This section will contain the final text of the rules proposed by agencies. The order of rulemaking is required to contain a citation to the legal authority upon which the order of rulemaking is based; reference to the date and page or pages where the notice of proposed rulemaking was published in the *Missouri Register*; an explanation of any change between the text of the rule as contained in the notice of proposed rulemaking and the text of the rule as finally adopted, together with the reason for any such change; and the full text of any section or subsection of the rule as adopted which has been changed from that contained in the notice of proposed rulemaking. The effective date of the rule shall be not less than thirty (30) days after the date of publication of the revision to the *Code of State Regulations*.

The agency is also required to make a brief summary of the general nature and extent of comments submitted in support of or opposition to the proposed rule and a concise summary of the testimony presented at the hearing, if any, held in connection with the rulemaking, together with a concise summary of the agency's findings with respect to the merits of any such testimony or comments which are opposed in whole or in part to the proposed rule. The ninety (90)-day period during which an agency shall file its order of rulemaking for publication in the *Missouri Register* begins either: 1) after the hearing on the proposed rulemaking is held; or 2) at the end of the time for submission of comments to the agency. During this period, the agency shall file with the secretary of state the order of rulemaking, either putting the proposed rule into effect, with or without further changes, or withdrawing the proposed rule.

Title 2—DEPARTMENT OF AGRICULTURE
Division 30—Animal Health
Chapter 2—Health Requirements for Movement of Livestock, Poultry and Exotic Animals

ORDER OF RULEMAKING

By the authority vested in the director of the Department of Agriculture under section 267.645, RSMo 2000, the director amends a rule as follows:

2 CSR 30-2.010 Health Requirements Governing the Admission of Livestock, Poultry and Exotic Animals Entering Missouri **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (27 MoReg 399). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 2—DEPARTMENT OF AGRICULTURE
Division 30—Animal Health
Chapter 2—Health Requirements for Movement of Livestock, Poultry and Exotic Animals

ORDER OF RULEMAKING

By the authority vested in the director of the Department of Agriculture under section 267.645, RSMo 2000, the director amends a rule as follows:

2 CSR 30-2.020 Movement of Livestock, Poultry and Exotic Animals Within Missouri **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (27 MoReg 399–400). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 2—DEPARTMENT OF AGRICULTURE
Division 30—Animal Health
Chapter 2—Health Requirements for Movement of Livestock, Poultry and Exotic Animals

ORDER OF RULEMAKING

By the authority vested in the director of the Department of Agriculture under section 267.645, RSMo 2000, the director amends a rule as follows:

2 CSR 30-2.040 Animal Health Requirements for Exhibition **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (27 MoReg 400). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 2—DEPARTMENT OF AGRICULTURE
Division 30—Animal Health
Chapter 6—Livestock Markets

ORDER OF RULEMAKING

By the authority vested in the director of the Department of Agriculture under section 277.160, RSMo 2000, the director amends a rule as follows:

2 CSR 30-6.020 Duties and Facilities of the Market/Sale Veterinarian **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 400). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 3—DEPARTMENT OF CONSERVATION
Division 10—Conservation Commission
Chapter 10—Wildlife Code: Commercial Permits: Seasons, Methods, Limits

ORDER OF RULEMAKING

By the authority vested in the Conservation Commission under sections 40 and 45 of Art. IV, Mo. Const., the commission rescinds a rule as follows:

3 CSR 10-10.745 Swan Lake Migratory Bird Preservation Permit: Privileges, Requirements **is rescinded**.

This rule relates to hunting seasons and limits and is excepted by section 536.021, RSMo from the requirement for filing as a proposed rescission.

PURPOSE: The commission is rescinding this rule and closing the Swan Lake Zone to waterfowl hunting prior to the waterfowl hunting season due to harvest declines, and therefore, making the collection of parts no longer necessary under the provisions of the Swan Lake Migratory Bird Preservation Permit.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. Original rule filed Aug. 7, 1986, effective Jan. 1, 1987. Rescinded: Filed May 9, 2003.

SUMMARY OF COMMENTS: Seasons and limits are excepted from the requirement for filing as a proposed rescission under section 536.021, RSMo.

This proposed rescission filed May 9, 2003, effective **June 2, 2003**.

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

ORDER OF RULEMAKING

By the authority vested in the State Board of Pharmacy under sections 338.140 and 338.280, RSMo 2000, the board rescinds a rule as follows:

4 CSR 220-2.200 Sterile Pharmaceuticals **is rescinded**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on January 2, 2003 (28 MoReg 10). No changes have been made to the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

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

ORDER OF RULEMAKING

By the authority vested in the State Board of Pharmacy under sections 338.010, 338.140, 338.240 and 338.280, RSMo 2000, the board adopts a rule as follows:

4 CSR 220-2.200 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on January 2, 2003 (28 MoReg 10–19). Changes have been made to the text of this rule. The rule is being reprinted in its entirety. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: A total of twelve (12) written comments were received. In addition, a public hearing was held and comments were made by three (3) individuals who had not submitted written comments.

COMMENT: One (1) entity commented on subsection (1)(H) regarding the definition of compounding which they believe is too broad and subsection (1)(N) regarding expiration date, noting that the term "expiration date" should not be used when referencing compounded products, this term applies to manufactured products. They suggested that the term "beyond-use date" be used.
RESPONSE AND EXPLANATION OF CHANGE: The board concurred with the comments and made changes to subsection (1)(H) and as well, established a definition of "beyond-use date" as a new subsection (1)(C).

COMMENT: One (1) entity commented on subsection (1)(P) stating that the requirement that a closed system made up of four (4) walls was unreasonable and that an isolation chamber would provide the same service.
RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made changes to subsection (1)(P).

COMMENT: Two (2) entities commented on subsection (1)(Z), regarding the definition of risk levels stating that the American Society of Health Care Pharmacists (ASHP) Guidelines should be used to define the risk levels and questioning the board's intent in defining that risk level 1 and 2 products can be stored at room temperature, thus implying that risk level 3 products must be refrigerated. One entity also questioned the twenty-eight (28) hour stipulation in this section.
RESPONSE AND EXPLANATION OF CHANGE: The board concurred and adopted the definition of risk levels as provided by ASHP and further decided to change the twenty-eight (28) hours in paragraph (1)(Z)2. to forty-eight (48) hours.

COMMENT: Two (2) entities commented on subsection (4)(A) noting that the requirement for daily removal of used supplies was unreasonable, since many pharmacies compounded small amounts of products or did not compound every day.
RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made wording changes to this subsection.

COMMENT: One (1) entity commented on subsection (4)(B) noting that only finished but untested Risk Level 3 products should be quarantined.
RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made changes to this subsection.

COMMENT: One (1) entity commented on subsection (5)(B) noting that the requirements for cleaning the controlled area were unnecessary unless the controlled area was used on a daily basis and that the rule does not allow for use of plexiglass or a glove box.
RESPONSE AND EXPLANATION OF CHANGE: The board concurred with the first comment and added language to this section for cleaning the controlled area, which is not utilized on a daily basis. The board feels that the rule does not preclude the use of new technology, such as plexiglass or a glove box, to achieve the same result required by this subsection and thus disagreed with that comment.

COMMENT: One (1) entity commented on section (6) noting that required garb was costly and should not be required of risk level 1 and 2.
RESPONSE AND EXPLANATION OF CHANGE: The board concurred and deleted (1)(A) from this section and added language to previously numbered (1)(B) to clarify this issue.

COMMENT: Three (3) entities commented on subsection (7)(B) alleging that testing for each batch of Risk Level 2 products was unnecessary and expensive; that language in this section conflicted with statements in subsection (12)(B) and thus should be removed.
RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made changes to subsection (7)(B).

COMMENT: Three (3) entities commented on subsection (7)(C) noting that not all components have *United States Pharmacopoeia* (USP) monographs and other validations of chemical potency and purity are accepted and used.
RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made changes to the language in this section.

COMMENT: One (1) entity commented on section (9) that the phrase "ingredient validation" is not defined and should be modified or removed.
RESPONSE AND EXPLANATION OF CHANGE: The board concurred and added clarifying language to section (9).

COMMENT: Two (2) entities commented on section (11) noting that expiration date is not an appropriate term for compounded products and that it should be "beyond-use date" and in addition, laboratory testing required in this section was excessive. Further, that in subsection (11)(C) the words "when necessary" be added to the end of the first sentence.
RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made changes to this section to change the term expiration date to beyond-use date and require testing for stability and potency only on those products which have a beyond use of more than thirty (30) days and to add the words "when necessary" as requested.

COMMENT: Four (4) entities commented on subsection (12)(C) noting that the language can be interpreted to mean that intermediate products must be tested as well as the final product, which is redundant and costly.
RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made changes to subsection (12)(C) to address the comments.

COMMENT: Two (2) entities commented on subsection (12)(D) noting that emergency dispensing should be clarified since requiring end product testing results prior to the release of these products would entirely preclude their use; pharmacies should be allowed to dispense the entire product, provided there is a mechanism for recalling dispensed products if testing yields unacceptable results.
RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made numerous changes to this subsection and in addition, moved this subsection to subsection (1)(O) of the rule under "definitions."

COMMENT: One (1) entity commented that the language in subsection (13)(A) was overly restrictive when applied to temperature and delivery services and submitted suggested language.
RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made appropriate changes using the suggested language.

COMMENT: One (1) entity commented that the exemption provided for in section (15) was very vague and should be removed or reworded.
RESPONSE: After review of section (15), the board feels that specific processes for being exempt from this rule are included in this section and disagreed that the section is vague and unenforceable. No change was made based on this comment.

COMMENT: During the public hearing, one (1) entity stated that the rule should exempt home care pharmacies from this rule because of their long history of providing safe and optimal therapies to residents in long-term care facilities. The commenter further suggested that the board engage in a study with long-term care pharmacy providers to determine the nature and extent of rules needed for the preparation of sterile products in long-term care pharmacies.
RESPONSE: The board did not agree with the comment to exempt home care pharmacies from this rule because this would be an unequal application of the rule. The board believes that all pharmacies providing sterile pharmaceuticals must be held to the same minimum standards. No changes were made based on this comment.

COMMENT: Several entities commented that the Private Entity Costs were grossly underestimated as were the Public Entity Costs.
RESPONSE AND EXPLANATION OF CHANGE: The board reviewed the cost statements and made changes to the annual costs by increasing the number of pharmacies to be affected but decreasing the number of batches, which will require full testing. The board also reviewed the public entity costs and deleted the cost of refractometers and increased the time to inspect. Public entity costs were also adjusted to indicate seven (7) inspectors, instead of six (6).

COMMENT: One (1) entity stated that implementation of this rule, if adopted, should be delayed to allow pharmacies to make system changes in order to comply.
RESPONSE AND EXPLANATION OF CHANGE: The board concurred with this comment and voted to establish the effective date of this rule as one year (twelve (12) months) after publication in the *Code of State Regulations*.

COMMENT: Several general comments were made. Several entities commented that the rule is anti-competitive and should be withdrawn. One entity stated that the entire approach was fundamentally flawed, with an over-reliance on product testing and the board should consider an alternative approach. One entity stated that section (11) would create a major constraint on practice.
RESPONSE: The board did not agree with these general comments given that most if not all of the standards portrayed in this rule come from model laws or national compendia. In addition, the board believes that any additional concerns of the ability to comply with these new standards were addressed through the changes made from comments received as well as the decision not to implement the rule for one year. The board also believes that changes made to section (11) and section (12) based on other comments addresses these concerns.

COMMENT: One (1) entity stated that the Robert Courtney case was the basis for this rule and it fails to meet the objectives. This entity also implied that board members had been motivated by competitive reasons and that Senator Bond had intervened on this issue. This entity stated that the language regarding advertising is a restriction on free speech.
RESPONSE: The board did not agree with the comments directed to the rule since there was no factual basis for the comments, that no specific information was provided to indicate that any portion of the rule was anti-competitive in any way, nor was there any specific information regarding the alleged restriction of free speech. Therefore, the board made no changes to the rule based on these comments.

4 CSR 220-2.200 Sterile Pharmaceuticals

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

(2) Definitions.

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

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

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

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

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

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

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

(A) Clinical services;

(B) Cytotoxics handling, storage and disposal;

(C) Disposal of unused supplies and medications;

(D) Drug destruction and returns;

(E) Drug dispensing;

(F) Drug labeling/relabeling;

(G) Drug storage;

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

(I) Equipment;

(J) Handling of infectious wastes;

(K) Infusion devices and drug delivery systems;

(L) Investigational drugs;

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

(N) Quality assurance procedures to include:

1. Recall procedures;

2. Storage and dating;

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

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

5. Sterility testing;

(O) Record keeping;

(P) Reference material;

(Q) Sanitation;

(R) Security;

(S) Sterile product preparation procedures; and

(T) Transportation.

(4) Physical Requirements.

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

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

1. Appropriate environmental control devices capable of maintaining at least Class 100 conditions in the work area where critical objects are exposed and critical activities are performed; furthermore, the devices are capable of maintaining Class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow systems of high efficiency particulate air filter (HEPA)-filtered air;

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

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

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

5. Refrigerator/freezer with a thermometer;

6. Temperature-controlled delivery container; and

7. Infusion devices, if appropriate.

(C) Supplies.

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

2. Disinfectant cleaning solutions;

3. Hand washing agent with bactericidal action;

4. Disposable, lint free towels or wipes;

5. Appropriate filters and filtration equipment;

6. Oncology drug spill kit; and

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

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

(5) Drug Distribution and Control.

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

1. Patient's full name;

2. Date of birth or age;

3. Weight;

4. Sex;

5. Sterile products dispensed;

6. Date dispensed;

7. Drug content and quantity;

8. Patient direction;

9. Identifying prescription number;

10. Identification of dispensing pharmacist;

11. Other drugs patient is receiving;

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

13. Primary diagnosis.

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

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

2. Date of compounding;

3. Expiration date and time;
4. Identity of pharmacist compounding and dispensing;
5. Storage requirements;
6. Auxiliary labels, where applicable; and
7. Cytotoxic drug auxiliary labels, where applicable.

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

1. Purchase records;
2. Policy and procedure manual;
3. Training manuals, where applicable;
4. Policies and procedures for cytotoxic waste, where applicable;
5. Other records and reports as may be required by law and the rules of the State Board of Pharmacy; and
6. Information regarding individual patients shall be maintained in a manner to assure confidentiality of the patient's record. Release of this information shall be in accordance with federal or state laws, or both.

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

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

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

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

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

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

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

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

(7) Quality Assurance.

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

1. Recall procedures;
2. Storage and dating; and
3. Environmental procedures which include a log of the temperature of the refrigerator, routine maintenance and report of any hood certification.

(B) Clean Room and Hood Certification. All clean rooms and laminar flow hoods shall be certified by an independent contractor according to Federal Standard 209B or National Sanitation Foundation Standard 49 for operational efficiency at a minimum of every twelve (12) months. Certification records shall be maintained as a part of the pharmacy record.

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

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

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

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

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

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

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

1. Situations where the sterile compound is needed and is unavailable from or inconvenient to obtain from other sources;
2. Compounding will be provided to the patient immediately and used within a twenty-four (24)-hour period; and
3. Products are provided to the patient as a single dosage unit and the drug is not intended to be provided beyond an immediate emergency period.

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

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

(11) Definitions.

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

(B) Batch: Compounding of multiple sterile product units in a single discrete process, by the same individuals, carried out during one (1) limited time period.

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

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

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

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

(G) Clean room: A room—

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

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

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

(H) Clean zone: Dedicated space—

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

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

3. In which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary. This zone may be open or enclosed and may or may not be located within a clean room.

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

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

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

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

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

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

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

(P) High-Efficiency Particulate Air (HEPA) filter: A filter composed of pleats of filter medium separated by rigid sheets of corrugated paper or aluminum foil that direct the flow of air forced through the filter in a uniform parallel flow. HEPA filters remove ninety-nine point ninety-seven percent (99.97%) of all particles three-tenths (0.3) microns or larger. When HEPA filters are used as a component of a horizontal- or vertical-laminar-airflow workbench, an environment can be created consistent with standards for a Class 100 clean room.

(Q) Isolator (or barrier isolator): A closed system made up of four (4) solid walls, an air-handling system, and transfer and interaction devices. The walls are constructed so as to provide surfaces that are cleanable with coving between wall junctures. The air-handling system provides HEPA filtration of inlet air. Transfer of materials is accomplished through air locks, glove rings, or ports. Transfers are designed to minimize the entry of contamination. Manipulations can take place through either glove ports or half suits.

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

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

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

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

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

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

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

(Y) Temperatures:

1. Frozen means temperatures between twenty below zero and ten degrees Celsius (–20 and 10°C) (four below zero and fourteen degrees Fahrenheit (–4 and 14°F)).

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

3. Room temperatures means room temperatures between fifteen and thirty degrees Celsius (15 and 30°C) (fifty-nine and eighty-six degrees Fahrenheit (59 and 86°F)).

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

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

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

A. Products:

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

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

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

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

C. Products prepared by closed-system aseptic transfer of sterile, nonpyrogenic, finished pharmaceuticals (e.g., from vials or ampules) obtained from licensed manufacturers into sterile final containers obtained from licensed manufacturers.

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

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

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

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

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

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

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

(12) Policy and Procedure Manual.

(A) A manual, outlining policies and procedures encompassing all aspects of Risk Level 1, 2 and 3 products, shall be available for inspection at the pharmacy. The manual shall be reviewed on an annual basis.

(13) Personnel Education, Training and Evaluation.

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

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

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

1. Aseptic processing;

2. Quality assurance of environmental, component, and end-product testing;

3. Sterilization; and

4. Selection and use of containers, equipment, and closures.

(14) Storage and Handling in the Pharmacy.

(A) Risk Level 1 and 2: Solutions, drugs, supplies and equipment must be stored according to manufacturer or USP requirements. Refrigeration and freezer temperatures shall be documented daily. Other storage areas shall be inspected regularly to ensure that temperature and lighting meet requirements. Drugs and supplies shall be shelved above the floor. Removal of products from boxes shall be done outside controlled areas. Removal of used supplies from the controlled area shall be done at least daily. Product recall procedures must permit retrieving affected products from specific involved patients.

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

(15) Facilities and Equipment.

(A) Risk Level 1: The controlled area shall be separated from other operations. The controlled area must be clean and well lit. A sink with hot and cold water must be near, but not in, the controlled area. The controlled area and inside equipment must be cleaned and disinfected regularly. Sterile products must be prepared in at least a Class 100 environment (the critical area). Computer entry, order processing, label generation, and record keeping shall be performed outside the critical area. The critical area must be disinfected prior to use. A workbench shall be recertified every six (6) months and when it is moved; prefilters must be visually inspected on a regularly scheduled basis and replaced according to manufacturer's specifications. Pumps utilized in the compounding process shall be recalibrated and documented according to manufacturer procedures.

(B) Risk Level 2: In addition to all Risk Level 1 requirements, the controlled area must meet Class 10,000 clean room standards; cleaning supplies should be selected to meet clean room standards; critical area work surface must be cleaned between batches; floors should be disinfected daily; equipment surfaces weekly; and walls monthly; with applicable environmental monitoring of air and surfaces. Automated compounding devices must be calibrated and verified as to accuracy, according to manufacturer procedures. Clean rooms not utilized on a daily basis must be cleaned prior to use as stated above.

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

(16) Apparel.

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

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

(17) Aseptic Technique and Product Preparation.

(A) Risk Level 1: Sterile products must be prepared in a Class 100 environment. Personnel shall scrub their hands and forearms for an appropriate period at the beginning of each aseptic compounding process. Eating, drinking and smoking are prohibited in the controlled area. Talking shall be minimized to reduce airborne particles. Ingredients shall be determined to be stable, compatible, and appropriate for the product to be prepared, according to manufacturer, USP, or scientific references. Ingredients and containers shall be inspected for defects, expiration and integrity before use. Only materials essential for aseptic compounding shall be placed in the workbench. Surfaces of ampules and vials shall be disinfected before placement in the workbench. Sterile components shall be arranged in the workbench to allow uninterrupted laminar airflow over critical surfaces of needles, vials, ampules, etc. Automated devices and equipment shall be cleaned, disinfected and placed in the workbench to enable laminar airflow. Aseptic technique shall be used to avoid touch contamination of critical sites of containers and ingredients. Particles shall be filtered from solutions. Needle cores shall be avoided. The pharmacist shall check before, during, and after preparation to verify the identity and amount of ingredients before release.

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

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, nonsterile components must meet standards if available, as verified

by a pharmacist and a certificate of analysis. Batch preparation files shall also include comparisons of actual with anticipated yields, sterilization methods, and quarantine specifications. Presterilized containers shall be used when feasible. Final containers must be sterile and capable of maintaining product integrity throughout the shelf life. Sterilization methods must be based on properties of the product.

(18) Process Validation.

(A) Risk Level 1: All pharmacy personnel who prepare sterile products shall pass a process validation of aseptic technique before compounding sterile products. Pharmacy personnel competency must be reevaluated by process validation at least annually, whenever the quality assurance program yields an unacceptable result, or whenever unacceptable techniques are observed. If microbial growth is detected, the entire sterile process must be evaluated, corrective action taken, and the process simulation test performed again.

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

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

(19) Record Keeping.

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

1. Training and competency evaluation of pharmacy personnel involved in sterile product preparation;
2. Refrigerator and freezer temperature logs;
3. Certification of workbenches;
4. Copies of any manufacturer standards that are relied upon to maintain compliance with this rule; and
5. Other facility quality control logs as appropriate including all maintenance, cleaning, and calibration records.

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

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

1. Preparation work sheet;
2. Sterilization records;
3. Quarantine records, if applicable;
4. End-product evaluation and testing records as required in section (22); and
5. Ingredient validation records as required in section (22).

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

(20) Labeling.

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

1. Beyond-use date;
2. Storage requirements;
3. Any device specific instructions; and
4. Auxiliary labels, when applicable.

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

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

(21) Beyond-Use Dating.

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

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

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

(22) End-Product Evaluation.

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

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

(C) Risk Level 3: In addition to all Risk Level 1 requirements, the process validation procedure shall be supplemented with a program of end-product sterility testing according to a formal sampling plan. Samples shall be statistically valid to ensure that batches are sterile. A method for recalling batch products shall be established if end-product testing results are unacceptable. All sterile products must be tested for sterility. All parenteral sterile products must also be tested for pyrogenicity. Sterile products compounded from nonsterile components must be quarantined pending results of end-product testing.

1. Sterility testing: Sampling for the sterility test shall occur promptly upon the completion of preparation. The sterility test, including the sampling scheme, shall be conducted according to one (1) of the USP methods.
2. Pyrogen/Endotoxin testing: Each sterile parenteral product prepared from nonsterile drug components shall be tested for pyrogen or endotoxin according to recommended USP methods.
3. Potency: The pharmacy shall have a procedure for a prerelease check of the potency of the active ingredients in the compounded sterile product prepared from nonsterile bulk active ingredients. The procedure shall include at least the following verifications by a pharmacist:

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

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

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

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

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

(23) Handling Sterile Products Outside the Pharmacy.

(A) Risk Level 1: The pharmacist-in-charge shall assure the environmental control of all sterile compounded products shipped. Sterile products shall be transported so as to be protected from excesses of temperatures and light within appropriate packaging or delivery containers that maintain necessary storage conditions to preserve the quality and integrity of sterile products. The pharmacy shall follow written procedures that specify packing techniques, configuration, and materials for groups of products with common storage characteristics and for specific products where unique storage conditions are required to retain adequate stability and product quality.

(B) Risk Level 2: All requirements for Risk Level 1 must be met.
(C) Risk Level 3: All requirements for Risk Level 1 must be met.

(24) Cytotoxic Drugs.

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

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

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

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

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

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

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

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

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

REVISED PUBLIC COST: The cost to the board is estimated at ten thousand eight hundred fourteen dollars ($10,814) versus the estimated twelve thousand five hundred ninety-seven dollars ($12,597) which we submitted in the original estimate.

REVISED PRIVATE COST: The cost to private entities is estimated at $1,351,600 during the first year of implementation of the rule and an estimated $2,996,200 annually for the life of the rule versus the estimated $1,351,600 during the first year of implementation of the rule and $3,322,500 which we submitted in the original estimate.

REVISED FISCAL NOTE
PUBLIC ENTITY COST

I. RULE NUMBER

Title: 4 -- Department of Economic Development
Division: 30 – State Board of Pharmacy
Chapter: 2 – General Rules
Type of Rulemaking: Proposed Rule
Rule Number and Name: 4 CSR 220-2.200 Sterile Pharmaceuticals

Revised March 27, 2003 by the State Board of Pharmacy

II. SUMMARY OF FISCAL IMPACT	
Affected Agency or Political Subdivision	**Estimated Annual Cost of Compliance**
State Board of Pharmacy (inspection of 29 Risk Level 1 Pharmacies)	$1,452.00
State Board of Pharmacy (inspection of 61 Risk Level 2 & 3 Pharmacies)	$6,110.00
State Board of Pharmacy (Inspector Training)	$2,352.00
State Board of Pharmacy (Training Video)	$200.00
State Board of Pharmacy (unknown costs estimates at $100 per inspector)	$700.
Total Annual Cost for the Life of the Rule	**$10,814.00**

WORKSHEET

Inspector time to inspect:
Inspector time to inspect:

Risk Level 1 – 29 Pharmacies
2 extra hours x $25.04 per hour (average Inspector Salary)
x 29 pharmacies = $1,452,32 (cents rounded down) $ 1,452.00

Risk Level 2 & 3 -- 61 Pharmacies
4 extra hours x $25.04 x 61 pharmacies = $6,109.76 (cents rounded up) $ 6,110.00

Training for Inspectors

Seminar Cost (est)	$200.00
1 Night Hotel (est)	$ 90.00 (St. Louis CONUS)
Meals 1 day (est)	$ 46.00 (St. Louis CONUS)

Total	$ 336.00 x 7 inspectors =	$ 2,352.00
Purchase of Training Videos 1 set to be shared (est)		$ 200.00
Unknown costs estimated at $100 per inspector =		$ 700.00
		$ 10,814.00

ASSUMPTIONS:

1. It will take an inspector approximately 2 extra hours of inspection time to inspect Risk Level 1 and 2 pharmacies providing sterile pharmaceutical products.

2. It will take an inspector approximately 4 extra hours of inspection time to inspect Risk Level 3 pharmacies providing sterile pharmaceutical products. This is the level where all non-sterile to sterile compounding of products will occur and will require the extra time for the inspector to inspect.

3. Refer to the table in Assumption 1 for breakdown of Risk Level 1 and 2 (combined) and Risk Level 3, used to calculate the number of pharmacies that will require extra inspection time.

4. It is anticipated that the total annual cost will recur each year for the life of the rule, may vary with inflation and are expected to increase annually at the rate projected by the Legislative Oversight Committee.

REVISED FISCAL NOTE
PRIVATE ENTITY COST

I. RULE NUMBER

Title:	4 – Department of Economic Development
Division:	30 – State Board of Pharmacy
Chapter:	2 – General Rules
Type of Rulemaking:	Proposed Rule
Rule Number and Name:	4 CSR 220-2.200 Sterile Pharmaceuticals

Revised March 27, 2003 by the State Board of Pharmacy

II. SUMMARY OF FISCAL IMPACT

First Year of Implementation

Estimate of the number of entities by class which would likely be affected by the adoption of the proposed rule:	**Classification by types of the business entities which would likely be affected:**	**Estimate annual cost of compliance with the rule by the affected entities:**
8	Class C: Long Term Care Pharmacies (barrier isolator - $8,950)	$71,600.00
8	Class C: Long Term Care Pharmacies (air conditioning, lighting, etc - $4,000)	$32,000.00
39	Pharmacies (construction of clean room - $32,000)	$1,248,000.00
	Total Cost Incurred During First Year of Implementation of the Rule	**$1,351,600.00**

Annual Costs

Estimate of the number of entities by class which would likely be affected by the adoption of the proposed rule:	**Classification by types of the business entities which would likely be affected:**	**Estimate annual cost of compliance with the rule by the affected entities:**
61	Pharmacies (apparel/clothing - $250 per pharmacy each month)	$183,000.00
20	Pharmacies (testing of batches – 1,040 total batches per year x $805 per batch) Sterility,	$ 837,200.00

	Potency and Pyrogenicity	
20	Pharmacies (testing of batches – 4,160 total batches per year x $475 per batch) Sterility and Potency only	$ 1,976,000.00
	Total Annual Cost for the Life of the Rule	**$ 2,996,200.00**

ASSUMPTIONS:

1. Pharmacies must maintain compliance with the class of pharmacy which they will practice, both when they complete a new application and when the renewal is submitted. Pharmacies may also complete a form to add to or delete classifications from their license at any time. The statistics used in this fiscal note are taken from the PROMO licensing system, and is based on information provided to the Board by pharmacies.

Type of Pharmacy	**Total #**	**% that will provide sterile products**	**Number that will provide sterile products**	**Risk level**	**Inspector reakdown Risk Level 1**	**2 & 3**
Class B: Hospital Outpatient + Class D Home Health	1	100%	1	1 – RL 2/3		1
Class C: Long Term Care + C combinations	231	25%	57.75 rounded to 58	29 – RL1 29 – RL 2 and 3	29	29
Class D: Home Health + D Combinations	31	75%	23	23 – RL 2 and 3		23
Class H: Sterile Product Compounding + H combinations	8	100%	8	8 – RL 2 and 3		8
			90		29	61

2. There are categories of Risk Level 1, 2 and 3 in the field of sterile product compounding.

   A. Risk Level 1: Applies to compounded sterile products that exhibit characteristics 1,2, and 3, stated below. All *risk level 1* products shall be prepared with sterile equipment, sterile ingredients and solutions and sterile contact surfaces for the final product. *Risk level 1* includes the following: (1) Products: (a) Stored at room temperature and completely administered within

48 hours after preparation or (b) Stored under refrigeration for seven days or less before complete administration to a patient over a period not to exceed 48 hours or (c) Frozen for thirty days or less before complete administration to a patient over a period not to exceed 48 hours. (2) Unpreserved sterile products prepared for administration to one patient or batch-prepared products containing suitable preservatives prepared for administration to more than one patient. (3) Products prepared by closed-system aseptic transfer of sterile, nonpyrogenic, finished pharmaceuticals (e.g., from vials or ampuls) obtained from licensed manufactures into sterile final containers obtained from licensed manufacturers.

B. Risk Level 2: Sterile products exhibit characteristic 1,2 or 3, stated below. All *risk level 2* products shall be prepared with sterile equipment, sterile ingredients and solutions and sterile contact surfaces for the final product and with closed-system transfer methods. *Risk Level 2* includes the following: (1) Products stored beyond seven days under refrigeration, stored beyond thirty days frozen or administered beyond 48 hours after preparation and storage at room temperature. (2) Batch-prepared products without preservatives that are intended for use by more than one patient. (3) Products compounded by complex or numerous manipulations of sterile ingredients obtained from licensed manufacturers in a sterile container or reservoir obtained from a licensed manufacturer by using closed-system aseptic transfer (e.g., automated compounder).

C. Risk Level 3: Sterile products exhibit either characteristic 1 or 2: (1) Products compounded from nonsterile ingredients or compounded with nonsterile components, containers or equipment before terminal sterilization. (2) Products prepared by combining multiple ingredients--sterile or nonsterile--by using an open-system transfer or open reservoir before terminal sterilization.

It is estimated that 50% of Class C: Long Term Care Pharmacies will be at Risk Level 1 and 50% will be at Risk Levels 2-3.

It is estimated that 75% of Class D: Home Health and 100% of Class H: Sterile Product Pharmacies will be at Risk Levels 2 and 3.

Risk Level 1 pharmacies that prepare I.V's currently will already have the equipment required and are in compliance with the existing regulation.

These estimates are based on the fact that a licensee has the option to select the types of products that s/he chooses to compound. The licensee may choose to operate at a specific risk level, depending on his/her choice on issues such as beyond use date.

It is estimated that a total of 61 pharmacies could be affected by this rule. It is further estimated that 25% of these 61 pharmacies which is equal to 15 pharmacies, are involved in sterile product compounding which includes non-sterile to sterile product compounding.

During a review of the proposed rule and fiscal note in preparation for the final order of rulemaking, and after evaluation of information obtained from pharmacy inspectors, there are approximately 20 pharmacies which are involved in sterile product compounding,

3. There is a great variance in the type of products involved in sterile product compounding, including but not limited to, antibiotics, parenteral nutrition products, chemotherapy and pain management medications. There is also a wide range of scenarios and it is virtually impossible to determine an "average" per pharmacy.

4. Sterile to sterile compounding does not require additional testing above present regulatory requirements. Non-sterile to sterile compounding does require testing. Since no average can be calculated and the size of a batch can be virtually any size and given that the majority of pharmacies directly affected by the requirement are small or part-time compounders. A reasonable estimate for batch testing is set at one (1) batch per day per 5 day work week.

PRIVATE ENTITY COSTS:

1. Apparel/Clothing – Estimated at $250 per month per pharmacy. The cost will be dependent on the number of individuals employed by the pharmacy.

   $250 x 61 Pharmacies x 12 months = $ 183,000.00

2. Testing: A batch is defined as one mixture or lot of one product. A batch can effectively be one (1) dose of a medication or it could consist of a large number of multiple doses of one product. Each batch must be tested for sterility, potency and pyrogenicity. The costs of testing will be determined by the number of batches prepared by a pharmacy. In many instances, 1 set of tests can be done. The Board of Pharmacy has no accurate method to measure the exact number of batches prepared in pharmacies. The number will be determined by the volume of compounding done in a pharmacy.

   For the purposes of this fiscal note, it is estimated that an average sterile compounding pharmacy would prepare 1 batch per day.

   Costs are:

Sterility Testing, per Batch	$175
Potency Testing	$300 per active ingredient
x 2 average active ingredients	$600
Pyrogenicity Testing (per batch)	$ 30.....Total per Batch $805.00

   1 Batch per day x 5 days x 52 weeks = 260 batches

   260 batches x 20 pharmacies = 5,200 batches

   It is further estimated that 20% of the 5,200 batches will require full testing i.e. 1,040

   1,040 batches at full testing x $805 per batch = $ 837,200.00

   It is further estimated that the remaining 4,160 batches would require only the sterility and potency testing at $475.00

4,160 batches x $475.00 = $ 1,976,000.00

3. Class C: Long Term Care Pharmacies classified as a Risk Levels 2 and 3 may require the use of a Barrier Isolator. It is estimated that 50% of the 29 total Class C: Long Term Care pharmacies already comply with this rule and can be taken out of this equation. (29-14 = 15 pharmacies) This results in the estimated number of pharmacies affected to be 15 pharmacies. It is estimated that 50% of these 15 pharmacies may choose to purchase a Barrier Isolator in order to comply with new environmental standards. This would be 7.5 pharmacies, rounded to 8 pharmacies

8 Class C: Long Term Care Pharmacies x $8.950 =	$ 71,600.00
Estimated additional costs for air conditioning, lighting, etc $4,000 x 8 Pharmacies	$ 32,000.00

4. The following classes of pharmacies which are Risk Level 2 and 3, will be required to maintain a clean room if a barrier isolator is deemed insufficient for compounding needs:

1	Class B: Hospital/Outpatient
7	Class C: Long Term Care Pharmacies
23	Class D: Home Health
8	Class H: Sterile Product Compounding
39	

A reasonable sized clean room is 8' x 10' x 10'. The current cost is $40.00 per cubic foot. 8' x 10' x 10' x $40.00 = $32,000.00

39 pharmacies x $32,000 = $1,248,000.00

Total Private Entity Costs $ 4,239,600.00

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

ORDER OF RULEMAKING

By the authority vested in the State Board of Pharmacy under sections 338.010, 338.140, 338.240 and 338.280, RSMo 2000, the board amends a rule as follows:

4 CSR 220-2.400 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on January 2, 2003 (28 MoReg 20–21). Changes have been made to the text of this rule. The rule is being reprinted in its entirety. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: A total of ten (10) written comments were received. In addition, a public hearing was held.

COMMENT: One (1) entity made general comments and did not direct any specific comment to a specific section of the rule. They stated that the Robert Courtney case was the basis for this amendment; that board members had been influenced by legislators and that one (1) or more board members may have been motivated by anti-competitive measures in promoting this amendment.
RESPONSE: The board did not agree with the comments directed to the rule since there was no factual basis for the comments, that no specific information was provided to indicate that any portion of the rule was anti-competitive in any way, and therefore, the board made no changes to the rule based on this comment.

COMMENT: One (1) entity stated that section (2) which is a broad restriction against the promotion of compounding products may invite a first amendment lawsuit.
RESPONSE AND EXPLANATION OF CHANGE: The original intent was to regulate against comparative, unsubstantiated claims between compounded medications and manufactured drugs, and the board feels that section (10) sufficiently addresses this issue. The board concurred with this comment and deleted the last sentence of section (2).

COMMENT: Two (2) entities commented that the definition of manufacturing in section (2) would preclude compounded prescriptions from being filled by Class J: Shared Service Pharmacies, as such activity would be considered manufacturing and that the prior rule's designation that promotion and marketing are considered manufacturing is in direct violation of the results of a recent lawsuit against the federal government which found that it was unconstitutional to limit a business's ability to promote its products. This should be corrected in the rule revision.
RESPONSE: The board disagreed with these comments and believes that the language would not prohibit compounding by Class J: Shared Service Pharmacies as long as there is a specific prescription for a specific patient involved in the process. The board disagreed with the comment regarding a pharmacy promoting its products. The board also agrees that it is a constitutional right of a pharmacy owner to promote his/her general pharmacy practices, as well as other beneficial services that the pharmacy offers. However, the promoting of specific products that have been compounded by a pharmacist, which are not the same as products that have been approved by the Food and Drug Administration (FDA), would be a violation of federal law. Any promotional claims concerning specific products of this type would be unsubstantiated. The board disagreed with this comment and no changes were made.

COMMENT: One (1) entity suggested the addition of an "and" in (5)(A)5., and that in (6)(A) the sentence beginning with "These responsibilities . . . .dispensing" should be deleted.
RESPONSE AND EXPLANATION OF CHANGE: The board concurred with these two (2) comments and changes were made accordingly.

COMMENT: One (1) entity suggested that in (6)(B), the term "reported" should be added to the last sentence regarding the drug monitoring system.
RESPONSE AND EXPLANATION OF CHANGE: The board concurred with this comment and the change was made.

COMMENT: Four (4) entities stated that subsection (5)(F) which requires the listing of all therapeutic ingredients be listed on the label is not feasible; that paragraph (6)(A)5., requiring adequate separation of quality control functions would be impossible for him to comply with since he is a one-man operation; and section (10) regarding the requirement that each compounded product be dispensed on a patient-specific prescription should be reviewed as concerns compounding for use by a physician or dentist in his/her office.
RESPONSE AND EXPLANATION OF CHANGE: The board agreed with the comment regarding therapeutic ingredients and changed the term "label" to "container." The board also agreed with the comment on paragraph (6)(A)5. and deleted that sentence. The board did not agree with the comment on section (10) and made no changes based on this comment. The practice of pharmacy is limited to the dispensing and/or compounding of drug products by prescription. Any activity in the area of compounding product outside this process could fall under the guise of manufacturing and become subject to the federal Food, Drug and Cosmetic Act.

COMMENT: One (1) entity commented that section (6) places the liability for proper preparation of manufactured drugs on pharmacies who have no direct contact with and no authority over manufacturers of drug products. Additionally, the language in paragraph (6)(A)2. is too restrictive since many commonly compounded drug products do not currently have USP monographs. The commenter suggested language to allow the pharmacist to satisfy ingredient quality requirements by utilization of the Certificate of Analysis. The commenter stated that in (6)(A)3. and 4. the language is too extreme and requires assurances that the pharmacist cannot provide.
RESPONSE AND EXPLANATION OF CHANGE: The board concurred and made changes to section (6) and its subsection based on these comments.

COMMENT: One (1) entity commented that in subsection (6)(B), the word "reported" should be added as clarification before the phrase "infection rates."
RESPONSE AND EXPLANATION OF CHANGE: The board concurred with this comment and made the change. The board felt it should clarify the language on recalls and added language in subsection (6)(C) to more completely address the recall issue.

COMMENT: Three (3) entities commented on various portions of section (7), stating that the amendments to this rule favor manufacturers; it requires pharmacists to be guarantors of the quality of products they receive, an impossible burden, it would increase the cost of liability insurance; the private entity cost is more than five hundred dollars ($500) in the aggregate; that it interferes with the physician's ability to prescribe appropriate therapies for their patients; that the word "food" should be "federal" and the entire new section (7) is outside the board's statutory authority.
RESPONSE AND EXPLANATION OF CHANGE: The board agreed with some of the comments and made appropriate changes in several areas of section (7), based on those comments, however they did not agree with the comments that section (7) is outside the board's statutory authority since the regulation of the practice of

pharmacy is clearly within the board's statutory authority under Chapter 338, RSMo. The board did not agree with the allegation that the language would prohibit the physician from prescribing appropriate therapies and noted that the intent of this language is not to bar different dosage forms but addresses the issue of making the same type of product. No change was made based on this comment.

COMMENT: Two (2) entities commented that section (10) restricts the compounding of products to patient-specific prescriptions, which may limit a patient's access to important medications during medical procedures where only a small amount of a compounded product would be used.
RESPONSE AND EXPLANATION OF CHANGE: The board disagreed with this comment because compounding, under federal law, must be done on a patient-specific prescription. The changes made to section (10) were not based on the comments, but on board review.

COMMENT: One (1) entity commented on several sections of the rule including section (1), subsection (5)(A), paragraph (5)(A)8., and sections (8), and (10) noting several minor wording changes. In addition, the commenter noted that throughout the rules, several terms are used such as "bulk compounded product," "batched product," "excess product" and "excess compounded product," all meaning the same thing. It was suggested that the board use the term "batched compounded product" and also provide a definition of this term.
RESPONSE AND EXPLANATION OF CHANGE: The board concurred with the comments and made appropriate changes throughout this rule and in addition, added a new section (3) to define a batch compounded product.

COMMENT: Several entities stated that the fiscal notes attached to this amendment were flawed.
RESPONSE: The board believes that the changes made to the amendment address the cost issue and the board did not see any additional costs.

4 CSR 220-2.400 Compounding Standards of Practice

(1) Compounding is defined as the preparation, incorporation, mixing and packaging or labeling of a drug or device as the result of a prescriber's prescription or prescription drug order based on the prescriber/patient/pharmacist relationship in the course of professional practice. Compounding may also be defined as the preparation, incorporation, mixing and packaging or labeling of a drug or device, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing purposes.

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

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

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

(5) Compounding Area and Equipment Requirements.

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

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

(C) Equipment used in the compounding of drug products shall be of appropriate design, adequate size and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in the compounding of drug products shall be of suitable composition so that surfaces that contact ingredients, in-process materials or drug products shall not be reactive, additive or absorptive so as to alter the safety, identity, strength, quality or purity of the drug product beyond that desired.

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

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

(B) Pharmacists shall only receive, store or use drug substances for compounding that have been made and/or distributed by Missouri licensed/registered drug distributors.

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

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

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

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

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

1. Methods for the compounding of drug products to insure that the finished products have the identity, strength, quality and purity they purport or are represented to possess;

2. Date of compounding;

3. Identity of the compounding pharmacist;

4. A listing of the drug products/ingredients and their amounts by weight or volume;

5. Description of the compounding process and the order of drug product/ingredient addition, if necessary for proper compounding;

6. The identity of the source, lot number and the beyond-use date of each drug product/ingredient, as well as an in-house lot number and a beyond-use date for bulk compounded products; and

7. An identifying prescription number or a readily retrievable unique identifier for which the compound was dispensed.

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

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

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

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

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

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

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

(8) Management of Compounding.

(A) A pharmacist dispensing any compounded drug is responsible for ensuring that the product has been prepared, labeled, controlled, stored, dispensed and distributed properly. The pharmacist is responsible for ensuring that quality is built into the preparation of products, with key factors including at least the following general principles:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Title 4—DEPARTMENT OF ECONOMIC DEVELOPMENT
Division 240—Public Service Commission
Chapter 120—New Manufactured Homes

ORDER OF RULEMAKING

By the authority vested in the Public Service Commission under section 700.040 and 700.115, RSMo 2000, the commission adopts a rule as follows:

4 CSR 240-120.140 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on March 17, 2003 (28 MoReg 547–548). Those sections with changes are reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: A hearing was held on April 23, 2003 at 9:00 a.m. in the Governor Office Building, 200 Madison Street, Jefferson City, Missouri. The Missouri Public Service Commission received one (1) comment on the proposed rule.

COMMENT: A manufactured home manufacturer recommended that the due date for remission of a fee that equals the number of new manufactured homes delivered or sold to dealers in the state of Missouri, multiplied by thirty dollars ($30), and for the submitting of monthly delivery reports, other filings, or other documentations required by the commission be extended from the tenth to the twentieth day following the month in which new manufactured homes were delivered or sold to dealers in the state of Missouri.

RESPONSE AND EXPLANATION OF CHANGE: The commission agrees to this change.

4 CSR 240-120.140 New Manufactured Home Manufacturer's Inspection Fee

(2) Manufacturers of new manufactured homes shall remit to the director on a monthly basis an amount that equals the number of new manufactured homes delivered or sold to dealers in the state of Missouri, multiplied by thirty dollars ($30). Each manufacturer shall submit said fee with any monthly delivery reports, or other filing, or documentation as may be required by the commission. Said fee shall be received no later than the twentieth day following the month in which new manufactured homes were delivered or sold to dealers in the state of Missouri.

Title 4—DEPARTMENT OF ECONOMIC DEVELOPMENT
Division 240—Public Service Commission
Chapter 123—Modular Units

ORDER OF RULEMAKING

By the authority vested in the Public Service Commission under section 700.040, RSMo 2000, the commission amends a rule as follows:

4 CSR 240-123.030 Seals **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 17, 2003 (28 MoReg 549–550). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 10—DEPARTMENT OF NATURAL RESOURCES
Division 10—Air Conservation Commission
Chapter 6—Air Quality Standards, Definitions, Sampling and Reference Methods and Air Pollution Control Regulations for the Entire State of Missouri

ORDER OF RULEMAKING

By the authority vested in the Missouri Air Conservation Commission under section 643.050, RSMo 2000, the commission amends a rule as follows:

10 CSR 10-6.100 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on December 16, 2002 (27 MoReg 2274–2276). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Missouri Department of Natural Resources' Air Pollution Control Program received comments from the U.S. Environmental Protection Agency (EPA).

COMMENT: The EPA commented that in paragraph (3)(D)3., the reference to 10 CSR 10-6.060(4)(A)2. should be 10 CSR 10-6.060(7)(C)2. In subparagraphs (3)(D)7.B., (3)(D)7.C. and paragraph (3)(E)3., the references to 10 CSR 10-6.060(8)(D) should be 10 CSR 10-6.410. In paragraph (3)(D)8., the reference to 10 CSR 10-6.060(8)(C) should be 10 CSR 10-6.410.

RESPONSE AND EXPLANATION OF CHANGE: The department's Air Pollution Control Program agrees and has changed the noted references.

10 CSR 10-6.100 Alternate Emission Limits

(3) General Provisions.

(D) Criteria for Approval.

1. An Alternate Emission Limits Permit application must demonstrate that the proposed control will not cause total emissions from the source operations to exceed the level of emissions determined in subsection (3)(C).

2. Applicants desiring to make use of emission reductions occurring at another installation must demonstrate that the emissions have occurred or will occur prior to the commencement of the alternate emission limit; and that the owner or operator of the installation from which emission reductions are obtained has entered a legally binding and enforceable agreement approved by the director or changed the installation's permit conditions to limit emissions of VOCs at the specified source operations to the levels and rates identified in the application.

3. No alternate emission limit may be approved which allows a new or modified source operation to exceed New Source Performance Standards (NSPS) in 10 CSR 10-6.070 or 40 CFR part 60 or the requirement for lowest achievable emission rate (LAER) in 10 CSR 10-6.060(7)(C)2.

4. No alternate emission limit may be approved which allows emissions of a hazardous pollutant from any source operation to exceed National Emission Standards for Hazardous Air Pollutants (NESHAPS) in 10 CSR 10-6.080 or 40 CFR part 61 or which allows emissions of a hazardous pollutant to increase for which a standard has not yet been promulgated.

5. An application proposing an emission decrease from process curtailments or source operation shutdowns will not be approved if the proposed decrease will be negated by countervailing emission increases occurring at other installations in the same area in response to the applicant's process curtailment or shutdown.

6. An application proposing to use emission reductions from the shutdown of an installation will not be approved. These reductions are available only to the owner of the shutdown installation for replacement purposes or to new or modified installations in the area as growth margin.

7. An application proposing to make use of emission reductions which occurred prior to applying for an alternate emission limit permit is subject to the following time constraints:

A. No application may be approved involving emission reductions which occurred prior to January 1, 1980 in the St. Louis metropolitan area or January 1, 1977 in the Kansas City metropolitan area unless the emission reductions were accounted for in the respective base year inventory as banked emission reduction credits;

B. For emission reductions which occurred between January 1, 1980 in St. Louis or January 1, 1977 in Kansas City and December 11, 1982, applications must be submitted within nine (9) months (September 11, 1983) after December 11, 1982 unless credit for the emission reductions is banked in accordance with 10 CSR 10-6.410; and

C. For emission reductions which occur after the effective date (December 11, 1982), applications must be submitted within one (1) year of the emission decrease unless credit for the emission reductions is banked in accordance with 10 CSR 10-6.410.

8. No application may be approved which proposes to use emission reductions which previously have been used to offset emission increases as described in 10 CSR 10-6.410 or to net against emission increases as discussed in the definitions of major modification and net emission increase in 10 CSR 10-6.020. Emission reductions used to create an alternate emission limit are likewise for the duration of the alternate emission limit not eligible to be banked, used for offset purposes or used to net against emission increases.

9. An application must include an expeditious schedule of implementation that adheres as closely as possible to any compliance dates the source operation would otherwise be subject to.

10. An application will be approved only if it is determined that the alternate emission limit will not interfere with attainment and maintenance of the ambient air quality standard or create any public nuisance.

11. All alternate emission limits that are approved by the director will not be considered federally enforceable (and will not shield a source from the federal obligation to comply with the underlying emission limits) by the United States Environmental Protection Agency (EPA) until submitted to the EPA and approved by the EPA.

(E) Quantification of Emission Reductions.

1. In cases where the director determines that the emission reduction estimates made by the applicant are uncertain, the director may calculate alternative emission limitations based on other estimates.

2. If necessary to quantify emission reductions to be used in an alternate emission limit, the director may require source tests, continuous monitors or any other acceptable means of measurement before and after reductions occur.

3. To quantify emission reductions which have already occurred, the director will rely on the installation's emissions reported in the base year inventory used to project attainment of the ozone standard in the State Implementation Plan and the emission inventory taken the twelve (12) months following the reduction or if credits for the emission reductions were banked in accordance with 10 CSR 10-6.410, the director will rely on the documentation provided at the time the credits were banked.

Title 15—ELECTED OFFICIALS
Division 30—Secretary of State
Chapter 45—Records Management

ORDER OF RULEMAKING

By the authority vested in the secretary of state under sections 59.319 and 109.221, RSMo 2000, the secretary amends a rule as follows:

15 CSR 30-45.030 Local Records Grant Program Administration **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 422). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 20—Division of Environmental Health and Communicable Disease Prevention
Chapter 8—Lead Program

ORDER OF RULEMAKING

By the authority vested in the director of the Department of Health and Senior Services under sections 701.340 through 701.349, RSMo Supp. 2001, the director adopts a rule as follows:

19 CSR 20-8.030 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on March 3, 2003 (28 MoReg 422–428). Those sections with changes are reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Department of Health and Senior Services received three (3) comments on the proposed rule.

COMMENT: Judith Riehl, Executive Director of the St. Louis Lead Prevention Coalition, requested that the rule be revised to underscore the importance of making considerable efforts to further define smaller geographic high-risk areas.

RESPONSE AND EXPLANATION OF CHANGE: Paragraph (2)(C)1. will be changed to reflect the importance of those efforts.

COMMENT: Judith Riehl, Executive Director of the St. Louis Lead Prevention Coalition, requests that paragraph (2)(E)2. be reconsidered as it may create "provider backlash" against lead screening.

RESPONSE AND EXPLANATION OF CHANGE: Paragraph (2)(E)2. is deleted as the department agrees that the language may cause confusion and unnecessary negative implications.

COMMENT: Judith Riehl, Executive Director of the St. Louis Lead Prevention Coalition, suggests that the rule specify how providers and communities will be notified of risk designation and the importance of screening in high-risk areas.

RESPONSE: Subsection (2)(B) provides for annual publishing of designated high-risk areas. The subsection also states that this publication shall be made available on the DHSS website. No changes have been made to the rule as a result of this comment.

19 CSR 20-8.030 Lead Poisoning Assessment, Testing, Follow-Up, and Reporting

(2) Criteria Designating Geographic Areas as High-Risk for Lead Poisoning.

(C) Reconfiguring Geographic Areas.

1. At the time of the annual lead data analysis described in subsection (2)(A) of this rule, the department will make efforts to reconfigure geographic areas into smaller areas, where at all possible, based on available census data, official population estimates, meeting acceptable margins of residential identification error for all lead tested children, new technology or software making it possible to accurately identify smaller areas, or an acceptable data-substantiated proposal made by a local health agency, as described in paragraph (2)(C)2. of this rule.

2. A local health agency may propose reconfiguration of the size or distribution of its high-risk areas, by submitting the proposal to the department by January 1 of each year. Supporting evidence must accompany the proposal. If the department adopts the proposal, it will by published in the annual listing.

(E) Redesignation of Area Risk Status. The department may redesignate a previously designated high-risk geographic area, either totally or in part, as non-high-risk for lead poisoning, or conversely, a previously designated non-high-risk geographic area may be redesignated, either totally or in part, as high-risk for lead poisoning based on the criteria in subsection (2)(A) of this rule or other new substantiated evidence.

1. Smaller geographic areas must be defined by easily recognized boundaries that are approved by the department such as, but not limited to, census tracts, city blocks, or a defined distance from a known lead hazard.

2. A local health agency may propose a redesignation of area risk status, by submitting the proposal to the department by January 1 of each year. Supporting evidence must accompany the proposal. If the department adopts the proposal, it will be published in the annual listing.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Health Standards and Licensure
Chapter 1—Controlled Substances

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 195.015 and 195.195, RSMo 2000, the department amends a rule as follows:

19 CSR 30-1.002 Schedules of Controlled Substances **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 429–434). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Health Standards and Licensure
Chapter 1—Controlled Substances

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under section 195.195, RSMo 2000, the department amends a rule as follows:

19 CSR 30-1.011 Definitions **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 434). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Health Standards and Licensure
Chapter 1—Controlled Substances

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 195.030 and 195.195, RSMo 2000, the department amends a rule as follows:

19 CSR 30-1.015 Registrations and Fees **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 434–435). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Health Standards and Licensure
Chapter 1—Controlled Substances

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under section 195.195, RSMo 2000, the department amends a rule as follows:

19 CSR 30-1.017 Registration Process **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 435–436). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Health Standards and Licensure
Chapter 1—Controlled Substances

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under section 195.195, RSMo 2000, the department amends a rule as follows:

19 CSR 30-1.019 Registration Location **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 436). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Health Standards and Licensure
Chapter 1—Controlled Substances

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under section 195.195, RSMo 2000, the department amends a rule as follows:

19 CSR 30-1.023 Registration Changes **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 436–437). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Health Standards and Licensure
Chapter 1—Controlled Substances

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under section 195.195, RSMo 2000, the department amends a rule as follows:

19 CSR 30-1.034 Security for Practitioners **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 437–438). No changes have been made to the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Health Standards and Licensure
Chapter 1—Controlled Substances

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under section 195.195, RSMo 2000, the department rescinds a rule as follows:

19 CSR 30-1.040 Dispensing and Distribution of Controlled Substances in Certain Situations **is rescinded**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on March 3, 2003 (28 MoReg 438). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 40—Division of Maternal, Child and Family Health
Chapter 9—Universal Newborn Hearing Screening Program

ORDER OF RULEMAKING

By the authority vested in the director of the Department of Health and Senior Services under section 191.937, RSMo 2000, the director amends a rule as follows:

19 CSR 40-9.020 Screening Methodologies and Procedures **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 438–439). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 60—Missouri Health Facilities Review Committee
Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rescission as follows:

19 CSR 60-50.300 Definitions for the Certificate of Need Process **is withdrawn**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on January 16, 2003 (28 MoReg 157). This proposed rescission is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars ($500).
RESPONSE: As a result, the Committee is withdrawing this proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 60—Missouri Health Facilities Review Committee
Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rule as follows:

19 CSR 60-50.300 Definitions for the Certificate of Need Process **is withdrawn**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on January 16, 2003 (28 MoReg 157–159). This proposed rule is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars ($500).
RESPONSE: As a result, the Committee is withdrawing this proposed rule.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 60—Missouri Health Facilities Review Committee
Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rescission as follows:

19 CSR 60-50.400 Letter of Intent Process **is withdrawn**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on January 16, 2003 (28 MoReg 159). This proposed rescission is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars ($500).
RESPONSE: As a result, the Committee is withdrawing this proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 60—Missouri Health Facilities Review Committee
Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rule as follows:

19 CSR 60-50.400 Letter of Intent Process **is withdrawn**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on January 16, 2003 (28 MoReg 159–160). This proposed rule is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars ($500).
RESPONSE: As a result, the Committee is withdrawing this proposed rule.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 60—Missouri Health Facilities Review Committee
Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rescission as follows:

19 CSR 60-50.410 Letter of Intent Package **is withdrawn**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on January 16, 2003 (28 MoReg 160). This proposed rescission is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars ($500).
RESPONSE: As a result, the Committee is withdrawing this proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 60—Missouri Health Facilities Review Committee
Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rule as follows:

19 CSR 60-50.410 Letter of Intent Package **is withdrawn**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on January 16, 2003 (28 MoReg 160–161). This proposed rule is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars ($500).
RESPONSE: As a result, the Committee is withdrawing this proposed rule.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 60—Missouri Health Facilities Review Committee
Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rescission as follows:

19 CSR 60-50.420 Review Process **is withdrawn**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on January 16, 2003 (28 MoReg 161). This proposed rescission is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars ($500).
RESPONSE: As a result, the Committee is withdrawing this proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 60—Missouri Health Facilities Review Committee
Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rule as follows:

19 CSR 60-50.420 Review Process **is withdrawn**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on January 16, 2003 (28 MoReg 161–162). This proposed rule is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars ($500).
RESPONSE: As a result, the Committee is withdrawing this proposed rule.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 60—Missouri Health Facilities Review Committee
Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rescission as follows:

19 CSR 60-50.430 Application Package **is withdrawn**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on January 16, 2003 (28 MoReg 162). This proposed rescission is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars ($500).
RESPONSE: As a result, the Committee is withdrawing this proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 60—Missouri Health Facilities Review Committee
Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rule as follows:

19 CSR 60-50.430 Application Package **is withdrawn**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on January 16, 2003 (28 MoReg 163–164). This proposed rule is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars ($500).
RESPONSE: As a result, the Committee is withdrawing this proposed rule.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 60—Missouri Health Facilities Review Committee
Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rescission as follows:

19 CSR 60-50.450 Criteria and Standards for Long-Term Care **is withdrawn**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on January 16, 2003 (28 MoReg 164). This proposed rescission is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars ($500).
RESPONSE: As a result, the Committee is withdrawing this proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 60—Missouri Health Facilities Review Committee
Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rule as follows:

19 CSR 60-50.450 Criteria and Standards for Long-Term Care **is withdrawn**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on January 16, 2003 (28 MoReg 164–165). This proposed rule is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars ($500).
RESPONSE: As a result, the Committee is withdrawing this proposed rule.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 60—Missouri Health Facilities Review Committee
Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rescission as follows:

19 CSR 60-50.700 Post-Decision Activity **is withdrawn**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on January 16, 2003 (28 MoReg 166). This proposed rescission is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars ($500).
RESPONSE: As a result, the Committee is withdrawing this proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 60—Missouri Health Facilities Review Committee
Chapter 50—Certificate of Need Program

ORDER OF RULEMAKING

By the authority vested in the Missouri Health Facilities Review Committee under section 197.320, RSMo 2000, the Committee withdraws a proposed rule as follows:

19 CSR 60-50.700 Post-Decision Activity **is withdrawn**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on January 16, 2003 (28 MoReg 166–167). This proposed rule is withdrawn.

SUMMARY OF COMMENTS: During the review period of the Joint Committee on Administrative Rules, issues were raised questioning how the Committee was delegating its authority to staff for non-applicability determinations, when the Criteria and Standards were being referenced as guidelines, and why the fiscal note did not exceed five hundred dollars ($500).
RESPONSE: As a result, the Committee is withdrawing this proposed rule.

Title 20—DEPARTMENT OF INSURANCE
Division 300—Market Conduct Examinations
Chapter 2—Record Retention for Market Conduct Examinations

ORDER OF RULEMAKING

By the authority vested in the director of the Missouri Department of Insurance under section 374.045, RSMo 2000, the director amends a rule as follows:

20 CSR 300-2.200 Records Required for Purposes of Market Conduct Examinations **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on March 3, 2003 (28 MoReg 439–440). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The Missouri Department of Insurance received seven (7) comments on the proposed amendment.
COMMENT: Each person or entity that submitted comments supported the proposed amendment, which deletes the provisions of the regulation relating to third-party vendors and service providers.
RESPONSE: The department concurs with the above-referenced comments and has, therefore, not made any changes to the language of the proposed amendment.

This section may contain notice of hearings, correction notices, public information notices, rule action notices, statements of actual costs and other items required to be published in the *Missouri Register* by law.

Title 4—DEPARTMENT OF ECONOMIC DEVELOPMENT
Division 100—Division of Credit Unions

APPLICATIONS FOR NEW GROUPS OR GEOGRAPHIC AREAS

Pursuant to section 370.081(4), RSMo 2000, the director of the Missouri Division of Credit Unions is required to cause notice to be published that the following credit unions have submitted applications to add new groups or geographic areas to their membership.

Credit Union	Proposed New Group or Geographic Area
Southeast Telephone Employees Credit Union 312 West Main PO Box 335 Park Hills, MO 63601	Persons who live or are employed in the Missouri Counties of St. Francois County, Ste. Genevieve County, and Madison County
Anheuser Busch Employees' Credit Union 1001 Lynch Street St. Louis, MO 63118	People who live or work, or legal entities in zip codes 63103, 63110, 63116, 63118, as well as legal entities in zip code 63104

NOTICE TO SUBMIT COMMENTS: Anyone may file a written statement in support of or in opposition to any of these applications. Comments shall be filed with: Director, Division of Credit Unions, PO Box 1607, Jefferson City, MO 65102. To be considered, written comments must be submitted no later than ten (10) business days after publication of this notice in the ***Missouri Register****.*

The Secretary of State is required by sections 347.141 and 359.481, RSMo 2000 to publish dissolutions of limited liability companies and limited partnerships. The content requirements for the one-time publishing of these notices are prescribed by statute. This listing is published pursuant to these statutes. We request that documents submitted for publication in this section be submitted in camera ready 8 1/2" x 11" manuscript.

NOTICE OF LIMITED LIABILITY COMPANY DISSOLUTION TO ALL CREDITORS AND CLAIMANTS AGAINST LEVINSON HOLDINGS, L.L.C.

On April 30, 2003, **LEVINSON HOLDINGS, L.L.C.**, a Missouri Limited Liability Company, filed its Articles of Termination with the Missouri Secretary of State. Any claims against the L.L.C., should be sent to Merle L. Silverstein, 7733 Forsyth Blvd., Suite 400, St. Louis, Missouri 63105. All claims must include the name, address and phone number of the claimant; the amount of the claim; the basis of the claim; and the date the claim arose.

All claims must be received by the L.L.C. within three (3) years after publication of this notice. Any claims not received by that date will be barred.

NOTICE TO ALL CREDITORS AND CLAIMANTS OF

CAPITAL CITY HOTEL COMPANY, L.L.C.

You are hereby notified that on March 31, 2003, Capital City Hotel Company, L.L.C., a Missouri limited liability company, agreed to dissolve and wind up the L.L.C. Any claims against the L.L.C. should be sent to RHW Management, Inc. 6704 West 121st Street, Overland Park, Kansas 66209. All claims must include the name, address and phone number of the claimant; amount of the claim; basis for the claim; and documentation of the claim. All claims must be received by the L.L.C. within three (3) years after publication of this Notice. Any claims not received by that date will be barred.

OFFICE OF ADMINISTRATION
Division of Purchasing

BID OPENINGS

Sealed Bids will be received by the Division of Purchasing, Room 630, Truman Building, PO Box 809, Jefferson City, MO 65102, telephone (573) 751-2387 at 2:00 p.m. on dates specified below for various agencies throughout Missouri. Bids are available to download via our homepage: www.moolb.state.mo.us.

B1E03314	Safety Supplies: WMD Protective Clothing 6/16/03
B1E03102	Diabetic Supplies Rebate 6/17/03
B1E03312	Raised Flooring: Tate 6/17/03
B3Z03248	Audit Services/Area Agencies 6/17/03
B3Z03260	1115 Demonstration and Senate Bill 632 Evaluation 6/17/03
B2Z03058	WIC/Data Warehouse Support Services 6/18/03
B1E03318	Foods, Frozen 6/19/03
B3E03258	Drug Testing using Sweat Patch 6/19/03
B1E03315	Chemical Products 6/20/03
B1E03322	Respiratory Protection 6//23/03
B1E03317	Maintenance: Aircraft 6/24/03
B1E03321	Self Contained Breathing Apparatus 6/24/03
B3Z03114	Underground Storage Tank Investigation and Remediation Services 6/24/03
B3Z03158	Banking Services for WIC 6/24/03
B3Z03253	Fund Administration Services 6/25/03
B3Z03160	Exhibit Production 8/6/03

It is the intent of the State of Missouri, Division of Purchasing to purchase each of the following as a single feasible source without competitive bids. If suppliers exist other than the ones identified, please call (573) 751-2387 immediately.

Secretary of State Knowledge Base (SOSKB) Ongoing Maintenance and Enhancement Services, supplied by Office Automation Solutions.

HemoCue Microcuvettes, supplied by HemoCue, Inc. of Lake Forest, CA.

James Miluski, CPPO,
Director of Purchasing

This cumulative table gives you the latest status of rules. It contains citations of rulemakings adopted or proposed after deadline for the monthly Update Service to the *Code of State Regulations*, citations are to volume and page number in the *Missouri Register*, except for material in this issue. The first number in the table cite refers to the volume number or the publication year—26 (2001), 27 (2002) and 28 (2003). MoReg refers to *Missouri Register* and the numbers refer to a specific *Register* page, R indicates a rescission, W indicates a withdrawal, S indicates a statement of actual cost, T indicates an order terminating a rule, N.A. indicates not applicable, RUC indicates a rule under consideration, and F indicates future effective date.

Rule Number	Agency	Emergency	Proposed	Order	In Addition
	OFFICE OF ADMINISTRATION				
1 CSR 10	State Officials' Salary Compensation Schedule				27 MoReg 189 27 MoReg 1724
1 CSR 20-2.015	Personnel Advisory Board and Division of Personnel		28 MoReg 225	28 MoReg 983	
	DEPARTMENT OF AGRICULTURE				
2 CSR 30-2.010	Animal Health		28 MoReg 399 28 MoReg 707	This Issue	
2 CSR 30-2.020	Animal Health		28 MoReg 399 28 MoReg 708 28 MoReg 708	This Issue	
2 CSR 30-2.040	Animal Health		28 MoReg 400 28 MoReg 711	This Issue	
2 CSR 30-6.020	Animal Health		28 MoReg 400	This Issue	
2 CSR 30-9.020	Animal Health		This Issue		
2 CSR 30-9.030	Animal Health		This Issue		
2 CSR 70-16.010	Plant Industries		28 MoReg 308		
2 CSR 70-16.015	Plant Industries		28 MoReg 308		
2 CSR 70-16.020	Plant Industries		28 MoReg 309		
2 CSR 70-16.025	Plant Industries		28 MoReg 309		
2 CSR 70-16.030	Plant Industries		28 MoReg 312		
2 CSR 70-16.035	Plant Industries		28 MoReg 314		
2 CSR 70-16.040	Plant Industries		28 MoReg 314		
2 CSR 70-16.045	Plant Industries		28 MoReg 314		
2 CSR 70-16.050	Plant Industries		28 MoReg 315		
2 CSR 70-16.055	Plant Industries		28 MoReg 315		
2 CSR 70-16.060	Plant Industries		28 MoReg 316		
2 CSR 70-16.065	Plant Industries		28 MoReg 318		
2 CSR 70-16.070	Plant Industries		28 MoReg 318		
2 CSR 70-16.075	Plant Industries		28 MoReg 318		
2 CSR 80-5.010	State Milk Board		28 MoReg 637		
2 CSR 90-10.040	Weights and Measures		27 MoReg 1161		
2 CSR 90-30.050	Weights and Measures		27 MoReg 1565		
	DEPARTMENT OF CONSERVATION				
3 CSR 10-4.111	Conservation Commission		This Issue		
3 CSR 10-6.405	Conservation Commission		28 MoReg 851		
3 CSR 10-7.410	Conservation Commission		This Issue		
3 CSR 10-7.455	Conservation Commission		This Issue		
3 CSR 10-9.110	Conservation Commission		28 MoReg 400 This Issue	28 MoReg 983	
3 CSR 10-9.565	Conservation Commission		28 MoReg 401	28 MoReg 983	
3 CSR 10-10.726	Conservation Commission		28 MoReg 851		
3 CSR 10-10.732	Conservation Commission		28 MoReg 852		
3 CSR 10-10.745	Conservation Commission		N.A.	This IssueR	
3 CSR 10-11.160	Conservation Commission		This Issue		
3 CSR 10-11.180	Conservation Commission		This Issue		
3 CSR 10-11.182	Conservation Commission		This Issue		
3 CSR 10-11.186	Conservation Commission		28 MoReg 402 This Issue	28 MoReg 983	
3 CSR 10-11.205	Conservation Commission		28 MoReg 402 This Issue	28 MoReg 984	
3 CSR 10-11.210	Conservation Commission		28 MoReg 403	28 MoReg 984	
3 CSR 10-12.110	Conservation Commission		This Issue		
3 CSR 10-12.135	Conservation Commission		This Issue		
3 CSR 10-12.140	Conservation Commission		This Issue		
	DEPARTMENT OF ECONOMIC DEVELOPMENT				
4 CSR 10-2.022	Missouri State Board of Accountancy		27 MoReg 2266	28 MoReg 984	
4 CSR 30 4.060	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Landscape Architects		28 MoReg 128	28 MoReg 897	

Rule Number	Agency	Emergency	Proposed	Order	In Addition
4 CSR 30-11.030	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Landscape Architects		28 MoReg 131	28 MoReg 897	
4 CSR 30-13.010	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Landscape Architects		27 MoReg 2145	28 MoReg 897	
4 CSR 30-16.020	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Landscape Architects		28 MoReg 852		
4 CSR 30-16.030	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Landscape Architects		28 MoReg 853		
4 CSR 30-16.040	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Landscape Architects		28 MoReg 854		
4 CSR 30-16.060	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Landscape Architects		28 MoReg 855		
4 CSR 30-16.070	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Landscape Architects		28 MoReg 855		
4 CSR 30-16.080	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Landscape Architects		28 MoReg 855		
4 CSR 30-16.090	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Landscape Architects		28 MoReg 856		
4 CSR 30-16.100	Missouri Board for Architects, Professional Engineers, Professional Land Surveyors, and Landscape Architects		28 MoReg 856		
4 CSR 90-13.010	State Board of Cosmetology		28 MoReg 135	28 MoReg 898	
4 CSR 90-13.050	State Board of Cosmetology		28 MoReg 137	28 MoReg 898	
4 CSR 100	Division of Credit Unions				28 MoReg 814 28 MoReg 914 This Issue
4 CSR 140-2.055	Division of Finance		28 MoReg 319		
4 CSR 140-2.140	Division of Finance		28 MoReg 320		
4 CSR 140-11.010	Division of Finance		28 MoReg 320R		
4 CSR 140-11.020	Division of Finance		28 MoReg 320R		
4 CSR 140-11.030	Division of Finance		28 MoReg 321		
4 CSR 140-11.040	Division of Finance		28 MoReg 322		
4 CSR 145-1.030	Missouri Board of Geologist Registration		28 MoReg 857		
4 CSR 145-2.030	Missouri Board of Geologist Registration		28 MoReg 857		
4 CSR 145-2.100	Missouri Board of Geologist Registration		28 MoReg 857		
4 CSR 150-5.100	State Board of Registration for the Healing Arts		27 MoReg 2146	28 MoReg 898	
4 CSR 150-8.140	State Board of Registration for the Healing Arts		28 MoReg 139	28 MoReg 898	
4 CSR 165-2.010	Board of Examiners for Hearing Instrument Specialists		28 MoReg 857		
4 CSR 165-2.030	Board of Examiners for Hearing Instrument Specialists		28 MoReg 858		
4 CSR 165-2.060	Board of Examiners for Hearing Instrument Specialists		28 MoReg 858		
4 CSR 196-1.010	Landscape Architectural Council		27 MoReg 2146R	28 MoReg 899R	
4 CSR 200-4.010	State Board of Nursing		28 MoReg 541		
4 CSR 200-4.200	State Board of Nursing		27 MoReg 2150	28 MoReg 899	
4 CSR 220-2.010	State Board of Pharmacy		28 MoReg 543		
4 CSR 220-2.020	State Board of Pharmacy		28 MoReg 9	28 MoReg 899	
4 CSR 220-2.030	State Board of Pharmacy		27 MoReg 2268	28 MoReg 900	
4 CSR 220-2.130	State Board of Pharmacy		28 MoReg 403		
4 CSR 220-2.190	State Board of Pharmacy		27 MoReg 2268	28 MoReg 900W	
4 CSR 220-2.200	State Board of Pharmacy		28 MoReg 10R 28 MoReg 10	This IssueR This Issue	
4 CSR 220-2.400	State Board of Pharmacy		28 MoReg 20	This Issue	
4 CSR 220-2.650	State Board of Pharmacy		28 MoReg 21	28 MoReg 900	
4 CSR 220-2.700	State Board of Pharmacy		27 MoReg 2268	28 MoReg 900	
4 CSR 220-2.900	State Board of Pharmacy		28 MoReg 543		
4 CSR 230-2.070	State Board of Podiatric Medicine		28 MoReg 139	28 MoReg 900	
4 CSR 235-1.020	State Committee of Psychologists		28 MoReg 545		
4 CSR 240-3.180	Public Service Commission		28 MoReg 1024		
4 CSR 240-3.250	Public Service Commission		28 MoReg 1028		
4 CSR 240-20.065	Public Service Commission		28 MoReg 711		
4 CSR 240-31.010	Public Service Commission		27 MoReg 2159	28 MoReg 1048	
4 CSR 240-31.050	Public Service Commission		27 MoReg 2160	28 MoReg 1048	
4 CSR 240-31.060	Public Service Commission		27 MoReg 2163	28 MoReg 1049	
4 CSR 240-31.065	Public Service Commission		27 MoReg 2166	28 MoReg 1049	
4 CSR 240-33.070	Public Service Commission		27 MoReg 2169	28 MoReg 1050	
4 CSR 240-40.018	Public Service Commission		28 MoReg 1032		
4 CSR 240-120.085	Public Service Commission		28 MoReg 1032		
4 CSR 240-120.140	Public Service Commission	28 MoReg 287	28 MoReg 547	This Issue	
4 CSR 240-121.065	Public Service Commission		28 MoReg 1035		
4 CSR 240-123.030	Public Service Commission	28 MoReg 288	28 MoReg 549	This Issue	
4 CSR 240-123.095	Public Service Commission		28 MoReg 1037		
4 CSR 263-1.010	State Committee for Social Workers		27 MoReg 2169	28 MoReg 900	
4 CSR 263-1.015	State Committee for Social Workers		27 MoReg 2170	28 MoReg 901	
4 CSR 263-1.025	State Committee for Social Workers		27 MoReg 2170	28 MoReg 901	
4 CSR 263-1.035	State Committee for Social Workers		27 MoReg 2170	28 MoReg 901	
4 CSR 263-2.020	State Committee for Social Workers		27 MoReg 2171	28 MoReg 902	
4 CSR 263-2.022	State Committee for Social Workers		27 MoReg 2171	28 MoReg 902	

Rule Number	Agency	Emergency	Proposed	Order	In Addition
4 CSR 263-2.030	State Committee for Social Workers		27 MoReg 2171	28 MoReg 902	
4 CSR 263-2.031	State Committee for Social Workers		27 MoReg 2172	28 MoReg 903	
4 CSR 263-2.032	State Committee for Social Workers		27 MoReg 2173	28 MoReg 903	
4 CSR 263-2.045	State Committee for Social Workers		27 MoReg 2174	28 MoReg 904	
4 CSR 263-2.047	State Committee for Social Workers		27 MoReg 2174	28 MoReg 904	
4 CSR 263-2.050	State Committee for Social Workers		27 MoReg 2178	28 MoReg 904	
4 CSR 263-2.052	State Committee for Social Workers		27 MoReg 2178	28 MoReg 905	
4 CSR 263-2.060	State Committee for Social Workers		27 MoReg 2182	28 MoReg 905	
4 CSR 263-2.062	State Committee for Social Workers		27 MoReg 2182	28 MoReg 905	
4 CSR 263-2.070	State Committee for Social Workers		27 MoReg 2186	28 MoReg 906	
4 CSR 263-2.072	State Committee for Social Workers		27 MoReg 2186	28 MoReg 906	
4 CSR 263-2.075	State Committee for Social Workers		27 MoReg 2186	28 MoReg 906	
4 CSR 267-4.020	Office of Tattooing, Body Piercing and Branding	28 MoReg 947			
4 CSR 270-1.021	Missouri Veterinary Medical Board		28 MoReg 859		
4 CSR 270-1.031	Missouri Veterinary Medical Board		28 MoReg 861		
4 CSR 270-2.051	Missouri Veterinary Medical Board		28 MoReg 861		
4 CSR 270-4.031	Missouri Veterinary Medical Board		28 MoReg 861		
4 CSR 270-4.042	Missouri Veterinary Medical Board		28 MoReg 861		
4 CSR 270-4.060	Missouri Veterinary Medical Board		28 MoReg 862		
4 CSR 270-7.010	Missouri Veterinary Medical Board		28 MoReg 864		
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5 CSR 30-4.010	Division of Administrative and Financial Services		28 MoReg 322R		
5 CSR 50-310.010	Division of School Improvement		28 MoReg 1039R		
5 CSR 50-340.110	Division of School Improvement		28 MoReg 1039		
5 CSR 50-340.150	Division of School Improvement		27 MoReg 2193	28 MoReg 909	
5 CSR 50-340.200	Division of School Improvement		28 MoReg 1040		
5 CSR 50-350.015	Division of School Improvement		28 MoReg 1042R		
5 CSR 50-350.040	Division of School Improvement		28 MoReg 640		
5 CSR 50-355.100	Division of School Improvement		28 MoReg 323		
5 CSR 50-360.010	Division of School Improvement		28 MoReg 1042R		
5 CSR 50-370.010	Division of School Improvement		28 MoReg 1042R		
5 CSR 60-900.050	Vocational and Adult Education		This Issue		
5 CSR 70-742.160	Special Education		28 MoReg 1042R		
5 CSR 80-850.045	Teacher Quality and Urban Education		27 MoReg 2198	28 MoReg 910	
5 CSR 90-4.410	Vocational Rehabilitation		28 MoReg 864		
5 CSR 90-4.420	Vocational Rehabilitation		28 MoReg 864		
5 CSR 90-5.410	Vocational Rehabilitation		28 MoReg 864		
5 CSR 90-5.420	Vocational Rehabilitation		28 MoReg 867		
5 CSR 90-5.440	Vocational Rehabilitation		28 MoReg 869		
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6 CSR 10-6.010	Commissioner of Higher Education		28 MoReg 956		
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7 CSR 10-6.020	Missouri Highways and Transportation Commission		28 MoReg 960		
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7 CSR 10-6.070	Missouri Highways and Transportation Commission		28 MoReg 964		
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7 CSR 10-6.090	Missouri Highways and Transportation Commission		28 MoReg 968		
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7 CSR 10-10.010	Missouri Highways and Transportation Commission		28 MoReg 21	28 MoReg 984	
7 CSR 10-10.030	Missouri Highways and Transportation Commission		28 MoReg 23	28 MoReg 984	
7 CSR 10-10.040	Missouri Highways and Transportation Commission		28 MoReg 23	28 MoReg 985	
7 CSR 10-10.050	Missouri Highways and Transportation Commission		28 MoReg 24	28 MoReg 985	
7 CSR 10-10.060	Missouri Highways and Transportation Commission		28 MoReg 24	28 MoReg 985	
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7 CSR 10-10.090	Missouri Highways and Transportation Commission		28 MoReg 26	28 MoReg 985	
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8 CSR 10-3.130	Division of Employment Security	28 MoReg 948	28 MoReg 969		
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9 CSR 10-5.220	Director, Department of Mental Health	28 MoReg 847	28 MoReg 873		
9 CSR 10-7.090	Director, Department of Mental Health	28 MoReg 848	28 MoReg 873		
9 CSR 10-7.130	Director, Department of Mental Health		28 MoReg 645		
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9 CSR 45-5.060	Division of Mental Retardation and Developmental Disabilities	28 MoReg 848	28 MoReg 874		
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10 CSR 10-2.340	Air Conservation Commission		28 MoReg 325		
10 CSR 10-2.390	Air Conservation Commission		28 MoReg 552		
10 CSR 10-3.090	Air Conservation Commission		28 MoReg 553		
10 CSR 10-4.070	Air Conservation Commission		28 MoReg 553		
10 CSR 10-5.160	Air Conservation Commission		28 MoReg 554		
10 CSR 10-5.480	Air Conservation Commission		28 MoReg 555		
10 CSR 10-6.020	Air Conservation Commission		28 MoReg 719		
10 CSR 10-6.060	Air Conservation Commission		28 MoReg 724		
10 CSR 10-6.061	Air Conservation Commission		28 MoReg 728		
10 CSR 10-6.062	Air Conservation Commission		28 MoReg 731		
10 CSR 10-6.065	Air Conservation Commission		28 MoReg 734		
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10 CSR 10-6.080	Air Conservation Commission		28 MoReg 559		
10 CSR 10-6.100	Air Conservation Commission		27 MoReg 2274	This Issue	
10 CSR 10-6.110	Air Conservation Commission		This Issue		
10 CSR 10-6.350	Air Conservation Commission		28 MoReg 141		
10 CSR 20-6.010	Air Conservation Commission		This Issue		
10 CSR 23-5.050	Division of Geology and Land Survey		28 MoReg 150	28 MoReg 986	
10 CSR 25-12.010	Hazardous Waste Management Commission		28 MoReg 874		
10 CSR 30-2.020	Land Survey		28 MoReg 878		
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10 CSR 30-2.040	Land Survey		28 MoReg 879		
10 CSR 30-2.060	Land Survey		28 MoReg 880		
10 CSR 30-2.070	Land Survey		28 MoReg 880		
10 CSR 30-2.080	Land Survey		28 MoReg 880		
10 CSR 30-2.090	Land Survey		28 MoReg 881		
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10 CSR 60-2.015	Public Drinking Water Program		28 MoReg 735		
10 CSR 60-4.010	Public Drinking Water Program		28 MoReg 969		
10 CSR 60-4.020	Public Drinking Water Program		28 MoReg 736		
10 CSR 60-4.030	Public Drinking Water Program		28 MoReg 737		
10 CSR 60-4.040	Public Drinking Water Program		28 MoReg 739		
10 CSR 60-4.050	Public Drinking Water Program		28 MoReg 739		
10 CSR 60-4.055	Public Drinking Water Program		28 MoReg 744		
10 CSR 60-4.070	Public Drinking Water Program		28 MoReg 746		
10 CSR 60-4.090	Public Drinking Water Program		28 MoReg 747		
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10 CSR 60-6.050	Public Drinking Water Program		28 MoReg 753		
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10 CSR 60-8.010	Public Drinking Water Program		28 MoReg 757R 28 MoReg 757		
10 CSR 60-8.030	Public Drinking Water Program		28 MoReg 764		
10 CSR 60-9.010	Public Drinking Water Program		28 MoReg 776		
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10 CSR 70-8.050	Soil and Water Districts Commission		27 MoReg 2279	28 MoReg 987	
10 CSR 70-8.060	Soil and Water Districts Commission		27 MoReg 2280	28 MoReg 987	
10 CSR 70-8.070	Soil and Water Districts Commission		27 MoReg 2281	28 MoReg 987	
10 CSR 70-8.080	Soil and Water Districts Commission		27 MoReg 2282	28 MoReg 987	
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10 CSR 70-8.120	Soil and Water Districts Commission		27 MoReg 2284	28 MoReg 988	
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11 CSR 40-2.040	Division of Fire Safety		28 MoReg 646R		
11 CSR 40-2.050	Division of Fire Safety		28 MoReg 646R		
11 CSR 40-2.060	Division of Fire Safety		28 MoReg 646R		
11 CSR 40-5.020	Division of Fire Safety		28 MoReg 27	28 MoReg 910	
11 CSR 40-5.050	Division of Fire Safety		28 MoReg 27	28 MoReg 910	
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11 CSR 40-5.070	Division of Fire Safety		28 MoReg 32	28 MoReg 911	
11 CSR 40-5.080	Division of Fire Safety		28 MoReg 33	28 MoReg 911	
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11 CSR 40-5.120	Division of Fire Safety		28 MoReg 33	28 MoReg 911	
11 CSR 40-6.010	Division of Fire Safety		28 MoReg 973		
11 CSR 40-6.020	Division of Fire Safety		28 MoReg 974		
11 CSR 40-6.031	Division of Fire Safety		28 MoReg 974		
11 CSR 40-6.040	Division of Fire Safety		28 MoReg 977		
11 CSR 40-6.045	Division of Fire Safety		28 MoReg 977		
11 CSR 40-6.050	Division of Fire Safety		28 MoReg 977		
11 CSR 40-6.055	Division of Fire Safety		28 MoReg 978		
11 CSR 40-6.060	Division of Fire Safety		28 MoReg 980		
11 CSR 40-6.075	Division of Fire Safety		28 MoReg 980		
11 CSR 40-6.080	Division of Fire Safety		28 MoReg 980		
11 CSR 40-6.085	Division of Fire Safety		28 MoReg 981		
11 CSR 45-3.010	Missouri Gaming Commission		28 MoReg 403		
11 CSR 45-4.260	Missouri Gaming Commission		28 MoReg 34		
11 CSR 45-5.200	Missouri Gaming Commission		28 MoReg 404		
11 CSR 45-9.030	Missouri Gaming Commission		This Issue		
11 CSR 45-10.030	Missouri Gaming Commission		28 MoReg 649		
11 CSR 45-30.540	Missouri Gaming Commission		This Issue		
11 CSR 45-30.550	Missouri Gaming Commission		This Issue		
11 CSR 50-2.430	Missouri State Highway Patrol	28 MoReg 629	28 MoReg 649		
11 CSR 50-2.440	Missouri State Highway Patrol	28 MoReg 629	28 MoReg 650		
11 CSR 75-13.010	Peace Officer Standards and Training Program		28 MoReg 1043		
11 CSR 75-14.030	Peace Officer Standards and Training Program		28 MoReg 1043		
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12 CSR 10-23.190	Director of Revenue *(Changed to 12 CSR 10-26.180)*		This Issue		
12 CSR 10-23.446	Director of Revenue		28 MoReg 981		
12 CSR 10-24.140	Director of Revenue		28 MoReg 404		
12 CSR 10-26.100	Director of Revenue		28 MoReg 150R	28 MoReg 912R	
12 CSR 10-26.180	Director of Revenue *(Changed from 12 CSR 10-23.190)*		This Issue		
12 CSR 10-110.900	Director of Revenue		28 MoReg 881		
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13 CSR 40-31.025	Division of Family Services		28 MoReg 34		
13 CSR 70-1.020	Division of Medical Services		28 MoReg 405		
13 CSR 70-3.065	Division of Medical Services	28 MoReg 288	28 MoReg 327		28 MoReg 592
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13 CSR 70-10.015	Division of Medical Services	28 MoReg 103	28 MoReg 150	28 MoReg 988	
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13 CSR 70-15.110	Division of Medical Services	28 MoReg 1023	28 MoReg 1044		
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13 CSR 70-40.010	Division of Medical Services	28 MoReg 397T	28 MoReg 650		
13 CSR 70-98.010	Division of Medical Services		This Issue		
13 CSR 73-1.010	Missouri Board of Nursing Home Administrators *(Changed to 19 CSR 73-1.010)*		28 MoReg 412		
13 CSR 73-2.015	Missouri Board of Nursing Home Administrators *(Changed to 19 CSR 73-2.015)*		28 MoReg 412		
13 CSR 73-2.020	Missouri Board of Nursing Home Administrators *(Changed to 19 CSR 73-2.020)*		28 MoReg 412		
13 CSR 73-2.025	Missouri Board of Nursing Home Administrators *(Changed to 19 CSR 73-2.025)*		28 MoReg 417		
13 CSR 73-2.031	Missouri Board of Nursing Home Administrators *(Changed to 19 CSR 73-2.031)*		28 MoReg 417		

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13 CSR 73-2.051	Missouri Board of Nursing Home Administrators *(Changed to 19 CSR 73-2.051)*		28 MoReg 419		
13 CSR 73-2.055	Missouri Board of Nursing Home Administrators *(Changed to 19 CSR 73-2.055)*		28 MoReg 419		
13 CSR 73-2.060	Missouri Board of Nursing Home Administrators *(Changed to 19 CSR 73-2.060)*		28 MoReg 420		
13 CSR 73-2.080	Missouri Board of Nursing Home Administrators *(Changed to 19 CSR 73-2.080)*		28 MoReg 420		
13 CSR 73-2.085	Missouri Board of Nursing Home Administrators *(Changed to 19 CSR 73-2.085)*		28 MoReg 421		
13 CSR 73-2.090	Missouri Board of Nursing Home Administrators *(Changed to 19 CSR 73-2.090)*		28 MoReg 421		
13 CSR 73-2.095	Missouri Board of Nursing Home Administrators *(Changed to 19 CSR 73-2.095)*		28 MoReg 421		
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15 CSR 30-54.015	Secretary of State		28 MoReg 562		
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15 CSR 30-54.070	Secretary of State		28 MoReg 563R 28 MoReg 563		
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15 CSR 30-54.220	Secretary of State		28 MoReg 564R		
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15 CSR 30-59.060	Secretary of State		28 MoReg 565R		
15 CSR 30-59.170	Secretary of State		28 MoReg 565		
15 CSR 30-80.010	Secretary of State	28 MoReg 949	28 MoReg 982		
15 CSR 60-11.010	Attorney General		28 MoReg 331		
15 CSR 60-11.020	Attorney General		28 MoReg 331		
15 CSR 60-11.030	Attorney General		28 MoReg 332		
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15 CSR 60-11.100	Attorney General		28 MoReg 335		
15 CSR 60-11.110	Attorney General		28 MoReg 335		
15 CSR 60-11.120	Attorney General		28 MoReg 335		
15 CSR 60-11.130	Attorney General		28 MoReg 335		
15 CSR 60-11.140	Attorney General		28 MoReg 336		
15 CSR 60-11.150	Attorney General		28 MoReg 336		
15 CSR 60-11.160	Attorney General		28 MoReg 337		
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16 CSR 50-2.090	The County Employees' Retirement Fund		28 MoReg 156 28 MoReg 1047	28 MoReg 913	
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19 CSR 20-20.020	Office of the Director	28 MoReg 7	28 MoReg 36	28 MoReg 913	
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19 CSR 20-20.092	Division of Environmental Health and Communicable Disease Prevention		28 MoReg 777		
19 CSR 30-1.002	Division of Health Standards and Licensure		28 MoReg 429	This Issue	
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19 CSR 30-1.017	Division of Health Standards and Licensure		28 MoReg 435	This Issue	
19 CSR 30-1.019	Division of Health Standards and Licensure		28 MoReg 436	This Issue	
19 CSR 30-1.023	Division of Health Standards and Licensure		28 MoReg 437	This Issue	
19 CSR 30-1.034	Division of Health Standards and Licensure		28 MoReg 437	This Issue	
19 CSR 30-1.040	Division of Health Standards and Licensure		28 MoReg 438R	This IssueR	
19 CSR 30-40.309	Division of Health Standards and Licensure	28 MoReg 849	28 MoReg 896		
19 CSR 40-5.010	Division of Maternal, Child and Family Health *(Changed to 19 CSR 45-5.010)*				28 MoReg 914
19 CSR 40-5.020	Division of Maternal, Child and Family Health *(Changed to 19 CSR 45-5.020)*				28 MoReg 914
19 CSR 40-5.050	Division of Maternal, Child and Family Health *(Changed to 19 CSR 45-5.050)*				28 MoReg 914
19 CSR 40-5.060	Division of Maternal, Child and Family Health *(Changed to 19 CSR 45-5.060)*				28 MoReg 914
19 CSR 40-9.020	Division of Maternal, Child and Family Health		28 MoReg 438	This Issue	
19 CSR 45-5.010	Division of Nutritional Health and Services *(Changed from 19 CSR 40-5.010)*				28 MoReg 914
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19 CSR 60-50.400	Missouri Health Facilities Review Committee	28 MoReg 108R 28 MoReg 109	28 MoReg 159R 28 MoReg 159	This IssueRW This IssueW	
19 CSR 60-50.410	Missouri Health Facilities Review Committee	28 MoReg 110R 28 MoReg 110	28 MoReg 160R 28 MoReg 160	This IssueRW This IssueW	
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19 CSR 73-2.015	Missouri Board of Nursing Home Administrators *(Changed from 13 CSR 73-2.015)*		28 MoReg 412		
19 CSR 73-2.020	Missouri Board of Nursing Home Administrators *(Changed from 13 CSR 73-2.020)*		28 MoReg 412		
19 CSR 73-2.025	Missouri Board of Nursing Home Administrators *(Changed from 13 CSR 73-2.025)*		28 MoReg 417		
19 CSR 73-2.031	Missouri Board of Nursing Home Administrators *(Changed from 13 CSR 73-2.031)*		28 MoReg 417		
19 CSR 73-2.050	Missouri Board of Nursing Home Administrators *(Changed from 13 CSR 73-2.050)*		28 MoReg 418		
19 CSR 73-2.051	Missouri Board of Nursing Home Administrators *(Changed from 13 CSR 73-2.051)*		28 MoReg 419		
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19 CSR 73-2.085	Missouri Board of Nursing Home Administrators *(Changed from 13 CSR 73-2.085)*		28 MoReg 421		
19 CSR 73-2.090	Missouri Board of Nursing Home Administrators *(Changed from 13 CSR 73-2.090)*		28 MoReg 421		
19 CSR 73-2.095	Missouri Board of Nursing Home Administrators *(Changed from 13 CSR 73-2.095)*		28 MoReg 421		
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20 CSR	Sovereign Immunity Limits				26 MoReg 75 27 MoReg 41 27 MoReg 2319
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20 CSR 500-1.210	Property and Casualty		27 MoReg 2219	28 MoReg 1050	
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22 CSR 10-2.010	Health Care Plan	28 MoReg 118	28 MoReg 226	28 MoReg 989	
22 CSR 10-2.020	Health Care Plan	28 MoReg 120	28 MoReg 229	28 MoReg 989	
22 CSR 10-2.040	Health Care Plan	28 MoReg 121R	28 MoReg 230R	28 MoReg 989R	
22 CSR 10-2.045	Health Care Plan	28 MoReg 122	28 MoReg 230	28 MoReg 989	
22 CSR 10-2.050	Health Care Plan	28 MoReg 123R	28 MoReg 231R	28 MoReg 989R	
22 CSR 10-2.055	Health Care Plan	28 MoReg 123	28 MoReg 232	28 MoReg 990	
22 CSR 10-2.060	Health Care Plan	28 MoReg 125R	28 MoReg 233R	28 MoReg 990R	
22 CSR 10-2.063	Health Care Plan	28 MoReg 125R	28 MoReg 233R	28 MoReg 990R	
22 CSR 10-2.064	Health Care Plan	28 MoReg 125R	28 MoReg 234R	28 MoReg 990R	
22 CSR 10-2.067	Health Care Plan	28 MoReg 125R	28 MoReg 234R	28 MoReg 990R	
22 CSR 10-2.075	Health Care Plan	28 MoReg 126	28 MoReg 234	28 MoReg 990	
22 CSR 10-2.080	Health Care Plan	28 MoReg 126	28 MoReg 235	28 MoReg 991	

Emergency Rules in Effect as of June 16, 2003

		Publication	Expires
Office of Administration			
Personnel Advisory Board and Division of Personnel			
1 CSR 20-2.015	Broad Classification Bands for Managers	28 MoReg 103	July 10, 2003
Department of Economic Development			
Public Service Commission			
4 CSR 240-120.140	New Manufactured Home Manufacturer's Inspection Fee	28 MoReg 287	August 1, 2003
4 CSR 240-123.030	Seals	28 MoReg 288	August 1, 2003
Office of Tattooing, Body Piercing and Branding			
4 CSR 267-4.020	Temporary Practitioner License	28 MoReg 947	October 24, 2003
Department of Transportation			
Missouri Highways and Transportation Commission			
7 CSR 10-3.040	Division of Relocation Costs	Next Issue	February 26, 2004
7 CSR 10-25.010	Skill Performance Evaluation Certificates for Commercial Drivers	Next Issue	February 26, 2004
Department of Labor and Industrial Relations			
Division of Employment Security			
8 CSR 10-3.130	Direct Deposit of Unemployment Benefits	28 MoReg 948	October 27, 2003
Department of Mental Health			
Director, Department of Mental Health			
9 CSR 10-5.220	Privacy Rule of Health Insurance Portability and Accountability Act of 1996 (HIPAA)	28 MoReg 847	October 14, 2003
9 CSR 10-7.090	Governing Authority and Program Administration	28 MoReg 848	October 14, 2003
Certification Standards			
9 CSR 30-3.032	Certification of Alcohol and Drug Abuse Programs	28 MoReg 848	October 14, 2003
Division of Mental Retardation and Developmental Disabilities			
9 CSR 45-5.060	Procedures to Obtain Certification	28 MoReg 848	October 14, 2003
Department of Public Safety			
Missouri State Highway Patrol			
11 CSR 50-2.430	Verification of Homemade Trailers	28 MoReg 629	September 22, 2003
11 CSR 50-2.440	Vehicle Identification Number and Odometer Reading Verification	28 MoReg 629	September 22, 2003
Department of Revenue			
Director of Revenue			
12 CSR 10-24.448	Proof of Identity and Proof of Social Security Number Required for Issuance of a Driver or Nondriver License	28 MoReg 5	June 23, 2003
12 CSR 10-41.010	Annual Adjusted Rate of Interest	27 MoReg 2125	June 29, 2003
Department of Social Services			
Division of Medical Services			
13 CSR 70-10.015	Prospective Reimbursement Plan for Nursing Facility Services	28 MoReg 103	July 15, 2003
13 CSR 70-15.110	Federal Reimbursement Allowance (FRA)	28 MoReg 1023	February 19, 2004
13 CSR 70-65.010	Rehabilitation Center Program	28 MoReg 291	August 27, 2003
13 CSR 70-70.010	Therapy Program	28 MoReg 293	August 27, 2003
Elected Officials			
Secretary of State			
15 CSR 30-80.010	Redaction of the Social Security Numbers and Date of Birth from Business Entity Filings	28 MoReg 949	November 6, 2003
Department of Health and Senior Services			
Office of the Director			
19 CSR 10-4.020	J-1 Visa Waiver Program	28 MoReg 5	June 23, 2003
Division of Environmental Health and Communicable Disease Prevention			
19 CSR 20-20.020	Reporting Communicable, Environmental and Occupational Diseases	28 MoReg 7	June 23, 2003
Division of Health Standards and Licensure			
19 CSR 30-40.309	Application and Licensure Requirements Standards for the Licensure and Relicensure of Ground Ambulance Services	28 MoReg 849	October 11, 2003
Missouri Health Facilities Review Committee			
19 CSR 60-50.300	Definitions for the Certificate of Need Process	28 MoReg 106	June 29, 2003
19 CSR 60-50.300	Definitions for the Certificate of Need Process	28 MoReg 106	June 29, 2003

19 CSR 60-50.400	Letter of Intent Process	28 MoReg 108	June 29, 2003
19 CSR 60-50.400	Letter of Intent Process	28 MoReg 109	June 29, 2003
19 CSR 60-50.410	Letter of Intent Package	28 MoReg 110	June 29, 2003
19 CSR 60-50.410	Letter of Intent Package	28 MoReg 110	June 29, 2003
19 CSR 60-50.420	Application Process	28 MoReg 111	June 29, 2003
19 CSR 60-50.420	Application Process	28 MoReg 112	June 29, 2003
19 CSR 60-50.430	Application Package	28 MoReg 113	June 29, 2003
19 CSR 60-50.430	Application Package	28 MoReg 113	June 29, 2003
19 CSR 60-50.450	Criteria and Standards for Long-Term Care	28 MoReg 115	June 29, 2003
19 CSR 60-50.450	Criteria and Standards for Long-Term Care	28 MoReg 116	June 29, 2003
19 CSR 60-50.700	Post-Decision Activity	28 MoReg 117	June 29, 2003
19 CSR 60-50.700	Post-Decision Activity	28 MoReg 117	June 29, 2003

Department of Insurance

Market Conduct Examination

20 CSR 300-2.200	Records Required for Purposes of Market Conduct Examinations	28 MoReg 397	August 22, 2003

Missouri Consolidated Health Care Plan

Health Care Plan

22 CSR 10-2.010	Definitions	28 MoReg 118	June 29, 2003
22 CSR 10-2.020	Membership Agreement and Participation Period	28 MoReg 120	June 29, 2003
22 CSR 10-2.040	PPO Plan Summary of Medical Benefits	28 MoReg 121	June 29, 2003
22 CSR 10-2.045	Co-pay and PPO Plan Summaries	28 MoReg 122	June 29, 2003
22 CSR 10-2.050	PPO Plan Benefit Provisions and Covered Charges	28 MoReg 123	June 29, 2003
22 CSR 10-2.055	Co-pay and PPO Plan Benefit Provisions and Covered Charges	28 MoReg 123	June 29, 2003
22 CSR 10-2.060	PPO and Co-pay Plan Limitations	28 MoReg 125	June 29, 2003
22 CSR 10-2.063	HMO/POS Premium Option Summary of Medical Benefits	28 MoReg 125	June 29, 2003
22 CSR 10-2.064	HMO/POS Standard Option Summary of Medical Benefits	28 MoReg 125	June 29, 2003
22 CSR 10-2.067	HMO and POS Limitations	28 MoReg 125	June 29, 2003
22 CSR 10-2.075	Review and Appeals Procedure	28 MoReg 126	June 29, 2003
22 CSR 10-2.080	Miscellaneous Provisions	28 MoReg 126	June 29, 2003

Executive Orders	Subject Matter	Filed Date	Publication
03-01	Reestablishes the Missouri Lewis and Clark Bicentennial Commission	February 3, 2003	28 MoReg 296
03-02	Establishes the Division of Family Support in the Dept. of Social Services	February 5, 2003	28 MoReg 298
03-03	Establishes the Children's Division in the Dept. of Social Services	February 5, 2003	28 MoReg 300
03-04	Transfers all TANF functions to the Division of Workforce Development in the Dept. of Economic Development	February 5, 2003	28 MoReg 302
03-05	Transfers the Division of Highway Safety to the Dept. of Transportation	February 5, 2003	28 MoReg 304
03-06	Transfers the Minority Business Advocacy Commission to the Office of Administration	February 5, 2003	28 MoReg 306
03-07	Creates the Commission on the Future of Higher Education	March 17, 2003	28 MoReg 631
03-09	Lists Governor's Staff Who Have Supervisory Authority Over Departments	March 18, 2003	28 MoReg 633
03-10	Creates the Missouri Energy Policy Council	March 13, 2003	28 MoReg 634
03-11	Creates the Citizens Advisory Committee on Corrections	April 1, 2003	28 MoReg 705
03-12	Declares Disaster Areas due to May 4 Tornadoes	May 5, 2003	28 MoReg 950
03-13	Calls National Guard to Assist in Areas Harmed by the May 4 Tornadoes	May 5, 2003	28 MoReg 952
03-14	Temporarily Suspends Enforcement of Environmental Rules due to the May 4th [et.al] Tornadoes	May 7, 2003	28 MoReg 954

The rule number and the MoReg publication date follow each entry to this index.

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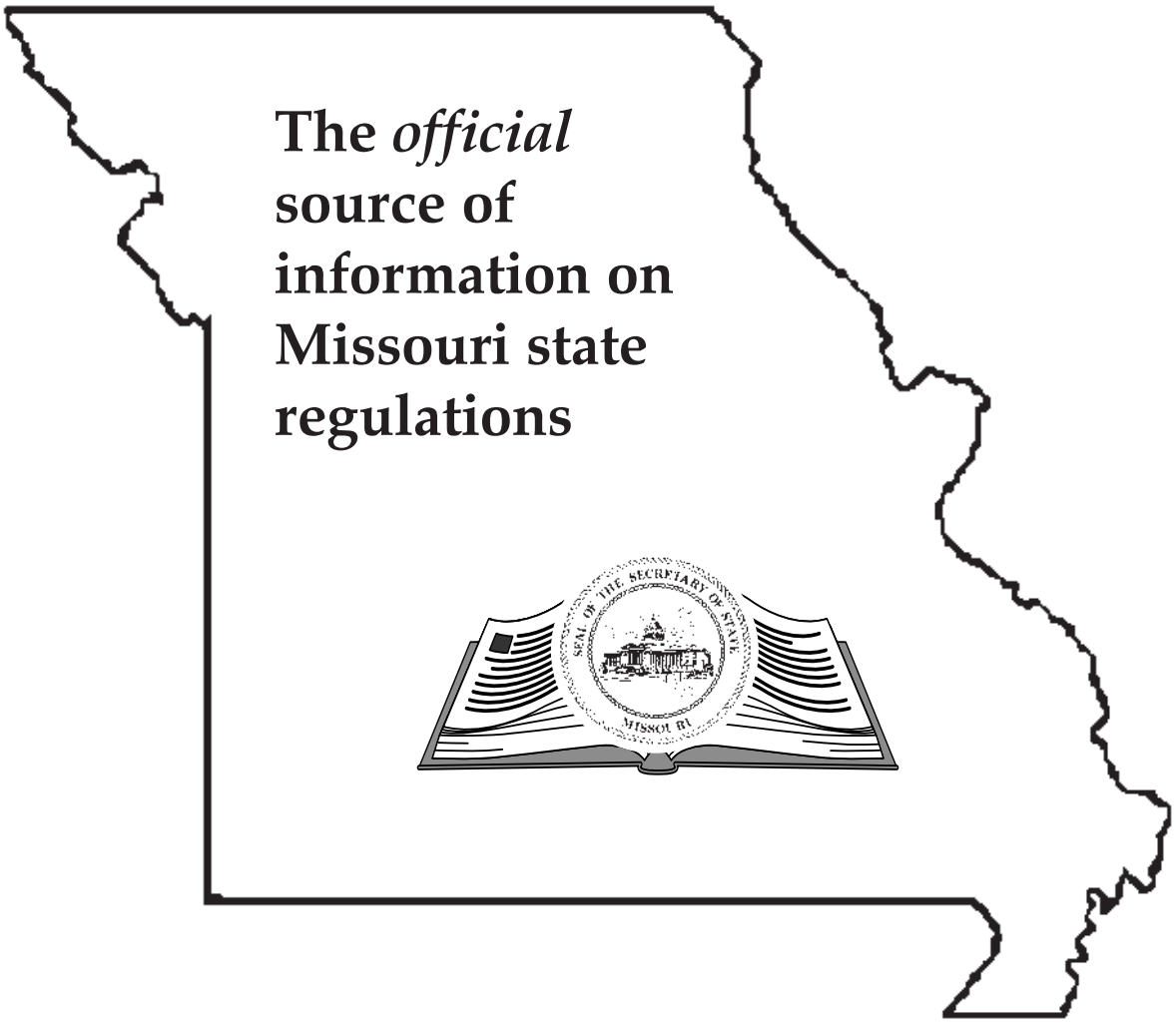

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