



Missouri Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

PO Box 625, Jefferson City, MO 65102

Revisions to Regulations

- ◆ **4 CSR 220-2.085 Electronic Transmission of Prescription Information, effective January 30, 2001.** Deleted requirement that a notation must be applied to the record stating a prescription was electronically transmitted.
- ◆ **4 CSR 220-2.130 Drug Repackaging, effective January 30, 2001.** Changed the standard for expiration of repackaged drugs by a licensed pharmacy from six months to 12 months or the manufacturer's expiration date, whichever is less.
- ◆ **4 CSR 220-2.140 Long Term Care, effective January 30, 2001.** Revised definitions of what constitutes a long-term care facility, provides for minimum standards and the appropriate use of remote dispensing systems, further defines a prescription drug order and standards for their use and provides for when a separate file system is allowed.

Technician Registration Renewals

Renewal forms for technicians to re-register were mailed during the first few days of March. The renewal fee is \$10. Pharmacists-in-charge should check with all technicians employed to make sure the registration renewal is completed and mailed prior to **May 31**, which is the expiration date of all technician registrations. No person may act in the capacity of a technician in a pharmacy (including hospitals) unless they hold an active registration or are pending an initial registration from an application provided to the Board office. State regulations note that if mail is returned to this office due to the failure of the registrant to maintain a current address with this office, no further attempt of mailing the renewal will be made until the correct address is provided. Pharmacists-in-charge should alert any technician who has not received a renewal registration form by the time this *Newsletter* is in circulation to immediately contact the Missouri Board of Pharmacy office by telephone at 573/751-0091 or by fax at 573/526-3464. If a registration is allowed to expire, the entire process of initial registration with the Board as a new applicant including fingerprinting and submission of full fees of \$46 will have to be completed. There is no grace period for the renewal process.

Self-Inspection for Change of Ownership

The Board will initiate a new policy on June 1, 2001, concerning the initial inspection process that is completed when an operating pharmacy changes ownership. The application process that is presently completed by the new owners of a pharmacy will remain the same. Once the application is accepted and processed by the office, an information packet will be sent to the pharmacy's address in care of the pharmacist-in-charge named on the application. A change in

the process will occur where, instead of instructions notifying the inspector when ready for an initial inspection, the pharmacist-in-charge will complete a form requesting responses to questions governing the new pharmacy's compliance with security and regulatory issues. Information on how to contact an inspector will be provided in case there are questions or complications. Once the form is completed along with all other present regulatory requirements, the pharmacist-in-charge shall mail the completed information to the Board office. Once received, and if everything is in order, a pharmacy license (permit) will be printed and issued. In addition, if the pharmacy has applied to the state Bureau of Narcotics and Dangerous Drugs for a controlled substance registration, the Board office will notify that agency that the license has been issued so that processing of the controlled substance registration can proceed. The Board hopes this new policy will help keep costs as low as possible and, at the same time, provide more flexibility to the pharmacist-in-charge in completing the process within the thirty (30) day time frame allowed by law to complete the change of ownership process. The inspector will, during the next regular inspection, follow up on the initial self-inspection completed by the pharmacist-in-charge.

Common Compliance Issues Noted During Inspections

During calendar year 2000, the Board of Pharmacy completed 1,399 inspections of pharmacies. On-site inspections have identified certain compliance issues that most often occur. In listing the most commonly found areas where deficiencies may occur below the minimum standard of compliance, it is hoped that the inspections will assist pharmacies and pharmacists-in-charge in their efforts to plan effectively for the next inspection. By far, the most frequent area of deficiency occurs in areas of compliance with controlled substance laws. This covers a wide range of issues, but the areas within these laws that are most frequently addressed during an inspection are an absence of or deficient inventory of controlled substances as required; lack of information required within the prescription record such as dispensing dates, patient addresses, pharmacist signature when required, proper completion of Schedule II order forms; and retrievable invoices showing transfers of drugs into the pharmacy from suppliers and transfers of drugs out due to the provision of drugs to other pharmacies or practitioners. The next area in which deficiencies are commonly found deal with compliance in providing the correct dispensing and labeling of drug containers as required per federal and state laws. This includes compliance with federal law dealing with childproof containers as well as compliance with Board standards on the repackaging of

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pharmaceuticals. In addition, over the last few years, with the rise in compounding taking place in some pharmacies, deficiencies in labeling and packaging of compounded products has been noted. This was noted more often during this past year than in any previous years. Another area where deficiencies have been noted is non-compliance with the technician registration program requirements. Technicians must first apply to the Board before they begin working in a pharmacy. Once an application is completed and mailed, the individual can be employed as a technician using a copy of the application as a temporary registration. The registration certificate or a copy of the application must be available for inspectors to review. In cases where technicians may be employed in more than one pharmacy, the registration should be maintained at the principal place of employment and the wallet card can be used at other locations. Finally, compliance with patient counseling laws is still an issue in a number of pharmacies. In most cases, the main compliance issue is the failure to offer counseling by pharmacy personnel. These examples comprise the most common compliance issues observed during the inspection process. In general, most pharmacies show excellent compliance with the various requirements that are reviewed during an inspection. It is important to remember that the inspector assigned to your pharmacy is always just a telephone call away should you have questions on compliance issues.

Licensing Statistics for Fiscal Year 2000

Pharmacists	6,599
Pharmacies (In-state)	1,287
Drug Distributors (Licensed)	971
Pharmacies (Non-resident)	241
Drug Manufacturers (Registered)	75
Student Interns	473
Registered Technicians	8,229

For further information and statistics on licensure breakdown and other information on Board of Pharmacy activities and operations, contact the Board office for a free copy of the annual report.

Licensing Actions

Jill R. Andrews, #41515, Columbia, Mo – January 8, 2001. Probation for five (5) years, until January 7, 2006. Pled guilty to two counts of Child Abuse-Serious Emotional Injury, a Class B felony. Section 338.065, RSMo Supp. 1999.

Annamarie T. Marden, #41010, Jefferson City, Mo – March 9, 2001. Censure of license. Dispensed wrong form of Amphotericin B

and failed to recognize dosage was inappropriate for the form of Amphotericin B dispensed. Section 338.055.2(13), RSMo Supp. 1999.

Fred M. Tichy, #28656, Arnold, Mo – January 27, 2001. Probation for two (2) years, until January 26, 2003. Licensee either misrecorded prescription dosage or was directed to record inappropriate dosage for patient, and did not make an offer to counsel. Section 338.055.2(5), (13), and/or (15), RSMo Supp. 1999.

Thomas R. Wooten, #38091, New London, Mo – November 30, 2000. Probation for two (2) years, until November 29, 2002. Drug security and accountability, misbranding, recordkeeping, and unauthorized dispensing. Section 338.055.2(5), (6), (13), (15), and (16), RSMo Supp. 1999.

Pharmacies/Drug Distributors

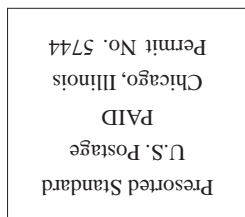
St. Marys Pharmacy, #5316, Hannibal, Mo – November 30, 2000. Probation for two (2) years, until November 29, 2002. Drug security and accountability, misbranding, recordkeeping, and unauthorized dispensing. Section 338.055.2(5), (6), (13), (15), and (16), RSMo Supp. 1999.

Express Pharmacy Services, #5484, Kansas City, Mo – March 7, 2001. Censure of license. Did not provide adequate security to deter theft of drugs by personnel, controlled substance shortages. Sections 338.285 and 338.055.2(6), RSMo 1994.

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