Missouri Public Service Commission

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May 20, 2003

Honorable Matt Blunt
Secretary of State
Administrative Rules Division
600 West Main Street
Jefferson City, Missouri 65101

Dear Secretary Blunt:

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

CERTIFICATION OF ADMINISTRATIVE RULE

I do hereby certify that the attached is an accurate and complete copy of the order of rulemaking lawfully submitted by the Missouri Public Service Commission on this Twentieth day of May 2003.

Statutory authority: 700.040 and 700.115, RSMo (2000)

If there are any questions regarding the content of this order of rulemaking, please contact:

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BY THE COMMISSION

Dale Hardy Roberts
Secretary/Chief Regulatory Law Judge
Missouri Public Service Commission

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SECRETARY OF STATE
ADMINISTRATIVE RULES

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 Secretary of State under section 536.023, RSMo 2000, the secretary adopts a rule as follows:

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

COMMENTS: 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.

(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.