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Ohio State Board of Pharmacy News

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2012 Year in Review

The 2012 year for the Ohio State Board of Pharmacy was very productive. The Board focused heavily on information technology (IT) strategies, as the Board created a new Web site and many behind-the-scenes IT services, enabling streamlined Ohio Automated Rx Reporting System (OARRS) use and registration as well as online licensing enhancements. The Board also focused more on communication, both through the Web site to all of you and to the media, as well as creating internal modes of communication for the agency. Additionally, the Board had some changes in leadership positions in the central office as well as in the field, which the Board is pleased to announce are working out very well. The Board is looking forward to many more improvements to Board processes this year with a goal of better serving the public and Board licensees.

Annual Reminder: Terminal Distributor License

Please check the Terminal Distributor of Dangerous Drugs (TDDD) license at your facility to ensure you have received your 2013 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 2013 TDDD license, please call the Board office immediately. The 2012 TDDD licenses expired on December 31, 2012.

2013 Jurisprudence CE Board Quiz

Just as last year, the Board's annual one-hour Jurisprudence Quiz is not attached to this *Newsletter.* Instead, it is posted separately on the Board's Web site at *www.pharmacy.ohio.gov*. Just click on the "Board Publications" link, then click on the "Newsletter" link, and finally click on the "Feb 2013 SBN quiz" link. The questions in the quiz relate to the topics covered in the February, May, August, and November 2012 *Newsletters*, which can also be viewed from this tab. Please note the deadline for submission of the completed quiz is **March 31, 2013.** Any answer sheets postmarked after March 31, 2013, will not be accepted. The steps for processing the quizzes have not changed. As in the past, the quizzes are **not** graded nor are the certificates handled by the Board, so please do not call the Board for status updates on your certificate as the Board will not know this information. The quizzes are processed, graded, and certificates mailed out by Justice Data Management. **For any questions regarding the status of your law continuing education (CE) quiz from this *Newsletter*, please contact Justice Data Management via e-mail at nancyjustice@yahoo.com, or via phone at 513/505-7474.**

CE Reminder for Those Who Report This Year

This is a reminder for those pharmacists whose license numbers begin with 031. You are due to report CE this year (except for those 031 newly licensed pharmacists who received their license for the first time this reporting year between June 1, 2012 and now). Per Rule 4729-7-02 (C), you may use certificates dated on or after March 1, 2010 (that were not used on a previous CE report), up to May 15, 2013. In addition, **please be sure that you have the certificates in hand by May 15, 2013. 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.** The Board will notify you when this rule gets amended so that the CE time frames match the pharmacist license renewal dates, but until then please follow the above directions regarding the CE reporting process.

As always, you will need to attest to a total of six continuing educations units (CEUs) (60 hours) of CE credit. **0.3 CEUs (3 hours) of those must be in Ohio Board-approved jurisprudence.** Please make sure that the jurisprudence courses are Board approved. The approved list is on the

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NIH Database Provides Information on Drugs Associated With Liver Injury

The National Institutes of Health (NIH) has launched a free searchable database with information on prescription and over-the-counter (OTC) drugs, herbals, and dietary supplements associated with liver injury. The LiverTox database, *www.livertox.nih.gov*, is a free resource for health care providers and researchers studying liver injury associated with these products. The database provides up-to-date, accurate, and easily accessed information on the diagnosis, cause, frequency, patterns, and management of liver injury attributable to prescription and nonprescription medications, herbals, and dietary supplements. The database currently contains information on 700 medications, and 300 more will be added.

Coalition Urges Consumers to 'Double Check, Don't Double Up' on Acetaminophen

With the start of cold and flu season in October 2012, the Acetaminophen Awareness Coalition began urging consumers to double check their medicine labels to make sure they do not double up on medicines containing acetaminophen. The coalition's "Double Check, Don't Double Up" message is aimed to reach the more than 50 million Americans who use acetaminophen every week, encouraging them to take three simple steps to avoid acetaminophen overdose: (1) know if your medicine contains acetaminophen; (2) never take two medicines with acetaminophen at the same time; and (3) always read your medicine label. The coalition also wants to educate consumers that taking more acetaminophen than directed is an overdose and can lead to liver damage. Health care providers can join the effort by educating patients about safe use of acetaminophen, and can refer patients to the *KnowYourDose.org* Web site for more information. The Acetaminophen Awareness Coalition is made up of a diverse group of organizations representing health care providers and consumers who have joined forces through the Know Your Dose campaign to inform consumers about safe acetaminophen use and preventing liver damage that can result from unintentional overdose.

Root Cause Analysis

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.*

To assist pharmacists in the process of minimizing the occurrence of medication errors, many state boards of pharmacy are contemplating or already requiring community pharmacies to have a continuous quality improvement program in place. Many of these state's regulations include the requirement of root cause analysis (RCA) in the case of sentinel events. The Joint Commission defines a sentinel event as an "unexpected occurrence involving death or serious physical or psychological injury or risk thereof," and recommends completing an RCA for all sentinel events for health care organizations in which they accredit. It is anticipated that RCA for sentinel events may be required as part of an accreditation program for community/ambulatory pharmacies.

RCA is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or risk of occurrence of a sentinel event. RCA focuses primarily on systems and processes, not individual performance. Finding and identifying root causes during an investigation adds considerable value by pointing out significant, underlying, fundamental conditions that increase the risk of adverse consequences. These analyses can be of enormous value in capturing both the big-picture perspective and the details of the error. They facilitate system evaluation, analysis of need for corrective action, and tracking and trending.

The RCA process starts by creating a team, holding a meeting, and stating the problem. The team gathers documentation (prescriptions, labels, computer reports, etc) and interviews staff involved in the error to determine the sequence of events.

The RCA team will review the documentation and review the sequence of events and continue asking themselves "Why did this happen?" until they arrive at each root cause.

The team must assume that any problem is preventable and caused by weak or vulnerable systems rather than individual incompetence. Even in the case of a person making a mistake, the team must ask "Why do our systems allow these types of mistakes to happen so easily?" or "What factors set this person up to make this error?"

The heart of the process is the analysis itself. Table 1 lists basic questions that should be answered during RCA.

Table 1. Basic Questions to Answer During RCA
1. What happened?
2. What normally happens?
3. What do policies/procedures require?
4. Why did it happen?
5. How was the organization managing the risk before the event?

It is important to answer "What normally happens?"(Question 2, in the above table). The difference between "What normally happens?" and "What do the policies and procedures require?" (Question 3) helps determine the reliability of processes and how often staff cut corners to get the work done.

RCA also includes a method to measure the effectiveness of these strategies over time. Targeting corrective measures at the identified root causes is the best way to ensure that similar problems do not occur in the future.

USP Releases Universal Standards for Prescription Labels

New United States Pharmacopeial Convention (USP) standards for a universal approach to the format, appearance, content, and instructions for medicines in containers dispensed by pharmacists have been released. "Wide variability in prescription container labels exists today across individual prescriptions, pharmacies, retail chains and states. The USP standards provide specific direction on how to organize labels in a 'patient-centered' manner that best reflects how most patients seek out and understand medication instructions," as explained in a USP press release. Lack of universal standards for medication labeling can contribute to patients

misunderstanding dosage instructions and can lead to medication errors. Elements of the new USP standards, contained in General Chapter <17> Prescription Container Labeling, of the USP and the National Formulary, include:

- Emphasizing instructions and other information important to patients
- Improving readability
- Giving explicit instructions
- Including purpose for use
- Addressing limited English proficiency
- Addressing visual impairment

Descriptions of each standard including examples, as well as more information about the development of the standards, are provided in a USP press release, available at *http://us.vocuspr.com/Newsroom/ViewAttachment.aspx?SiteName=USPharm&Entity=PRAsset&AttachmentType=F&EntityID=109587&AttachmentID=5dc9eb96-5706-4e61-b0fa-ce9673fb3010*.

Enforcement of the standards will be the decision of individual state boards of pharmacy, which may choose to adopt it into their regulations, notes USP. The National Association of Boards of Pharmacy® (NABP®) member boards adopted Resolution 108-1-12 at the NABP 108th Annual Meeting stating that the Association should support state boards of pharmacy in efforts to require a standardized prescription label. NABP also convened a task force on this issue in December 2008. The resolution and the Report of the NABP Task Force on Uniform Prescription Labeling Requirements are available in the Members section of the NABP Web site.

New Law Increases Penalties on Medical Cargo Theft

New legislation signed into law by President Obama on October 5, 2012, increases penalties for medical product cargo theft, a significant problem that threatens patient safety when these stolen products are reintroduced into the legitimate supply chain. The Strengthening and Focusing Enforcement to Deter Organized Stealing and Enhance Safety Act of 2012 (SAFE DOSES Act) prohibits theft of medical products as well as trafficking, buying, selling, or distributing illegally obtained pre-retail medical products. The law "prescribes criminal and civil penalties for violations, including a civil penalty of up to the greater of 3 times the economic loss attributable to the violation or $1 million." According to the Coalition for Patient Safety and Medicine Integrity, "current federal criminal laws do not distinguish between stealing a load of insulin and stealing a truck full of paper clips." By increasing the penalties for medical theft, the SAFE DOSES Act should help deter such theft. The text of the new law is available for download from the Government Printing Office Web site at *www.gpo.gov/fdsys/pkg/BILLS-112hr4223enr/pdf/BILLS-112hr4223enr.pdf*.

NABP Implements Action Plan to Assist States in Regulating Compounding Pharmacies

Supporting state board of pharmacy efforts to enforce compounding regulations, NABP is implementing a four-part action plan centered around inspection of nonresident compounding pharmacies and creating an information-sharing network of regulatory details on such pharmacies. Focusing on inspections of nonresident compounding pharmacies and sharing this data among boards of pharmacy nationwide was determined by NABP and its member state boards of pharmacy to be key to preventing future tragedies like the current meningitis outbreak.

NABP developed the action plan at a November 2012 meeting of board of pharmacy executive directors where the attendees expressed a strong commitment to correcting system failures that allowed the meningitis outbreak to occur, and implementation began quickly thereafter. The Iowa Board of Pharmacy recently requested NABP to develop an inspection program for entities that are licensed by the state as nonresident pharmacies and dispensing compounded drugs in Iowa. Those in attendance expressed their support of this inspection initiative, which became a cornerstone of the four-part action plan.

In the first part of its action plan, NABP shared the list of nonresident compounding pharmacies provided by the Iowa Board with other NABP member boards of pharmacy and began coordinating the collection of information on these pharmacies. The boards' collaboration on this data helped NABP identify the initial pharmacies to inspect. NABP believes that the list provided by Iowa represents a significant number of nonresident pharmacies dispensing compounded drugs across the country.

Implementing the inspection program is the second part of the action plan and is currently underway. Initial results will reveal whether the selected pharmacies are compounding pursuant to a prescription in compliance with state regulations, or instead are engaging in manufacturing. Entities that refuse inspection may be subject to disciplinary action by the Iowa Board and such actions will be shared with all of NABP's member boards.

The third part of the action plan includes NABP collecting and maintaining data on the compounding pharmacies identified by the Iowa Board and by other boards of pharmacy. Initial data collected from the boards and the inspection reports will be stored in an NABP Pharmacy e-Profile, allowing the Association to disseminate pertinent public information among state boards. Ultimately, states will be able to submit inspection reports and other related information to NABP for inclusion in pharmacies' e-Profiles. The network will be made available at no cost to boards for use in making licensure and registration determinations for pharmacies, and may also help to identify pharmacies whose operations are more akin to manufacturing than compounding.

As the final part of the action plan, NABP plans to schedule immediate and ongoing training of board of pharmacy inspectors and compliance officers via Webinar and field training opportunities. NABP will also continue cooperative efforts with Food and Drug Administration and legislators to address the regulatory quagmire that exists when traditional compounding is exceeded and manufacturing may be occurring.

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Board's Web site. Beware: there are a large number of courses coded as law that are **not** approved by the Board for Ohio's jurisprudence/law CE requirement. These courses cannot be used to meet the three-hour law requirement; however, they can be used to satisfy the other 5.7 CEUs required. The other 5.7 CEUs (57 hours) may be in any category of pharmacy CE that you wish, as long as the provider has an Accreditation Council for Pharmacy Education provider number or has an Ohio Board CE provider number. Additionally, you may satisfy these 57 hours by maintaining an active certificate of a Board-approved specialty practice. 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.

Every year, the Board has a few pharmacists who submit their CE attestment stating they have the required 6 CEUs before receiving certificates from the CE provider because they assume they must have been successful. Sometimes, that certificate then fails to arrive because they did not pass the exam. Even if you do get the certificate after you file/attest your CE form with the Board, **any certificates dated after May 15, 2013, will not be accepted if you are audited.** Falsifying the CE report form is something that the Board does not take lightly. As long as you have the originals in your possession when you complete the online report form, you should have no problem with this reporting period. If you fail to attest CE in a timely manner (by September 15, 2013 – during the pharmacist license renewal), you will be subject to Board action on your license. Rule 4729-7-02(C) states, "A pharmacist shall be subject to further action of the board if the continuing pharmacy education report forms are not filed by the date indicated on the continuing pharmacy education report form, or if the hours submitted are incomplete."

Legislative Update: Senate Bill 301 and House Bill 284 Now Passed and Signed

Recently, Governor John Kasich signed Senate Bill (SB) 301, and this bill becomes effective on March 13, 2013. This is a clean-up bill for House Bill (HB) 93, the "Pill Mill Bill." Highlights of this bill include allowing pharmacists to use delegates to run OARRS reports for them (explained in detail in the following article). It also exempts the previous prescriber "personally furnishing" limitations (72-hour maximum supply per patient or 2,500 doses for the entire prescriber practice) of buprenorphine used for treatment of addiction as is currently in place for methadone. These two drugs, when prescribed for addiction, now have no quantity limitations attached for "personally furnishing" out of the prescriber's office. For more information about this bill, please review the link to the final bill at *www.legislature.state.oh.us/bills.cfm?ID=129_SB_301*.

Governor Kasich also signed HB 284, **which enables physician assistants with a valid Certificate to Prescribe and a Drug Enforcement Administration number the ability to prescribe Schedule II controlled substances (CS).** This bill goes into effect on March 22, 2013, and essentially mirrors the recently enacted advanced practice nurse bill, which gives physician assistants similar Schedule II CS prescriptive authority. For more information about this bill, please review the link to the final bill at *www.legislature.state.oh.us/bills.cfm?ID=129_HB_284*.

New in OARRS – Pharmacist Delegates Allowed per SB 301 Starting March 13, 2013!

Pharmacists

- Be sure you have an OARRS account if you anticipate having a delegate run the OARRS report for you. If you do not have an account yet, send your application as soon as possible; do not get caught in the flood of delegate applications the Board is expecting.
- Be sure your account is current and correct. Log in and click on "My Account." The e-mail address is where OARRS will send information or questions to you.
- Do not allow anyone to use your username and password. Every person needs his or her own account to access OARRS.
- The responsible person on a TDDD license should be the supervisor of each technician or support staff person in that pharmacy who will have OARRS access.
- Every pharmacist who has one or more pharmacist delegates:
  - You are responsible for all OARRS activity linked to your account. To help you monitor the activity, you will receive bi-weekly e-mails that summarize all requests linked to your account.
  - When an OARRS delegate is no longer under your supervision, fax an "Add/Remove Delegate" form (available on the OARRS Web site) to OARRS. The fax number, 614/644-8556, is also listed on the form.
- A delegate's only responsibility is to obtain the OARRS report. A pharmacist is still responsible for interpretation of the data.

Pharmacy Technicians/Support Staff

- OARRS accounts will be available in mid-March. Send your application early to receive a username and password as soon as the law becomes effective.
- Be sure your supervising pharmacist already has an OARRS account. This pharmacist may be the responsible pharmacist on the pharmacy's TDDD license.
- Do not use anyone else's username and password to access OARRS.

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- Do not allow anyone to use your username and password to access OARRS.

Pharmacy Students – Interns and Externs

- A student on rotation does not need an OARRS account. The preceptor should obtain the OARRS report for use as a teaching tool.
- A student working in a pharmacy (not part of a pharmacy school rotation) may register as a pharmacist delegate, supervised by a pharmacist at that pharmacy.

Attention Pharmacies: Information Regarding Submission of OARRS Data

For those responsible for submitting your weekly pharmacy OARRS data, please remember to keep your OARRS data upload account contact information current. When the OARRS Department needs to contact a pharmacy about their OARRS accounts/data uploads, the Board uses the name of the contact person on file. If this information is not correct, the pharmacy will not receive important information about uploads, changes to formatting, and most importantly, the pharmacy will not receive the notices about delinquent accounts. Delinquencies are reported to Board agents who have the right to issue a citation for noncompliance in reporting to OARRS. Most pharmacies include both the name of the responsible person and the name of the person who typically uploads reports. It is the responsible person's responsibility to ensure all data uploads are being completed. He or she is ultimately accountable. Please check your pharmacy accounts now. Be sure the contact information is correct and current.

Please Register on the New Web Site for Your Board Updates!

For those of you who are not aware, the Board's new Web site offers a free subscription service, which is a great communication tool for the Board. Please visit the Board's Web site at *www.pharmacy.ohio.gov* and click on "Click here to subscribe to updates" on the home page. The Board is getting great feedback from many of you regarding this communication option for things such as licensing updates, Sunshine Notices, and compliance press releases that the Board sends out to the media. Any time a new "item" is put on the Board Web page, you will get an e-mail with that information. If you have not been receiving the e-mails sent by the Board, please make sure that your system is not blocking the Board's e-mails. Please be sure that you have exec@bop.ohio.gov listed as safe so your system does not filter the e-mails out. If that does not work, then you might need to check with your e-mail provider.

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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