



Missouri Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

PO Box 625, Jefferson City, MO 65102

Revisions to Regulations

The following changes to regulations went into effect on June 30, 2001.

- ◆ **4 CSR 220-2.018 Prescription Requirements.** Changes the requirement from a prescription number to providing for a unique, readily retrievable identifier to be applied to a prescription.
- ◆ **4 CSR 220-2.080 Electronic Data Processing.** The requirement of a prescription or hard copy number was changed to recognize a prescription number that can be linked to a unique readily retrievable identifier. Prescription hard copies must be retrievable during the time of inspection. The option of using a daily printout for prescription activity was deleted in favor of maintaining a signature logbook as the minimum requirement. Any records within the Electronic Data Processing (EDP) system concerning the filling or refilling of prescriptions must be retrievable online within two hours of the time of request made by an inspector, or the pharmacy must make a terminal available to the inspector for immediate use. Any records stored on electronic media must be retrievable within three working days.
- ◆ **4 CSR 220-2.090 Pharmacist-in-Charge.** Additional responsibility of maintaining compliance of automated dispensing and storage systems with applicable Missouri Board of Pharmacy regulations was added.
- ◆ **4 CSR 220-2.300 Record Confidentiality and Disclosure.** Amended to clarify the authority for Board inspectors or other authorized designees to review, inspect, or take possession of pharmacy records.
- ◆ **4 CSR 220-2.900 Automated Dispensing and Storage Systems.** A new regulation that defines such systems and sets minimum standards for recordkeeping, use, security, quality assurance, and required policies and procedures. Restocking of these systems by pharmacy staff under supervision of a pharmacist and the ability to measure accountability of the systems from installation throughout the life of the system including, but not limited to, system downtime and malfunctions.
- ◆ **4 CSR 220-5.020 Drug Distributor Licensing Requirements.** Increases the exemption from licensure as a drug distributor on sales from a pharmacy to other outlets and practitioners that are not licensed as pharmacies from one percent to five percent.
- ◆ **4 CSR 220-5.030 Definitions and Standards for Drug Wholesale and Pharmacy Distributors.** Increases the record retention time from the current two-year requirement to three years for all records involving the storage, acquisition, and sale of drugs.

The full text of the regulations noted here as well as all other statutes and regulations of the Missouri Board of Pharmacy can be viewed by visiting the Board's Web site at www.ecodev.state.mo.us/pr/pharmacy/.

Pharmacy, Drug Distributor License Renewals

Renewals for pharmacy and drug distributor licenses will be mailed out around the end of August. All licenses will be renewed for a two-year (biennial) period, and the fee for renewing the license will be doubled in

order to reflect the additional time period. No increase in licensure fees is being made for this renewal cycle. Both licenses expire on **October 31**, and there is no grace period for renewal notices completed and postmarked after this date. It will be illegal to operate or do business as a pharmacy or drug distributor in this state without proper renewal of the license before the expiration date. Completion and submission of the renewal form along with the appropriate fee should be done as soon as possible after receipt of the renewal notice in order to allow time for processing and return of the renewal notice for the correction of any errors or omissions. It is important to review the permit class(es) that are listed on the pharmacy renewal, and report any change in classifications due to changes in services that are provided by the pharmacy. Licensure law requires that each pharmacy accurately maintain the list of classes of services that are provided on the license. While renewal notices will continue to be accepted or rejected due to errors up to the expiration date, it will not be possible to correct a rejected renewal notice during the last few days before the expiration date. Any pharmacy or drug distributor not receiving a renewal notice by September 1 should contact the Board office immediately. **It is the responsibility of the licensee to make sure that his or her license is renewed prior to its expiration.** Any business continuing to act in the capacity of a pharmacy or drug distributor without a current license is subject to investigation and possible disciplinary action by the Board.

Gold Certificates

The following pharmacists received gold certificates in honor of maintaining a license with the Board for 50 years. Each gold certificate is signed by the Board members, executive director, and Governor Bob Holden and is accompanied with a letter of congratulations from the Board. Congratulations to those who have served the public of the state of Missouri for 50 years as a licensed pharmacist.

Francis O. Adrian, Jr, Hannibal, Mo
 Gene C. Caldwell, Springfield, Mo
 Eugene F. Felder, St Louis, Mo
 M. S. Fox, Miami, Fla
 Omer R. Gaskins, Kennett, Mo
 Joseph A. Glenski, St Joseph, Mo
 Barbara B. Gose, Independence, Mo
 Robert R. Kullman, St Louis, Mo
 Taylor E. Lindhorst, St Louis, Mo
 Harold P. Magee, St Joseph, Mo
 Edward A. McMurray, Jr, Florissant, Mo
 Eugene H. Myers, Lincolnshire, Ill
 John W. Murphy, Kirkwood, Mo
 John M. Overman, Independence, Mo
 Charles H. Powers, Kansas City, Mo
 Millard A. Randall, Festus, Mo
 John W. Reese, Lebanon, Mo
 Francis C. Runde, St Charles, Mo

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Ruth L. Scott, Excelsior Springs, Mo
Leo Shalinsky, Prairie Village, Kan
James D. Sisk, Licking, Mo
Gary Sosnoff, Maitland, Fla
Thomas D. Stephens, Granite City, Ill
Carl E. Stoker, Murphrysboro, Ill
John R. Stotts, Little Rock, Ark
Albert R. Torres, Florissant, Mo
Maurice Williams, St Louis, Mo

Drug Compounding

Compounding of drugs by pharmacists has been one of the cornerstones of the profession since its inception. The importance of this service to the consumer is invaluable, especially in situations where no alternative therapy exists. Pharmacists who are involved in compounding must remember that the practice of pharmacy is limited to the preparation and dispensing of drug products by prescription for specific patients. A prescription for any reason that is received by a pharmacy and indicates "For Office Use" or some other terminology in place of a patient's name is not considered a bona fide prescription, and such orders do not fall under the exemption from federal law as the practice of pharmacy. Pharmacists need to make sure that they limit their compounding practices to what falls under state jurisdiction as the practice of pharmacy and that all minimum requirements as outlined by state law for compounding are adhered to. See 4CSR 220-2.400 Compounding Standards of Practice pages 67-69 of the "red law book" or the Board's Web site.

Substitution of Pre-1938 Approved Drugs

In a past *Newsletter*, the subject of substituting drug products that were approved and marketed in the US prior to 1938 was covered. State law does not prohibit the substitution of these products when the prescriber signs on the left side of the prescription or indicates verbally on oral prescriptions that substitution is permitted. However, caution needs to be exercised concerning these products since no official generic equivalency standards exist for them. Unlike products approved for marketing after this date, the Food and Drug Administration has not required the same comparative testing between a parent compound and its generic counterparts. Examples of drugs that fall into this category would include, but are limited to, digoxin and thyroid products. Pharmacists should take this into account when dispensing a generic form of the drug. In addition, switching patients from one manufacturer's product to another could affect drug bioavailability and in some cases have an adverse effect on patient care since maintaining specific blood levels of some of these drugs is critical.

Maintaining Sanitary Practices During the Dispensing Process

The Board periodically receives complaints from the public about certain dispensing practices that are unsanitary. The chief complaint is that pharmacy personnel handle drugs, usually for counting purposes, with their bare hands. It is important to remember that handlers of food or drugs must take appropriate steps to maintain sanitation. It is not considered appropriate to use bare hands for this practice. Counting trays, counting machines, or the use of hand coverings such as gloves are recommended ways to maintain proper dispensing practices.

Licensing Actions

Pharmacists

William B. Tilley II, #29614, Mountain Grove, Mo – April 19, 2001. Suspended for two (2) weeks, until May 3, 2001; followed by Probation for five (5) years, May 4, 2001, to May 3, 2006. Misappropriated, possessed, and consumed legend and controlled drugs from employer. Section 338.055.2(5), (13) and (15), RSMo Supp. 1999.

Daniel J. Vossman, #42029, Osage Beach, Mo – March 21, 2001. Revocation Order May 3, 1998, licensee appealed and revocation stayed, March 21, 2001, court of appeals dismissed case, license revoked and cannot reapply for licensure for five years from May 3, 1998. Pled guilty to one count of making a false statement to receive health care payment, a Class D felony. Section 338.065, RSMo.

Pharmacies/Drug Distributors

Pet Med Express, Inc, #6306, Pompano Beach, Fla – April 5, 2001. Probation for four (4) years, until April 4, 2005. Dispensing without valid prescription or prescriber authorization, unlicensed practice of pharmacy in Missouri, and disciplinary action in Florida. Section 338.055.2(5), (6), (8), (13), and (15), RSMo.

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