



Ohio State Board of Pharmacy

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www.pharmacy.ohio.gov

Published to promote voluntary compliance of pharmacy and drug law.

Terminal Distributor Renewals

The terminal distributor of dangerous drugs (TDDD) license renewal forms were mailed out in early October. If you are the responsible person on the license, please be sure that the renewal forms are completed and returned to the Ohio State Board of Pharmacy in a timely manner along with the appropriate fee. Remember that your current TDDD license will not be valid after December 31, 2006. If you have questions or, particularly, if you did not receive or cannot find your renewal form, please contact the Board office.

One Board Member Appointed, One Reappointed

Heather Lee Pasquale, RPh, was appointed to her first term on the Board of Pharmacy by Governor Bob Taft this past summer. Her term began on July 1, 2006, and runs through June 30, 2010. She is a graduate of Albany College of Pharmacy and is currently a district sales manager for CVS/Pharmacy. At the same time, the Governor reappointed Elizabeth I. Gregg, RPh, to the Board for her second four-year term also beginning July 1, 2006. Board members may serve no more than two terms on the Board. The current Board members, their cities of residence, terms, and the expiration dates of their current terms in office are listed below:

- ◆ **James E. Turner**, RPh, president, Ada, second term ending June 30, 2008
- ◆ **Gregory Braylock**, RPh, vice president, Cleveland, second term ending June 30, 2009
- ◆ **Suzanne R. Eastman**, RPh, member, Cincinnati, second term ending June 30, 2007
- ◆ **Robert P. Giacalone**, RPh, member, Dublin, second term ending June 30, 2007
- ◆ **Elizabeth I. Gregg**, RPh, member, Columbus, second term ending June 30, 2010
- ◆ **Nathan S. Lipsyc**, RPh, member, Cleveland, second term ending June 30, 2009
- ◆ **Kevin J. Mitchell**, RPh, member, Marion, first term ending June 30, 2008
- ◆ **Heather L. Pasquale**, RPh, member, Dublin, first term ending June 30, 2010
- ◆ **Dorothy S. Teater**, public member, Columbus, second term ending June 30, 2008

New Rules Under Consideration

By the time this *Newsletter* arrives, the Board probably will have already held a public hearing on proposed new and changed rules. For those who are interested in the content of these proposed rules, please go to the Board's Web site, www.pharmacy.ohio.gov and click on "What's New" to see a copy showing the changes. The document is titled "Full Text of Proposed Rules Showing Changes for November 6, 2006 Public Hearing."

Among the rules undergoing significant changes this year are the rules relating to pharmacy internship (Chapter 4729-3, Administrative Code). The method of documenting internship hours will change drastically. If you are involved in the pharmacy internship program as an intern or a preceptor, you should review these rules so you can be aware of what is coming.

The rules that have been filed will not be finalized by the Board until after both the public hearing on November 6, 2006, and a hearing before the Joint Committee on Agency Rule Review. Once the Board has considered all of the comments received, it will determine which rules to implement and a starting date for those rules to become effective.

DEA Issues

Drug Enforcement Administration (DEA) has recently published several items that should be of interest to health care practitioners around the country. These items may all be found on the DEA Diversion Web site www.deadiversion.usdoj.gov.

In the *Federal Register* of September 6, 2006 (Volume 71, Number 172, Page 52724-52726), DEA published a proposed rule dealing with the issuance of multiple prescriptions for Schedule II controlled substances. The notice may be found at www.deadiversion.usdoj.gov/fed_regs/rules/2006/fr0906.htm. By issuing this proposed rule, DEA is once again proposing to allow prescribers to issue, where appropriate, multiple Schedule II prescriptions to a patient on one visit. **Please note that this is a proposed rule.** The comment period will be open until November 6, 2006. After reviewing the comments received, DEA will make a decision about making the rule permanent. The wording of the proposed rule changes is as follows.

Sec. 1306.12 Refilling prescriptions; issuance of multiple prescriptions.

- (a) The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.
- (b)(1) An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met:
 - (i) The individual practitioner properly determines there is a legitimate medical purpose for the patient to be prescribed that controlled substance and the individual practitioner is acting in the usual course of professional practice;
 - (ii) The individual practitioner writes instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill the prescription;

Continued on page 4



FDA Launches Consumer Educational Program on the Safe Use of OTCs

The United States Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cooperation with the National Council on Patient Information and Education and Maryland's Montgomery County Public Schools, has launched "Medicines in My Home," an interactive educational program aimed at informing middle school students about the safe and effective use of over-the-counter (OTC) medicines. Key concepts students will learn from the program are:

- ◆ the Drug Facts label tells you what a medicine treats, if it is right for you and your problem, and how to use the medicine;
- ◆ read the label and follow the directions carefully and correctly;
- ◆ two medicines with the same active ingredient should not be used at the same time; and
- ◆ measure medicines correctly with measuring tools made for medicines.

The program emphasizes that medicines should be used only with permission from an adult and that if there are questions about medicine use, ask a pharmacist or doctor. Materials are provided to encourage students to share what they learn with their families so that all family members can learn to use OTC medicines more safely. Program information can be found at www.fda.gov/medsinmyhome.

HHS Warns Public of Heroin and Fentanyl Deadly Combo

In efforts to warn the public and health care professional communities regarding a recent rash of drug-related deaths due to an illicit street drug combination consisting of the prescription medication fentanyl and either heroin or cocaine, the Department of Health and Human Services (HHS) released a fact sheet containing specific information with the goal of saving lives.

A letter from H. Westley Clark, director of HHS Center for Substance Abuse Treatment, to health care professionals warned that in "just one week, an estimated 33 individuals in the Detroit, MI area are reported to have died after using this fatal mix of drugs; the same drug combination may have been responsible for more than 100 deaths in the same region last September [2005]." Philadelphia, PA; Chicago, IL; St Louis, MO; and Camden, NJ have also recently experienced similar clusters of drug-related deaths.

Fentanyl, an injectable Schedule II prescription opioid analgesic, is roughly 50 to 80 times more potent than morphine but can also be produced in clandestine laboratories in powder form and then mixed with or substituted for heroin. Fentanyl-related overdoses can result in sudden death through respiratory arrest, cardiac arrest, severe respiratory depression, cardiovascular collapse, or severe anaphylactic reaction. In some cases, heroin or cocaine users are aware they are purchasing this dangerous combination of drugs and in other cases, they are not. Because the potency of street-sold heroin or cocaine is amplified markedly by fentanyl and because the inclusion of fentanyl

may not be disclosed, any use, even a reduced dose, can result in overdose or death. The fact sheet advises that suspected overdoses should be treated rapidly with a naloxone injection, 0.4 to 2 mg intravenously, subcutaneously, or intramuscularly every two to three minutes, which should rapidly reverse symptoms related to a narcotic overdose; if there is no response after 10 minutes, then a different diagnosis should be considered.

For additional information, contact Kenneth Hoffman at the Substance Abuse and Mental Health Services Administration at 240/276-2701 or via e-mail at Kenneth.Hoffman@samhsa.hhs.gov.

Pharmacy Technicians and Medication Error Prevention



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, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (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.

In an October 2005 article in the *American Journal of Health-System Pharmacists*, the results of a random nationwide survey of more than 800 pharmacy technicians' views about their medication errors was published (Desselle SP. Certified pharmacy technicians' views of their medication preparation errors and educational needs. *Am J Health-Syst Pharm*. October 1, 2005; 62:1992-97). Most of the technicians worked in community pharmacies, but more than a quarter (27%) were employed in hospitals.

As one might expect in both settings, interruptions and inadequate staffing were among the most frequent factors perceived to contribute to technician medication preparation errors. Inadequate staffing was perceived as especially problematic in chain pharmacies, while inadequate supervision by pharmacists was cited as a factor more frequently by hospital technicians. It also may come as no surprise that the pharmacists' most frequently cited response to an error that was caught during the checking process was to make the technician aware of the error and require him or her to correct it. However, only about 17% of the technicians reported that the pharmacist had used the error as an opportunity to provide instructions on how to avoid the same or similar errors in the future.

While many of these respondents attributed this responsibility to the organization as a whole, not necessarily the individual pharmacist who detects an error, it appears technicians may not be receiving guidance about system and process changes that can help avert errors. After an



error is corrected, the checking pharmacist should find time that same day (or the next day, if necessary) to review the error with the technician and suggest ways to avoid it, including safer behavioral choices if applicable. Later, during pharmacy staff meetings or other forms of intradepartmental communication, errors, their causes, and ways to prevent them should be shared with all staff in a way that does not embarrass those who were possibly involved in the errors.

One or Both Nostrils?

Submitted by ISMP

Although many nasal sprays are intended for administration in each nostril for a single dose, there are notable exceptions. For example, some medications are meant to be delivered via the nasal passage but **not** sprayed into each nostril. Calcitonin salmon (**Fortical**[®], **Micalcin**[®]) is a prime example. Patients should administer a single spray (200 international units) into one nostril daily, using alternate nostrils each day. Other examples in metered-dose or unit-dose nasal spray containers include butorphanol, desmopressin (**DDAVP**[®]), sumatriptan (**Imitrex**[®]), and zolmitriptan (**Zomig**[®]).

Some pharmacy and/or physician electronic prescribing systems have been preprogrammed to print directions that default to "spray in each nostril" when nasal sprays are selected. For the previously mentioned drugs, this would result in the administration of a double dose of medication. One health care facility recently reported that about 50 patients, who had been prescribed medications intended to be given into one nostril, had prescription container labels that instructed the patients to administer the spray into both nostrils. Some physicians might anticipate patients' confusion and write the prescription for "half" doses in each nostril. Even if instructed to use the spray in one nostril, patients who administer other nasal medications in both nostrils may spray these medications into both nostrils without thinking.

Explicit verbal directions and written instructions that emphasize administration via one nostril only are critical to avoid an overdose.

FDA/ISMP National Campaign to Help Eliminate Ambiguous Medical Abbreviations

FDA and the ISMP have launched a national education campaign that focuses on eliminating the use of potentially harmful abbreviations by health care professionals, medical students, medical writers, and the pharmaceutical industry. The campaign addresses the use of error-prone abbreviations in all forms of medical communication, including written medication orders, computer-generated labels, medication administration records, pharmacy or prescriber computer order entry screens, and commercial medication labeling, packaging, and advertising. For more information visit www.fda.gov/cder/drug/MedErrors.

DEA Provides Retail Training Materials

Drug Enforcement Administration (DEA) recently announced the availability of training materials regarding self-certification training for regulated retail sellers of non-prescription drug products containing

ephedrine, pseudoephedrine, and phenylpropanolamine as required by the Combat Methamphetamine Epidemic Act of 2005 (Title VII of Public Law 109-177).

Two sets of training materials have been developed: one for regulated persons who are mobile retail vendors, and one for regulated persons who are not mobile retail vendors. Both sets of training materials may be found on the Diversion Control Program Web site, www.deadiversion.usdoj.gov, under "Combat Methamphetamine Epidemic Act of 2005."

DEA notes that regulated sellers must use the content of these training materials in the training of their employees who sell scheduled listed chemical products. A regulated seller may utilize additional content in its training program, but DEA's posted material must be included.

DEA is continuing to work to promulgate regulations to implement the Combat Methamphetamine Epidemic Act of 2005.

FDA Announces Release of Guidance on Useful Written Consumer Medication Information

In the July 18, 2006 *Federal Register*, FDA announced the availability of a guidance entitled "Useful Written Consumer Medication Information (CMI)." This guidance is intended to assist individuals or organizations (eg, pharmacies, private vendors, health care associations) in developing useful written consumer medication information to comply with Public Law 104-180. CMI is written information about prescription drugs developed by organizations or individuals, other than a drug's manufacturer, that is intended for distribution to consumers at the time of dispensing. Since neither FDA nor the drug's manufacturer reviews or approves CMI, FDA recommends that the developers of written medication information use the factors discussed in this guidance to help ensure that their CMI is useful to consumers.

This guidance can be accessed at www.fda.gov/cder/guidance/7139fnl.htm.

2007 Survey of Pharmacy Law Available Soon

NABP's 2007 *Survey of Pharmacy Law* CD-ROM will be available in early December 2006. New topics include whether or not licensure for wholesale distributors of non-prescription drugs is required and the recognition of Verified-Accredited Wholesale Distributors[®] accreditation.

The *Survey* consists of four sections: organizational law, licensing law, drug law, and census data. The *Survey* can be obtained for \$20 from NABP by downloading the publication order form from www.nabp.net and mailing in the form and a money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from AstraZeneca Pharmaceuticals. If you do not have Web access or would like more information on the *Survey*, please contact NABP at 847/391-4406 or via e-mail at custserv@nabp.net.

Continued from page 1

- (iii) The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;
 - (iv) The issuance of multiple prescriptions as described in this section is permissible under the applicable state laws; and
 - (v) The individual practitioner complies fully with all other applicable requirements under the Act and these regulations as well as any additional requirements under state law.
- (2) Nothing in this paragraph (b) shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

Sec. 1306.14 Labeling of substances and filling of prescriptions.

- (e) Where a prescription that has been prepared in accordance with Sec. 1306.12(b) contains instructions from the prescribing practitioner indicating that the prescription shall not be filled until a certain date, no pharmacist may fill the prescription before that date.

Once again, please note that this is a **proposed** change to DEA rules. It will not be permanent until DEA makes that decision some time in the future. Meanwhile, the Board encourages prescribers and pharmacists to continue to care for their patients in an appropriate manner. Many of you know that the Board disagreed with DEA's comments in November 2004 that multiple Schedule II prescriptions were "tantamount to a refill" and have encouraged and expected you to continue to treat patients effectively, including the issuance of multiple Schedule II prescriptions when appropriate. This proposed rule shows that the policy makers at DEA have changed their opinions to be more in line with our thinking. Please continue to treat patients effectively and appropriately during this interim period until the proposed regulations become final.

In the same issue of the *Federal Register*, DEA also published a policy statement on the use of controlled substances in the treatment of pain. That policy statement is also available on the DEA Web site at www.deadiversion.usdoj.gov/fed_regs/notices/2006/fr09062.htm.

This policy statement outlines the approach and reasoning of DEA in its enforcement of the controlled substance laws and regulations. Prescribers and pharmacists who routinely treat patients with controlled substances should read this carefully. Hopefully, a careful reading will

eliminate some of the fears that health care practitioners have when treating legitimate patients.

One of the most important concepts to keep in mind in both of these cases, multiple Schedule II prescriptions and pain treatment, is the mandate that the medication be prescribed and dispensed "**for a legitimate medical purpose**" (quoting from federal and Ohio requirements). If a health care practitioner is prescribing, dispensing, or administering controlled substances for a legitimate medical purpose, there will be no problems with law enforcement agencies. Legitimate medical purpose is defined by your fellow practitioners and the licensing boards, not by the law enforcement agencies. Always act in the best interests of the patient and there should be no problems.

One other new publication from DEA that may be of interest to prescribers and pharmacists alike is the revised version of DEA's Practitioner's Manual. This was issued in August of this year, so it contains current information about the laws, regulations, and DEA policy for prescribers. This Manual as well as DEA's other practice oriented manuals may be found at www.deadiversion.usdoj.gov/pubs/manuals/index.html.

Disciplinary Actions

Anyone with a question regarding the license status of a particular practitioner, nurse, pharmacist, pharmacy intern, or dangerous drug distributor in Ohio should contact the appropriate licensing board. The professional licensing agency Web sites listed below may include disciplinary actions for their respective licensees.

State Dental Board – 614/466-2580, www.dental.ohio.gov

State Medical Board – 614/466-3934, www.med.ohio.gov

State Nursing Board – 614/466-3947, www.nursing.ohio.gov

State Optometry Board – 614/466-5115, www.optometry.ohio.gov

State Pharmacy Board – 614/466-4143, www.pharmacy.ohio.gov

State Veterinary Medical Board – 614/644-5281,

www.ovmlb.ohio.gov

Drug Enforcement Administration – 1-800/230-6844,

www.deadiversion.usdoj.gov

Page 4 – November 2006

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