

Legislation Changes Portions of the Practice Act

The 2004 legislature passed legislation affecting a number of agencies within the Division of Professional Registration. The Pharmacy Practice Act was amended with several important changes that went into effect on August 28th. First, a number of changes were made to the technician registration law. Anyone now seeking registration as a technician must be, “at a minimum, legal working age” in order to qualify for registration. Changes were also made to enhance the application process, as well as further define and refine language concerning the disqualification of applicants and registrants. An important addition to this section provides for the **mandatory reporting** of any registered technician by a hospital or licensed pharmacy of “any final disciplinary action taken against a technician or the voluntary resignation of a pharmacy technician against whom any complaints or reports have been made which might have led to final disciplinary action that can be a cause of action for discipline by the board.”

Pharmacists-in-charge should note this requirement and make sure that any such reports are filed on a timely basis with the board should the above conditions take place. Such reports are now a **requirement** under state law. The expedited hearing authority of the board was amended to expand the authority to all licensees and registrants within the practice act instead of only pharmacists. The expedited hearing process is located in section 338.055.4 and is used to take action against licensees who pose a “clear and present danger to the public health and safety.” A new section of law grants authority to the board for limited subpoena power. This will be used in situations where records are sought that are not otherwise available to the board and are held at

unlicensed locations. Subpoenas can be enforced through the board applying to the circuit court for an order to obey the subpoena. A new section, 338.155, was enacted providing any person with immunity from civil damages as a result of providing information, reports, cooperating with the board or assisting the board in any manner in the course of its investigations, hearings or other proceedings conducted by or before the board. In addition, it provides for sovereign immunity in situations where a physician or other authorized prescriber cooperates with the board by writing a prescription or drug order at the request of the board pursuant to an inspection or investigation and treats such an individual as an agent of the state. Any licensee or registrant who fills a prescription that is presented by the board as part of an inspection or investigation shall not be considered in violation of the law, provided that it is prepared and dispensed in a lawful manner. An amendment was made to pharmacy permit classifications. Class D: Home health care was changed to Class D: Nonsterile compounding and a new class was added, Class K: Internet. Those pharmacies with Class D classification on their permit or those pharmacies involved in non-sterile compounding should take steps to have the permit amended properly.

State Generic Formulary Law Requirements

The state generic substitution law has been around for many years. Pharmacists still note at times confusion over the law and how it applies to substitution practices. Pharmacists should take advantage of contacting their inspectors when questions arise concerning substitution requirements. The law requires that any substitution of a brand name product with a generic counterpart must meet two criteria before the process can

occur. First, the prescriber must provide authority to substitute by signing on the appropriate line on the prescription or provide authority through verbal or other documented means (electronic verification). Second, the drug must be considered a generic equivalent to the brand called for on the prescription. State law dictates that the board use policy decisions made by the FDA in this matter. The FDA has a process whereby a drug is considered first as to its equivalency to a particular brand name product. If equivalency is established then a separate process is completed to consider the drug's rating of interchangeability. If the drug is rated as interchangeable with a parent or brand name product, then it will be provided an "A" rating and appear in the federal publication "Approved Drug Products with Therapeutic Equivalence Evaluations" or "orange book." If a generic drug is not considered interchangeable, it will be given a "B" rating. Each of these two ratings will appear as the first of two letters next to each manufactured product. The board office will review the orange book each month and note any "B" rated drugs. These will appear on the board of pharmacy web site as an entry in the negative generic formulary. If the drug has no interchangeable generic counterparts then it will be listed in the formulary. If the drug has at least one interchangeable generic counterpart but has other generics that are not considered interchangeable, then a list of those companies whose products are interchangeable will appear. When this occurs and a manufacturer of a generic counterpart is not listed, that particular product cannot be used as a substitute on a brand name prescription. When prescriptions are received that are written by generic name, any FDA approved drug product can be used to prepare and dispense the prescription.

Licensing Actions**Pharmacists:**

Jeffery K. Connell, #29369, Goreville, IL—August 9, 2004. Suspended until May 5, 2005, followed by probation for five (5) years. Pled guilty to one count of making a false material writing and document, and one count of misbranding a food or drug. Section 338.065, RSMo.

Charles M. Miller, #29253, Camden Point, MO—September 4, 2004. Suspended for one (1) month, until 10/3/04, followed by probation for five (5) years. Fraudulently billed insurance companies for commercially-available product when a compounded product was dispensed, substituted compounded drugs for commercially-available products without prescriber authorization, records not accurately reflecting what was dispensed. Section 338.055.2(4), (5), (6), (13), and (16), RSMo Supp 2002.

Aaron R. Roberts, #44313, Manchester, MO—September 14, 2004. Revoked, cannot reapply for seven (7) years. Found guilty of one count of knowingly and intentionally distributing a mixture of substance containing a detectable amount of Alprazolam, a felony. Section 338.065.

Valjean Vanwinkle, #41140, Olathe, KS—July 22, 2004. Probation for five (5) years from 7/22/04. Pled guilty to one count of conspiracy to possess hydrocodone, a felony. Section 338.065.

Pharmacies:

Miller Professional Pharmacy, #5109, Platte City, MO—September 4, 2004.

Probation for five (5) years. Fraudulently billed insurance companies for commercially-

available product when a compounded product was dispensed, substituted compounded drugs for commercially-available products without prescriber authorization, records do not accurately reflect what was dispensed. Section 338.055.(4), (5), (6), (13), and (16, RSMo Supp 2002; Section 338.056.1-5, RSMo 2000; 4 CSR 220-2.400(2); Section 338.100, RSMo; 4 CSR 220.080(2); and 4 CSR 220.2.010(1)(N).

Prescriptions By Mail, #2000171993, Las Vegas, NV—June 17, 2004. Revoked, cannot reapply for seven (7) years from 6/17/04. Failure to investigate a prescription's validity, misbranding by dispensing a prescription it knew to be invalid, failure to retain prescription record. Section 338.055.2(5) as to misconduct and incompetence, (6), and (15), RSMo.

Drug Distributors:

Kirk Welding Supply, Inc., #2003028696, Springfield, MO—June 17, 2004. Restricted license issued on Probation for three (3) years from 6/17/04. Operated without a current license from 6/30/98 to 11/20/03, failure to secure and store Nitrous Oxide, failure to provide appropriate signage for Nitrous Oxide noting whether it was empty, full, quarantined. Section 338.055.1, and 338.055.2(5), (6), (7), (13), and (15), RSMo Supp 2002.

Patterson Dental Supply, Inc., #900962, Springfield, MO—August 5, 2004. Probation for two (2) years from 8/5/04. Changed its location and continued to operate without timely giving notice to the Board, failure to timely complete and submit change of manager-in-charge, inspection violations. Section 338.353(1), Supp. 2002.

STATE OF: MISSOURI

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