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Ohio State Board of Pharmacy News

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2013 Year in Review

The 2013 year for the Ohio State Board of Pharmacy was very busy, much being dedicated to strategies to prevent and minimize opiate diversion, encourage appropriate opiate prescribing, and ensure optimal compounding practice. The Board has ramped up its efforts in services, resources, and legislation to accommodate the demands of these serious issues. The Board has also implemented many updates to its Ohio Automated Rx Reporting System (OARRS), including a major change in the report format to accommodate the morphine equivalency dosing initiative (featured in the November 2013 *Newsletter)* from Governor John R. Kasich's office. This initiative has been widely accepted as positive, making the Board's OARRS a key tool for prescribers, pharmacists, and law enforcement to comply with this statewide effort to improve treatment of patients and prevent overdose deaths from opiates and combinations thereof. The Board looks forward in 2014 to maintaining this momentum, continually improving and streamlining its services to the public and to its licensees.

2014 Jurisprudence CE Board Quiz – New Online Law CE Program – No Fee Required and No Need to Mail in!

The Board is pleased to offer the annual Jurisprudence Quiz. The Board has updated the process this year to earn continuing education (CE) credit. The quiz is now posted on the Board's website homepage at *www.pharmacy.ohio.gov.* You may also access it by clicking on "Board Publications," then "Newsletters," and finally click on "SBN Quiz (Feb 2014)." The questions in the quiz relate to the topics covered in the February, May, August, and November 2013 *Newsletters,* which can also be viewed from this tab.

This year's test is taken online and electronically graded as soon as you "submit" your test. You may preprint the exam, but will have only one opportunity to actually take and submit the test for grading. Seventy-five percent correct is needed to pass. After successful completion you will have the ability to immediately print your certificate or reprint it at a later date. A copy of the certificate will also be e-mailed to you, providing you submit an e-mail address during sign on for the quiz. Additionally, another benefit of this online process is that there is no charge for this CE and it will not expire until September 15, 2014. National Association of Boards of Pharmacy® CPE Monitor® is in the process of building a mechanism for the Board to report successful completions of this program to CPE Monitor in the future. In the meantime, be sure to keep a copy of your certificate.

Please do not mail any quizzes to the Board. The Board does not have the mechanism to hand-process or mail a certificate to you. The entire process must be completed online. As this is a new process this year, the Board welcomes feedback about what you like and what the Board can do to improve it.

What Do You Need to Know About Reporting Drug Loss to the Board?

Do you know your local compliance agent's phone number? If not, you should. Under Ohio law, "each prescriber, terminal distributor of dangerous drugs, or wholesale distributor of dangerous drugs shall notify . . . the state board of pharmacy **by telephone immediately** upon discovery of theft or significant loss" of all dangerous drugs and controlled substances (CS) (4729-9-15(A)(1)). A timely phone call to your agent will allow the Board to begin its investigation as soon as possible. Your local compliance agent is the friendly face you see during Board inspections. If you do not know your agent's contact information, call the Board at 614/466-4143.

In addition to notifying the Board by phone when there is a loss of CS, you must also send the Board a copy of the federally mandated Drug Enforcement

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Changes to Fentanyl Pain Patch Warnings Required by FDA

To reduce the risk of accidental exposure, Food and Drug Administration (FDA) has announced new requirements that change the appearance of fentanyl pain patch warnings to make them more visible. The change also requires new language in the warning that emphasizes the risk of death from accidental exposure, particularly in children. The announcement coincided with a Consumer Update that stressed the potential danger of improperly discarded fentanyl patches to children and pets. FDA reminded consumers of the agency's previous advice for securely storing unused patches and disposing of used fentanyl patches by folding the sticky sides together and then flushing them down the toilet. The agency also advises patients to cover in-use patches with an adhesive film to keep them from coming loose, and to regularly check patches to ensure they are securely in place. FDA offers additional information for health care providers on the "Fentanyl Transdermal System (marketed as Duragesic) Information" page, available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm114961.htm*. Consumer information about safe drug disposal methods is also available on the AWAR$_X$E® website at *www.AWAREprogram.org*.

New: Free ISMP Medication Safety Alert! Newsletter for LTC Facilities

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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.*

In July, ISMP began publishing *Long-Term Care Advise-ERR,* a new *ISMP Medication Safety Alert!* newsletter for nurses and administrators in long-term care (LTC) facilities. ISMP receives error reports that have occurred in LTC facilities. The newsletter is provided free to LTC facilities in the United States thanks in part to corporate sponsorship from Lilly and for a nominal subscription fee for pharmacies that service LTC facilities and others. Please visit ISMP's website at *www.ismp.org/Newsletters/longtermcare* for more information, and let your LTC facilities know about this free offer.

Here are a few excerpts from a recent issue.

Immediate Vs Extended Release Error

A physician called a LTC facility to change a resident's oxycodone order from an extended-release formulation to an immediate release formulation at the same dose and frequency. The nurse receiving the verbal order transcribed it as "Discontinue OxyContin 10 mg BID, Start OxyContin 10 mg IR BID," with "IR" meant to represent immediate release. Although Oxy**Contin**® is a brand of oxy**codone,** it is only available as an extended-release tablet. The pharmacy had previously been dispensing Oxy**Contin** for the resident, so the nurse thought she could communicate the prescriber's order by discontinuing the current Oxy**Contin** order and then ordering Oxy**Contin** as an immediate-release product. The pharmacy continued dispensing Oxy**Contin.** The differences between these products and formulations were brought to the attention of nursing staff via an in-service. To minimize the risk of confusion, do not attach modifiers such as "IR" for immediate-release or "RS" for regular strength unless it is part of the official drug name.

Errors Occur During Transitions of Care

A pharmacist reported the following hazardous situation that can occur during a hospital to LTC transfer. Residents are often admitted to a LTC facility with a list of medications printed from the hospital pharmacy computer. On these printouts, doses are expressed along with the number of tablets. For example, the printout may list hydrochlorothiazide 50 mg/2 tablets daily for an order in which the total dose was 50 mg because the hospital only stocks the 25 mg tablets. During hospitalization the patient required two tablets for each dose; however, the LTC nurse may misinterpret the order to mean two 50 mg tablets, making the total dose 100 mg, or two times more than prescribed. This issue arises every time the resident's total dose in the hospital requires more than one tablet or capsule. Discharge medication summaries and transfer orders should only list the total dose in mg or mcg and other directions for use (ie, frequency, route, drug name) to avoid misinterpretation.

2013 USP Chapter <797> Compliance Survey Shows Compliance Trends Unchanged From 2012

The 2013 United States Pharmacopoeia (USP) Chapter <797> Compliance Survey, the third annual report released since 2011, shows that the overall compliance rate of 77.2% remains nearly unchanged from the 2012 rate. Budgetary restrictions and physical plant limitations were among the top challenges to compliance by survey respondents. The report also details the

survey's findings on what types of facilities are participating in compounding, and compliance in specific domain areas such as environmental sampling and gloved fingertip sampling. Of the survey's 1,045 participants, 97% of the survey's respondents said that USP Chapter <797> "has had a positive influence on patient safety." The report notes National Association of Boards of Pharmacy® (NABP®) efforts to assist state boards of pharmacy in evaluating pharmacy compliance with USP Chapter <797> requirements for sterile compounding in their states. The report also noted that those who participated in the 2011 survey had a higher compliance score than those who did not. The survey's authors encouraged pharmacy owners with multiple areas of noncompliance to target one or two areas to improve. They also encouraged organizations that participated in the survey to make use of the free Action Plan – generated upon completion of the survey – and other free resources to "reshape" their sterile compounding practices. The full report on the survey's results is available in the October 2013 issue of *Pharmacy Purchasing & Products Magazine* and on the magazine's website at *www.pppmag.com/article/1403*.

FDA Recommends Schedule II Classification for Hydrocodone Combination Products

FDA planned to submit a formal recommendation to reclassify hydrocodone combination products as Schedule II controlled substances to the Department of Health and Human Services by early December 2013. FDA expects the National Institute on Drug Abuse to concur with the recommendation, indicates a statement on the FDA Web site. FDA also indicates that while "the value of and access to these drugs has been a consistent source of public debate," the agency has "been challenged with determining how to balance the need to ensure continued access to those patients who rely on continuous pain relief while addressing the ongoing concerns about abuse and misuse." Drug Enforcement Administration makes the final decision about the appropriate scheduling of these drugs. In January 2013, FDA's Drug Safety and Risk Management Advisory Committee made a recommendation that hydrocodone combination products be classified as Schedule II drugs following a 19-to-10 vote that concluded a two-day meeting during which members discussed the potential for abuse and misuse of the medications and the potential impact of rescheduling the drug products. FDA's statement on the recommendation is available at *www.fda.gov/Drugs/DrugSafety/ucm372089.htm*.

New FDA Drug Info Rounds Training Videos Available

FDA Drug Info Rounds, a series of online 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 two Drug Info Rounds videos, pharmacists discuss the review and approval of new drug names and the review of marketing and advertising materials for new drugs. The videos can be viewed at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm368620.htm* and *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm371785.htm,* respectively. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information.

CPPA Developing Specialty Pharmacy Accreditation Program

The Center for Pharmacy Practice Accreditation® (CPPA) has announced the development of a new accreditation program for specialty pharmacy practices. CPPA Executive Director Lynnae Mahaney, MBA, RPh, FASHP, VHA-CM, indicates that "CPPA will be able to develop the new specialty pharmacy standards quickly and efficiently with the existing standards development methodology, infrastructure, and network of specialty pharmacy expertise."

CPPA is a partnership between the American Pharmacists Association, the American Society of Health-System Pharmacists, and NABP. CPPA develops and implements comprehensive programs of pharmacy practice site accreditation, including the promotion, development, and maintenance of principles, policies, and standards. CPPA offers the general public and users of pharmacy services a means of identifying those pharmacies that satisfy the accreditation criteria and are focused on advancing patient care, safety, and quality.

More information may be found in the press release, available at *www.pharmacypracticeaccredit.org/news/2013/10/cppa-to-develop-specialty-pharmacy-accreditation-program*.

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Administration (DEA) Form 106 within 30 days following the discovery of the loss (4729-9-15(B)). DEA Form 106 may be filled out on DEA's website at *www.deadiversion.usdoj.gov*. Printed or scanned copies of the completed forms should be submitted to the Board via e-mail at dea106reporting@bop.ohio.gov; fax at 614/752-4836; or mail at Ohio State Board of Pharmacy, Attn: DEA-106 Reporting, 77 S High St, Rm 1702, Columbus, OH 43215.

OARRS Updates

Those pharmacists who regularly read this *Newsletter* may notice there is a significant amount of ink devoted to OARRS, which is a direct reflection on the dramatic improvements and overall health care impact that this tool has had in Ohio and on the pharmacy profession. Per Ohio Administrative Code 4729-5-20(D), the OARRS report may be a required factor in the prospective drug utilization review you are required to perform on every prescription. The OARRS team works to make this process work as seamlessly as possible. The Board will continue to keep you informed as it improves the system and makes updates that impact your daily functions. Suggestions are welcome and may be submitted to the Board at info@ohiopmp.gov.

Improving Your OARRS Experience: Why Can I Not Find My Patient in OARRS?

If you submit a request and receive the message "No results were found," this means that the system could not find any patients matching the criteria that you provided. If you provided faulty information, please correct it and submit your request again. Submitting the same request without changing any of the search criteria will not produce a different set of results.

The "submit request" screen has minimum search requirements (patient name, date of birth, and zip code). By entering the street name and phone number, the system will usually find nicknames, misspellings, different addresses, etc. This is particularly beneficial when searching for very common names (eg, John Smith) or names that are so unique that they may be spelled slightly different between pharmacies.

Unlike many other search programs, providing additional information in the search criteria will always result in the same number of prescriptions or more; it will **never** decrease the number of prescriptions returned. (If you have a question about this, please contact the OARRS support team.) If the patient recently moved to your area, you may also try using the zip code of his or her previous address to locate him or her in the database.

Understanding Your OARRS Request Responses

A small number of requests (less than 1%) result in a message that states "Your request could not be automatically processed/under review/delayed. . ." This happens when the OARRS search engine returns prescriptions that have a high probability of belonging to multiple patients. Most of the time, this is due to a father and son with the same first and last name (eg, Jr, Sr) living at the same address or family members with similar names (like Michelle and Michael). These requests are reviewed by an OARRS pharmacist before being released to the requestor. Resubmitting your request will **not** result in obtaining a report any sooner. It only delays your other reports that will process automatically.

Conversely, there is the even rarer occasion that you receive a report that appears to contain more than one patient. This could be the result of a name change (marriage, hyphenated names) or names so similar at the same address the system is unable to differentiate a unique patient. This often occurs with residents of assisted living facilities. Be sure to review the box labeled "Patients included in this report that appear to match search criteria." When you see more than one unique person in the box, please call the Board so it may manually isolate each individual patient.

Eminent Changes to OARRS Reporting

As previously mentioned in the August 2013 *Newsletter,* OARRS reporting is moving to the American Society for Automation in Pharmacy (ASAP) 4.2 format. The Board will accept files in ASAP 4.1 or ASAP 4.2 until May 31, 2014, to allow vendors to make the necessary changes and also use the same format for multiple states. You should have already discussed this upcoming change with your software vendors. Effective June 1, 2014, files submitted in an incorrect format will **not** be accepted and the pharmacy will be accountable for all delinquencies.

Annual Reminder: Terminal Distributor License

Please check the Terminal Distributor of Dangerous Drugs (TDDD) license at your facility to ensure you have received your 2014 TDDD license from the Board. The office has sent all successfully renewed TDDD licenses out at this time. The TDDD license is the license required for all pharmacies, hospitals, clinics, emergency medical services squads, etc, typically needed to purchase or store prescription drugs at that location. If you have not renewed or received your 2014 TDDD license, please call the Board office immediately. The 2013 TDDD licenses expired on December 31, 2013.

CE Reminder for Those Pharmacists Who Report This Year

This is a reminder for those pharmacists whose license numbers begin with 032. You are due to report CE this year (except for those 032 newly licensed pharmacists who received their license for the first time this reporting

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year between June 1, 2013 and now). Per Rule 4729-7-02 (C), you may use certificates dated on or after March 1, 2011 (that were not used on a previous CE report) through May 15, 2014. Just as last year, **the date range for CE inclusion/completion has not changed, but the date when you will actually attest your CE completion online is now done simultaneously during your pharmacist license renewal in late summer.** This rule is up for review this month during the Board's Rules Review Committee with hopes of setting a new CE date that will not take multiple paragraphs to explain! The Board will notify you when this rule gets amended, but until then please follow the above directions regarding the CE reporting process.

As always, you will need to attest to a total of 6 continuing education units (CEUs) (60 hours) of CE credit and **0.3 CEUs (3 hours) of those must be in Ohio Board-approved jurisprudence.** Please make sure that the jurisprudence courses are Ohio Board approved. Also, for pharmacists with a current pharmacist license in another state and who did **not** practice pharmacy in Ohio at all during the CE time frame, you may still use that state's license to satisfy Ohio's CE requirement to renew your Ohio license. Additionally, you may satisfy 57 of the 60 hours required by maintaining an active certificate of a Board-approved specialty practice.

What Is the Best Way to Profile and Label Pet Prescriptions?

Ohio Administrative Code 4729-5-16 addresses the labeling of drugs dispensed on prescriptions. Section (A)(2) states such label "shall include the full name of the patient for whom the drug is prescribed; or, if the patient is an animal, the **full name of the owner and identification of the animal."** The rule does not specifically define **how** to "identify." What is clear is that the pharmacy needs to have a mechanism in place to be able to recognize each unique patient/pet profile so that the pet's profile is not merged with the owner's profile. Best practice profile and labeling suggestions may include for example: last name "Parker," first name "Laura's dog Reagan," or last name "Parker," first name "Reagan dog of Laura." This example of nomenclature into your systems allows for OARRS to differentiate between the owners and their pets.

Human Trafficking Initiative from Governor Kasich

The Board is pleased to partner with Governor Kasich to support *Human Trafficking – Ohio's Tragic Reality,* Ohio's official public awareness campaign. Please take a moment to review some of the resources below and visit *www.publicsafety.ohio.gov/ht/campaign.html* to download fact sheets, posters, and other materials to help raise awareness of this important issue. You probably are thinking how does this apply to me as a pharmacist? Please read the Board letter available at *http://bit.ly/traffickingrx*. This will give you tips for recognizing this issue in your day-to-day practice while treating your patients. To report a tip, connect with anti-trafficking services in your area, or for information about anti-trafficking resources, call the national hotline number at 1-888/373-7888. It is toll-free, confidential, and available 24 hours a day. Everyone has a role in ending human trafficking, and by working together we can end this tragic issue.

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 professional licensing agency websites 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

DEA.....800/882-9539
www.deadiversion.usdoj.gov

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