



Ohio State Board of Pharmacy

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77 S High St, Room 1702 • Columbus, OH 43215-6126 • Tel: 614/466-4143

Fax: 614/752-4836 • www.pharmacy.ohio.gov

Attention Pharmacists: Major Change in the OARRS Report to Address the MED Ohio Initiative

The “MED” initiative was created to curtail the prescription drug epidemic and rising overdose death rates from opiates and combinations therein. MED stands for morphine equivalency dosing. This is essentially a system to equate different opiates and potencies into a standard morphine equivalent value via a conversion chart created by the Centers for Disease Control and Prevention. This chart and an example of how the score is calculated will be located on the last page of the new Ohio Automated Rx Reporting System (OARRS) report. Each active opiate prescription (identified by having days supply remaining), will have a daily MED value. All active (concurrent) prescription values are then combined into one daily MED value, which will be bolded and located on the upper right portion of the OARRS report. It is important to note that this value is a snapshot of the day when you run the report. **It is not a “90-day average.”** This could mean that something may not show up on the report (due to lag in report time to OARRS versus the fill date) or that tomorrow the score may lower due to “active” prescriptions running out the next day. These are scenarios that you should understand when viewing this MED value.

Where did the “80” MED threshold recommendation come from? The threshold of equal to or greater than 80 MED was identified by a team of pain management physicians and specialists that were convened by the governor’s office. For a specific example, #16, 5 mg hydrocodone tablets taken in one day would equate to an MED value of exactly 80. However, be aware that normal dosing (OxyContin® 40 mg twice daily) may also generate a value exceeding 80 MED (120 MED) for that prescription.

At 80 MED, it was deemed that prescribers should “press pause” before prescribing the opiate. This pause

includes a number of clinical considerations that the **prescriber** should take into account prior to issuing the prescription, as specified in the prescribing guideline statement for the MED initiative, available online at www.med.ohio.gov/webhost/ooat.html. This review is all that is required. If a patient’s MED value is greater than 80, **it does not preclude the prescriber from issuing or the pharmacist from filling the prescription, it just requires that you should “press pause,” making sure that your patient absolutely requires this treatment.**

For pharmacists, things to consider when pressing pause may include review of the OARRS report, review of the drug profile in your system, prior knowledge of this patient and physician, and ultimately your professional judgment. **Remember that the 80 MED threshold is a tool, not a definitive number to determine whether you fill or do not fill the prescription.** However, if after review of the OARRS report you suspect a legitimacy issue, do not fill the prescription and notify the Ohio State Board of Pharmacy of your concern. There are a number of nice additions to the OARRS report that have been added to assist you. For more information, please review the OARRS report example with explanations for each section. This can be viewed from the Board’s home page under “Changes Coming to OARRS for Opiate Guidelines” or directly at www.med.ohio.gov/webhost/PDF/OARRS/MED%20OARRS%20Report%20with%20balloons.pdf.

Continuing Education Audit

The Board is beginning the audit process for those pharmacists that attested to completion of their continuing education (CE) requirements this past renewal cycle (License #03-1). Those randomly selected will receive a notification letter through the United States Postal Service. The Board asks that requested information be provided to the Board office within 30 days. Please remember that CE must be dated from March 1, 2010 to May 15, 2013. If you have any questions or concerns,

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Enteric-Coated Aspirin Recalled for Potential Acetaminophen Mix-Up

In June 2013, Advance Pharmaceutical Inc initiated a voluntary recall of Rugby Laboratories label enteric-coated aspirin tablets, 81 mg (Lot 13A026; expiration date: January 2015) due to a complaint that a bottle labeled with this product name actually contained acetaminophen 500 mg tablets. This over-the-counter (OTC) product is packaged in bottles of 120 tablets with National Drug Code 0536-3086-41 and Universal Product Code 3 0536-3086-41 9. The affected lot was distributed nationwide by Rugby Laboratories to wholesalers and retailers. The manufacturer warns that inadvertently taking acetaminophen, 500 mg, instead of enteric coated aspirin, 81 mg, according to the directions on the label, can lead to an acetaminophen overdose and potential severe liver damage. The manufacturer indicates that consumers who take the dosage as indicated on the defective product labeling may be ingesting up to 24,000 mg of acetaminophen, which is about six times the maximum recommended daily dose of acetaminophen (4,000 mg).

Consumers who have bottles from the affected lot should stop using the product and return it to the pharmacy or store where it was purchased and should contact a health care provider if they are experiencing any problems that may be related to using the product. Food and Drug Administration (FDA) notes that any adverse reactions related to the use of the product should be reported to FDA's MedWatch Program. More information about this recall is available on the FDA Web site at www.fda.gov/Safety/Recalls/ucm357909.

Barcoding Technology for Community Pharmacy

 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.

Barcoding technology is well-established in industries outside of the health care sector and is now being used within health care to enhance efficiency and safety, and in pharmaceutical wholesale operations to improve supply chain inventory and efficiency. Numerous studies prove the effectiveness and cost benefits of using barcoding technology during the drug dispensing process. About 75% of wrong drug or wrong dose errors are captured and corrected using barcode technology¹ and there is sufficient evidence that barcode scanning is becoming the standard of practice in pharmacies.

Although barcoding technology is mature with abundant evidence regarding its effectiveness, a 2006² study showed that only half (53.5%) of United States community pharmacies utilize a barcode scanner for verification/identification of medications. The study also

revealed significantly lower adoption in independent pharmacies (11.5%) compared to chain pharmacies (62.6%).

According to a survey conducted by ISMP in 2009, the most frequently reported reasons for implementing barcode scanning for product verification included a desire to improve the accuracy and safety of the dispensing process, the ease with which the technology fits with pharmacy workflow, improvement of staff efficiency and inventory control, and a belief that the technology was necessary to stay in business. The most common reasons for **not** implementing barcode scanning for product verification, other than cost, included uncertainty regarding the "right" vendor product, satisfaction with the current system (without barcode product verification), and perceptions that the technology would reduce staff efficiency.

ISMP has developed a tool, Assessing Barcode Verification System Readiness in Community Pharmacies, to help address the reasons why barcode scanning has not been implemented and to facilitate the adoption of this technology in an estimated 27,327 community pharmacies that do not currently utilize it for product verification.

Given the resource commitment to purchase barcoding systems and the potential for technology to have a profound effect upon the work environment, this tool will help community pharmacy managers and owners better understand the issues related to barcode product verification systems. It will also help managers assess the pharmacy's readiness for the technology, prepare for the selection of a system, and implement the technology effectively.

Barcode scanning to verify prescription products prior to dispensing improves the safety and quality of pharmacy care provided to patients and increases efficiency during the provision of pharmacy services. Although technology should not be seen as a panacea, it can be a useful tool when used appropriately and combined with other patient safety strategies.³ Does your pharmacy use barcode technology for product verification? If not, please access this free tool, at www.ismp.org/AHRQ/Default.asp?link=sa.

¹ Cochran GL, Jones KJ, Brockman J, Skinner A, et al. "Errors prevented by and associated with barcode medication systems." *Joint Comm J Qual Pt Safety*. 2007;33(5):293-301.

Ukens C. "New study sheds light on medication errors." *Drug Topics*. 2002;146(21):33.

² Skrepnek GH, Armstrong EP, Malone DC, Abarca J, et al. "Workload and availability of technology in metropolitan community pharmacies." *J Amer Pharm Assoc*. 2006; 46(2):154-160.

³ American Hospital Association, Health Research and Educational Trust, Institute for Safe Medication Practices. "Pathways for medication safety: assessing bedside bar-coding readiness." 2002. Accessed on October 15, 2010 at: www.ismp.org/selfassessments/PathwaySection3.pdf.

ISMP Launches Medication Safety Alert! Newsletter Tailored for LTCFs

ISMP has launched a new *ISMP Medication Safety Alert!* publication, *Long-Term Care Advise-ERR*, as a means to provide medication error prevention information tailored to assist staff and providers in long-term care facilities (LTCFs).

With *ISMP Medication Safety Alert!* publications making a significant impact on preventing medication errors, ISMP is now providing this new resource tailored to LTCFs. ISMP notes that medication errors reported to ISMP Medication Errors Reporting Program include reports from LTCFs. More information and a link to subscribe to this new publication are available in the Newsletters section of the ISMP Web site at www.ismp.org/newsletters/longtermcare.



FDA Warns of Rare Skin Reactions in Patients Taking Acetaminophen

FDA has issued a consumer update that warns of rare but serious skin reactions that may occur in patients taking acetaminophen. These complications include three serious skin reactions: Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP). SJS and TEN can both be fatal, and usually require hospitalization. Patients suffering from AGEP commonly recover within a few weeks after they stop taking the medication that caused the reaction.

Symptoms of these conditions include skin rashes, blisters, and widespread damage to the surface of the skin. Patients taking acetaminophen or other compounds that contain acetaminophen should be advised to stop taking the medication if they experience such symptoms and should consult their health care providers or seek an emergency department immediately.

FDA emphasizes that this information should be viewed within the context of millions of patients who, over generations, have used and benefited from acetaminophen and stresses that severe allergic skin reactions are an extremely rare condition. Further, the agency notes that many medications can cause allergic reactions, and skin allergy warnings have already been added to the drug labels of other categories of OTC analgesics including ibuprofen and naproxen. "This new information is not intended to worry consumers or health care professionals, nor is it meant to encourage them to use other medications," said Sharon Hertz, MD, deputy director of FDA's Division of Anesthesia, Analgesia, and Addiction Products. "However, it is extremely important that people recognize and react quickly to the initial symptoms of these rare but serious side effects, which are potentially fatal." The full consumer update is available on the FDA Web site at www.fda.gov/ForConsumers/ConsumerUpdates/ucm363010.htm.

Reminder to Purchase Drugs Only from Licensed Wholesalers, Including VAWD-Accredited Wholesale Distributors

To ensure that patients are receiving safe, FDA-approved medications, pharmacists and other health care providers should purchase prescription drugs either directly from the manufacturer or from wholesale drug distributors licensed in the US as advised by FDA. The agency provides a list of state agencies for assistance in verifying licensure at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws and NABP's VAWD criteria. NABP has recently revised the VAWD criteria to allow virtual manufacturers and virtual wholesale distributors – a growing segment of the pharmaceutical wholesale industry – to qualify for VAWD, as well as to implement other changes aimed to help to ensure that the drug supply chain remains secure.

The revised VAWD criteria responds to changing business models and helps safeguard drugs in distribution at a time when there is an increased risk of counterfeit and substandard drugs entering the legitimate US drug supply chain. In particular, the criteria have been revised

to provide stronger assurance that drugs diverted from pharmacies and unlawful sources are prevented from entering into the supply chain.

For a listing of VAWD-accredited facilities, please visit www.nabp.net/programs/accreditation/vawd.

Voluntary Recall of Unexpired Sterile Products After Reports of Adverse Events

FDA has announced a voluntary recall of all lots of unexpired sterile products produced by Specialty Compounding, LLC, in Cedar Park, TX. FDA received reports of 15 adverse events at two hospitals (Corpus Christi Medical Center Doctors Regional and Corpus Christi Medical Center Bay Area) potentially related to the use of these sterile products. Affected patients received an intravenous infusion of calcium gluconate supplied by the company.

Patients who were administered the injectable drug products are at risk of life-threatening infections. The recall applies to all unexpired sterile compounded medications dispensed by the company, including all strengths and dosage forms. Recalled products were distributed directly to hospitals and physicians' offices in Texas, and to patients located nationwide (with the exception of North Carolina). No calcium gluconate was shipped outside the state of Texas. Health care providers and patients should stop using all recalled products and return them to Specialty Compounding.

Veterinarians Not Eligible for NPIs, CMS Clarifies

Centers for Medicare and Medicaid Services (CMS) has become aware of cases in which veterinarians are told, incorrectly, that they must provide a National Provider Identifier (NPI) number for prescriptions they have written to be dispensed. The agency has issued a clarification, stressing that veterinarians do not meet the regulatory definition of "health care provider," and thus may not obtain NPI numbers. The clarification also states that "Any entity that insists veterinarians obtain an NPI [is] attempting to require veterinarians to obtain NPIs fraudulently." CMS also notes that "if a veterinarian fulfills the definition of 'health care provider' in a profession other than furnishing veterinary services," such as if they are also a nurse practitioner, "the veterinarian would be eligible for an NPI but would select a Nurse Practitioner code (not a Veterinarian code) from the Healthcare Provider Taxonomy Code Set when applying for an NPI."



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

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide a National Association of Boards of Pharmacy® (NABP®) e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor 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.*

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please e-mail the Board office utilizing the “Contact the Board” selection along the left side of the Web site. Be sure to select “General Licensing Information” as your subject line.

2014 Terminal Distributor Renewals

The 2014 renewal notices for terminal distributor licenses have been sent out by the Board and should have been received by all licensees before the end of October. If you are the responsible person on the license, you are responsible for seeing that the license is **renewed before January 1, 2014**.

This year’s process for renewal is similar to last year’s process. The Board will be accepting online terminal distributor renewal applications with payment by a credit card for most licensed sites. Please note that only terminal distributors with unlimited licenses or limited licenses who have submitted their paperwork via the Board’s new online process will be able to renew online this year. A terminal distributor license cannot be renewed online if any of the following apply: there is a change of address of the licensed site, change of the business name, change of business ownership, or a change of the drug category of the license. This is explained on the renewal application and the online renewal screens that give directions on how to handle these situations. For most renewals, the process should be painless if you read and follow the directions contained in your renewal packet and on the renewal screens. And as always, **do not hit the “back” button after you authorize payment with your credit card!** This will cause your credit card to be charged again, each time you hit the back button. The Board tries to catch those duplicate charges before they get posted to your card. If it does occur, please contact the Board office so it can reverse the extra charges.

Does OARRS Reporting Apply to Me?

Ohio Administrative Code (OAC) 4729-37-03 outlines the entities required to submit information to OARRS. Most retail pharmacies are familiar with this and have been reporting in accordance with the rules. Hospitals and wholesalers need to be aware of how this rule applies to them.

OAC 4729-37-03 (B) states “All pharmacies located within this state and licensed as a terminal distributor of dangerous drugs shall report all drugs identified in rule 4729-37-02 of the Administrative Code that are dispensed to all outpatients.”

While hospitals often believe they are exempt from reporting as they typically service inpatients, hospitals still must report if they dispense **any outpatient** prescriptions, such as discharge medications and outpatient prescriptions filled for hospital employees. If in doubt, it is better to report than not. Remember that reporting must be done at least weekly, either by reporting pre-

scriptions dispensed or by submitting a “zero report” if you have a seven-day time span of not dispensing any reportable prescriptions. Not reporting is not the same as submitting a zero report.

OAC 4729-37-03 mandates that all wholesalers licensed as a wholesale distributor of dangerous drugs that sell drugs identified in Rule 4729-37-02 of the OAC at wholesale shall report those drug transactions. The Board will continue an enhanced focus on this to ensure that everyone who is supposed to report is actually complying with this requirement.

Immunizations: Who Is Calling the Shots?

The Board frequently receives questions about acceptance of a multitude of immunization training courses. Per ORC 4729.41 (B), for a pharmacist or pharmacy intern to be authorized to engage in the administration of immunizations, the pharmacist or pharmacy intern shall have successfully completed a course in the administration of immunizations that has been approved by the Board. Currently, the Board has approved the programs offered by American Pharmacists Association (APhA), Ohio Pharmacists Association, the colleges of pharmacy located in Ohio, and the Kroger’s Corporation. Programs taken elsewhere need to have written documentation that it is based on the APhA program. Additionally, to provide immunization services, the pharmacist or pharmacy intern must receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American Red Cross or American Heart Association and practice in accordance with a definitive set of treatment guidelines specified in a protocol established by a physician and approved by the Board. Protocols must include the individual names of each person who will be authorized to give the injections and be readily retrievable on site at your practice.

Recent Press Release: Synthetic Cannabinoids/Cathinones

The Board has recently released a press release in conjunction with the Ohio Attorney General’s Office regarding a Board emergency proposed rule that will schedule synthetic cannabinoids (“spice”)/cathinones (“bath salts”) as Schedule I illicit substances. This release can be viewed from the Board’s home page under the “Recent Updates” section or at <http://pharmacy.ohio.gov/Documents/Pubs/NewsReleases/Attorney%20General,%20Pharmacy%20Board%20Announce%20Proposed%20Rule,%20October%2011,%202013.pdf>.

As you may know, these substances are growing in popularity with youth, and many young people are seriously harmed or losing their lives from these horrendous but “legal” compounds, typically sold at gas stations

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and drug paraphernalia shops. Side effects typically experienced by individuals using these drugs mimic the effects of hallucinogenic drugs like ecstasy, PCP, LSD, and THC, the principal chemical in marijuana.

Essentially the rule will outlaw these substances by their basic “pharmacophore” backbone chemical structure, which all of them have, not by their exact complete molecular structure. Previously (and the current way other states regulate these illicit drugs) these drugs were outlawed individually by the exact chemical structure of each compound, thus the “street” chemist could simply change one element of a side chain of these molecules and create a legal substance. This pharmacophore strategy will hopefully eliminate these substances from being sold legally to the general population by outlawing the backbone structure that all of these substances share.

The science behind this rule was based on the extensive research of Jon Sprague, PhD, RPh, current director of research and development at Ferris State University and former dean of Ohio Northern University’s Raabe College of Pharmacy. The Board appreciates all the assistance Dr Sprague gave to the Board in writing this rule and his expertise regarding this state and national drug epidemic. Following his work with the Board on this issue, Dr Sprague’s pharmacophore approach reached the federal level and is being introduced as proposed federal legislation.

Disciplinary Actions

Anyone having a question regarding the license status of a particular prescriber, nurse, pharmacist, pharmacy

intern, or dangerous drug distributor in Ohio should contact the appropriate licensing board. The 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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