum standards of practice:
(B) Documentation—
2. Maintain documentation that *[the pharmacist-in-charge or]* the permit holder has provided training to all personnel on all operations associated with the pharmacy;

(C) Security—Records and Internet—
2. Data processing systems must utilize sufficient security software; *[and]*

(D) Licensure and Inspection—
4. The audits required in paragraph *[(9)(B)3.]* **(10)(B)3**. shall be available for review during the inspection; and

20 CSR 2220-2.030 Educational and Licensing Requirements – Effective 8/30/08 – Amends section (2), paragraph (3)(B)1. and 2., subsection (3)(H), and subsection (7)(A), and deletes subsection (7)(B).
PURPOSE: This amendment clarifies the requirements for training as a pharmacy intern and makes a grammatical correction.

(2) Application shall be made on forms provided by the *[executive director]* **State Board of Pharmacy**. 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 all practical experience programs that are required and are approved by the board. An application will be considered filed 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:

(3) Requirements for Practical Experience.
(B) 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]* **State** Board of Pharmacy and must be accompanied by the appropriate licensure fee. **An application for an intern pharmacist license 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.**
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]* **State** 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.

(H) The provisions of this rule are not applicable to those students who gain their advanced practice experience in another state. The minimum practical experience shall be fifteen hundred (1,500) hours of advanced practice experience to qualify to take the examination for licensure as a pharmacist. If any portion of the required fifteen hundred (1,500) hours are to be earned in Missouri, the applicant must be licensed as an intern under the provisions of this rule. When intern hours are to be earned within the state of Missouri by a student enrolled in or by a graduate of an out-of-state accredited school of pharmacy, the candidate must apply directly to the board of pharmacy to seek approval of any site and preceptor to be used. Any pharmacy that is submitted for approval as an intern training site for an out-of-state student or graduate shall meet the criteria outlined in *[(4)(B)1.–3.]* **(4)(A)1.–3.**

(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.]

20 CSR 2220-2.036 Temporary License – Effective 8/30/08 – Amends sections (3), (7), (8), (11), adds new section (12), and renumbers the remaining section.
PURPOSE: Pursuant to Executive Order 06-04, the Division of Professional Registration was transferred from the Department of Economic Development (Title 4), to the Department of Insurance, Financial Institutions and Professional Registration (Title 20); therefore, references to 4 CSR 220 are being amended throughout the rule. This amendment also clarifies acceptable proof of licensure that can be used until a hard copy of the license is received by the applicant.

(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)]* **20 CSR 2220-2.030(1)**, then all the requirements as outlined in *[4 CSR 220-2.032]* **20 CSR 2220-2.032** must be completed.

(7) The temporary licensing program is not intended to replace or conflict with any requirements or provisions of *[4 CSR 220-2.030]* **20 CSR 2220-2.030** 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]* **20 CSR 2220-2.030** must be completed.

(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.]* **A copy of proof of licensure from the Division of Professional Registration, Board of Pharmacy website may be used as proof of licensure by an applicant until delivery of a hard copy license is completed to the applicant.**
(12) 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)]***(13)** All fees are nonrefundable.

20 CSR 2220-2.120 Transfer of Prescription Information for the Purpose of Refill – Effective 8/30/08 – Amends section (1), adds subsection (1)(E), amends paragraph (2)(B)10, and adds section (3).
PURPOSE: Pursuant to Executive Order 06-04, the Division of Professional Registration was transferred from the Department of Economic Development (Title 4), to the Department of Insurance, Financial Institutions and Professional Registration (Title 20); therefore, references to 4 CSR 220 are being amended throughout the rule. This amendment also makes grammatical corrections, clarifies the criteria for prescription transfers, and gives the time frame for which it should be completed within.

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

(E) The transfer of original prescription information for a controlled substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one (1)-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(2) When a prescription on record is transferred, the following record keeping is required:
(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:
10. Any electronic transfer must maintain patient confidentiality in accordance with *[4 CSR 220-2.300]* **20 CSR 2220-2.300**; and

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

20 CSR 2220-2.200 Sterile Pharmaceuticals – Effective 8/30/08 – Deletes sections (1) through (10), renumbers the sections thereafter, amends new subsection (1)(I), new section (2), new subsection (2)(A), new sections 9(C)4. and 5., new section (16), and adds subsections (16)(A) and (16)(B).
PURPOSE: Pursuant to Executive Order 06-04, the Division of Professional Registration was transferred from the Department of Economic Development (Title 4), to the Department of Insurance, Financial Institutions and Professional Registration (Title 20); therefore, references to 4 CSR 220 are being amended throughout the rule. This amendment also deletes obsolete information, clarifies requirements for sterile product reference materials, and provides an exemption for pharmacies that are registered with the Food and Drug Administration (FDA).

[(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)]***(1)** Definitions.
(I) Compounding: For the purposes of this regulation, compounding is defined as in *[4 CSR 220-2.400(1)]* **20 CSR 2220-2.400(1)**. Compounded sterile medications may include, but are not limited to, injectables, parenteral nutrition solutions, irrigation solutions, inhalation solutions, intravenous solutions and ophthalmic preparations.

[(12)]**(2)** Policy and Procedure Manual/**Reference Manuals**.
(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. **The pharmacy shall have current reference materials related to sterile products.**

*[(13)]***(3)** Personnel Education, Training and Evaluation.

*[(14)]***(4)** Storage and Handling in the Pharmacy.

*[(15)]***(5)** Facilities and Equipment.

*[(16)]***(6)** Apparel.

*[(17)]***(7)** Aseptic Technique and Product Preparation.

[(18)](**8)** Process Validation.

*[(19)]***(9)** Record Keeping.
(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, record requirements for Risk Level 3 products must include:
4. End-product evaluation and testing records as required in section *[(22)]***(12**); and
5. Ingredient validation records as required in section *[(22)]***(12)**.

*[(20)]***(10)** Labeling.

*[(21)]***(11)** Beyond-Use Dating.

*[(22)]***(12)** End-Product Evaluation.

*[(23)]***(13)** Handling Sterile Products Outside the Pharmacy.

*[(24)]***(14)** Cytotoxic Drugs.

*[(25)]***(15)** 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)]***(16)** In addition to the requirements outlined in this rule, all standards and requirements as outlined in *[4 CSR 220-2.400]* **20 CSR 2220-2.400** must be maintained. **Pharmacies that are registered with the Food and Drug Administration (FDA) are exempt from the distribution restrictions in 20 CSR 2220-2.400(12) for compounded sterile pharmaceuticals distributed with FDA's knowledge and enforcement discretion. This exemption applies only to a twenty-four (24)-hour course of therapy which is needed:**
(A) To treat an emergency situation; or
(B) For an unanticipated procedure for which a time delay would negatively affect a patient outcome. In order to continue beyond twenty-four (24) hours, the pharmacy must obtain a prescription and comply with all record and labeling requirements as defined by law or regulation.

20 CSR 2220-2.450 Fingerprint Requirements – Effective 8/30/08 – Amends the original purpose statement and subsections (1)(F) and (1)(G), adds subsection (1)(H), adds a new section (4), and renumbers the remaining section.
PURPOSE: This amendment deletes obsolete information in the original purpose statement, establishes fingerprinting requirements for intern pharmacists, and states circumstances for which an applicant can be re-fingerprinted.
PURPOSE: **This amendment establishes fingerprinting requirements for intern pharmacists.**

(1) Applicants for licensure or registration that must provide fingerprints to the Board of Pharmacy shall include:
(F) Pharmacy technician; *[and]*
(G) Owners with a ten percent (10%) or more interest in a drug distributor entity (applying to non-publicly held companies only)*[.]*; **and**
(H) Intern pharmacist.

(4) The board may require an applicant to be fingerprinted again and pay any required fingerprinting fees, if the application process is not completed within six (6) months of the board's receipt of the application.

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

20 CSR 2220-3.040 Return and Reuse of Drugs and Devices – Effective 8/30/08 – Adds section (3).

PURPOSE: This amendment clarifies labeling and storage requirements for prescriptions that are not claimed.

(3) Pharmacists and pharmacies may return to stock prescriptions that have not been received by the patient and shall delete the dispensing from the pharmacy's records and reverse the claim with the third party payor, if applicable. In order for a product to be returned to stock, it must have been stored at all times at the manufacturer's labeled storage requirements. The drug must be maintained in the patient container with the dispensing date, prescription number, and name of drug visible. The expiration date of the drug shall become the lesser of one (1) year from the dispensing date on the label or the manufacturer's original expiration date, if known.

20 CSR 2220-4.010 General Fees – Effective 8/30/08 – Amends section (1).
PURPOSE: Pursuant to section 338.070.1, RSMo, the board shall not set the amount of the fees which this chapter authorizes and requires by rules and regulations promulgated pursuant to chapter 536, RSMo. The fees shall be set at a level to produce revenue which shall not substantially exceed the cost and expense of administering this chapter.

(1) The following fees are established by the State Board of Pharmacy:

(A) Licensure by Examination Fee	*[$105.00]* **$150**
(B) Licensure by Transfer of License (Reciprocity)	*[$350.00]* **$375**
(C) Original Pharmacy Permit Fee	*[$250.00]* **$300**
(D) Pharmacist License Renewal Fee	*[$160.00]* **$225**
(E) Pharmacy Permit Renewal Fee	*[$400.00]* **$450**
(F) Delinquent Pharmacist Renewal Fee (in addition to the Pharmacist License Renewal Fee)	*[$ 50.00]* **$250**
(G) Duplicate License/Permit/Registration Fee	*[$ 10.00]* **$20**
(H) Change of Pharmacy or Drug Distributor Name Fee	$ 25*[.00]*
(I) Fee for Retake of Multistate Pharmacy Jurisprudence Examination (MPJE)	*[$100.00]* **$150**
(J) Foreign Graduate Preliminary Filing Fee (Candidates for licensure by examination, who are graduates of schools/colleges of pharmacy not accredited by the board)	*[$ 50.00]* **$250**
(K) Change of Pharmacy or Drug Distributor Location Fee	*[$125.00]* **$175**
(L) Original Pharmacy Distributor/Wholesale Drug Distributor License Fee (includes both temporary and permanent license)	*[$250.00]* **$300**
(M) Pharmacy Distributor/Wholesale Drug Distributor License Renewal Fee	*[$400.00]* **$450**
(N) Original Drug Distributor (Manufacturer) Registration Filing Fee	$ 10*[.00]*
(O) Renewal of Drug Distributor (Manufacturer)	

Registration Filing Fee	$ 10*[.00]*
(P) Original Intern Pharmacist License	*[$ 40.00]* **$50**
(Q) Intern Pharmacist License Renewal	*[$ 25.00]* **$80**
(R) Temporary Pharmacist License Fee (original issue/renewal)	*[$ 50.00]* **$100**
(S) Fingerprint Fee for Criminal Background Check —Determined by Federal Bureau of Investigation (FBI) and Missouri State Highway Patrol (MSHP) (pass through fee)	
(T) Pharmacy Technician Initial Registration Fee	*[$ 10.00]* **$35**
(U) Pharmacy Technician Annual Renewal Fee	*[$ 10.00]* **$35**
(V) Delinquent Continuing Education Pharmacist Fee	*[$500.00]* **$1,000**
(W) Score Transfer Fee	**$150**
(X) Pharmacy Classification Change Fee	**$50**
(Y) Manager-in-Charge Change Fee	**$50**
(Z) Pharmacist-in-Charge Change Fee	**$50**
(AA) Verification Fee	**$25**
(BB) Returned Check Fee	**$25**
(CC) Certification of Medication Therapeutic Plan Authority	**$50**

20 CSR 2220-5.030 Definitions and Standards for Drug Wholesale and Pharmacy Distributors – Effective 8/30/08 – Amends subsection (3)(B), paragraph (3)(C)10., and subsection (3)(K).
PURPOSE: This amendment requires thermostatically controlled temperatures within drug distributor facilities; prohibits animals, except for service animals, in drug storage areas; and requires records to be made available to a board of pharmacy representative upon request.

(3) Minimum standards of practice for drug distributors shall include the following:

(B) The temperature of the facility where drugs are stored must be maintained **thermostatically** within temperature requirements as provided for by the manufacturer or the latest edition of the United States Pharmacopeia (USP). Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, logs, or all of these, shall be utilized to document proper storage of prescription drugs;

(C) Appropriate housekeeping, sanitation, lighting, ventilation and humidity of all areas where drugs are stored must be maintained.
10. Procedures must be in place to prevent, control and alleviate infestation by insects, rodents, birds or vermin of any kind. **Animals, except for service animals as defined by the Americans with Disabilities Act (ADA), are not allowed in the drug storage areas.**

(K) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by *[an authorized official of a federal, state or*

local law enforcement agency] **the board or its representatives**;

20 CSR 2220-5.070 Standards of Operation for Medical Gas Distributors – Effective 8/30/08 – Amends subsection (3).
PURPOSE: Pursuant to Executive Order 06-04, the Division of Professional Registration was transferred from the Department of Economic Development (Title 4), to the Department of Insurance, Financial Institutions and Professional Registration (Title 20); therefore, references to 4 CSR 220 are being amended throughout the rule. This amendment also deletes obsolete information.

(3) Medical gas distributors that are not involved in the storage or transfer of any other federal legend drugs and only store, transfer or transfill medical grade gas products other than nitrous oxide are exempt from the following regulation sections: *[4 CSR 220-5.030(3)(B)]* **20 CSR 2220-5.030(3)(B**); (3)(C)4., 9., *[11.,]* 12., 13.; (3)(E); *[(3)(H)]* and (3)(M)4. Medical gas distributors that store, transfer or transfill nitrous oxide are exempt from *[4 CSR 220-5.030(3)(B)*] **20 CSR 2220-5.030(3)(B)**; (3)(C)4., 9.*[, 11.]*; (3)(E) and (3)(M)4. All other drug distributor requirements contained within the board's regulations shall be considered applicable to medical gas distributors.

20 CSR 2220-6.040 Administration by Medical Prescription Order – Emergency Rule effective 5/11/08 and expires 2/18/09 – Original Rule Effective 11/30/08 – New regulation.
PURPOSE: This rule is proposed to establish procedures for pharmacists to administer drugs and devices pursuant to medical prescription orders.
20 CSR 2220-6.040 Administration by Medical Prescription Order

(1) A pharmacist may administer drugs pursuant to a medical prescription order.
(2) The pharmacist may not delegate the administration to another person, except to a pharmacist intern who has met qualifications under subsections (3)(B), (C), and (E) and is working under the direct supervision of a pharmacist qualified to administer drugs pursuant to a medical prescription order.
(3) Pharmacist Qualifications. A pharmacist who is administering drugs pursuant to a medical prescription order must—
(A) Hold a current, unrestricted license to practice pharmacy in this state;
(B) Hold a current provider level cardiopulmonary resuscitation (CPR) certification issued by the American Heart Association or the American Red Cross or equivalent;
(C) Successfully complete a certificate program in the administration of drugs accredited by the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the state board of pharmacy. The certificate program must cover all routes of administration the pharmacist utilizes;
(D) Complete a minimum of two (2) hours of continuing education per calendar year related to administration of drugs. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal;
(E) Maintain documentation of the above requirements; and
(F) On a yearly basis prior to administering drugs, notify the State board of pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered, and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), and (D) of this section.
(4) General requirements.
(A) A pharmacist shall administer drugs in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC) or in accordance with manufacturer's guidelines.
(B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed

consent requirements.
(C) A pharmacist shall have a written policy and procedure covering all aspects of the administration of drugs, including the disposal of used and contaminated supplies and appropriate handling of acute adverse events. The manual shall be reviewed annually and be available for inspection by the State board of pharmacy or authorized representative.
(5) Requirements of medical prescription order. The medical prescription order from a licensed prescriber must contain at a minimum the following:
(A) The name of the licensed prescriber issuing the order;
(B) The name of the patient to receive the drug;
(C) The name of the drug and dose to be administered;
(D) The route of administration;
(E) The date of the original order;
(F) The date or schedule, if any, of each subsequent administration; and
(G) A statement that the drug is to be administered by a pharmacist.
(6) Record keeping.
(A) A pharmacist who administers a drug pursuant to a medical prescription order shall maintain the following records regarding each administration. These records must be separate from the prescription files of a pharmacy.
1. The name, address, and date of birth of the patient;
2. The date, route, and anatomic site of the administration;
3. The name, dose, manufacturer, lot number, and expiration date of the drug;
4. The name and address of the patient's primary health care provider, as identified by the patient;
5. The name or identifiable initials of the administering pharmacist; and
6. The nature of an adverse reaction and who was notified, if applicable.
(B) All records required by this regulation shall be kept by the pharmacist and be available for two (2) years from the date of such record for inspecting and copying by the State board of pharmacy and/or its authorized representatives.
(7) Notification requirements.
(A) A pharmacist administering drugs pursuant to a medical prescription order shall notify the prescriber within seventy-two (72) hours after administration of the following:
1. The identity of the patient;
2. The identity of the drug administered;
3. The route of administration;
4. The anatomic site of the administration;
5. The dose administered; and
6. The date of administration.
(B) In the event of any adverse event or reaction experienced by the patient, the pharmacist shall notify the prescriber within twenty-four (24) hours after learning of the adverse event or reaction.
(C) A pharmacist administering drugs pursuant to a medical prescription order shall report the administration to all entities as required by state or federal law.

20 CSR 2220-6.050 – Administration of Influenza Vaccines Per Protocol - Emergency Rule effective 11/3/07 and expires 4/30/08 – Original Rule Effective 5/30/08 – New regulation.

PURPOSE: This rule is proposed to establish the procedures for pharmacists to administer viral influenza vaccinations per written protocol with a physician.

(1) A pharmacist may administer viral influenza vaccinations:
(A) To persons twelve (12) years of age or older; and
(B) Pursuant to a written protocol authorized by a physician licensed pursuant to Chapter 334, RSMo, who is actively engaged in the practice of medicine in the state of Missouri.

(2) A pharmacist may not delegate the administration of viral influenza vaccinations to another person, except to a pharmacist intern who has met qualifications under subsections (4)(B), (C), and (D) and is working under the direct supervision of a pharmacist qualified to administer viral influenza vaccinations.

(3) The authorizing physician is responsible for the oversight of, and accepts responsibility for, the viral influenza vaccinations administered by the pharmacist.

(4) Pharmacist Qualifications—A pharmacist who is administering viral influenza vaccinations must:
(A) Hold a current, unrestricted license to practice pharmacy in this state;
(B) Hold a current provider level cardiopulmonary resuscitation (CPR) certification issued by the American Heart Association or the American Red Cross or equivalent;
(C) Successfully complete a certificate program in the administration of viral influenza vaccinations accredited by the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the State Board of Pharmacy;
(D) Maintain documentation of the above certifications;
(E) Complete a minimum of two (2) hours (0.2 CEU) of continuing education per year related to administration of viral influenza vaccinations. A pharmacist may use the continuing education hours required in this subsection as part of the total continuing education hours required for pharmacist license renewal;
(F) Provide documentation of subsections (A), (B), (C), and (E) of this section to the authorizing physician(s) prior to entering into a protocol or administering viral influenza vaccinations; and
(G) On a yearly basis prior to administering viral influenza vaccinations, establish a new protocol with the authorizing physician and notify the State Board of Pharmacy of their qualifications to do so. This notification shall include the types of drugs being administered and a statement that the pharmacist meets the requirements of subsections (A), (B), (C), (E), and (F) of this section.

(5) General Requirements.
(A) A pharmacist shall administer viral influenza vaccinations in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC) or in accordance with manufacturer's guidelines.
(B) A pharmacist shall comply with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.

(6) Administration by Written Protocol with a Missouri Licensed Physician.
(A) A pharmacist may enter into a written protocol with a physician for the administration of viral influenza vaccinations to patients twelve (12) years of age or older. The physician must be no further than fifty (50) miles by road, using the most direct route available, from the pharmacist who is administering the viral influenza vaccinations. The written protocol may be valid for a time period not to exceed one (1) year. The protocol must include the following:
1. The identity of the participating pharmacist and physician, including signatures;

2. Time period of the protocol;
3. The identification of the viral influenza vaccination which may be administered;
4. The identity of the patient or groups of patients to receive the authorized viral influenza vaccination;
5. The identity of the authorized routes and anatomic sites of administration allowed;
6. A provision to create a prescription for each administration under the authorizing physician's name;
7. A provision establishing a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;
8. A provision establishing a length of time the pharmacist shall observe an individual for adverse events following an injection;
9. A provision establishing the disposal of used and contaminated supplies;
10. The street address of the pharmacy at which the pharmacist may administer the authorized viral influenza vaccination;
11. Record keeping requirements and procedures for notification of administration; and
12. A provision that allows for termination of the protocol at the request of any party to it at any time.

(B) The protocol shall be signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying that both are aware of its content and agree to follow the terms of the protocol. The authorizing physician and pharmacist shall each maintain a copy of the protocol from the beginning of implementation to a minimum of eight (8) years after termination of the protocol.

(7) Record Keeping.

(A) A pharmacist who administers a viral influenza vaccination shall maintain the following records regarding each administration. These records must be separate from the prescription files of a pharmacy and include:
1. The name, address, and date of birth of the patient;
2. The date, route, and anatomic site of the administration;
3. The name, dose, manufacturer, lot number, and expiration date of the vaccination;
4. The name and address of the patient's primary health care provider, as identified by the patient;
5. The name or identifiable initials of the administering pharmacist; and
6. The nature of an adverse reaction and who was notified, if applicable.

(B) All administrations of viral influenza vaccinations must have a prescription as authorized by protocol on file within seventy-two (72) hours after administration at a pharmacy documenting the dispensing of the drug.

(C) All records required by this regulation shall be kept by the pharmacist and be available for two (2) years from the date of such record, for inspecting and copying by the authorizing physician, the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or their authorized representatives.

(8) Notification Requirement.

(A) A pharmacist administering viral influenza vaccinations shall notify the authorizing physician within seventy-two (72) hours after administration of the following:
1. The identity of the patient;
2. The identity of the viral influenza vaccination administered;
3. The route of administration;
4. The anatomic site of the administration;
5. The dose administered; and
6. The date of administration.

(B) The pharmacist shall provide a written report to the patient's primary health care provider, if different than the authorizing physician, containing the documentation required in subsection (A) of this section within fourteen (14) days of the administration.

(C) In the event of any adverse event or reaction experienced by the patient pursuant to a written protocol, the pharmacist shall notify the patient's primary health care provider and authorizing physician, if different, within twenty-four (24) hours after learning of the adverse event or reaction.

(D) A pharmacist administering viral influenza vaccinations shall report the administration to all entities as required by state or federal law.

20 CSR 2220-2.010 Pharmacy Standards of Operation – Effective 4/30/07 – Adds section (9).

Purpose: This amendment sets forth minimum standards of practice for Class I: Consultant Pharmacies located within a residence.

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

(A) Location Requirements—

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

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

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

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

5. Patients are not allowed in the pharmacy.

(B) Documentation—

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

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

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

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

(C) Security-Records and Internet—

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

2. Data processing systems must utilize sufficient security software; and

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

(D) Licensure and Inspection—

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

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

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

4. The audits required in paragraph (9)(B)3. shall be available for review during the inspection; and
5. The pharmacy shall provide copies of inspections completed by the state in which they are located if such inspections are required within seven (7) business days of the inspection date.

20 CSR 2220-2.020 Pharmacy Permits – Effective 4/30/07 - Amends subsections (9)(D),(9)(H), (9)(I), (9)(J), and adds subsection (9)(K).
PURPOSE: This amendment clarifies the definition and criteria for the Class D Pharmacy classification and provides a definition for Class K: Internet Pharmacies.

(9) The following classes of pharmacy permits or licenses are hereby established:
(D) Class D: Non-Sterile Compounding. A pharmacy that provides services as defined in section 338.010, RSMo and provides a non-sterile compounded product as defined in *[4 CSR 220-2.400]* **20 CSR 2220-2.400**(1) *[which comprises five percent (5%) or more of the annual prescription volume of the pharmacy;]* **and meets the following criteria:**
1. Any product made from any bulk active ingredient in a batch quantity as defined 20 CSR 2220-2.400(3).

(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]* **20 CSR 2220-2.200**(11)(I) and (AA). Pharmacies providing sterile pharmaceuticals within the exemptions outlined in *[4 CSR 220-2.200]* **20 CSR 2220-2.200**(25) shall not be considered a Class H pharmacy;

(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; *[and]*

(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*[.]***; and**

(K) Class K: Internet. A pharmacy that provides services as defined in section 338.010, RSMo, and is involved in the receipt, review, preparation, compounding, dispensing or offering for sale any drugs, chemicals, medicines or poisons for any new prescriptions originating from the Internet for greater than ninety percent (90%) of the total new prescription volume on any day. A prescription must be provided by a practitioner licensed in the United States authorized by law to prescribe drugs and who has performed a sufficient physical examination and clinical assessment of the patient.

20 CSR 2220-2.190 Patient Counseling – Effective 4/30/07 - Amends section (1).
PURPOSE: This amendment establishes patient counseling requirements when an automated dispensing machine is used to provide medication to patients.

(1) Upon receipt of a prescription drug order and following a review of the available patient information, a pharmacist or his/her designee shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of each patient. Counseling shall be conducted by the pharmacist or a pharmacy extern under the pharmacist's immediate supervision to allow the patient to safely and appropriately utilize the medication so that maximum therapeutic outcomes can be obtained. If the patient or caregiver is not available, then a written offer to counsel with a telephone number of the dispensing pharmacy at no cost to the patient must be supplied with the medication so that the patient or caregiver may

contact the pharmacist for counseling when necessary. **In situations where automated pick-up systems are used for providing refill prescriptions to patients, the offer to counsel may be provided within the information provided by the kiosk to the patient during the processing phase prior to release of the medication to the patient.** The elements of counseling shall include matters which the pharmacist deems significant in the exercise of his/her professional judgment and is consistent with applicable state laws.

20 CSR 2220-2.450 Fingerprint Requirements – Effective 4/30/07 – Adds subsection (1)(G), deletes section (2), renumbers remaining sections, and amends the newly renumbered section (4).
PURPOSE: This amendment requires owners of drug distributors to provide criminal history background information to the board.

(1) Applicants for licensure or registration that must provide fingerprints to the Board of Pharmacy shall include:
(E) Drug distributor license manager-in-charge (unless currently licensed as a pharmacist in the state of Missouri); *[and]*
(F) Pharmacy technician*[.]***; and**
(G) Owners with a ten percent (10%) or more interest in a drug distributor entity (applying to non-publicly held companies only).

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

[(3)] **(2)** 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)] **(3)** 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)] **(4)** 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.

20 CSR 2220-2.900 Automated Dispensing and Storage System – Effective 4/30/07 – Amends sections (1)(E), (1)(J), (1)(K), (1)(L), and (2).
PURPOSE: This amendment provides guidelines for automated refill patient self-service devices.

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

(E) Automated systems shall maintain adequate security systems and procedures to prevent unauthorized access or use and shall at all times maintain compliance with all state and federal drug laws including all controlled substance requirements and patient confidentiality laws.
1. Any remote automated system that stocks controlled substances must maintain a perpetual inventory from each site.
2. Automated systems in ambulatory care settings must be located in an area that will provide adequate space for private consultations to occur and must only be installed within the same area utilized by the prescriber for the provision of clinical services.
3. Automated refill patient self-service devices must be physically attached to the pharmacy so that access to areas used to restock the device are only accessible through the pharmacy physical plant by pharmacy personnel.

(J) Drugs that are repackaged for use in automated systems **at remote locations** must comply with *[4 CSR 220-2.130]* **20 CSR 2220-2.130** Drug Repackaging requirements. **Automated refill patient self-service devices must comply with all labeling and dispensing laws governing the provision of medication refills to patients. Products that are considered temperature sensitive or products that require further manipulation in order to be ready for use by a patient shall not be provided through patient self-service devices, unless the device has the capability to provide storage conditions in compliance with Food and Drug Administration (FDA) requirements.**

(K) If an automated system uses removable cartridges or containers to hold drugs, the prepackaging of the cartridges or containers must occur at the pharmacy where the original inventory is maintained unless provided by a *[Federal Drug Administration (FDA)]* **FDA** approved repackager and who is licensed as a drug distributor. The prepackaged cartridges or containers may be sent to the automated system **at remote locations** to be loaded into the machine by registered technicians under the supervision of a pharmacist or by a pharmacist provided that—
1. A pharmacist has verified the container has been properly filled and labeled;
2. The individual containers are transported to the automated system in a secure, tamper-evident container; and
3. The automated system utilizes technologies to ensure that the containers are accurately loaded in the automated system.

(L) Any pharmacy that maintains an automated system for remote dispensing to ambulatory patients must maintain a video camera and audio system to provide for effective communication between pharmacy personnel and consumers. It must be a system that will allow for the appropriate exchange of oral as well as written communications to facilitate patient counseling as provided in *[4 CSR 220-2.190]* **20 CSR 2220-2.190** and other matters involved in the correct transaction or provision of drugs.
1. Video monitors used for the proper identification and communication with persons receiving prescription drugs shall be a minimum of twelve inches (12") wide and provided at both the pharmacy and remote location for direct visual contact between pharmacist and patient.
2. Both the video monitor and the audio system must be in good working order or operations utilizing the automated system shall cease until appropriate corrections or repairs are made to the system(s).
3. Backlighting or other factors that may inhibit video or audio performance must be taken into account when using such systems to identify recipients of prescription drugs. Positive identification of recipients must be made before any drug is delivered.

(2) Each automated system shall maintain a manual of policies and procedures that, at a minimum, shall include the following:
(A) System operations that include specific and measurable accountability for safety, security, accuracy, patient confidentiality, access, data retention and retrieval, downtime procedures, emergency *[or]* first dose **or refill patient self-service** procedures, inspection of systems by pharmacy personnel, installation requirements, maintenance, medication security, quality assurance, inventory levels and control, staff education and training and system set-up and malfunction.
(B) Documentation by the automated system **at remote locations** for on-site patient administration and remote dispensing of medications that includes specific identification of patients, medications used along with dates and times the system is utilized.

20 CSR 2220-5.020 Drug Distributor Licensing Requirements – Effective 4/30/07 - Amends subsection (4)(F) and add section (9).
PURPOSE: This amendment requires drug distributor managers-in-charge to provide the board with employment history and requires out-of-state drug distributors to designate a registered agent in Missouri for service of process purposes.

(4) Drug distributor license applications and renewal applications shall be completed and submitted to the Board of Pharmacy along with the appropriate fees before any license is issued or renewed. Information required on the application shall include:
(F) The name of the manager in charge who meets the requirements as set forth in *[4 CSR 220-5.030(2) and completes the]* **20 CSR 2220-5.030(2); a complete notarized** manager-in-charge affidavit of the license application *[and has it notarized]*; and **a history of employment/occupations and offices held during the past seven (7) years; and**

(9) Each licensed corporate wholesale distributor located outside of this state that distributes drugs in this state shall designate a registered agent in this state for service of process. Any licensed corporate wholesale distributor that does not designate a registered agent shall be deemed to have designated the secretary of state of this state to be its true and lawful attorney, upon who may be served all legal process in any action or proceeding against any licensed corporate wholesale distributor growing out of or arising from such distribution. Service of process shall be accomplished as authorized by law.

20 CSR 2220-5.030 Definitions and Standards for Drug Wholesale and Pharmacy Distributors – Effective 4/30/07 - Amends subsections (2)(A), (2)(E), (3)(M) and (3)(O).
PURPOSE: This amendment adds language which requires a drug distributor manager-in-charge to be present and involved in the daily operation of the facility; requires procedures for record keeping, investigating and reporting counterfeit or suspected counterfeit drugs/devices to the board and other federal/state agencies; and prohibits issuance of a drug distributor license to a location that is a residence.

(2) No drug distributor license will be issued unless the facility is under the direct supervision of a manager-in-charge.
(A) The board shall consider the same factors in reviewing the qualifications of someone who is appointed as a manager-in-charge as those outlined in *[4 CSR 220-5.020]* **20 CSR 2220-5.020**(8)(A)1.

(E) Drug distributor operations must be conducted at all times under the supervision of a properly designated manager-in-charge. **The manager-in-charge must be actively involved and aware of the actual daily operations of the drug distributor operation. The manager-in-charge must be physically present at the drug distributor operation during normal business hours, except for time periods when absent due to illness, scheduled vacation or other authorized absence; and be aware of, and knowledgeable about, all polices and procedures pertaining to the operations of the drug distributor operation.** When the person who is manager-in-charge resigns or is terminated from the position, the holder of the license shall immediately notify the board office of the resignation or termination of the manager-in-charge and by notarized affidavit give the name of the new manager-in-charge.

(3) Minimum standards of practice for drug distributors shall include the following:
(M) Wholesale drug and pharmacy distributors shall establish, maintain and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Drug distributors shall include in their written policies and procedures the following:
1. A procedure where the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate;

2. A procedure to be followed for handling recalls and withdrawals of prescription drugs. This procedure shall be adequate to deal with recalls and withdrawals due to any—
A. Action initiated at the request of the FDA or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy;
B. Voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or
C. Action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;
3. A procedure to ensure that drug distributors prepare for, protect against and handle any crisis that affects the security or operation of any facility in the event of strike, fire, flood or other natural disaster, or other situations of local, state or national emergency; *[*and*]*
4. A procedure for reporting counterfeit or suspected counterfeit drugs or devices or counterfeiting or suspected counterfeiting activities to the board;
5. A procedure for the mandatory reporting to the board and any other appropriate federal or state agency of all shortages of prescription drugs and devices where it is known or suspected that diversion or theft is occurring;
6. A procedure for investigating discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband in the inventory and reporting such discrepancies within seven (7) business days to the board and any other appropriate federal or state agency shall be maintained by each drug distributor;
7. A procedure for reporting criminal or suspected criminal activities involving the inventory of drug(s) and device(s) to the board within the seven (7) business days; and
*[4.]***8.** A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for three (3) years after disposition of the outdated drugs;

(O) No drug distributor license shall be issued to any location, regardless of zoning, **that is a residence or** that shares an address and/or physical space with a business not related to the distribution of prescription drugs or drug-related devices, or not licensed and regulated by the state of Missouri.

NOTE: AS A RESULT OF EXECUTIVE ORDER 06-04, THE DIVISION OF PROFESSIONAL REGULATION WAS TRANSFERRED FROM THE DEPARTMENT OF ECONOMIC DEVELOPMENT TO THE DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION. EFFECTIVE 8/26/06, THE BOARD OF PHARMACY'S REGULATIONS WERE RENUMBERED TO TITLE 20, DIVISION 2220, INSTEAD OF TITLE 4, DIVISION 220, OF THE CODE OF STATE REGULATIONS.

4 CSR 220-2.100 - Continuing Pharmacy Education - Effective 1/30/06 - Amends section (10), adds a new section (11), and renumbers and amends the remaining section.
PURPOSE: This amendment establishes specific time frame for pharmacists to earn continuing education (CE) for renewal of a license, establishes that an incomplete or incorrect renewal application will be rejected to the applicant, and provides that when a pharmacist fails to provide appropriate CE when requested for audit purposes, the renewal application is considered false and license is not renewed, and delinquent fees will be required.

(10) **Continuing education credits must be earned from the time a renewal cycle begins, until the cycle ends as prescribed by the board. For purposes of this section, the renewal cycle begins on September 1 and ends on a biennial cycle on August 31.** Each such form of proof of completion of the required continuing education credits shall be retained by the licensee for the preceding two (2) reporting periods prior to renewal.

(11) The renewal application must be completed correctly and in its entirety in order for it to be processed and the license renewed. Any portion of the application that is incomplete or inaccurate shall result in the rejection of the renewal application and require its return to the

applicant for correction.

(12) 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. Failure to provide proof of completion of the necessary required continuing education credits **when requested to do so by the board,** shall be considered a violation**. In accordance with section 338.060, RSMo any licensee that has not completed and retained the required evidence of all required continuing education shall pay any delinquent fees as prescribed by the board** and may *[result in]* **be subject to** disciplinary action pursuant to 338.055, RSMo*[,]***. The board may also** initiate auditing *[or]* **of** other past renewal periods and/or require proof of completion of future continuing education credits be submitted with any application for a renewal of a license.

4 CSR 220-4.010 General Fees - Effective 1/30/06 - Adds a new subsection (1)(V).
PURPOSE: This amendment adds a fee authorized by Chapter 338, RSMo.

(1) The following fees are established by the State Board of Pharmacy:
(V) Delinquent Continuing Education Pharmacist Fee $500.00

4 CSR 220-5.020 Drug Distributor Licensing Requirements - Effective 1/30/06 - Amends sections (3)–(5).
PURPOSE: This amendment allows for a drug distributor application to be voided if the process is not completed within six (6) months of receipt by the board, allows for issuance of temporary license after change of ownership application is received, removes thirty (30)-day grace period for filing of an application after a change of ownership occurs, adds limited liability company to be considered a separate person concerning ownership, and changes notification requirements.

(3) Drug distributor licenses shall be issued on the application of the owners. If the owner is a corporation *[or partnership]*, an officer of the corporation *[or partner]* must sign the application as the applicant. **If the owner is a partnership, a partner must sign the application as the applicant. If the owner is a limited liability partnership, a general partner must sign the application as the applicant. If the owner is a limited liability company, a member must sign the application as the applicant**.

(4) Drug distributor license applications and renewal applications shall be completed and submitted to the Board of Pharmacy along with the appropriate fees before any license is issued or renewed. Information required on the application shall include:
(E) The name(s) of the owner, operator, or both, of the licensed entity, including:
1. If a person, the name of the person;
2. If a partnership, the name of each partner and the name of the partnership;
3. If a corporation, the name of the corporate president, vice president, secretary, treasurer, chief executive officer, board of directors, and senior vice presidents or their equivalents, the corporate name(s) and the name of the state of incorporation; and
4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity; *[and]*
(F) The name of the manager in charge who meets the requirements as set forth in 4 CSR 220-5.030(2) and completes the manager-in-charge affidavit of the license application and has it notarized*[.]***; and**
(G) An application for a wholesale or pharmacy drug distributor license 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.

(5) When a drug distributor changes ownership, the original license becomes void on the effective date of the change of ownership. Before any new business entity resulting from that change opens a facility as a drug distributor, it must obtain a new license from the board. *[However, a grace period of thirty (30) days may be allowed after the change of ownership.]* **A temporary license shall be issued once a completed application and fee have been received by the board. The effective date of the temporary license shall be the date the change of ownership is listed as effective on the application. Such license shall remain in effect until a permanent license is issued or denied by the board.**
(B) *[A corporation is considered by law to be a separate person. If a corporation owns a drug distributor facility, 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 drug distributor facility or ceases ownership of that facility, 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 Board of Pharmacy within ten (10) days after that change occurs. This notification must be in writing and certified.]* **If a corporation owns a drug distributor facility, it is not necessary to obtain a new license if the owners of the stock change. If a limited liability partnership or a limited liability company owns a drug distributor company, it is not necessary to obtain a new license if the partners or members of the company change, as long as the partnership or company is not dissolved by that change. It is necessary to file written notice with the Board of Pharmacy within thirty (30) days after a change occurs of twenty-five percent (25%) or more in the ownership of corporation stock, or in partners in a limited liability partnership, or in members of the limited liability company. This notification must be in writing and certified. However, when a corporation, limited liability partnership, or limited liability company begins ownership of a drug distributor company or ceases ownership of a drug distributor company, a new license must be obtained regardless of the relationship between the previous and subsequent owners.**

4 CSR 220-1.010 General Organization - Effective 10/30/05 - Adds a new section (6) and renumbers the remaining section accordingly.
PURPOSE: This amendment defines the term "open premises" as used in Chapter 338, RSMo.

(6) "Open premises" as used in Chapter 338, RSMo means all premises accessible to employees in the regular course of any business which engages in practices regulated by this chapter, including, but not limited to, locked or otherwise secured storage areas that are used for the purpose of storing drugs, poisons, chemicals, or equipment used in any practice regulated by this chapter, and/or storage areas that are used for the purpose of storing records related to any practice regulated by this chapter.

*[(6)]***(7)** The public may obtain information from the board, or make submissions or requests to the board, by writing the executive director of the board. The information request shall be reviewed for appropriate action.

4 CSR 220-2.020 Pharmacy Permits - Effective 10/30/05 - Amends sections (1), (2), (3) and (9), and adds a new section (11).
PURPOSE: This amendment allows for issuance of a temporary pharmacy permit, removes the thirty (30)-day grace period for filing of an application after a change of ownership occurs, and adds limited liability companies to what is considered a separate person concerning ownership.

(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]* **pursuant to 4 CSR 230-2.031**.

(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. **If the owner is a partnership, a partner must sign the application as the applicant. If the owner is a limited liability partnership, a general partner must sign the application as the applicant. If the owner is a limited liability**

company, a member must sign the application as the applicant. In the case where a pharmacy is owned and operated by a person(s) who is a licensed pharmacist and in active charge of the pharmacy, the application for permit can be made by either party.

(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 temporary license shall be issued once a completed application and fee have been received by the board. The effective date of the temporary license shall be the date the change of ownership is listed as effective on the application. Such license shall remain in effect until a permanent license is issued or denied by the board.**
(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.]* **If a limited liability partnership or a limited liability company owns a pharmacy, it is not necessary to obtain a new license if the partners or members of the company change, as long as the partnership or company is not dissolved by that change.** It is necessary to file written notice with the State Board of Pharmacy within ten (10) days after *[that]* **a** change occurs **in partners in a limited liability partnership, or in members in a limited liability company**. This notification must be in writing and certified. **However, when a corporation, limited liability partnership, or limited liability company begins ownership of a pharmacy or transfers ownership of a pharmacy, a new license must be obtained regardless of the relationship between the previous and subsequent owners.**

(9) The following classes of pharmacy permits or licenses are hereby established:
(D) Class D: *[Home Health]* **Non-Sterile Compounding**. 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]* **and provides a non-sterile compounded product as defined in 4 CSR 220-2.400(1) which comprises five percent (5%) or more of the annual prescription volume of the pharmacy**;
(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)]***(11)(I)** and *[(15)]***(AA)**. Pharmacies providing sterile pharmaceuticals within the exemptions outlined in 4 CSR 220-2.200**(25)** 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*[.]***; and**

(11) Prescriptions processed by any classification of licensed pharmacy must be provided by a practitioner licensed in the United States authorized by law to prescribe drugs and who has performed a sufficient physical examination and clinical assessment of the patient. A pharmacist shall not dispense a prescription drug if the pharmacist has knowledge, or reasonably should know under the circumstances, that the prescription order for such drug was issued on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation, all without a valid preexisting patient-practitioner relationship.

4 CSR 220-2.050 Public Complaint Handling and Disposition Procedure - Effective 10/30/05 - Amends sections (1), (4) and (5).
PURPOSE: This rule amends the text of the rule to be consistent with the terminology used by the board.

(1) The State Board of Pharmacy shall receive and process each complaint made against any *[licensed pharmacist or pharmacy possessing a valid permit,]* **licensee or registrant** or other person or entity, which complaint alleges certain acts or practices which may constitute one (1) or more violations of the provisions of Chapter 338, RSMo. Any member of the public, the profession or any federal, state or local official may make and file a complaint with the board. Complaints shall be received from sources outside Missouri and will be processed in the same manner as those originating

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

(4) Each complaint received under this rule shall be *[logged in a book maintained]* **recorded** by the board *[for that purpose]*. Complaints shall be logged in consecutive order as received. The *[logbook]* **record** 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]* **record** 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.

4 CSR 220-5.030 Definitions and Standards for Drug Wholesale and Pharmacy Distributors - Effective 10/30/05 - Amends section (3) and deletes section (10).
PURPOSE: This amendment establishes a requirement that licensed drug distributors and pharmacy distributors report to the board office the finding of counterfeit drugs within seven (7) days of gaining knowledge of the problem, prohibits issuance of drug distributor licenses in residences or residential areas or to a location that shares physical space with a business not licensed and regulated by the state of Missouri and deletes section (10) relating to brokers/agents.

(3) Minimum standards of practice for drug distributors shall include the following:

(C) Appropriate housekeeping, sanitation, lighting, ventilation and humidity of all areas where drugs are stored must be maintained.
1. All aisles and walkways must be free and clear of debris, dirt or filth.
2. Dust shall be kept at low levels through adequate ventilation, cleaning procedures, or both.
3. All shelves and storage areas shall be kept free of debris, dirt, dust and filth.
4. Full cases of drug products shall be raised above floor level and placed on a pallet or similar device.
5. Upon receipt of legend drugs, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
6. Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
7. Drugs stored in a facility or being processed for distribution must be physically separated at all times from articles, supplies or other drugs that are outdated, distressed, misbranded or adulterated. An area separate from drug storage must be used to store quarantined, nonusable substances or accumulated waste/garbage. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall

be identified as such and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier. **If a drug is received or further distributed, either directly or through a secondary broker (paper) transaction, that is wholly or in part found to be counterfeit, a report which includes the name of the drug, quantity and lot number(s) must be forwarded to the Board of Pharmacy within seven (7) days of gaining knowledge of the transaction. Any recall of a product that is initiated by the Food and Drug Administration (FDA) or by a vendor licensed with the state of Missouri shall not be subject to the reporting requirement.**
8. Flammable articles must be stored separately and away from drug products held for later wholesale distribution.
9. Drugs which may be held for later distribution that are labeled for veterinary use must be stored separately from those drugs that are to be distributed for human use.
10. Procedures must be in place to prevent, control and alleviate infestation by insects, rodents, birds or vermin of any kind.
11. Appropriate sewage disposal and a hot and cold water supply must be available.
12. The outside perimeter of the premises shall be well-lighted.
13. All facilities shall be equipped with an alarm system to detect entry after hours.
14. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records;

(F) The labeling of drug products held for wholesale distribution must conform to requirements as set forth by the manufacturer, *[Food and Drug Administration (FDA)]* **FDA**, the USP and section 338.059.2, RSMo;

(M) Wholesale drug and pharmacy distributors shall establish, maintain and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Drug distributors shall include in their written policies and procedures the following:
1. A procedure where the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate;
2. A procedure to be followed for handling recalls and withdrawals of prescription drugs. This procedure shall be adequate to deal with recalls and withdrawals due to any.
A. Action initiated at the request of the FDA or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy;
B. Voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or
C. Action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;
3. A procedure to ensure that drug distributors prepare for, protect against and handle any crisis that affects the security or operation of any facility in the event of strike, fire, flood or other natural disaster, or other situations of local, state or national emergency; and
4. A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for three (3) years after disposition of the outdated drugs; *[and]*

(N) Drug distributors will be responsible for security procedures for the delivery of drugs from the wholesale facility to the destination site of all drug shipments*[.]***; and**

(O) No drug distributor license shall be issued to any location, regardless of zoning, that shares an address and/or physical space with a business not related to the distribution of prescription drugs or drug-related devices, or not licensed and regulated by the state of Missouri.

[(10) Brokers, their agents and employees, who act only in the capacity of an agent who arranges or negotiates agreements or contracts for the transfer of drugs or drug related devices and do not take actual possession of the drugs or drug related devices are exempt from maintaining any equipment or physical location requirements involved in the actual storage and distribution of drugs. Brokers shall be responsible for all record keeping requirements as outlined in subsections (3)(I), (J), (K) and (L).]

4 CSR 220-2.030 Educational and Licensing Requirements - Effective 6/30/05 - Amends sections (2)–(4).
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.

(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]* **all practical experience programs that are required and are approved by the board**. 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:
(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) Advanced practice experience is defined as practice based training which is documented as required, complies with training standards outlined in this rule and is considered a part of the school curriculum for training students within standards approved by the board of pharmacy.
*[(A)]***(B)** 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.]* **Advanced practice experience hours shall include a minimum of one hundred sixty (160) hours in a community/ambulatory pharmacy practice component, an institutional pharmacy practice component and a clinical and/or related area of pharmacy practice component.**
[4. Not more than forty (40) hours' credit per week shall be given for experience obtained.]
*[5.]***4.** *[Practical]***Advanced practice** 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]* **Advanced practice** 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)]***(D)** 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]* **licensure** as an intern; **and**
[2. Intern employment form; and
3. Intern evaluation of each training period or site.]
2. Academic internship report(s).
*[(G)]***(E) Advanced practice** *[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)] **(F)** 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)]***(G)** *[In the management of a Certified Intern Training Pharmacy, the e]***E**mphasis 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)](**H**) The provisions of this rule are not applicable to those students who gain their *[practical]* **advanced practice** experience in another state. **The minimum practical experience shall be fifteen hundred (1,500) hours of advanced practice experience to qualify to take the examination for licensure as a pharmacist.** *[However, i]* **I**f any portion of the required fifteen hundred (1,500) hours are to be earned in Missouri, the applicant must be licensed as an intern under the provisions of this rule. **When intern hours are to be earned within the state of Missouri by a student enrolled in or by a graduate of an out-of-state accredited school of pharmacy, the candidate must apply directly to the board of pharmacy to seek approval of any site and preceptor to be used. Any pharmacy that is submitted for approval as an intern training site for an out-of-state student or graduate shall meet the criteria outlined in (4)(B)1.–3.**

(4) Requirements for a**n** *[Certified Intern]* **Advanced Practice Experience** 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:]
(A) Requirements for a licensed pharmacy to participate as a site for practical experience training that is approved by the board include the following:
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]* **it must remain in good standing with the board**; **and**
[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.]***3.** 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)](**B**) 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. **A school of pharmacy may petition the board for an exception to this requirement in order to allow the facility to be approved for providing advanced practice experience training.**
(C) Accredited schools of pharmacy located within this state shall provide to the board, on an annual basis, a list of all preceptors and sites that are used in providing advanced practice experience through rotations toward the advanced practice experience requirement. The board shall approve any site for training interns that will be used within the college curriculum to fulfill the advanced practice experience requirements for licensure as a pharmacist. Any preceptors or sites that may be added by a school outside the annual approval process of the board must be approved by the board before the site can be used for practical experience purposes. In addition, the board shall approve the training standards, policies and procedures that are proposed by the schools of pharmacy in fulfilling the advanced practice experience requirements.
(D) Interns that have accumulated hours outside of the school of pharmacy program may submit those hours for credit up to one (1) year from the date that the requirements for advanced practice experience are in effect. All other requirements involving licensure, training and reporting to the board of pharmacy shall be adhered to before any credit of hours is provided.

4 CSR 220-3.040 Return and Reuse of Drugs and Devices - Effective 12/30/04 - Amends subsection (2)(D) and adds new language in subsection (2)(E).
PURPOSE: This amendment is being proposed due to new packaging availability on the market and amendments that have been made to national standards which allow for a wider variety of packaging to be returned and reused.

(2) A pharmacist or pharmacy may receive and reuse drugs from long-term care facilities, hospitals, and hospice facilities (as regulated by the Department of Health **and Senior Services**, in 19 CSR 30-35.020 Hospices Providing Direct Care in a Hospice Facility), provided that the following conditions are met:
(C) There is an established mechanism to trace the expiration date and the manufacturer's lot number of the drugs being returned; *[and]*
(D) Only drug products dispensed *[in the original manufacturer's packaging that remains sealed in tamper-evident packaging may be reused.]* **by a licensed pharmacy utilizing one (1) of the following sources may be reused and no drug products for reuse shall be in any way subject to further repackaging:**
1. Drug products in the original manufacturer's packaging that remains sealed in tamper-evident packaging;
2. Drug products repackaged by facilities that are federally registered as a repackager of medications and the packaging remains sealed in tamper-evident packaging;
3. Drug products that have been repackaged by a licensed pharmacy and are returned unused by the facility and remain sealed in tamper-evident packaging;
4. Drug products that have been repackaged by a licensed pharmacy and are provided in unit of use packaging whereby unused portions can be separated and reused without any further repackaging processes necessary on the returned product; and
(E) Any products that are accepted for return and can be reused based on standards provided in this rule shall be re-labeled to provide accurate information concerning patient and prescription information. Original lot numbers, expiration or beyond-use-dates assigned to a product that is reused by a pharmacy shall not be altered or in any way updated.

4 CSR 220-4.010 General Fees - Effective 12/30/04 - Amends subsections (1)(A), (1)(B), (1)(F), (1)(G), (1)(H), (1)(J), (1)(K), and (1)(L), deletes the existing subsections (1)(M) and (1)(N) and adds new language in subsections (1)(M) and (1)(N), amends (1)(O), deletes subsections (1)(P)–(1)(R), renumbers the remaining sections accordingly, and amends the newly numbered subsections (1)(R) and (1)(S).
PURPOSE: This amendment deletes obsolete information, amends the titles of fees collected, and incorporates fees from 4 CSR 220-4.020.

(1) The following fees are established by the State Board of Pharmacy:
(A) Licensure by Examination Fee $105.00
1. Exam candidate shall contact the National Association of Boards of Pharmacy and pay any fee required directly *[to]* **by** that agency *[to take the National Association Boards of Pharmacy Licensure Examination (NAPLEX) and Multistate Pharmacy Jurisprudence Examination (MPJE) which will be implemented October 1, 1999].*
(B) Licensure *[Without Examination Fee]* **By Transfer of License (Reciprocity)** $350.00
(F) *[Lapsed License]* **Delinquent Pharmacist** Renewal Fee (in addition to the Pharmacist License Renewal Fee) $ 50.00
(G) Duplicate *[Certificate of Renewal]* **License/Permit/Registration** Fee $ 10.00
(H) Change of *[D/B/A]* **Pharmacy or Drug Distributor** Name Fee $ 25.00
(J) **Foreign Graduate** Preliminary Filing Fee (Candidates for licensure by examination, who are graduates of schools/colleges of pharmacy not accredited by the board) $ 50.00
(K) Change of **Pharmacy or Drug Distributor** Location Fee $125.00
(L) Original **Pharmacy Distributor/**Wholesale Drug Distributor License Fee (includes both temporary and permanent license) $250.00

[(M) Original Out-of-State Wholesale Drug Distributor License Fee (includes both temporary and permanent license) $250.00
(N) Original Pharmacy Distributor License Fee (includes both temporary and permanent license) $250.00]
(M) Pharmacy Distributor/Wholesale Drug Distributor License Renewal Fee $400.00
(N) Original Drug Distributor (Manufacturer) Registration Filing Fee $ 10.00
(O) *[Original and]* Renewal **of** Drug Distributor *[Out-of-State]* **(Manufacturer)** Registration **Filing** Fee $*[20.00]***10.00**
[(P) Wholesale Drug Distributor License Renewal Fee $400.00
(Q) Out-of-State Wholesale Drug Distributor License Renewal Fee $200.00
(R) Pharmacy Distributor License Renewal Fee $200.00]
*[(S)]***(P)** Original Intern Pharmacist License $ 40.00
*[(T)]***(Q)** Intern Pharmacist License Renewal $ 25.00
*[(U)]***(R)** Temporary **Pharmacist** License Fee (original issue/renewal) $ 50.00
*[(V)]***(S)** Fingerprint Fee for Criminal *[b]***B**ackground *[c]***C**heck—**Determined by** Federal Bureau of Investigation (FBI) *[$ 22.00]*
and Missouri State Highway Patrol (MSHP) *[$ 14.00]* (pass through fee) *[$ 36.00]*
*[(W)]***(T)** Pharmacy Technician Initial Registration Fee $ 10.00
*[(X)]***(U)** Pharmacy Technician Annual Renewal Fee $ 10.00*[.]*

4 CSR 220-4.020 Miscellaneous Fees - Effective 12/30/04 - This rule established and fixed certain fees and charges statutorily authorized to be made by the State Board of Pharmacy.
PURPOSE: This rule is being rescinded because the fees are no longer being charged by the board.

4 CSR 220-2.100 Continuing Pharmacy Education - Effective 9/30/04 - Amends section (2), paragraph (2)(C)1., and section (9), adds a new section (10), and renumbers and amends section (11).
PURPOSE: This amendment allows the board to implement a random auditing process for continuing education.

(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]* **renewal** 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.
(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]* **renewal** 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-1through 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.

(9) The proof of completion of continuing education requirements shall be submitted with the renewal notice and the appropriate fees by submitting *[—]* **an affidavit that clearly attests to the fact that all continuing education requirements for the purpose of renewal of a pharmacist license have been met and that proof of completion of continuing education credits are maintained by the pharmacist in the form of one (1) or more of the following:**

(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]* **renewal** by that state board.

(10) Each such form of proof of completion of the required continuing education credits shall be retained by the licensee for the preceding two (2) reporting periods prior to renewal.

[(10)] **(11)** 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. **Failure to provide proof of completion of the necessary required continuing education credits shall be considered a violation and may result in disciplinary action pursuant to 338.055, RSMo initiate auditing of other past renewal**

periods and/or require proof of completion of future continuing education credits be submitted with any application for a renewal of a license.

4 CSR 220-2.300 Record Confidentiality and Disclosure - Effective 7/30/04 - Amends the original purpose statement, section (1) and subsections (2)(B), (2)(C), (2)(E), (2)(F), (2)(G), adds a new subsection (2)(H) and section (4) to comply with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).
PURPOSE: This amendment will create language to require pharmacies to comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

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

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

(2) Confidential records shall not be released to anyone except—
(B) *[The authorized prescriber who issued the prescription order or a licensed health professional who is currently treating the patient]* **A health care provider involved in treatment activities of the patient**;
(E) Any other person **or entity** authorized by a patient to receive such information;
(F) **For** *[T]***t**he transfer of medical or prescription information between pharmacists as provided by law; *[or]*
(G) Government agencies acting within the scope of their statutory authority*[.]***; or**
(H) A person or entity to whom such information may be disclosed under 45 CFR Parts 160, 164, and 165 (the Privacy Standards of the Health Insurance Portability and Accountability Act of 1996).

(4) Methods to access, transmit, store, analyze, or purge confidential information shall be implemented using procedures generally recognized as secure by experts qualified by training and experience. Procedures shall be in place to ensure that purged confidential information cannot be misused or placed into active operation without appropriate authorization as provided in this rule. Internet connectivity or remote access tied directly to systems containing confidential information must be secure as provided for in 4 CSR 220-2.085(2)(B).

4 CSR 220-5.020 Drug Distributor Licensing Requirements - Effective 1/30/04 - Amends section (1), adds new language in subsections (1)(C) and (1)(D) and amends subsection (4)(A).

PURPOSE: This amendment redefines the term "wholesale drug distributor," requires that licensed drug distributors purchase only from other licensed drug distributors; compiles current fax numbers of licensees in order to establish a fax communication system so that information about unlicensed entities may be communicated to licensed drug distributors.

(1) *[As defined in section 338.315, RSMo, pharmacies and all individuals employed by pharmacies shall purchase or receive legend drugs only from a licensed or registered drug distributor or licensed pharmacy. For purposes of this rule, the term drug distributor is used to define anyone engaged in an activity as defined in section 338.330, RSMo. Drug distributors as defined in 338.330, RSMo, shall only purchase or receive legend drugs and drug*

related devices from a licensed or registered drug distributor or licensed pharmacy.] **A "wholesale drug distributor" is defined in section 338.330(3), RSMo. No wholesale drug distributor with physical facilities located in the state of Missouri shall knowingly purchase or receive legend drugs and/or drug related devices from a wholesale drug distributor or pharmacy not licensed or registered by the board. Knowledge of the licensure status of a drug distributor or pharmacy includes, but is not limited to, actual or constructive knowledge. Knowledge of the license status of a drug distributor or pharmacy shall also include, but not be limited to, notification from the board by mail or electronic transmission.**
(C) Wholesale drug distributors shall inform the board of their current FAX number, any change in FAX number, and/or the fact that the wholesale drug distributor does not have a working FAX. In the event a wholesale drug distributor notifies the board that the wholesale drug distributor does not have a working FAX, notification from the board will be made to the wholesale drug distributor by first class mail. For the purposes of this rule, such notification by mail shall be considered effective three (3) days after mailing and shall have the same effect as notification by FAX.
(D) Failure to receive notification from the board shall not be a defense to violations of section (1) of this rule when the wholesale drug distributor has failed to comply with the requirements of subsection (1)(C) of this rule.

(4) Drug distributor license applications and renewal applications shall be completed and submitted to the Board of Pharmacy along with the appropriate fees before any license is issued or renewed. Information required on the application shall include:
(A) The name, full business address**, electronic facsimile transmission number (FAX)** and telephone number of the licensee;