



Ohio State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Annual CE Reminder – New Process for Reporting CE!

If your Ohio pharmacist license number begins with 031, it is your year to attest (report) that you have met your continuing education (CE) requirements. Though this process began last year, it will still be new for those reporting this year as it has been three years since your last attestation of CE. Know that the date range for CE has not changed for you (March 1, 2010 through May 15, 2013), however the time that you actually attest completion of your CE will be done simultaneously during your pharmacist renewal in late summer, not in the spring as was done in the past. The pharmacist license renewals will be mailed by the end of July. For more details on the CE process, please visit the Ohio State Board of Pharmacy's Web site at www.pharmacy.ohio.gov and click on "R.Ph. with the license number beginning with 031, report C.E. THIS year" located just above the "Recent Updates" section on the home page.

Be Aware – Unintended Consequences of Expanded Scope for Limited Prescribers

The Board has been informed that some pharmacies are being penalized by third-party payer auditors for filling Schedule II prescriptions for advanced practice nurses (APNs) and physician assistants. That is because these prescribers have **not** updated their personal Drug Enforcement Administration (DEA) licenses to match their recent scope of practice change. For example, APNs may now write prescriptions for Schedule II drugs (eg, Percocet®) with minimal restrictions as long as they include their certificate to prescribe and DEA numbers on the prescription. However, their current DEA license may dictate that they can only prescribe Schedule III through V drugs, thus they **need** to update their license with DEA to legally write for these drug products. This communication is to educate you, as this is not something that most would think of, but is a very valid issue for pharmacies. Legally the prescription is not valid because the prescriber did not have appropriate DEA licensure to write it, which creates payment and legal issues.

Latest Data Mined Out of Ohio Automated Rx Reporting System

Please see the following chart regarding the 2012 year-end statistics for the top 10 drugs (by volume and number of doses).

Top Ten Drugs in OARRS 2012		
Drug Class	Number of Solid Doses	% Change Since 2011
Hydrocodone & Combos.	288,916,417	-1.4%
Oxycodone & Combos.	259,859,420	5.2%
Tramadol	163,532,246	10.7%
Alprazolam	128,018,592	1.2%
Lorazepam	73,281,529	2.9%
Pregabalin	71,352,325	48.6%
Clonazepam	64,176,546	5.5%
Amphetamine & Combos.	55,462,943	32.6%
Zolpidem	48,588,443	3.4%
Methylphenidate	44,778,675	30.5%
2013 Ohio State Board of Pharmacy Source: Ohio Automated Rx Reporting System		

As you can see, hydrocodone products have dropped from the previous year, however, oxycodone products have increased. This increase in oxycodone products may be due to more prescribers that are now allowed to prescribe these products (APNs since June 2012), as well as the closure of many "pill mills" that were personally furnishing drugs directly out of their offices. Logic dictates that these patients are now getting prescriptions from prescribers and filling them at pharmacies, which could be increasing the quantities in the Ohio Automated Rx Reporting System (OARRS) database.

Drug Utilization Review – Legal Review and Case Scenario: 'Check the Box' or 'Press Pause'?

In Ohio, prospective drug utilization review (DUR) is a legal requirement for every pharmacist prior to dispensing any prescription. The administrative rule mandating DUR for every prescription can be found at Ohio Administrative Code Section 4729-5-20. Often a busy pharmacist will rely on pharmacy software, interns, and technicians to perform this function and simply "check the box" without thoughtful consideration of all the factors specific to his or her patient. This practice may save time, energy, and effort in a busy pharmacy. However, it can lead to lethal drug interactions, allow for errors in dispensing, and result in the dispensing of a prescription for no legitimate medical reason. Each one of these risks could lead to licensure discipline and/or criminal charges for the dispensing

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FDA Issues New Guidelines for Sleep Aids Containing Zolpidem

Food and Drug Administration (FDA) has issued new dosing recommendations for sleep aids containing zolpidem. The new recommendations are based upon new data that shows that when taken at night, blood levels of zolpidem remain high enough in the morning to impair activities that require alertness, such as driving. The new guidelines halve the dosage for women because the new data showed that their bodies take longer to eliminate the drug.

FDA urges drug manufacturers and health care providers to follow the new dosing instructions, which apply to brand name and generic drugs containing zolpidem:

- ◆ Ambien®, Edluar™, and Zolpimist®: 5 mg for women, 5 mg or 10 mg for men
- ◆ Ambien CR®: 6.25 mg for women, 6.25 mg or 12.5 mg for men

Additionally, manufacturers of these drugs have been instructed to follow the new guidelines and print new patient information drug labels containing the new recommendations.

The recommended doses of Intermezzo®, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men. Additional details are available in an FDA Drug Safety Communication, available at www.fda.gov/Drugs/DrugSafety/ucm334033.htm.

What is the National Medication Error Rate? What Standards Are Available for Benchmarking?



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.

A national or other regional medication error rate does not exist. It is not possible to establish a national medication error rate or set a benchmark for medication error rates. Each pharmacy organization is different. The rates that are tracked are a measure of the number of **reports** at a given organization, not the actual number of **events** or the quality of the care given. Most systems for measuring medication errors rely on voluntary reporting of errors and near-miss events. Studies have shown that even in good systems, voluntary reporting only captures the “tip of the iceberg.” For this reason, counting **reported** errors yields limited information about how safe a pharmacy actually is. It is very possible that a pharmacy organization with a good

reporting system, and thus what appears to be a high error “rate,” may have a safer system.

The National Coordinating Council for Medication Error Reporting and Prevention published a statement refuting the use of medication error rates. The statement, which is posted on the council's Web site (www.nccmerp.org), states the “Use of medication error rates to compare health care organizations is of no value.” The council has taken this position for the following reasons:

- ◆ Differences in **culture** among health care organizations can lead to significant differences in the level of reporting of medication errors.
- ◆ Differences in the **definition** of a medication error among health care organizations can lead to significant differences in the reporting and classification of medication errors.
- ◆ Differences in the **patient populations** served by various health care organizations can lead to significant differences in the number and severity of medication errors occurring among organizations.
- ◆ Differences in the **type(s) of reporting and detection systems** for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded.

According to the statement, the council believes that there are no acceptable incidence rates for medication errors. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Pharmacies should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication-use system to prevent future errors and potential patient harm. The value of medication error reporting and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication-use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the organization's analysis of the information, and its actions to improve the system to prevent harm to patients.

It is more important to create the open environment that encourages the reporting of errors and near errors than to develop less meaningful comparative error rates.

ISMP Launches Program to Track Vaccine Errors

ISMP has launched a National Vaccine Error Reporting Program (VERP) that allows health care providers to confidentially report vaccine administration errors and near misses. Health care providers from all practice settings, including pharmacies and physicians' offices, are encouraged to report all mistakes related to vaccines, regardless of whether any harm resulted from the incident. The program will help ISMP “better quantify the sources of errors and advocate for vaccine name, labeling, device, information, and other needed product changes to ensure patient safety,” stated Michael Cohen, ISMP president. The ISMP VERP was designed with the assistance of the California Department of Public Health and with input from experts in the field, indicates ISMP. Reports sent to the ISMP VERP will be shared with FDA and forwarded to the vaccine manufacturer when applicable. ISMP also plans to work with the Centers for Disease Control and Prevention on information received to address vaccine-related safety. VERP can be accessed at <http://verp.ismp.org/>.



Providers Should Ensure Only Diluted Forms of Acetic Acid Are Used, ISMP Warns

ISMP has issued a National Alert Network (NAN) notice advising that health care organizations should take immediate steps to ensure that only diluted acetic acid solutions are used in patient care. ISMP advises that the use and purchase of glacial acetic acid, the most concentrated form of acetic acid available, should be eliminated. Several cases of severe burns, scarring, and other permanent damage to skin or mucous membranes due to the inadvertent application of glacial acetic acid have been reported to the National Medication Errors Reporting Program operated by ISMP. ISMP provides the following steps for preventing further such events:

- ◆ Remove glacial acetic acid, which has no use in its current form in clinical medicine, from the pharmacy and replace with vinegar (5% solution) or commercially available diluted acetic acid 0.25% (for irrigation) or 2% (for otic use).
- ◆ Restrict purchasing so that pharmacy staff is purchasing acetic acid for all procedural areas.
- ◆ Restrict choices for purchasing so that glacial acetic acid is not selected by mistake.
- ◆ Ensure the correct strength is ordered.
- ◆ Educate staff about the differences between glacial acetic acid and diluted forms of acetic acid.
- ◆ Order 5% as “vinegar,” which reduces the potential for confusion with glacial acetic acid.
- ◆ Verify the product by requiring an independent double-check of acetic acid solutions before dispensing or applying the product.

Information on the cases reported and common reasons for the cases are included in the NAN alert, which is available on the ISMP Web site at www.ismp.org/NAN/files/20130121.pdf.

New FDA Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss how FDA Drug Safety Communications let health care providers, patients, and consumers know about newly observed potential risks of FDA-approved drugs. Drug Info Rounds videos are developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information and are available on the FDA Web site at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

Progress Made in Implementing Recommendations Intended to Prevent Acetaminophen Overdose

Compelling progress has been made by stakeholders seeking to address the public health issue of acetaminophen overdose, indicates a white paper published by the National Council for Prescription Drug Programs (NCPDP). In 2011, NCPDP made recommendations that the health care industry take actions to support the safe use of acetaminophen, including recommending that pharmacies produce prescription labels with the complete spelling of acetaminophen and eliminating use of abbreviations such as “acet” or “APAP.” Previous to that, in July 2010, the National Association of Boards of Pharmacy® (NABP®) recommended that “state boards of pharmacy

prohibit the use of the abbreviation ‘APAP’ on prescription labels, and require that ‘acetaminophen’ be spelled out to assist in preventing the well-recognized danger of acetaminophen induced hepatotoxicity.” The recommendation was based on established policy and a letter, sent by FDA to state boards of pharmacy, regarding the pharmacist’s role in educating patients about acetaminophen induced hepatotoxicity caused by unintentional overdose. The recommendation was also consistent with the report of the NABP Task Force on Uniform Prescription Labeling Requirements, which made recommendations to encourage use of prescription labels that are organized in a patient-centered manner. NCPDP reports that pharmacy retailers “estimated to collectively represent more than half of the prescriptions dispensed in 2011, have either implemented or committed to a phased implementation” of the recommendation to use the complete spelling of acetaminophen on prescription labels. “This update to our white paper provides additional guidance for those industry stakeholders who have not yet implemented the new pharmacy labeling practices for acetaminophen-containing medicines,” states Lee Ann Stember, president, NCPDP. The updated white paper is accompanied by a bulletin (PDF), available at www.ncdpd.org/pdf/wp/NCPDPAcetaminophenInfoBulletin_PharmacyStakeholders.pdf, developed for pharmacists that summarizes some of NCPDP’s key recommendations regarding acetaminophen. In addition, the white paper, available for download at www.ncdpd.org/ind_WP.aspx, includes a list of resources for pharmacists to use in educating staff and pharmacy staff to use in educating patients (see Appendix D of the white paper). More information is available in an NCPDP news release available at www.ncdpd.org/press/013113_NCPDP_Acetaminophen%20WP_FINAL.pdf.

Pharmacists Rated High for Honesty and Ethical Standards in Gallup’s 2012 Poll

Pharmacists ranked as the second most trusted profession in the 2012 Gallup Poll that asked consumers to rate 22 professions according to their honesty and ethical standards. Pharmacists were ranked as very high or high in this category by 75% of those surveyed, with nurses ranking first at 85%, and medical doctors third at 70%. Additional information on the results of the 2012 poll is available on the Gallup Web site at www.gallup.com/poll/159035/congress-retains-low-honesty-rating.aspx.



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pharmacists. Instead of checking the box, press pause and make DUR a thoughtful part of your pharmacy practice.

The requirements in Ohio for DUR provide excellent guidance for the factors each pharmacist should consider before dispensing any prescription. Put into practice, the DUR analysis will prevent nearly every error in dispensing, every drug interaction, and protect you from any criminal or administrative charges for dispensing dangerous drugs without a legitimate medical purpose.

What to Look at When Performing DUR

- ◆ Over/under-utilization of the drug
- ◆ Therapeutic duplication
- ◆ Contraindications for the drug or disease state
- ◆ Drug interactions
- ◆ Incorrect dosage
- ◆ Drug allergy
- ◆ Abuse/misuse
- ◆ Inappropriate duration of drug treatment
- ◆ Food/nutritional supplement interactions

Further Indicators of Abuse/Misuse

- ◆ Receiving controlled substances (CS) from multiple prescribers
- ◆ Receiving CS for more than 12 consecutive weeks
- ◆ Early refills
- ◆ Patient appears sedated or intoxicated
- ◆ Unfamiliar patient requests CS by street name, specific manufacturer, color, or identifying marks
- ◆ Patient or prescriber are not geographically close to pharmacy

How Could DUR Have Prevented License Discipline and/or Criminal Charges in the Following Case?

A retail pharmacy starts to see prescriptions from a new doctor on a regular basis. Most of the prescriptions are for high-potency CS in high quantities. Most of the patients walk into the pharmacy and pick up their prescriptions without appearing to suffer from any chronic illness, and some appear intoxicated. These same patients return every month for the same prescriptions without any significant change to the amount or strength of drugs prescribed. Patients often receive a mix of opiates, amphetamines, and methadone. After criminal and administrative investigations, the prescribing doctor as well as the pharmacists who filled his or her prescriptions consistently for over a year face criminal and administrative charges for bad prescribing, drug trafficking, and failure to perform DUR. Effective DUR could have prevented any professional or criminal charges for the pharmacists as it would have revealed over-utilization, excessive duration of drug therapy, possible drug interactions, and many red flags for abuse/misuse. The doctor is primarily responsible for writing the prescription, but the pharmacist has a corresponding responsibility to ensure legitimate medical purpose. As the final gatekeeper of patient safety, a pharmacist performing engaged and actual DUR would have refused some of these prescriptions and ultimately may have saved a life or turned a patient toward drug abuse treatment, rather than enabling what became an obvious problem.

In a time period where there is a push for more automation, quicker prescription processing, and less professional involvement in the “pill counting,” pharmacists have an opportunity to put their professional training to work. Become the expert health professional in your organization. Understand prospective DUR and insist on the opportunity to press pause and execute your professional judgment on each prescription.

Supplying Medications to Prescribers

Scenario: A prescriber wants to purchase product from the pharmacy to be used in his or her office. This is permitted, but how should the pharmacy accomplish this?

- ◆ For Schedule II CS, the **only** legal way is for the purchaser (in this case the prescriber) to complete his or her own DEA Form 222 and give it to the pharmacy, much like how a pharmacy completes a DEA Form 222 for their wholesaler (back before Controlled Substance Ordering System). The pharmacy must comply with all rules regarding processing the DEA Form 222. Store the pharmacy copy of the DEA Form 222 with your other Schedule II invoices.
- ◆ For all other dangerous drugs, both controlled and non-controlled, the pharmacy may sell product to the prescriber by using an itemized invoice detailing precisely how much and what medications are being sold.
- ◆ **Under no circumstance should you fill a prescription labeled with “office use” as the patient.** Prescriptions and the prescription numbering sequences are for unique, individual patients. Prescription numbers are **not** to be used as an office accounting system.
- ◆ **Remember that all sales of CS must also be reported as a wholesale transaction in OARRS.** This will require the pharmacy to establish an **OARRS** wholesale account. As long as the pharmacy limits sales to less than 5% of their volume, they will not need to obtain a wholesale license from the licensing department.

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

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