



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

Annual CE Reminder – New Process This Year to Report CE!

If your Ohio pharmacist license number begins with 033, it is your year to attest (report) that you have met your continuing education (CE) requirements. The Ohio State Board of Pharmacy has determined that the process of spring CE attestation and fall pharmacist license renewal is redundant and confusing. Historically, CE reporting and license renewal were separated to allow for the paper, labor-intensive process of collecting the CE program numbers, checking for complete forms, and, finally, auditing them, before allowing the renewal of a license. As this process has improved and become automated to allow pharmacists to “attest” to completion of the required hours of CE, along with the future use of the National Association of Boards of Pharmacy® (NABP®) CPE Monitor™, the Board has decided to simplify and combine the CE attestation and pharmacist license renewal into one process. The Board has seen pharmacists fail to renew their license in September, because they “attested” their CE in the spring and thought that was their license renewal. So, these processes will be combined into one with the pharmacist license renewal. The pharmacist online renewal notices will be mailed by July 15, 2012. However, the date range for the allowable CE program certificates will remain the same.

For this reporting cycle, just as before, you must only count your CE program certificates dated between March 1, 2009 and May 15, 2012. The only thing that has changed is when you attest (report), which will be done simultaneously with your pharmacist license renewal. A great question came out at the Ohio Pharmacists Association Annual Conference asking if the date range for CE program certificates would be changing. Currently the answer is no, it is not changing. But, if this changes in the future, it will be expanded, ie, will still allow for program certificates dated from March 1, through an end date yet to be decided.

If you are certified in one of the Board-approved specialty programs, you may still use this in lieu of 57 hours

of CE (5.7 CEUs) but you still must do the required three hours of Ohio Board-approved jurisprudence CE. If you do not work in Ohio, have a current pharmacist license in another state, and currently practice pharmacy in that state, you may still use that current license to report that you have met the CE requirements to renew your Ohio pharmacist license. If you practice pharmacy in Ohio, you **must** report 60 hours of CE (6.0 CEUs), including the 3 hours of CE (0.3 CEUs) of Board-approved jurisprudence CE.

You **do not** send in your original CE program certificates unless audited. You will only have to produce the certificates if you are one of the pharmacists randomly chosen to be audited. Please be sure the certificates are dated on or after March 1, 2009 through May 15, 2012, and keep your original certificates for a period of one year. Remember, you no longer have to list your individual program numbers at any time in the process. All you are asked to do is select a statement certifying that you have done the required CE and that you have the certificates in hand dated between March 1, 2009 and May 15, 2012; have an approved specialty with required 0.3 CEUs of Ohio Board-approved jurisprudence; or have another current state license and do not practice in Ohio. Those pharmacists who are required to report this year should have received a letter explaining all of these changes. If your license begins with 033 and you have not received the instructions from the Board telling you the new reporting process (other than pharmacists newly licensed after June 1, 2011), please contact the Board office immediately. Again, make sure you have your certificates in hand before submitting the attestation statement during pharmacist license renewal. If you are audited and cannot provide the certificates or if your certificates are dated after the date of May 15, you will face Board action. In addition, you should be aware that the Board now randomly audits a higher percentage of pharmacists than in the past. Previously, we audited about 10% of those reporting. With this new procedure, that figure is about 20%, so your chances of being audited will be greater.

Continued on page 4



DEA Provides Information Regarding Carisoprodol Prescriptions

A Drug Enforcement Administration (DEA) announcement provides information regarding the scheduling of carisoprodol, effective as of January 11, 2012. The DEA Final Rule making the drug a Schedule IV controlled substance was published December 12, 2011, and states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with DEA regulations. Specifically, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met:

- ◆ the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 CFR §1306.04);
- ◆ the prescription contains all the information required by 21 CFR §1306.05; and
- ◆ the number of refills authorized by the prescribing practitioner is five or less (21 USC §829(b)).

The full text of the notice is available on the DEA Web site at www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html.

Pfizer Recalls Several Lots of Two Oral Contraceptive Products

Pfizer Inc recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) tablets and 14 lots of norgestrel and ethinyl estradiol tablets (generic) due to potential for inexact count and out-of-sequence tablets. A Pfizer investigation found that some blister packs of the affected products may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. Food and Drug Administration (FDA) advises that patients who have the affected product should notify their physician and return the product to the pharmacy. A Pfizer press release includes a list of the affected products with the National Drug Code (NDC) number, lot number, and expiration date for each, and is available at www.fda.gov/Safety/Recalls/ucm289770.htm.

Changes in Medication Appearance Should Prompt Investigation by Pharmacists and Patients

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit 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 an 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.

As the numbers of generic products continue to increase, it seems that both patients and practitioners have become desensitized to changes

in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

Your pharmacy may be providing an important patient safety tool on the prescription label that may be overlooked by patients and their caregivers: a description of the shape, color, and imprint code of the medication that should be inside. This information can help ensure accuracy since it's based on the NDC number. Teach patients to look for this description and question any differences. In addition, the patient needs to know if the medication name on the pharmacy generated label is the medication he or she was expecting to receive. Even if the generic manufacturer is different each time the prescription is renewed, the description on the label should match the NDC number and thus the product inside.

With so much information on prescription labels such as patient and doctor name, drug name, instructions, and warnings – this added information can easily be missed. But it's important, so look for it and put it to use!

FDA Reminder: Purchasing Unapproved Injectable Cancer Medications Threatens Patient Safety

FDA is reminding health care providers to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the United States. FDA explains that “current shortages of injectable cancer medications may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply, which could result in

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



serious harm to patients.” FDA reports that the agency is aware of promotions and sales of unapproved injectable cancer medications directly to clinics in the US and that the medications were likely administered to patients. Examples of products include unapproved versions of FDA-approved medications such as Faslodex® (fulvestrant), Neupogen® (filgrastim), Rituxan® (rituximab), and Herceptin® (trastuzumab). FDA stresses the risks to patients when such unapproved medications are used. The agency outlines several steps health care providers should take to ensure patient safety:

1. Obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the US. An FDA Web page, www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm, provides the online resource for each state for verifying that a wholesale distributor is appropriately licensed.
2. Determine if the medication you have received is FDA-approved by checking the Orange Book or searching the Drugs@FDA database.
3. Question whether a price sounds too good to be true. Deep discounts may be offered because the product is stolen, counterfeit, or unapproved.
4. Carefully inspect the product and packaging and be alert for signs that the product is not FDA approved, such as if the packaging looks different or the dosing recommendations are unfamiliar.

FDA also notes that if a health care provider receives multiple complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

FDA reminds health care providers that in certain circumstances the agency may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the US through a controlled network, and would not be sold in direct-to-clinic solicitations. If FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available in the Drug Shortages section of the FDA Web site, www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm.

Additional details are provided in an FDA Drug Safety Communication, available at www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf.

Insulin Pens Should Not Be Used for Multiple Patients, Stresses CDC

Centers for Disease Control and Prevention (CDC) issued a notice, reminding health care providers that insulin pens are intended for use by a single patient, and should never be used on more than one patient. CDC indicates that the agency has become “increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV).” The notice explains that regurgitation of blood into the insulin cartridge can occur after injection, creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed. CDC provides the following recommendations to help protect patient safety:

- ◆ Insulin pens containing multiple doses of insulin are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- ◆ Insulin pens should be clearly labeled with the person’s name or other identifying information to ensure that the correct pen is used only on the correct individual.

- ◆ Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- ◆ If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

The notice may be downloaded from the CDC Web site at www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf.

US Public Health Service Report Supports Maximizing the Scope of the Pharmacist as Part of Health Care Team

Presenting an evidence-based discussion of the comprehensive patient care services that pharmacists currently provide, a new government report calls for expanded support for such pharmacist-delivered patient care models. The report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice*, prepared by the Office of the Chief Pharmacist, US Public Health Service (PHS), is organized into four focus points as follows:

- ◆ Focus point 1 discusses how pharmacists are integrated in many practice settings as health care providers, such as through collaborative practice agreements, and provides data showing interprofessional support for such models.
- ◆ Focus points 2 and 3 support recognition of pharmacists as health care providers and compensation models that will allow pharmacists to continue to improve patient and health care system outcomes.
- ◆ Focus point 4 presents a review of numerous peer-reviewed studies that demonstrate favorable outcomes from pharmacist-delivered care.

RADM Scott Giberson, chief professional officer, PHS Pharmacists, and the primary author of the report, stated that “one of the most evidence-based and cost-effective decisions we can make as a nation is to maximize the expertise and scope of pharmacists, and minimize expansion barriers to successful health care delivery models.” The report may be downloaded from the US PHS Web site at www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile Today!

CPE Monitor™ integration is underway. Soon all Accreditation Council for Pharmacy Education (ACPE)-accredited providers will require you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity. Many have already begun to do so.

Visit www.MyCPEmonitor.net to set up your e-Profile and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

In addition, make sure the program certificates you are using to meet the three hours of Board-approved jurisprudence requirement are listed on the Board's Web site. Do not assume that your courses on pharmacy law will count unless they are listed on the Board's Web site (www.pharmacy.ohio.gov and then click on CE News and S.B.N.). If you have at least 60 hours worth of certificates in hand and you have verified that your jurisprudence credits are Board approved when you certify that you have met the requirement, you should not have any difficulty with the audit.

If you are audited, please submit the original documents to the Board when requested. Make copies of your documents before you send the originals to the Board office. Every year, the Board has one or two people whose documents end up disappearing within the United States Postal Service system.

OARRS Review: More on Rule 4729-5-20

As you know, since the Ohio Automated Rx Reporting System (OARRS) Rule 4729-5-20 went into effect on October 27, 2011, all pharmacists who are filling prescriptions for OARRS reportable drugs (all controlled substances and tramadol containing products) must run an OARRS report if certain conditions occur for that prescription. You must run an OARRS report if the patient is being treated with an OARRS reportable drug for greater than 12 weeks or if certain "red flag" issues occur during the fill process, such as:

- ◆ Patient is being treated with an OARRS reportable drug by multiple prescribers
- ◆ Abuse/overuse (ie, early refills)
- ◆ Patient coming from outside your normal fill area
- ◆ Prescriber from outside your normal fill area
- ◆ Patient appears impaired upon delivery of script
- ◆ Patient asks for certain drug by color/trade name/markings

These red flag issues are obviously up to the judgment of the pharmacist. Does the pharmacist have to run another OARRS report after the initial run at the 12-week time frame? Technically no, but the pharmacist must run the report if any red flag issues arise in the future after this 12-week report. Also, please note, the Board of Pharmacy does not mandate how you prove the running of these reports. There are many ways to do this such as notes in the profile, printing the reports and keeping files, etc. However, keep in mind these reports contain confidential information and are protected by state and federal law (Health Insurance Portability and Accountability Act), so whatever method you choose be aware that you cannot share this report with anyone other than another registered pharmacist who is also taking care of this patient. You cannot give the OARRS report to the patient or fax it to the prescriber. You can only share the data that you get out of the report, but not the

report itself. If the patient wants the actual report, please direct them to the OARRS Department at the phone number 614/466-4143, option No. 1. If the prescriber or law enforcement wants your report you must direct them to run their own report under their username and password.

OARRS Data: Garbage In, Garbage Out

With the increased use of OARRS by multiple professionals and agencies, it is imperative that the data is as accurate as possible. Please do your best to enter the correct data in your pharmacy systems. Typical errors the Board sees that cause issues are incorrect prescriber name, incorrect Drug Enforcement Administration (DEA) number, incorrect date of birth, and incorrect address of the patient (demographic info). These types of errors can cause a serious skew in the appearance of the patient's OARRS report, so please recognize the importance of accurate order entry of the data in your pharmacy computer systems.

Legislative Update: SB 83 – APN Prescribing of CII Drugs

This recent law was signed by Governor John Kasich and goes into effect 90 days after his signature, which will be June 8, 2012. At this time you will start seeing CII prescriptions written by advanced practice nurses (APNs) with their appropriate certificate to prescribe (CTP) number and DEA number on the script. It allows APNs with these credentials to write for CII prescriptions without the typical restrictions previously in place for these drugs. The CII drugs are categorized in groups, which include opiates, sedatives/hypnotics, and amphetamines/stimulants. Each formulary group has its own restrictions for APN prescribing and the Board recommends that you refer to the Ohio Board of Nursing's Web site at www.nursing.ohio.gov for more detail. The only places that are specifically prohibited for the APN prescribing of these drugs include APN-owned/run clinics and convenience care clinics.

There is also liability protection for the pharmacist built into this law, as pharmacists can only be responsible for knowing what they can regarding where the prescriptions are being written from.

The Nursing Board and their Committee for Prescription Governance, is currently tweaking the formulary and prescribing regulations for APNs based on the new law, so please stay tuned . . .

Corresponding Responsibility Is Needed More Than Ever

In last year's May *Newsletter*, the Board mentioned that it is having a tremendous problem in Ohio with so-called "pain clinics" who are doing nothing but providing large amounts of controlled substances, particularly oxycodone and hydrocodone, to people who have no legitimate medical need for them. The temptation resulting from the large

amounts of money that can be made by trafficking in “legal” drugs has been an enticement to doctors, pharmacists, and other criminally inclined individuals. HB 93 appears to have corralled the worst pill mills; however, there is still a long way to go. The point being, please remember that corresponding responsibility, which was previously mandated, is needed more than ever. With the tool you now have in the OARRS report, you have much better data from which to make your professional decision to determine legitimacy of these prescriptions.

Multi-State Sharing of OARRS Data – Update!

Through the efforts of the NABP PMP InterConnectSM initiative, more states than ever are sharing prescription monitoring program (PMP) data. Please note that this also gives you the ability to see the dispensing in those states for your patients. The current list of states that are sharing data with Ohio include:

- ◆ Indiana
- ◆ Michigan
- ◆ Virginia
- ◆ North Dakota
- ◆ Connecticut
- ◆ South Carolina
- ◆ Arizona
- ◆ Kansas

Other states coming online soon will be New Mexico, West Virginia, and Kentucky (hopefully by end of summer). Pennsylvania cannot currently share data across state lines. The Board is hopeful that soon at least all of its surrounding states will be sharing PMP data.

Congratulations Danna Droz!

The Board is proud to announce its OARRS administrator, Danna Droz, JD, RPh, has been awarded the NABP 2012 John F. Atkinson Service Award for outstanding achievement in the area of protecting the public through

her work with the OARRS program and its impact across the country. Congratulations Danna!

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