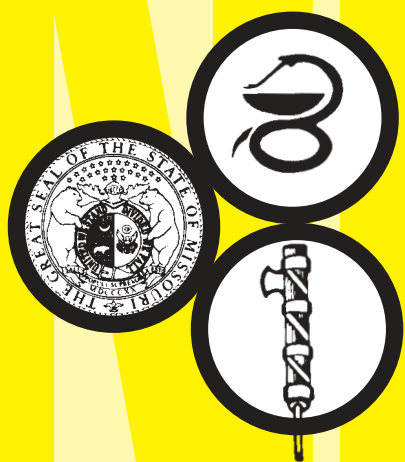


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Missouri Board of Pharmacy

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Waivers Required to Employ Certain Individuals

Any pharmacy or drug distributor who wishes to employ a person who has entered a plea of guilty, no contest, nolo contendere, or has otherwise been convicted of a criminal controlled substance violation must obtain a waiver before granting the person access to any controlled substances. If the violation was a misdemeanor, you must obtain a waiver only from the Missouri Bureau of Narcotics and Dangerous Drugs (BNDD). If their violation was a felony, you must obtain a waiver from both the BNDD and federal Drug Enforcement Administration (DEA) agencies. In any case, a person with a felony record cannot be employed for seven years where access to controlled substances is possible. If a person has a misdemeanor record, they cannot be employed for two years where access to controlled substances is possible. Waivers must be in writing and signed. A waiver request must include justifications for the request, a job description at the registered location where the waiver is being sought, and whether or not the person seeking the waiver will have access to controlled substances. Any waiver request made within the time restrictions noted above for employment must also provide what specific guarantees will be made to ensure that the person seeking a waiver will have no access to controlled substances.

Message from the Director of Professional Registration

Marilyn Taylor Williams, Division Director

My office has been working diligently, through team input and much planning, to develop an optical imaging system that will meet the needs of the Division of Professional Registration. I am glad to report that we have begun implementing the new optical imaging system. The board staff will be trained on how to use the system. Once trained, they will begin using the system and have the ability to scan daily mail received or other paper files and documents maintained in the licensing boards offices. The boards will each determine what documents are to be scanned. As of February 19, 2002, we had 14 production boards that had been trained. These boards were using the optical imaging system and were scanning their documents. At that time, there had already been 50,000 pages imaged. As of March 15, 2002, there were six (6) boards who were being trained on the system and it was anticipated that in the very near future, these boards would also go to production and begin scanning their paper files. It is expected that the remaining boards will begin training on the system very soon and, shortly thereafter, go into production. It is projected that the entire Division will be trained on and using the system in the next few months. Please stay tuned as we continue to improve the services provided by the Division.

Regulation Update

Changes to the following regulation will take effect on November 30, 2002.

4CSR 220-3.040(2)(D) Return and Reuse of Drugs and Devices: This rule was amended to restrict the return of drugs for reuse to only those drug products that are dispensed in the original manufacturer's packaging and that remain sealed in tamper-evident packaging. Pharmacies and pharmacists should note the effective day of this amendment to the rule so that proper quality assurance of drugs returned to the pharmacy can be initiated in order to maintain compliance.

Transfer of Pharmacist License Into Missouri

Pharmacies and pharmacists-in-charge must provide direct supervision to any pharmacist that has applied to have their license transferred to Missouri from another state, but has not yet completed the transfer process and who does not hold a current Missouri license. Persons transferring their license may work in a pharmacy in the capacity of a technician without being registered as a technician under certain conditions: 1) An application for transfer has been received and is pending at the board of pharmacy office, 2) the transfer process is completed within three (3) months, and 3) the applicant successfully completes the required law examination on the first attempt. Any variance from these requirements within the stated time frame will require the pharmacist to register as a technician in order to continue employment in a pharmacy prior to licensure as a pharmacist. It is also important to note that the individual whose licensure is pending cannot provide any services that are outlined in Section 338.010 RSMo, regardless of whether such services are provided through a licensed pharmacy or are provided as a part of an individual's practice at an unlicensed location.

Unlicensed Drug Distributor Activity

The Board is observing an alarming number of pharmacies and in-state drug distributors that are ordering and receiving drugs from unlicensed, out-of-state entities. Sections 338.333 and 338.337 RSMo, note that it is unlawful for a person acting as a drug distributor to do business in this state without first securing licensure. Any person found to be violating these licensure sections is guilty of a class C felony. Yet a number of inspections completed note the continued use of unlicensed entities by both pharmacies and drug distributors. There are reasons for maintaining a licensure requirement of this type due to the many problems associated with operations that attempt to circumvent consumer protection laws. Some brokers, wholesalers, and brokerage houses attempt to distribute questionable or adulterated drugs into the state. The Board has

Continued on page 4

Continued from page 1

seen evidence of pedigree falsification, transfer of drugs that have been held under unsanitary or other conditions that violate state and federal standards, and the distribution of stolen and counterfeit drugs. In every case, the source of these products was an unlicensed distributor. It is the responsibility of each licensee to ensure that drug products obtained from various sources are done so in compliance with chapter 338 RSMo, which includes the requirement that all in-state and out-of-state distributors maintain a current license with the Board of Pharmacy.

Controlled Substance Dispensing

Board inspectors have observed the dispensing of controlled substances too soon to the same patient. This may involve the processing of several prescriptions from different prescribers or the refill of prescriptions on a cycle that does not match up with previously dispensed amounts and directions for administration. Pharmacists have a professional responsibility under state and federal drug laws to ensure that controlled substances are dispensed for bonafide purposes and are not being abused or diverted due to excessive purchases. When prescriptions are received, proper review of patient records is essential to ensure that excessive quantities or multiple numbers of controlled substances above what is clinically necessary are not dispensed.

Flavoring of OTC Products

Flavoring agents are often requested when prescription medications are compounded in order to improve the taste. However, pharmacies and pharmacists should note that the Board has reviewed state and federal laws on compounding as well as the Federal Food, Drug and Cosmetic Act and has interpreted the law to not allow for any alteration of over-the-counter (OTC) products unless ordered by a prescription from an authorized prescriber. This would include any attempt to flavor OTC products through the incorporation of an agent to the product. A manufactured OTC product should not be altered since it is considered a finished product unless a prescription is provided for the alteration of the product.

Awards and Accomplishments

Tom Glenski, RPh, chief inspector for the Board of Pharmacy, received recognition by the Board for completion of five years of service. He was presented with a lapel pin for his service. Kevin E. Kinkade, RPh, executive director of the Board, was the recipient this past year of the Missouri Society of Health-System Pharmacists (MSHP) Thomas J. Garrison Achievement Award. The award was presented at the MSHP annual meeting in Kansas City.

Licensing Actions

Pharmacists

Cynthia A. Maciak, #45173, St Louis, MO – August 8, 2002. Suspend for one year, until August 7, 2003, followed by probation for five years. Violation of previous disciplinary order. Positive urinalyses, failure to submit counselor and personal compliance reports.

Donald Scott Martin, #41602, Kansas City, MO – August 21, 2002. Probation for two years, until August 20, 2004. Practiced with an expired license, and diversion of controlled substance for personal use. Section 338.055.2(6) and (15), RSMo 2000.

Steven D. Russ, #41923, Nevada, MO – July 11, 2002. Suspension for three years, until July 10, 2005, followed by probation for five years. Drug diversion for personal use, impaired pharmacist. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo Supp. 2001.

Eugene H. Weinheimer, #28926, Columbia, MO – August 4, 2002. Revoked, cannot reapply for licensure for four years. Violation of previous disciplinary order. Positive urinalysis for alcohol resulting in an employment action, failure to submit compliance report. Section 338.055.2(1)(5)(13), RSMo. Supp. 2000.

Pharmacies

Danny's IGA, #6571, Lebanon, MO – August 6, 2002. Probation for three (3) years, until August 5, 2005. Controlled substance losses, inadequate security system. Section 338.055.2(5), (6), and (15), RSMo 2000.

Page 4 – November 2002

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