



# Missouri Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

PO Box 625, Jefferson City, MO 65102

## Board of Pharmacy Licensing Statistics

The Missouri Board of Pharmacy currently licenses/registers a total of 20,903 individuals and businesses. The following provides a breakdown for each category of license/registration:

Drug Distributor License (Temporary/Permanent).....	1,134
Drug Distributor Registration (out of state distributors).....	88
Pharmacists .....	7,088
Pharmacies .....	1,682
Interns .....	843
Technicians .....	10,068

## Law Book

By now, many licensees are aware that no law book was published and distributed by the Board this year. There are several reasons why this occurred. First, with technology advancing at the Division of Professional Registration, all of the information in the previous law book can be found on the Board of Pharmacy Web site located at [www.pr.mo.gov](http://www.pr.mo.gov). Second, the law book is expensive to compile and publish. The Board will save money on these costs as well as mailing costs to both licensees and others who request copies of the reference. The Board office is also working on making enhancements to our Web site that will make it easier to review and download information about the practice act as well as state and federal drug laws.

## Gold Certificates

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

- Alper, Stanley – St Louis, MO
- Asner, Herschel – St Louis, MO
- Barks, R. D. – Florissant, MO
- Bernstein, Marvin – St Louis, MO
- Chapin, James T. – St Louis, MO
- Charles, Ray C. – Carbondale, IL
- Chura, George R. – Lake St Louis, MO
- Coran, Aubert – Longboat Key, FL
- Dempsey, Kenneth J. – Sikeston, MO
- Dunstan, Kenneth W. – Eldon, MO
- Ellis, James H. – Chesterfield, MO

- Goodman, Abert – St Louis, MO
- Gray, Ellis E. – Cherryville, MO
- Handler, Lee R. – Creve Coeur, MO
- Horr, Ronald D. – Niceville, FL
- Hudacek, Clement F. – St Louis, MO
- Lubick, Morris – Winnetka, CA
- Mallams, George E. – Gulf Breeze, FL
- Mason, Robert E. – Cincinnati, OH
- Medley, Raymond J. Jr – Camdenon, MO
- Miller, Milton H. – Little Rock, AR
- Neff, Owen H. – Kansas City, MO
- Pearlstone, Howard S. – Creve Coeur, MO
- Pirtle, Virgil E. Jr – St Louis, MO
- Pitts, Billy G. – Kansas City, MO
- Rosenberg, Albert M. – Clayton, MO
- Scott, Joann S. – Richmond, MO.
- Simms, Charles – Glen Echo, MO
- Skinner, Don F. – Independence, MO
- Snead, Carroll M. – Cape Girardeau, MO
- Watkins, Richard M. – St Louis, MO
- Yociss, Frank J. – Brentwood, MO
- Zelenovich, Mike – St Charles, MO

## Rule Update

4 CSR 220-2.300 Record Confidentiality and Disclosure has been amended and went into effect on July 31, 2004. Several changes have been made to the rule with the main revision centering around compliance with federal Health Insurance Portability and Accountability Act requirements. Revisions were also made in order to better define when and to whom confidential information can be legally provided. The rule may be accessed through the Board's Web site at [www.pr.mo.gov](http://www.pr.mo.gov) and clicking on the icon for rules. Once on the Missouri Secretary of State Web site, click on Division 220 and then click on Chapter 2 and look for the rule number noted above.

## House Bill 600

House Bill 600 was enacted in 2003 to increase the tax revenue collected by the State of Missouri. This bill contains several "income tax accountability" provisions requiring the Department of Revenue to take steps to collect income taxes owed by state employees and licensed professionals. One provision of the bill was specifically aimed at professionals licensed by the Division of Professional Registration. The statute requires the Department of Revenue to

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# National Pharmacy C

(Applicability of the contents of articles in the National Pharmacy Compliance and can only be ascertained by examining the

## **FDA Issues Final Rule Prohibiting the Sale of Ephedra Supplements**

On February 6, 2004, Food and Drug Administration (FDA) announced the issuance of a final rule prohibiting the sale of dietary supplements containing ephedrine alkaloids (ephedra).

At the end of last year, FDA issued letters to manufacturers who market ephedra-containing supplements, informing them of the upcoming rule. FDA also urged consumers to stop using ephedra-containing dietary supplements immediately. Studies show that ephedra-containing dietary supplement have adverse effects on the cardiovascular and central nervous systems including high blood pressure, heart palpitations, tachycardia, stroke, and seizures. FDA has linked at least 155 deaths with the use of dietary supplements containing ephedra.

For more information, including a Web link to the final rule, visit the following Web site: [www.fda.gov/bbs/topics/NEWS/2004/NEW01021.html](http://www.fda.gov/bbs/topics/NEWS/2004/NEW01021.html).

The final rule became enforceable on April 12, 2004. California, Illinois, and New York were the first states to ban the sale of ephedra.

## **DEA Issues Clarification of the Exemption of Sales of Pseudoephedrine and Phenylpropanolamine**

In attempts to clarify existing laws and regulations regarding the over-the-counter (OTC) sale of pseudoephedrine and phenylpropanolamine, Drug Enforcement Administration (DEA) issued an interpretive rule this past January. This interpretive rule does not change any of DEA's regulations, nor will it have an impact on individual retail customers of such products who have been purchasing them from retailers that have been properly following DEA's regulations.

Specifically, the interpretive rule emphasizes that sales transactions of ordinary OTC pseudoephedrine and phenylpropanolamine products ("safe harbor" products) are exempt from being regulated transactions as long as each transaction is below the 9-gram threshold to an individual for legitimate medical use. Apparently, some retail distributors have misinterpreted current DEA regulations and believe that they may sell as much "safe harbor" pseudoephedrine and phenylpropanolamine to any person for any purpose as often as that person wishes to make a purchase. The DEA interpretive rule clearly dispels that belief.

Currently, retail distributors of ordinary OTC pseudoephedrine and phenylpropanolamine products are exempt from registering with DEA as a distributor of List I chemicals and complying with the record keeping and other regulatory requirements as long as individual transactions for legitimate personal medical use remain below the 9-gram threshold (in packages of not more than 3 grams).

To obtain more information, please visit DEA's Diversion Control Program Web site, [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov).

Note: Although most products containing phenylpropanolamine were discontinued pursuant to the action of FDA in November 2000, there remains some legitimate veterinary uses for phenylpropanolamine that will ensure some level of its continued production and availability. Therefore, these products are subject to the existing DEA regulations and this interpretive rule.

## **DEA Introduces Pharmacy Theft Prevention Program**

In response to increasing theft and armed robberies against pharmacies, DEA's Office of Diversion Control has introduced the Pharmacy Theft Prevention Program. The program is based on a previous initiative that was developed during the late 1970s and early 1980s when there was a similar unprecedented spike in the occurrence of thefts and robberies against pharmacies.

The intent of the program is to provide education and increased communication to pharmacists and pharmacy staff to prevent pharmacy theft. The program includes collaboration with and participation from law enforcement, regulators including state pharmacy boards, state and federal prosecutors, the media, and the public along with the pharmacy community. The Pharmacy Theft Prevention Program will also provide a means to maximize the use of limited resources available to law enforcement to address, minimize, and eliminate pharmacy thefts in areas that experience such problems.

Staff members of the DEA's Office of Diversion Control have begun a series of regional meetings to promote the program to DEA Diversion field elements, state pharmacy boards, and local pharmacy associations. To implement the program in your community, or to obtain more information regarding the program and its operation, call DEA Headquarters, Office of Diversion Control, Liaison and Policy Section, at 202/307-7297.

## **Concentrated Morphine Solutions and Serious Medication Errors**

*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site ([www.ismp.org](http://www.ismp.org)) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*



According to a recent newspaper report, a 91-year-old man being treated for a mild heart attack was mistakenly given a 100-mg dose of ROXANOL™ (concentrated morphine solution) instead of 5 mg as prescribed. The error may have contributed to the patient's death the following day. Last fall, Elan Pharmaceuticals (the manufacturer of Roxanol at the time; aaiPharma recently acquired the product from Elan) issued a safety alert warning about deaths from accidental overdoses ([www.fda.gov/medwatch/SAFETY/2003/roxanol.htm](http://www.fda.gov/medwatch/SAFETY/2003/roxanol.htm)). Most overdoses involved morphine solutions that were mistakenly ordered, dispensed, and labeled by volume (mL), not milligrams. For example, in some cases, patients received 5 mL of



Roxanol 20 mg/mL (100 mg) instead of the prescribed 5 mg. The newspaper report did not describe how this most recent error happened; however, it mentioned that Roxanol 100 mg had been given instead of 5 mg, pointing once again to the scenario described in the recent safety alert from Elan.

Several manufacturers distribute morphine solution in different formulations, primarily labeled (and listed in drug references) in mg/mL (eg, 20 mg/mL) or mg/5 mL (eg, 100 mg/5 mL, 20 mg/5 mL). When concentrated morphine is stored in pharmacies or in patient care areas in hospitals or long-term care facilities, it is often kept next to conventional concentrations. Thus, it is easy to confuse these products and dosage strengths. Also, some physicians have prescribed the medication in terms of mL instead of mg, which has led to errors because multiple concentrations exist. Because we continue to hear about these tragic overdoses, we make these recommendations to reduce the risk of errors with concentrated morphine products:

- ◆ If you consult with nursing homes or hospitals, avoid stocking concentrated morphine solutions in patient units when possible, including the emergency department. Keep in mind that the drug is used primarily to treat chronic pain.
- ◆ Dispense concentrated solutions only when ordered for specific patients who require higher-than-usual doses due to severe chronic pain.
- ◆ Affix an auxiliary label to the morphine concentrate bottle to warn about its high concentration and segregate the solution from the other concentrations.
- ◆ Working with local physicians, purchase and dispense concentrated solutions in dropper bottles (available from at least two manufacturers) to help prevent dose measurement errors and differentiate the concentrated product from the conventional products. For patients in hospitals or long-term care, dispense concentrated solutions in unit doses whenever possible.
- ◆ Educate others to never prescribe or dispense liquid medications without the dose specified in milligrams.
- ◆ Educate staff about the risk of morphine errors and develop guidelines to promote its safe use.
- ◆ Manufacturers should standardize the way strength is expressed on labels, preferably in terms of mg/mL for all forms. This would improve clarity when comparing product labels (eg, it is easier to differentiate 4 mg/mL and 20 mg/mL; harder to differentiate 20 mg/mL and 20 mg/5 mL).

Finally, we disagree with Elan's suggestion in its recent safety alert for prescribers to include the desired concentration of morphine along with the patient's dose in milligrams and the corresponding volume (eg, Roxanol 10 mg/5 mL, give 10 mg [5 mL] prn pain). Listing the desired concentration could actually lead to confusion and errors. If the prescribed concentration is not available and a different concentration is substituted, the prescriber's directions regarding the volume to administer would no longer apply. Yet, if these directions remain on a medication administration record, or a prescription bottle, the wrong dose could be administered.

## **NABP Releases Updated Model Rules for the Licensure of Wholesale Distributors**

On February 20, 2004, the National Association of Boards of Pharmacy® (NABP®) released the updated Model Rules for the Licensure of Wholesale Distributors. The updated Model Rules, part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, were provided to assist state boards of pharmacy in maintaining the integrity of the US medication distribution system through the regulation of wholesale distributors. The updated Model Rules are the result of a concerted effort between NABP and other representatives from pharmacy, government, and the wholesale distributor industry to protect the public from the ill effects of counterfeit drugs and devices.

In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific drug pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products." Also, the updated Model Rules introduce the position of "Designated Representative." The "Designated Representative" of a wholesale distributor is the person who is actively involved in and aware of the actual daily operation of the Wholesale Distributor.

The Model Rules for the Licensure of Wholesale Distributors along with the National Specified List of Susceptible Products can be downloaded from NABP's Web site, [www.nabp.net](http://www.nabp.net).

## **New Bar Code Requirements Aim to Reduce Risk of Medication Errors**

In late February, FDA issued the final rule Bar Code Label Requirements for Human Drug Products and Biological Products. This final rule requires the inclusion of linear bar codes on most prescription drugs and certain OTC drugs. Each bar code must, at minimum, contain the drug's National Drug Code number, but companies are encouraged to include additional information such as the product's lot number and expiration date. For blood and blood products used in a transfusion, the final rule also requires the use of machine-readable information in a format approved for use by FDA. The machine-readable information must include, at a minimum, the facility identifier, the lot number relating to the donor, the product code, and information on the donor blood type.

FDA is hoping that the bar code rule will encourage the widespread adoption of advanced information systems that, in some institutions, have reduced medication errors by 85%.

FDA expects that, with full implementation, the linear bar codes will result in more than 500,000 fewer adverse events over the next 20 years and a 50% reduction in medication errors that would otherwise have occurred upon dispensing or administration. New medications covered by the rule must comply within 60 days of their approval and previously approved medications and blood/blood products must comply within two years.

More information including a link to the final rule is available on FDA's Web site at [www.fda.gov/oc/initiatives/barcode-sadr](http://www.fda.gov/oc/initiatives/barcode-sadr).

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notify licensees, at the time of application or renewal, that they must file delinquent income tax returns or pay any delinquent taxes owed to the state. Since May of 2003, the Division of Professional Registration has been working with the Department of Revenue and the Attorney General's Office to establish procedures and define each agency's responsibilities under this new law. As of July 2003, the effective date of the new law, the Division has been transmitting licensee data for each renewal cycle. Because of the amount of time that the Department of Revenue has needed for technical implementation of the law, the Department's first notices did not go out to licensees until January of this year. The law, as written, gives no discretion to either the Department of Revenue or the Division of Professional Registration. Revenue must send notices to every licensee who has no record of filing a return or paying taxes in the three years prior to renewing or applying for licensure. The Board must suspend any licensee that fails to either respond that he or she does not live or work in Missouri, or resolve his or her tax delinquency. There are no appeal rights built into the law and no right to cure the default after a 90-day period from notification. If a licensee pays his or her tax or files his or her return even one day after the 90-day period, the license may still be suspended. It is important that you act on any correspondence you receive from the Department of Revenue on this matter.

## Licensing Actions

### Pharmacists

**Gordon E. Gengler**, #41486, St Louis, MO – June 30, 2004. Probation for three (3) years from June 30, 2004. Worked as a pharmacist with an expired license. Section 338.055.2(12), (13), and (15), RSMo Supp. 2002.

**Fred R. Haefner**, #28381, St Louis, MO – July 2, 2004. Probation for one (1) year from July 2, 2004. Cooperated with a drug distributor to receive money from drug manufacturers for drugs his pharmacy never received or possessed. Section 338.055.2(4), RSMo.

### Pharmacies

**Kennel Vaccine Vet Supply, Inc.**, #2004011854, David City, NE – May 6, 2004. Restricted license issued on Probation for three (3) years from May 6, 2004. Operated as a pharmacy before licensed and continued to do so after notified of licensure requirement. Section 338.055.1 and .2(6) and (7), RSMo. Supp. 2002.

**Pet Med Express, Inc.**, #6306, Pompano Beach, FL – April 20, 2004. Probation for three (3) years from April 20, 2004. Violation of discipline concerning dispensing veterinary legend products without valid prescriptions, and submitted false compliance reports to the Board. Section 338.055.2(5), (6), (8), (13), and (15), RSMo.

**PBM Pharmacy, Inc, d/b/a Prescriptions By Mail**, #2000171993, Las Vegas, NV – June 17, 2004. Revoked, cannot reapply for seven (7) years from June 17, 2004. Failure to investigate the validity of a prescription, misbranding, failure to retain prescription record in any form. Section 338.055.2(5), (6), and (15), RSMo.

**West Pine Pharmacy**, #3843, St Louis, MO – July 2, 2004. Probation for three (3) years from July 2, 2004. Cooperated with a drug distributor to receive money from drug manufacturers for drugs the pharmacy never received or possessed. Section 338.055.2(4), RSMo.

### Drug Distributors

**EB-Tide Marketing, Inc**, #2000172068, St Charles, MO – May 5, 2004. Suspended for one (1) month from May 5, 2004, followed by Probation for five (5) years from June 5, 2004. Purchased legend drugs from an unlicensed entity, and inspection revealed opened bottle of Viagra® for which no invoices or prescriptions could be produced. Section 338.055.2 (5), (6), and (10), RSMo Supp. 2002.

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