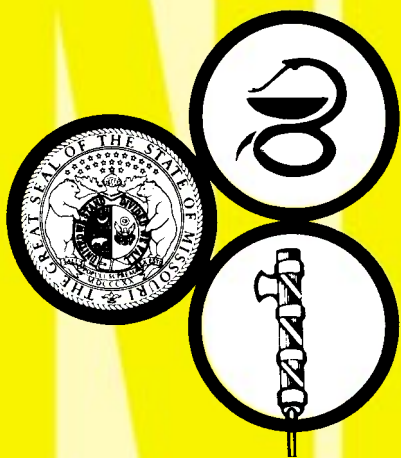


November 2001



Missouri Board of Pharmacy

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Revisions to Regulations

Changes to the following regulation will go into effect on November 30, 2001.

4 CSR 220-2.085 Electronic Transmission of Prescription Data.

Revisions will define electronic signature and minimum standards for how a pharmacist shall ensure the validity of a prescription as to its source of origin. Hard copies that use an electronic method for applying signatures must be applied to paper with security features that will not allow any copying and/or alteration.

Prescription Compounding

Compounding by pharmacies continues to increase across the state. Some of the products being compounded have been discontinued by the manufacturer and are no longer commercially available. Pharmacists, when considering the compounding of such products, must ensure that the drug under consideration was not withdrawn from the market due to any action by the Food and Drug Administration (FDA). Any drug that is considered unsafe within a specific dosage form should not be compounded. In addition, since demand of compounded drugs can be high for drugs that are no longer commercially available, a pharmacist compounding such a drug must make sure that all compounding is done pursuant to a prescription provided by a practitioner who is authorized by law to prescribe. Federal law only exempts pharmacies from the Federal Food, Drug and Cosmetic Act when providing compounded products by prescription. In addition, state law defines the practice of pharmacy in part as "the compounding, dispensing, and labeling of drugs and devices pursuant to prescription orders," and Missouri Board of Pharmacy rules governing compounding note the requirement of a valid prescriber/patient/pharmacist relationship. Compounded drugs that are provided to practitioners or institutions based on invoices or "for office use" orders are not considered part of the practice of pharmacy since the product(s) are not being provided pursuant to a valid prescription order and may be considered misbranded.

Board Quality Assurance Program

Previous *Newsletters* have introduced briefly, the concepts behind the Board's quality assurance program. Presently, the Board is involved in the review of prescriptions for potential discrepancies during routine inspections. If a record discrepancy is noted, then the inspector will complete a quality assurance form and discuss each completed form with the pharmacist-in-charge or attending pharmacist to consider possible follow-up reviews of the prescription in question and then report any findings to the Board office. Whether any further review is completed by the pharmacist-in-charge, the form is to be returned to the Board. Once received by the Board, the information provided will be used to build a database concerning the number and types of discrepancies that are observed in pharmacies. This information will better assist the Board in dis-

covering what type of discrepancies seem to be the most prevalent in the practice setting and whether specific pharmacies may need assistance in changing some practices in order to reduce discrepancies within their dispensing processes. So far, statistics show that the most often observed discrepancies are labeling directions at 64%. Many of these discrepancies may be due to the way that the dispensing process is supervised by the pharmacist, or it may be due to various computer default programs for the labeling process that do not remain consistent with the actual directions on the prescription. In either case, pharmacists should consider these issues among others when discrepancies are found, whether it be during an inspection or during management reviews by pharmacy personnel. The wrong strength of a drug made up 18% of discrepancies observed. Discrepancies involving the wrong drug provided to a consumer was observed at 10%. Together, all other discrepancy rates comprised 8% and included the wrong label attached to a prescription, the prescription provided to the wrong patient, or other unexplained discrepancies.

Given these statistics, the Board can begin to formulate possible solutions for pharmacists as well as educational efforts through this *Newsletter* and in presentations about ways to avoid such discrepancies. The other effort by the Board is to work with pharmacists and pharmacies that may have discrepancy rates that are consistently high by initiating quality assurance **plans** specific to pharmacist/pharmacy needs. Such plans can be instituted and monitored in order to see if decreases in either the rate or types of discrepancies are observed. It is important to note, whether it is the type or rate of discrepancies that is of concern, that utilizing quality controls or reviews is the answer to most situations and not using disciplinary measures. Only by such reviews, with the cooperation of both the pharmacist, the pharmacy, and the Board, can solutions for such problems be attempted and promoted in order to improve services to consumers. While there may always be a small fraction of practitioners who are incompetent or negligent, by and large, most issues involve system or simple personnel mistakes that, when analyzed, can be reduced or eliminated. Given the pharmacist shortage, which is predicted to worsen, the increases in the number of prescriptions that pharmacies will see in the coming years and the national concern over the issue of medical and drug errors, it is better to consider a more open team approach to solving such issues. Ultimately, for the Board, as well as for most pharmacists, providing quality products and services to consumers is what is most important. Finding nonpunitive ways to deal with prescription discrepancies within a cooperative voluntary compliance effort seems to work well, based on the results that the Board has seen from the quality assurance programs initiated in those pharmacies needing improvement. While the Board must always consider prescription discrepancies with serious outcomes carefully, most discrepancies are not considered within the discipline process. The

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inspectors can assist you in providing specific information for reducing discrepancies or can answer questions concerning this ongoing effort by the Board.

Suspended Imposition of Sentences

The Board office receives many applications for technicians daily. As noted on the application for technician registration, the Board will have access to records that are normally closed to other private sector entities. Even if a sentence has been served successfully by an applicant and is a suspended sentence, which is not a public record, the Board will still have access to this information as a part of a governmental sharing of criminal records review. Pharmacists who are considering hiring individuals as registered technicians should share this information with applicants to make sure they understand how to answer questions posed on the application. The office receives a number of applications on which the applicant answers no to all questions involving past criminal conduct, yet the results of the criminal background check show a "Suspended Imposition of Sentences" (SIS) report for a felony or misdemeanor record. When this occurs, it greatly lengthens the application process in that the application is considered false at that point. Such applications will require further information from the applicant and may result in the application being nullified. When possible, pharmacists should advise potential technicians about how to answer questions on the application and read the directions for completing the application carefully since the special issue of SIS records is covered.

Licensing Report

Pharmacists

John B. Brandon, Jr, #2001015108, Knoxville, Tenn – July 2, 2001.

Restricted license issued on probation for five (5) years, until July 25, 2006. Disciplinary action in Tennessee, impaired pharmacist. Sections 338.055.1 and 338.055.2(1), (8), (13), and (15), RSMo 2000.

Richard F. Hansen, #28018, Florissant, Mo – August 28, 2001. Probation for five (5) years, until August 27, 2006. Attempted to work under the influence of alcohol. Section 338.055.2(13), RSMo 2000.

Gordon A. Peistrup, #25835, St Louis, Mo – July 17, 2001. Suspended for fifteen (15) months, until October 16, 2002; followed by five (5) years probation, until October 16, 2007. Pled guilty to felony stealing, fabrication of prescriptions. Section 338.055.2(2), (4), (5), and (13), RSMo Supp. 1999.

Benny E. Thomas, #27593, Crocker, Mo – June 15, 2001. Probation for five (5) years, until June 14, 2006. Overfilled drug containers, audit overages. Section 338.055.2(5), (6), (13), and (15), RSMo Supp. 1999.

Ronald W. Wrestler, #40629, Lamar, Mo – July 3, 2001. Probation for two (2) years, until July 2, 2003. Misappropriated cash from employer, pled guilty to misdemeanor stealing. Section 338.055.2(2), (5), and (13), RSMo Supp. 1999.

Interns

Jerrod S. Brown, #701293, St Louis, Mo – September 1, 2001. Intern license suspended for six (6) months, until February 28, 2002. Upon successful completion of suspension period and licensure examination process, restricted pharmacist license will be issued on five (5) years probation. Diverted controlled substances from employer for personal use. Section 338.055.2(1), (5), (13), and (15), RSMo Supp. 1999.

Pharmacies/Drug Distributors

KV Pharmaceutical Company, #900173, St Louis, Mo – April 10, 2001. Probation for three (3) years, until April 9, 2004. Pled guilty on July 18, 1995, to two counts of violating 21 U.S.C. 331(e) and 355(k)(1) concerning failure to investigate or report an antibiotic drug below the required potency levels of the label claim and two counts of violating 21 U.S.C. 331(a) and 352(a) concerning interstate distribution of misbranded drugs. Section 338.055.2(2), RSMo. Supp. 1999.

Special Notice

Board *Newsletters* are considered one of the Missouri Board of Pharmacy's official methods of notification to pharmacists and pharmacies. They have been, and will continue to be, used in hearings as proof of notification. It is important to read the *Newsletters* carefully and to retain them for future reference.

New Inspector for Southeast Region

Robert "Bud" Alexander, RPh, has been retained by the Board as an inspector. He resides in Florissant, Mo, and his telephone number is 314/972-7581.

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