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Ohio State Board of Pharmacy News

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West Virginia Now Online With OARRS!

The Ohio Automated Rx Reporting System (OARRS) continues to share data with other states through the National Association of Boards of Pharmacy® PMP InterConnect®. This allows the consolidation of information from multiple states to appear on a single report. This is particularly valuable for pharmacists and prescribers who are near the states' borders. **OARRS is now able to share data with West Virginia.** This should be useful for pharmacists in the southeastern area of the state. Be sure to select neighboring states (when appropriate) when submitting your OARRS requests.

Annual CE Reminder for Pharmacists Whose License Begins in 032!

If your Ohio pharmacist license number begins with 032, it is your year to attest (report) that you have met your continuing education (CE) requirements. This will be done simultaneously while renewing your pharmacist license prior to September 15. You may count CE from March 1, 2011 through May 15, 2014, for this audit. The pharmacist online license renewal notices will be e-mailed to all licensees by July 15, 2014. **Reminder:** The free Ohio jurisprudence CE program is still available on the Ohio State Board of Pharmacy website!

Partial Dispensing of Schedule II Controlled Substances

As a refresher to this commonly asked question, there are specific rules on this topic. Ohio Administrative Code 4729-5-26 clearly outlines the conditions under which this is acceptable and instructs on the mechanics of accomplishing this.

At the time of partial dispensing of a schedule II controlled substance prescription for a "terminally ill" patient or a patient residing in a "long term care facility", in accordance with 21 C.F.R. 1306.13, the following must be observed:

(A) Prior to a partial dispensing of a schedule II controlled substance, the pharmacist must confirm that the patient is "terminally ill" or a patient residing in a "long term care facility" and note this on the prescription.

(B) The partial dispensing of a schedule II prescription can only occur at the pharmacy where the original prescription is on file.

(C) At the time of partial dispensing of a schedule II controlled substance, the following must be noted on the back of the original prescription: the date dispensed, quantity dispensed, remaining quantity authorized to be dispensed, prescription number of this partial dispensing if different, and the manual initials of the dispensing pharmacist.

(D) If an alternate record keeping system is being used and the system will not permit refills of schedule II controlled substances, a new prescription number for the partial dispensing must be assigned.

(1) A notation must also be made in the database that identifies this new prescription number as a partial dispensing and provides the serial number of the original prescription.

(2) A prescription bearing the new serial number must be placed in the schedule II file. The prescription for each partial filling must also show the serial number of the original prescription.

(E) The total quantity of schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed.

(F) All partial dispensings of schedule II controlled substances must occur within sixty days from the date of issuance of the prescription by the prescriber.

New USP Webpage Answers Common Questions About USP Chapters <795> and <797>

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at *www.usp.org/support-home/frequently-asked-questions/compounding*. Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

Only You Can Prevent Look-Alike Sound-Alike Drug Names

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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Error Reporting Program. Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

VESIcare/Vesanoid Mix-Up. A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESIcare®** (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid®** (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESIcare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

Benazepril Confused With Benadryl. A pharmacist reported a mix-up between benazepril **(Lotensin®)** and **Benadryl®** (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazapryl." The pharmacist who received the fax interpreted it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

Your Help Is Needed With Product Safety Testing. If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit *www.med-errs.com* and click on "Become a Reviewer."

FDA Issues Alert on Acetaminophen Products

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations,* commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at *www.fda.gov/Safety/Recalls/ucm382076.htm.*

FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm.*

New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- The preliminary application and first state transfer fee will increase from $350 to $375
- Each additional state transfer will increase from $50 to $75
- Change of states will increase from $50 to $75
- Time extensions will increase from $50 to $75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at *www.nabp.net.* Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at nwatson@nabp.net.

Legislative Updates

On March 11, 2014, two important pieces of legislation were signed into law.

- **HB 44** provides pharmacists with a role in public health emergencies by requiring the director of health to develop one or more protocols regarding the availability of drugs during a public health emergency that authorize pharmacists and pharmacy interns to dispense limited quantities of certain dangerous drugs without a prescription or record of a prescription.
- **HB 170** aims to address Ohio's growing opioid drug overdose epidemic. This law permits doctors, advanced practice nurses, and physician assistants to prescribe, administer, dispense, or furnish naloxone to a person who is, or a person who is in a position to assist a person who is, apparently experiencing or who is likely to experience an opioid-related overdose. The law also permits law enforcement officers to obtain and use naloxone in the event of an opioid overdose.

For more information, including the status of **pending** legislation, please visit *www.legislature.state.oh.us/.*

Administrative Rules Update

Please note that there are many rules that are **proposed** but may be final as soon as May 22, 2014. Since these may be passed prior to the next quarterly *Newsletter,* **please be advised and check the Board's Administrative Rule Change website for updates at *www.pharmacy.ohio.gov/LawsRules/RuleChanges.aspx.***

OARRS: How it Helps You Fulfill Your Corresponding Responsibility

Scenario (real life, seen frequently): You are presented with a prescription for a high dose of a narcotic (eg, oxycodone 30 mg, quantity #180 to take six tablets a day). You run the OARRS as required by OAC 4729-5-20 (D) and see this is the first and only time the patient has received this medication. Clinical judgment suggests questioning why an opiate-naive patient would be starting at this level of a narcotic. Referencing OAC 4729-5-30 (A), "a prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a **corresponding responsibility** rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law."

If you suspect a forgery (which might account for why this "patient" has nothing else on OARRS) or any type of suspicious/illegal activity from a prescriber, patient, or other pharmacy, you are required to report that to your local law enforcement agency. Additionally, filing a "complaint" on the Board website will alert the Board to inappropriate activity.

Big Changes to OARRS Reporting!

As mentioned in previous issues of this *Newsletter,* effective June 1, 2014, pharmacies will be required to submit all OARRS data using American Society for Automation in Pharmacy 4.2 standards. Files submitted in the old format will not be accepted. Additionally, OARRS is most likely changing to **daily reporting** in the next few months. Watch this *Newsletter* and your OARRS reporting confirmation reports for updates on this. Pharmacies will be expected to comply with these new rules.

What I Need to Know About Filling Prescriptions for Belviq and Qsymia

The State Medical Board of Ohio website has an excellent document on prescribing rules for these two weight control medications. Here are some of the highlights of that document, which should address most situations you see in the dispensing environment. Remember, this is an abridged version of the complete document on the Medical Board's website.

Qsymia® (phentermine and topiramate extended-release) and Belviq® (lorcaserin hydrochloride) are Food and Drug Administration (FDA)-approved Schedule IV medications. They are indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of 30 or higher. The drugs may also be used for overweight adults with a BMI of 27 or higher and at least one weight-related condition such as high blood pressure, type 2 diabetes, or high cholesterol.

Qsymia and Belviq are specifically designed for chronic weight management in adults.

Q: Does the "12-week" treatment limitation apply to Qsymia or Belviq?

A: No, it does not. Rule 4731-11-04(C)(2), OAC, requires the drug to be prescribed strictly in accordance with FDA-approved labeling. The instructions for the new drugs have more specific instructions for usage, but they are approved for "chronic weight management" and are not limited to use for "a few weeks." Therefore, the 12-week period is not applicable.

Q: Does the requirement that the physician meet face-to-face with the patient at a minimum of every 30 days apply when prescribing Qsymia or Belviq?

A: Yes. Qsymia and Belviq are controlled substances. The physician must personally meet face to-face with the patient, at a minimum, every 30 days.

Q: Can Qsymia or Belviq be refilled?

A: There is no explicit prohibition in Rule 4731-11-04 against writing refills for one of the new drugs. **But the**

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physician is still required to personally meet face-to-face with the patient, at a minimum, every 30 days. To refill a prescription that had refills issued with it, it is your responsibility to contact the doctor and document whether a true face-to-face meeting occurred.

Q: Can I prescribe Qsymia or Belviq to a patient who has been on phentermine for 12 weeks?

A: Yes. The patient may be switched to one of the new drugs after 12 weeks on phentermine if there is no interruption in treatment.

Latest 2013 Data Mined Out of OARRS

Please see the following chart regarding the 2013 year-end statistics for the top 10 drugs (by volume, number of doses) as compared to 2012.

Top Ten Drugs in OARRS 2012

Drug Class	Number of Solid Doses	% Change Since 2011
Hydrocodone & Comb.	288,916,417	-1.4%
Oxycodone & Comb.	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 & Comb.	55,462,943	32.6%
Zolpidem	48,588,443	3.4%
Methylphenidate	44,778,675	30.5%

Source: Ohio Automated Rx Reporting System 2013 OH State Board of Pharmacy

Top 10 Drugs in OARRS 2013

Drug Class	Number of Solid Doses	% Change Since 2012
Hydrocodone & Comb.	280,443,578	-3.5%
Oxycodone & Comb.	256,055,057	-1.7%
Tramadol	188,354,820	9.7%
Alprazolam	128,373,214	-0.3%
Lorazepam	74,285,513	0.6%
Clonazepam	66,893,093	3.7%
Pregabalin	66,405,099	-7.5%
Amphetamine & Comb.	58,421,539	4.9%
Zolpidem Tartrate	47,350,681	-3.4%
Methylphenidate	42,927,110	-4.6%

As you can see, the number of doses of hydrocodone and oxycodone products has dropped from the previous year. Note that in both years, the tramadol products have risen. Initially, you may think this is an indicator that there may be a problem with the tramadol products, however, this also may be an indicator of prescribing behavior change from prescribing a more addictive drug class to that of a lesser addictive one.

Use Your Board as a Resource

The Board continues to be a resource for answering general questions specific to pharmacy rules. Some questions are common, so the Board is hoping to address these periodically in this *Newsletter.* You may opt to print these *Newsletters* and keep them readily available for easy reference. Pharmacists are welcome to suggest topics of general interest they would like to see addressed in future editions.

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 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

Drug Enforcement Administration.....800/882-9539
www.deadiversion.usdoj.gov

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