

February 2011

News



Ohio State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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

Do You Have Your New Terminal Distributor License?

Please check the Terminal Distributor of Dangerous Drugs (TDDD) license at your facility to be sure you have received your 2011 TDDD license from the Ohio State Board of Pharmacy. The TDDD license is the license required for all pharmacies, hospitals, clinics, EMS squads, etc. If you have not renewed or received your 2011 TDDD license, please call the Board office immediately. The 2010 TDDD licenses expired on December 31, 2010.

Jurisprudence Continuing Pharmacy Education Note

Since the Board is not mailing the *Newsletter* anymore, the Board's annual Jurisprudence Quiz is not attached to this *Newsletter* as before. Instead, it is posted on the Board's Web site (www.pharmacy.ohio.gov). Click on "C.E. News and S.B.N." The questions in the quiz relate to the topics covered in this *Newsletter* as well as the May, August, and November 2010 issues. If you need them, copies of the previous *Newsletters* can be found on the Ohio State Board of Pharmacy Web site by clicking on "C.E. News and S.B.N."

Please note that the deadline for submission of the completed quiz is **March 31, 2011**. Any answer sheets postmarked after March 31, 2011, will not be accepted.

Final CPE Reminder

This is a final reminder to those pharmacists whose license number begins with 03-2. This is the year for you to report your continuing pharmacy education (CPE). Your CPE statement will be due in the Board of Pharmacy office **no later than May 15, 2011**. The CPE report notice should be arriving in your mail sometime early in March with the instructions on the reporting process. Your license 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 the Board office so you can be sent a replacement.

You will need to attest to a total of 6 CEUs (60 hours) of continuing education 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 jurisprudence programs 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 5.7 CEUs (57 hours) may be in any approved category that you wish.

You may use certificates dated on or after March 1, 2008, that you did not use when reporting in 2008. In addition, **please be sure that you have the certificates in hand before you certify your compliance with the CPE requirements.** Every year, the Board has a few pharmacists who submit the form attesting that they have the required 6 CEUs 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 file your CPE form with the Board, **any certificates dated after the date you filed the CPE form will not be accepted if you are audited.** Falsifying the CPE report form is something that the Board does not take lightly. As long as you have the originals 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.")

Changes to Rules 4729-5-19 – Serial Numbering of Prescriptions and 4729-5-24 – Prescription Copy

On January 1, 2011, two important rule changes took effect. Rule 4729-5-19 – Serial Numbering of Prescriptions was changed to mandate that after the refills authorized on an initial prescription are used up, any additional "refills" authorized by the prescriber must be assigned a new prescription number. In the past, it was permissible to use the same number by just adding additional refills to the first prescription, as long as the time limit on refills had not expired. That option is no longer allowed. Once the original prescription and its authorized refills have run out, a new prescription and a new prescription number is required. The new wording in the rule is as follows:

Continued on page 4



DEA Policy Statement on Role of Agents in Communicating CS Prescriptions

Drug Enforcement Administration (DEA) issued a statement of policy that clarifies the proper role of a duly authorized agent of a DEA-registered individual practitioner in communicating controlled substance (CS) prescription information to a pharmacy. The statement, published October 6, 2010, in the *Federal Register*, reminds health care providers that a prescription for a CS medication must be issued by a DEA-registered practitioner acting in the usual course of professional practice. Such a practitioner may authorize an agent to “perform a limited role in communicating such prescriptions to a pharmacy in order to make the prescription process more efficient,” and the guidance emphasizes that medical determinations to prescribe CS medications may be made by the practitioner only.

The specific circumstances in which an agent may assist in communicating prescription information to a pharmacy are detailed and include:

- ♦ An authorized agent may prepare the prescription, based on the instructions of the prescribing practitioner, for the signature of that DEA-registered practitioner.
- ♦ For a Schedule III-V drug, an authorized agent may transmit a practitioner-signed prescription to a pharmacy via facsimile, or may communicate the prescription orally to a pharmacy on behalf of the practitioner.
- ♦ An authorized agent may transmit by facsimile a practitioner-signed Schedule II prescription for a patient in a hospice or long-term care facility (LTCF) on behalf of the practitioner.

The guidance also makes clear that generally, Schedule II prescriptions may not be transmitted by facsimile and that hospice and LTCFs are exceptions. Further, Schedule II prescriptions may only be communicated orally by the DEA-registered practitioner and only in emergency situations. DEA stresses that the practitioner should decide who may act as his or her authorized agent and advises that such designation be established in writing. An example written agreement is included in the policy statement, along with additional guidance related to designating an authorized agent. DEA also notes that as electronic prescribing for CS is implemented and its use increases, the role of the agent in communicating CS prescriptions will likely be reduced over time. The DEA policy statement is available on the *Federal Register* Web site at www.federalregister.gov/articles/2010/10/06/2010-25136/role-of-authorized-agents-in-communicating-controlled-substance-prescriptions-to-pharmacies.

FDA and NABP Partner to Help Prevent Acetaminophen Toxicity

In partnership with the National Association of Boards of Pharmacy® (NABP®), and as part of its Safe Use Initiative, Food and Drug Administration (FDA) encourages pharmacies to stop using the abbreviation APAP and to spell out the drug name, acetaminophen, in effort to help patients avoid acetaminophen toxicity. As explained in an FDA drug safety notice, liver injury

due to acetaminophen overdose is a serious public health problem, and by spelling out the drug name on prescription labels, pharmacies are enabling patients to know when their medication contains the drug. Patients can then compare their prescription and over-the-counter medications to determine whether both contain acetaminophen and avoid taking two medicines containing the drug. The FDA drug safety notice provides more information and is available at www.fda.gov/Drugs/DrugSafety/ucm230396.htm.

In July 2010, NABP recommended that the state boards of pharmacy prohibit the use of the abbreviation APAP on prescription labels, and require that acetaminophen be spelled out. In situations where the board is unable to mandate such a provision, NABP recommended that the boards strongly encourage practitioners to follow this guideline. More information is available on the NABP Web site at www.nabp.net/news/nabp-recommends-boards-of-pharmacy-prohibit-use-of-acetaminophen-abbreviation/.

The ISMP Ambulatory Care Action Agenda: Learn from Others' Mistakes



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent non-profit agency that analyzes 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 risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also a FDA MedWatch partner. Call 1-800-FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at www.ismp.org. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

No news is **not** good news when it comes to patient safety. Each organization needs to accurately assess how susceptible its systems are to the errors that have happened in other organizations, and acknowledge that the absence of similar errors is not evidence of safety. Personal experience is a powerful teacher, but the price is too high to learn all we need to know from firsthand experiences. Learning from the mistakes of others is imperative.

A great way to utilize the ISMP Medication Safety Alert!® Community/Ambulatory Care Edition is by using the Ambulatory Care Action Agenda*. Three times a year, selected items are prepared for you and your staff to stimulate discussion and collaborative action to reduce the risk of medication errors previously reported to the ISMP Medication Errors Reporting Program (MERP). The agenda topics appeared in the ISMP Medication Safety Alert! Community/Ambulatory Care Edition during the preceding four

Compliance News

Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)



months. Each item includes a brief description of the medication safety problem, recommendations to reduce the risk of errors, and the issue number to locate additional information as desired.

The Action Agenda is presented in a format that allows community practice sites to document their medication safety activities, which is important for internal quality improvement efforts but also important for any external accrediting or regulatory organizations. Each pharmacy practice site should convene a staff meeting to discuss each item in the Action Agenda. The staff should ask themselves, "Can this error occur at our site?" If the answer is "yes," the ISMP recommendations for prevention should be reviewed for applicability at that specific site. If the recommendations are germane to the practice site, the columns on the Action Agenda indicating "Organization Assessment" and "Action required/Assignment" should be completed and a reasonable time set for completion. The staff should reconvene in three months time to determine if the proposed recommendation strategies have been implemented, if they are still pertinent, and if other strategies have been offered or considered since the initial meeting.

According to the 2011 *Survey of Pharmacy Law*, published by NABP, at least 19 states regulate, require, or recommend a continuous quality improvement (CQI) program to monitor and prevent quality related events. The purpose of the CQI program is to detect, document, and assess prescription errors in order to determine the cause, develop an appropriate response, and prevent future errors. Utilization of the Action Agenda to review externally reported errors combined with review and analysis of internally reported events constitutes a feasible and effective CQI program.

*The Action Agenda is available at no charge on the ISMP Web site, www.ismp.org/Tools/communitySafetyProgram.asp.

Iowa Tracks Group Using Fraudulent CS Prescriptions

The Iowa Department of Public Safety seeks assistance in tracking a group of individuals using fraudulent prescriptions to obtain CS. Specifically, four unidentified individuals have obtained oxycodone using fraudulent prescriptions at a number of pharmacies in Iowa. Similar cases have occurred in Missouri, and it is believed that the same group of people is involved. The subjects are reported to have used multiple aliases, to be in their 20s or 30s, and to have paid in cash. They have also been reported to use crutches when dropping off and picking up prescriptions. The fraudulent prescriptions were on legitimate prescription paper with valid prescriber names, but the addresses on them had been computer generated. Similar cases or relevant information can be reported to Criminal Intelligence Analyst Crystal Munson at the Mid-Iowa Narcotics Enforcement Task Force by calling 515/270-8233, extension 119, or by e-mailing crystal.munson@polkcountyiowa.gov.

Stolen Carbatrol, Adderall XR Surfacing in Supply Chain

Shire, along with FDA, alerts pharmacists and distributors that certain lots of Carbatrol® that were stolen on October 17, 2008,

have been found in the supply chain as expired returns. The stolen shipment also contained Adderall XR®. The manufacturer warns that more stolen product may still be on the market and that stolen Carbatrol and Adderall XR should not be used or sold because the safety and effectiveness of the product could have been compromised by improper storage and handling or tampering while outside of the legitimate supply chain. The following products and lot numbers are affected:

- ♦ Adderall XR 15 mg, Lot No: A38146A, Expiration Date: 02/29/2012
- ♦ Carbatrol 200 mg, Lot No: A40918A, Expiration Date: 04/30/2010
- ♦ Carbatrol 200 mg, Lot No: A40919A, Expiration Date: 04/30/2010
- ♦ Carbatrol 200 mg, Lot No: A41575A, Expiration Date: 05/31/2010

These lots of Carbatrol and Adderall XR were stolen while in transit from Shire's manufacturing facility in North Carolina to Shire Distribution Center in Kentucky. FDA seeks assistance and asks that any information regarding the stolen Carbatrol or Adderall XR, including suspicious or unsolicited offers for these products, be reported by contacting FDA's Office of Criminal Investigations (OCI) at 800/551-3989, or by visiting the OCI Web site at www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.

Survey of Pharmacy Law's 60th Edition Now Available!

Celebrating its 60th edition as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2011 *Survey of Pharmacy Law* is now available.

The *Survey*, produced in a CD format, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 18, Drug Control Regulations, asks whether or not states have CS or drugs of concern scheduled differently than the federal Controlled Substances Act.

Updates for the 2011 *Survey* were graciously provided by the state boards of pharmacy. In addition to the boards' support, NABP requested data from relevant health care associations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25, and laws pertaining to the possession of non-controlled legend drugs and possession of CS in Sections 26 and 27.

The *Survey* can be purchased online for \$195 by visiting the Publications section of the NABP Web site at www.nabp.net/publications.

All final-year pharmacy students receive the *Survey* free of charge through the generous grant of Purdue Pharma L.P.

For more information on the *Survey*, please contact Customer Service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

- (C) All prescriptions which are not refillable, either because of the dispensing of all refills or the length of time since issuance, shall be assigned a new serial number upon an authorization for additional dispensings by a prescriber.

This change becomes important when the next rule is considered. Rule 4729-5-24 – Prescription Copy was also changed significantly. As of January 1, 2011, each prescription will be limited to one transfer **during the life of that prescription**. The wording of the changed paragraph in this rule is as follows:

- (A) A pharmacist may transfer a copy of a prescription; a pharmacist may refill a copy of a prescription; such actions must be in accordance with the following:
- (1) Copies of prescriptions for dangerous drugs, including both non-controlled substances and controlled substances, shall only be transferred one time. Pharmacies electronically sharing a real time, online database may transfer a prescription up to the maximum number of refills permitted by law and the prescriber's authorization pursuant to paragraph (A)(5) of this rule.

There are several things that pharmacists should consider as they try to comply with the requirements of this rule:

1. This rule took effect on January 1, 2011. Therefore, the one-time transfer limit applies to transfers occurring **after** the effective date, not before.
2. This rule is now worded identically to the rule for transfers of controlled substance prescriptions that has been in effect for years.
3. The one-time transfer limit applies to the life of each prescription. The rule does not say one transfer per year like the news media has mistakenly reported. If a prescription is written for a 30-day supply with three refills, then this prescription can be transferred once between the original fill and the third refill. If the pharmacist then calls the prescriber for additional "refills" on this medication, a new prescription number will be assigned (see changes to rule 4729-5-19 above) and the new prescription may be transferred once during its lifetime. The only time the refill limit applies for a whole year would be for those prescriptions with refills authorized for one year.
4. The Board, as usual, expects pharmacists to act in the best interests of the patients at all times when following this rule. As with all rules, it is not possible to foresee all potential situations. If a patient has a true emergency need arise, the pharmacist should see to it that the patient receives his or her necessary medications, even if the prescription has already been transferred once.

The Board has received both positive and negative comments about the change to the prescription transfer rule. The Board will be considering this rule again during its rule review process this spring. The overall goal of the change was to ensure patient safety due to the greatly increased chances of error when patients are requesting multiple transfers to multiple pharmacies month after month. Since the majority of transfers are still

done by word of mouth, the chances of error increase drastically with every transfer. It is the Board's hope that limiting the number of transfers that can be done will improve patient safety by decreasing the opportunities for error. If anyone has ideas about how the rule should be adjusted while still maintaining the goal of patient safety, please submit those ideas to the Board office for consideration during the rule review process.

Are You Getting the Board's E-Mails?

If you have not been receiving the e-mails sent by the Board, please make sure that your system is not blocking the Board's e-mails. Please be sure that you have exec@bop.ohio.gov listed as safe so your system does not filter the e-mails out. If that does not work, then you might need to check with your e-mail provider. After receiving comments from several pharmacists, the Board checked through the "rejected" list and found some similarities in the vendors, so the Board is wondering if a few of the e-mail systems are blocking the Board's transmissions from reaching your system.

You should receive a notice at the beginning of February, May, August, and November notifying you that the State Board News is available on the Board's Web site. In addition, the Board occasionally sends out other e-mails, such as the one sent at the end of December to alert everyone to the change in the Prescription Copy rule. The Board tries to avoid sending something unless it is important, since everyone gets too many e-mails already. Please try to ensure that you are able to receive the Board's few messages when they are sent.

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 – 800/882-9539,
www.deadiversion.usdoj.gov