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SALUS POPULI SUPREMA LEX ESTO

"The welfare of the people shall be the supreme law."

ROBIN CARNAHAN

SECRETARY OF STATE

MISSOURI REGISTER

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IN THIS ISSUE:

Register Filing Deadlines	Register Publication Date	Code Publication Date	Code Effective Date
June 1, 2010	**July 1, 2010**	July 31, 2010	August 30, 2010
June 15, 2010	**July 15, 2010**	July 31, 2010	August 30, 2010
July 1, 2010	**August 2, 2010**	August 31, 2010	September 30, 2010
July 15, 2010	**August 16, 2010**	August 31, 2010	September 30, 2010
August 2, 2010	**September 1, 2010**	September 30, 2010	October 30, 2010
August 16, 2010	**September 15, 2010**	September 30, 2010	October 30, 2010
September 1, 2010	**October 1, 2010**	October 31, 2010	November 30, 2010
September 15, 2010	**October 15, 2010**	October 31, 2010	November 30, 2010
October 1, 2010	**November 1, 2010**	November 30, 2010	December 30, 2010
October 15, 2010	**November 15, 2010**	November 30, 2010	December 30, 2010
November 1, 2010	**December 1, 2010**	December 31, 2010	January 30, 2011
November 15, 2010	**December 15, 2010**	December 31, 2010	January 30, 2011
December 1, 2010	**January 3, 2011**	January 29, 2011	February 28, 2011
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January 3, 2011	**February 1, 2011**	February 28, 2011	March 30, 2011
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Documents will be accepted for filing on all regular workdays from 8:00 a.m. until 5:00 p.m. We encourage early filings to facilitate the timely publication of the *Missouri Register*. Orders of Rulemaking appearing in the *Missouri Register* will be published in the *Code of State Regulations* and become effective as listed in the chart above. Advance notice of large volume filings will facilitate their timely publication. We reserve the right to change the schedule due to special circumstances. Please check the latest publication to verify that no changes have been made in this schedule. To review the entire year's schedule, please check out the website at http://www.sos.mo.gov/adrules/pubsched.asp

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The rules are codified in the *Code of State Regulations* in this system—

Title	***Code of State Regulations***	**Division**	**Chapter**	**Rule**
1	CSR	10-	1.	010
Department		Agency, Division	General area regulated	Specific area regulated

They are properly cited by using the full citation , i.e., 1 CSR 10-1.010.

Each department of state government is assigned a title. Each agency or division within the department is assigned a division number. The agency then groups its rules into general subject matter areas called chapters and specific areas called rules. Within a rule, the first breakdown is called a section and is designated as (1). Subsection is (A) with further breakdown into paragraph 1., subparagraph A., part (I), subpart (a), item I. and subitem a.

RSMo—The most recent version of the statute containing the section number and the date.

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PS Form **3526,** September 2007 *(Page 2 of 3)*

Rules appearing under this heading are filed under the authority granted by section 536.025, RSMo 2000. An emergency rule may be adopted by an agency if the agency finds that an immediate danger to the public health, safety, or welfare, or a compelling governmental interest requires emergency action; follows procedures best calculated to assure fairness to all interested persons and parties under the circumstances; follows procedures which comply with the protections extended by the *Missouri* and the *United States Constitutions*; limits the scope of such rule to the circumstances creating an emergency and requiring emergency procedure, and at the time of or prior to the adoption of such rule files with the secretary of state the text of the rule together with the specific facts, reasons, and findings which support its conclusion that there is an immediate danger to the public health, safety, or welfare which can be met only through the adoption of such rule and its reasons for concluding that the procedure employed is fair to all interested persons and parties under the circumstances.

Rules filed as emergency rules may be effective not less than ten (10) days after filing or at such later date as may be specified in the rule and may be terminated at any time by the state agency by filing an order with the secretary of state fixing the date of such termination, which order shall be published by the secretary of state in the *Missouri Register* as soon as practicable.

All emergency rules must state the period during which they are in effect, and in no case can they be in effect more than one hundred eighty (180) calendar days or thirty (30) legislative days, whichever period is longer. Emergency rules are not renewable, although an agency may at any time adopt an identical rule under the normal rulemaking procedures.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 2—General Rules

EMERGENCY RULE

20 CSR 2220-2.005 Definitions

PURPOSE: This emergency rule defines the term "drug" as utilized in Chapter 338, RSMo, and the rules of the board.

EMERGENCY STATEMENT: In August 2010, the board was made aware that several Missouri hospitals were participating in federally-authorized clinical trials for high-risk cancer patients utilizing investigational new drugs governed by 21 CFR 312, et. seq. The clinical trials are being conducted by the National Cancer Institute (NCI), an institute of the National Institutes of Health, an agency of the U.S. Department of Health and Human Services. NCI is a United States government agency and the largest single funder of cancer research in the world.

The investigational new drugs utilized in these cancer trials are being shipped into Missouri by third-party distributors located throughout the country. According to NCI, these investigational new drugs are used to treat patients in Missouri "who in most cases have failed standard treatment options for a life-threatening condition," including pediatric neuroblastoma. The investigational new drugs are also being used in "landmark double-blinded prevention trials in breast cancer."

Pursuant to section 338.333, RSMo, any entity shipping "drugs" into Missouri must be licensed as a Missouri drug distributor. The third-party entities utilized by NCI are not licensed Missouri drug distributors and are financially or administratively unable to obtain licensure because of their corporate structure and/or their limited research and manufacturing functions. These entities include reputable agencies like the Mayo Clinic who, in some instances, are the sole manufacturers of these novel investigational products. As provided by section 338.315, RSMo, operating as an unlicensed distributor is a Class A misdemeanor for primary offenses and a Class D felony for subsequent offenses.

Based on section 338.333, RSMo, and the criminal penalties established by section 338.315, RSMo, several Missouri hospitals will reportedly cease all applicable cancer trials if drugs cannot be shipped into Missouri. In fact, one (1) such trial has already been suspended resulting in the interruption of therapy/treatment. NCI has also indicated that it may be required to cease providing these investigational agents into the state of Missouri threatening the continued care and treatment of these high-risk cancer patients. In a letter dated August 18, 2010, NCI specifically provided "For those investigational agents for which there is no commercial supply, the patients would have to cease participation on the clinical trial as they would not be able to obtain the investigational agents under clinical study." According to Missouri physicians and treatment providers, cessation of these federally-authorized clinical trials will detrimentally and substantially threaten the continued care of hundreds of Missouri patients with life-threatening conditions. Significantly, many of the investigational drugs are not covered by standard insurance but are provided free of charge by NCI.

After the board's review of applicable drug and pharmacy law, it is the board's position that the term "drug" as utilized in Chapter 338, RSMo, was not intended to include investigational new drugs that are being utilized for the purposes of conducting a Food and Drug Administration (FDA)-approved clinical investigation of that drug or product, as referenced in the emergency rule. The board seeks to promulgate the emergency rule to define the term "drug" consistent with the aforementioned legal conclusion. The proposed definition would authorize the continued shipment of the investigational new drugs currently being utilized without a Missouri drug distributor license. Absent this definition and as represented to the board by the involved federal agencies, current clinical trials would be immediately terminated resulting in detrimental impact on hundreds of high-risk Missouri cancer patients. Notably, the distribution and manufacturing activities of the involved entities are already under extensive and detailed federal regulation.

As a result, this emergency rule is necessary to preserve a compelling governmental interest in the advancement of scientific research and the continuing necessary medical treatment of Missouri citizens. The emergency rule is also needed to prevent immediate danger to the public health, safety, and/or welfare by ensuring the availability of needed, affordable, and continued medical treatment for hundreds of Missouri adult and pediatric cancer patients with life-threatening conditions that have failed standard treatment options.

*As a result, the Missouri State Board of Pharmacy finds that there is an immediate danger to the public health, safety, and/or welfare and a compelling governmental interest that requires this emergency action. A proposed rule, which covers the same material, is published in this issue of the **Missouri Register**. The scope of this emergency rule is limited to the circumstances creating the emergency and complies with the protections extended in the **Missouri** and **United States Constitutions**. The Missouri State Board of Pharmacy believes this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed September 3, 2010, becomes effective September 13, 2010, and expires March 11, 2011.*

(1) "Drug," "prescription drug," or "legend drug" means:

(A) Any drug subject to section 503(b) of the Federal Food, Drug and Cosmetic Act, including, finished dosage forms and active ingredients subject to section 503(b);

(B) Any drug required under federal law to be labeled with one (1) of the following statements, prior to being dispensed or delivered:

1. "Caution: Federal law prohibits dispensing without prescription";

2. "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

3. "Rx Only"; or

(C) Any drug required by any applicable federal or state law or regulation to be dispensed by prescription only or that is restricted to use by practitioners only.

(2) The term "drug," "prescription drug," or "legend drug" shall not include an investigational new drug or biological product that is being utilized for the purposes of conducting a Food and Drug Administration (FDA)-approved clinical investigation of that drug or product. An "investigational new drug" shall be defined as any new drug or biological product that is governed by, and being distributed pursuant to, 21 CFR 312, et. seq.

AUTHORITY: section 338.010, RSMo Supp. 2009 and sections 338.140, 338.280, and 338.350, RSMo 2000. Emergency rule filed Sept. 3, 2010, effective Sept. 13, 2010, expires March 11, 2011. A proposed rule covering this same material is published in this issue of the ***Missouri Register****.*