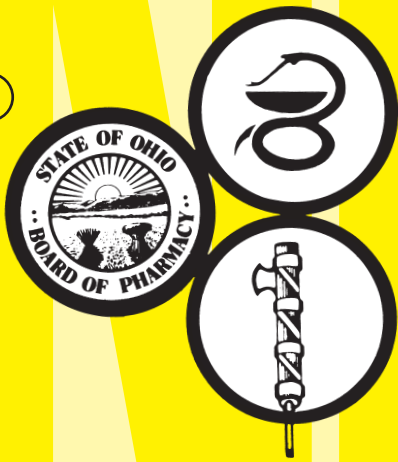


February 2009



Ohio State Board of Pharmacy

77 S High St, Room 1702, Columbus, OH 43215-6126
Tel: 614/466-4143 Fax: 614/752-4836
www.pharmacy.ohio.gov

Published to promote voluntary compliance of pharmacy and drug law.

Do You Have Your New Terminal Distributor's License?

Please check the Terminal Distributor of Dangerous Drugs (TDDD) license at your facility to be sure you have received your 2009 TDDD license from the Ohio State Board of Pharmacy. The TDDD license is the license required for all pharmacies, hospitals, clinics, emergency medical services squads, etc. If you have not renewed or received your 2009 TDDD license, please call the Board office immediately. The 2008 TDDD licenses expired on December 31, 2008.

Jurisprudence Continuing Pharmacy Education (CPE) Note

The Board's annual Jurisprudence Quiz is included as part of this *Newsletter*. The questions in the quiz relate to the topics covered in this *Newsletter* as well as the May, August, and November 2008 issues. If you need them, copies of the previous *Newsletters* can be found on the Ohio State Board of Pharmacy Web site at www.pharmacy.ohio.gov by clicking on "CPE News and S.B.N."

Please note that the deadline for submission of the completed quiz is **March 31, 2009**. Any answer sheets postmarked after March 31, 2009, will not be accepted.

Final CPE Reminder

This is a final reminder to those pharmacists whose license number begins with 03-3. This is the year for you to report your CPE. It will be due in the Pharmacy Board of office **no later than May 15, 2009**. The CPE report notice should be arriving in your mail sometime early in March while your renewal instructions will not be arriving until mid-summer. If you have not received your CPE report notice by the end of March, please notify us at the Board office so we can get you a replacement. The CPE report form is also available on the Board's Web page under "FORMS." You can print it, sign it, and mail it to the Board office.

You will need to show a total of six continuing education units (CEUs) (60 hours) of CPE credit. 0.3 CEUs (3 hours) of those must be in Board-approved jurisprudence. Please make sure that the jurisprudence courses are Board approved. The approved list is on the Board's Web site. There are a large number of courses coded as law that are not approved by the Board for use in meeting this requirement. The other 57 hours may be in any approved category that you wish.

You may use certificates dated on or after March 1, 2006, that you did not use when reporting in 2006. In addition, please be sure that you have the certificates in hand before you certify your compliance with the CPE requirements on the form. Every year, we have a few pharmacists who submit the form before receiving certificates from

the CPE provider because they assume they must have been successful. Sometimes, that certificate then fails to arrive because they did not pass the examination. Even if you do get the certificate after you submit the signed CPE form to the Board, if you are audited, any certificates dated after the date you signed the CPE form will not be accepted. Falsifying the CPE report form is something that the Board does not take lightly. As long as you have the original certificates in your possession when you complete the report form, you should have no problem with this reporting period. If you fail to submit a CPE form in a timely manner, you will be subject to Board action on your license. Rule 4729-7-02(C) states:

A pharmacist shall be subject to further action of the board if the continuing pharmacy education report forms are not filed by the date indicated on the continuing pharmacy education report form, or if the hours submitted are incomplete.

New and Revised Rules are in Effect

The Board approved the adoption and filing of several new and revised rules at the December 2008 Board meeting. A copy of all the new and revised rules is available on the Board's Web site under "What's New." This copy has the changes in each rule highlighted to make reviewing the changes easier. In addition, the "Laws and Rules," "Administrative Code Rules" section has been updated with the new and changed rules. Please review these changes so you are familiar with them in your practice.

Ohio Administrative Code rule 4729-9-02 is one rule that applies to nearly every pharmacist and pharmacy employee. This rule requires everyone in the pharmacy to wear a nametag bearing their name and title. The rule does not specify first name, last name, or both, so all or part of the individual's name will meet the requirements. The important issue that was also part of the Pharmacy Technician Bill (SB203) is the requirement for the person's title. Concern was noted that people did not always know if they were speaking to a pharmacist, a technician, or a clerk. In order to resolve this, the Board implemented the nametag requirement. Please see that this requirement is followed.

Last Minute Bills Approved by the Legislature

During the last session of the 127th General Assembly, several bills were approved by the Legislature that could affect pharmacy practice. There were also several bills that did not get approved. The bills that were approved were SB 203 (Pharmacy Technicians), HB 215 (Salvia Divinorum), and HB 130.

SB 203 is a bill that addresses the functions and requirements of pharmacy technicians. For the first time, pharmacy technicians

Continued on page 6



FDA Web Site Upgrades Support MedWatch's Patient Safety Goal

Two recently launched additions to the Food and Drug Administration's (FDA) Web site are intended to support the "Patient Safety" goal that MedWatch shares in public health efforts to protect patients from serious harm and improve outcomes. The entry pages assist health care professionals and patients to locate timely safety information for FDA-regulated human medical products and assist them in making diagnostic and therapeutic decisions.

The content and links on the new FDA entry page specifically for health care professionals allows busy doctors, pharmacists, nurses, and other health care professionals to find information to make point-of-care decisions. There is information that is specifically safety-related, such as easy access to reporting adverse events or finding new safety alerts, warnings, and recalls. Users can also find content regarding new approvals information, or access to the current version of the label, or prescribing information in "DailyMed." This page can be accessed through www.fda.gov/healthprofessionals.

FDA's other new page is specifically for patients and provides two patient-friendly articles about reporting adverse events and product quality problems to FDA and to the patient's caregivers. These articles are also available to pharmacists in printer-friendly PDF versions that can be downloaded and distributed to patients. FDA relies on properly and timely reporting of serious and unexpected drug and device-related adverse events, use errors, and quality problems. Pharmacists can ascertain and teach their patients to understand the "what, why, and how" to report to FDA and also learn about what happens to each received report and whether it leads to FDA action that may make product use safer for both patients and providers. FDA's patient specific page can be found at www.fda.gov/consumer/default.htm.

Retail Pharmacies Now Providing Medical Clinics to Improve Public Safety



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with 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. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to **ISMP Medication Safety Alert!**® Community/Ambulatory Edition by visiting www.ismp.org. 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: 200 Lakeside Dr;

Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Retail pharmacy corporations have set up medical clinics within pharmacies. These nurse-practitioner or physician-assistant run clinics aim to rapidly diagnose and treat a limited number of health problems. Many also offer vaccination programs. The first pharmacy-based medical clinics were opened in Minnesota as QuickMedx in 2000, later becoming MinuteClinic in 2002. Currently there are approximately 1,000 sites in 37 states representing almost three million cumulative visits.

The emergence of pharmacy-based medical clinics offers a unique set of opportunities to improve the safety in prescribing and dispensing medications. Do you have a clinic opening in your store? If so, consider these safety recommendations:

Meet the nurse practitioners and physician assistants and introduce them to your staff. Show them how your operation works and invite them in for a tour.

If you have prescription scanning capabilities, show them how a scanned prescription displays on your monitor. Show them how different prescription blanks scan (eg, colored prescription blanks, blanks with water marks or seals for diversion) and what to avoid using so as not to distort the actual order.

If they are using a device that allows them to send prescriptions electronically, have them send test prescriptions to you, invite them in to see how their prescriptions display on your computer and send them back test refill requests.

Work together on any issues that arise, such as conflicting directions and special instructions, where the automatic sig indicates one set of patient directions and then the free text special instructions contradict the sig (see image below).

R	LORAZEPAM 0.5MG TABLET
Sig:	1 Tablet(s) PO Q6-8H PRN anxiety, insomnia x 30 days
Dispense:	90 Tablet(s)
Special Instructions:	Take one tab as needed for anxiety or insomnia, may repeat x1.
Refills:	5
Signature:	_____

Ask prescribers to include the indication for use whenever they write or call in a prescription.

Educate them that it is your policy to read back the entire prescription order to them after transcribing it in the pharmacy including spelling the medication name. Let them know you will be using "cock-pit" language, for example, "one six" for "16."

Ask them to include both the generic and brand names on all written orders for medications with look-alike and/or sound-alike names.

Share with them ISMP safety tools (eg, List of Error Prone Abbreviations, List of Confused Drug Names) found at www.ismp.org/Tools.



Let them know you will dispense measuring devices every time they order a liquid medication.

Let them know that safety is your priority when filling prescriptions, and invite them to be part of your safety team.

FDA Launches Web Sites on Promotion of Medical Products

On September 3, 2008, FDA launched two new Web sites to provide information for consumers and industry about how FDA regulates the promotion of medical products. Pharmacists can obtain useful information regarding prescription drug advertising regulations as well as refer their patients who may have questions to the site.

The “Advertising Prescription Drugs and Medical Devices” Web site provides a “one-stop shop” portal to information on FDA regulation of medical product promotion. Pharmacists access relevant laws, regulations, and guidances. This site can be found at www.fda.gov/oc/promotion/.

The direct-to-consumer Web site, “Be Smart about Prescription Drug Advertising: A Guide for Consumers” is designed to educate consumers about how to view such advertising to help inform their discussions with health care providers, and consequently to help improve patient’s understanding and medical care. This site was created in collaboration with EthicAd, an independent, nonprofit organization dedicated to helping consumers, health care professionals, and the pharmaceutical and advertising industries with direct-to-consumer advertising for prescription drugs. More information can be found at www.ethicad.org.

The direct-to-consumer site provides interactive example ads for fictitious drugs to illustrate the different requirements for the various types of ads. It also includes a list of questions patients should ask themselves when they see a prescription drug ad. This list can be printed for patients to use while discussing questions with their health care providers. This site can be found at www.fda.gov/cder/ethicad/index.htm.

FPGEE Returns to Computer-based Format

As advancements in secure testing technology forge ahead, the push for more electronically based systems and less use of the traditional paper-and-pencil mechanisms continues. With this in mind, NABP will soon be returning the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) to a computer-based format, eliminating the paper-and-pencil examination.

The FPGEE is the third computerized examination to be developed by NABP, after the North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® (MPJE®). The new computerized FPGEE will debut at the April 14, 2009 administration.

The computerized FPGEE examination will continue to be administered one day in the spring and one day in the fall; however, instead of limiting the available testing locations to three sites, applicants will be able to choose from more than

200 Pearson VUE testing sites located within the continental United States. In addition, it is anticipated that applicants will be able to schedule their test sites electronically 48 to 72 hours after having been accepted to take the FPGEE.

The NABP test vendor, Pearson VUE, will administer the computerized FPGEE as it does with the NAPLEX and the MPJE. Demonstrating a record of solid customer service combined with a secure and consistent test center network, Pearson VUE is committed to providing a reliable and professional testing environment for applicants on behalf of NABP.

The FPGEE is one component of the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) certification process. In addition to passing the examination, FPGEC applicants are required to have certain documents submitted from educational and licensure institutions that present their educational backgrounds and licensure and/or registration to practice pharmacy. Applicants must also pass the Test of English as a Foreign Language™ (TOEFL®) and the Test of Spoken English™ (TSE®), or the TOEFL Internet-based Test (iBT). The FPGEC certificate allows foreign graduates to partially fulfill eligibility requirements for licensure in the 50 United States and the District of Columbia where the certification is recognized.

To prepare for the FPGEE, NABP recommends that applicants take the Pre-FPGEE®, the official FPGEE practice examination written and developed by NABP. This practice examination is designed to help familiarize applicants with the FPGEE by exhibiting the types of questions provided on the actual examination as well as providing a score estimate.

Additional information on the FPGEE as well as the Pre-FPGEE is available in the Examination Programs section on the NABP Web site at www.nabp.net.

Updated 2009 Survey of Pharmacy Law Now Available

The NABP 2009 *Survey of Pharmacy Law*, providing a concise research source for key regulatory questions in pharmacy practice for all 50 states, the District of Columbia, and Puerto Rico, is now available.

The *Survey* updates, graciously provided by the state boards of pharmacy, consist of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Also, a new question in Section VII, “Issuance of Initial Pharmacist Licensure,” asks whether or not states require criminal history record checks for initial licensure as a pharmacist.

To order the *Survey*, visit the NABP Web site at www.nabp.net and download an order form; the *Survey* costs \$20.

All final-year pharmacy students receive the CD-ROM free of charge through the generous sponsorship of Purdue Pharma LP.

More information on the *Survey* is available by contacting customer service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

2009 JURISPRUDENCE QUIZ

(covering May 2008, August 2008, November 2008, and February 2009 issues of the State Board Newsletter)

No credit can be granted for Answer Sheets postmarked **after March 31, 2009**.
Certificates will be mailed to those receiving a passing score of 75 or better.

- Which of the following is true regarding physician assistant (PA) prescribing?
 - Prescribing is based on a formulary.
 - The PA must have a Certificate to Prescribe prior to authorizing prescriptions.
 - The supervising physician may further limit the prescribing of their PAs.
 - All of the above.
- Which of the following is true about physician assistants?
 - They must have their own Drug Enforcement Administration (DEA) number to write for a controlled substance.
 - They may prescribe a Schedule II narcotic for a terminal patient.
 - Their DEA number will begin with the letter "F."
 - They may prescribe controlled anorexiant.
- The deadline for submitting a continuing pharmacy education (CPE) report form is?
 - March 1
 - May 15
 - July 1
 - September 15
- An optometrist may now prescribe from a listing of classes of drugs instead of a strict formulary
 - True
 - False
- Which of the following is true about the recall on Bayer's Contour Test Strips?
 - The recall was for all lots of these test strips.
 - This affects both the test strips and the meter itself.
 - The recalled test strips could result in blood glucose readings with a positive bias that could demonstrate 5% to 17% higher test results.
- As of January 1, 2008, which is true about methadone 40 mg tablets?
 - They are no longer available to a retail pharmacy.
 - The manufacturers voluntarily stopped distribution except to authorized facilities for detoxification and maintenance treatment for opioid addiction.
 - This restriction was the result of an increase in methadone related adverse events.
 - All of the above.
- Which of the following is true about the new compounding standards?
 - They were effective on June 1, 2008.
 - These revisions tighten standards and conditions for sterile compounding.
 - These revisions can be found in USP 32-NF 27.
 - All of the above.
- When a pharmacy receives a traditional fax, ie, fax-to-fax transmission, the prescription must have an original signature by the prescriber.
 - True
 - False

[Questions continued on reverse side > > >]



PLEASE DETACH HERE



— PLEASE COMPLETE REVERSE SIDE BEFORE MAILING —

JURISPRUDENCE REQUIREMENT FOR CPE

To receive a certificate of credit, please complete this form and mail it to the address below with a check for \$4 payable to **Justice Data Management**. A certificate will be mailed to those receiving a passing score of 75 or better.

**JURISPRUDENCE CPE; JUSTICE DATA MANAGEMENT;
PO BOX 43056; CINCINNATI, OH 45243-0056**

Program Evaluation:

[1=Poor / 2=Fair / 3=Satisfactory / 4=Good / 5=Excellent]

(Please rate this program in the following areas)

- | | | | | | |
|--------------------------------|---|---|---|---|---|
| ◆ Quality of information | 1 | 2 | 3 | 4 | 5 |
| ◆ Usefulness to my practice | 1 | 2 | 3 | 4 | 5 |
| ◆ Readability and presentation | 1 | 2 | 3 | 4 | 5 |

State Board Newsletter (February 2009) Answer Sheet:

(Please fill in your answer to each question)

- | | A | B | C | D | | A | B | C | D |
|----|--------------------------|--------------------------|--------------------------|--------------------------|-----|--------------------------|--------------------------|--------------------------|--------------------------|
| 1. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 9. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 10. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 11. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. | <input type="checkbox"/> | <input type="checkbox"/> | | | 12. | <input type="checkbox"/> | <input type="checkbox"/> | | |
| 5. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | | 13. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 14. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 15. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. | <input type="checkbox"/> | <input type="checkbox"/> | | | 16. | <input type="checkbox"/> | <input type="checkbox"/> | | |

Continued from page 1

in Ohio now have requirements that must be met before they may routinely perform three tasks:

1. Engage in the compounding of any drug
2. Package or label any drug
3. Prepare or mix any intravenous drug to be injected into a human being

The requirements that must be met before a person routinely performs these three functions are:

1. Must be eighteen (18) years of age or older
2. Must possess a high school diploma or a certification of high school equivalence (except those employed on the effective date of the law)
3. Must pass an examination approved by the Board
4. Must submit to a criminal records check that shows no felony convictions

There are some exceptions to each of those requirements that will be clarified further as the implementation date arrives. The Board is required to promulgate rules about acceptable tests and will probably need to clarify other issues as well.

At the time of the writing of this *Newsletter*, the bill had been sent to the governor for his signature. The bill will become effective 90 days after his signature, meaning that it will probably take effect in March 2009. The Board will need to be ready with rules by then or shortly thereafter. Of course, the governor has the right to veto the bill if he chooses. Hopefully, that will not be the case.

HB 215 makes *Salvia divinorum* (and its active ingredient *Salvinorin A*) a Schedule I controlled substance in Ohio. If you are not familiar with *Salvia*, you should probably take the time to learn about its properties. It is becoming widely abused as a hallucinogen. Even though it is not a controlled substance federally, the Drug Enforcement Administration has an excellent article on this substance at www.deadiversion.usdoj.gov/drugs_concern/salvia_d/salvia_d.htm. (Instead of typing all of the address, you can go to the main Web site at www.deadiversion.usdoj.gov and search for "Salvia" to find the article.)

HB 130 (DYS Operations) deals mostly with issues involving the Department of Youth Services and the Department of Rehab/Corrections. However, included in the bill is a section that would require all boards who issue licenses to create a rule listing all those sections of law for which a felony conviction would result in an immediate denial of licensure **without a hearing**. Some boards do have that ability to deny licensure without a hearing, but the Board of Pharmacy does not. The only way the Board of Pharmacy may deny a license is after having a hearing where the prospective licensee has the opportunity to meet with the Board.

In a past *Newsletter*, HB 253 was discussed. This bill would have allowed advanced practice nurses (APN) to prescribe Schedule II controlled substances. Please note: **This bill did not pass**. Pharmacists need to be aware of this failure as we have been hearing in the Board office that some APNs mistakenly believe they may now write for Ritalin®, Concerta®, and other Schedule II controlled substances. Since the bill failed to pass, the APN prescribing abilities have not changed.

Disciplinary Actions

Anyone having 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 – 800/230-6844,

www.deadiversion.usdoj.gov

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