February 2012

Ohio State Board of Pharmacy News

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Let Me Introduce Myself

My name is Kyle Parker and I am the new executive director of the Ohio State Board of Pharmacy. I am a native Ohioan, born and raised in Clinton County. I am honored to have been hired into this position and am looking forward to serving the citizens of Ohio and continuing the incredible work that this Board has performed since its inception. My previous role with the State Board was as the licensing administrator and director of internship. Before coming to work here, I worked 15 years in hospital practice as a staff pharmacist, clinical pharmacist, director of pharmacy, and finally in hospital administration as director of clinical services. Prior to my hospital work, I worked in retail pharmacy for a few years, and worked throughout my career "PRN" for a few independent pharmacies. I graduated from Ohio Northern University and completed my master of business administration degree from Thomas More College.

I would like to take this opportunity to extend my congratulations to Bill Winsley on his retirement and all the tremendous work he has performed for the citizens of Ohio and for our profession. Also, for his national accomplishments through the National Association of Boards of Pharmacy® (NABP®) that he continued from his predecessor, Frank Wickham.

Clearly this Board's reputation is impressive and I will strive to continue the tradition of excellence that my predecessors have so successfully accomplished. I am looking forward to the challenges and opportunities that are inherent to this job and ensuring the highest quality of pharmacy service for the citizens of Ohio.

Do You Have Your Renewed Terminal Distributor License?

Please check the Terminal Distributor of Dangerous Drugs (TDDD) license at your facility to be sure you have received your 2012 TDDD license from the Board. The TDDD license is the license required for all pharmacies, hospitals, clinics, emergency medical service squads, etc. If you have not renewed or received your 2012 TDDD license, please call the Board office immediately. The 2011 TDDD licenses expired on December 31, 2011.

Jurisprudence CE Board Quiz Note

Just as last year, the Board's annual Jurisprudence Quiz is not attached to this *Newsletter.* Instead, it is posted on the Board's Web site at *www.pharmacy.ohio.gov*. Just click on "C.E. News and S.B.N." The questions in the quiz relate to the topics covered in the February, May, August, and November 2011 issues. If you need copies of the previous *Newsletters,* they can be found on the Ohio State Board of Pharmacy's Web site by clicking on "C.E. News and S.B.N."

Please note that the deadline for submission of the completed quiz is **March 31, 2012.** Any answer sheets postmarked after March 31, 2012, will not be accepted. Please note that the quizzes are **not** graded by the Board nor are the certificates handled by the Board, so please do not call us for status updates on your certificate as we will not know this information. The quizzes are processed, graded, and certificates are mailed out by Adherence Inc. Please mail your quiz answer sheets to Adherence Inc, PO Box 42407, Cincinnati, OH 45242-0407. For inquiries into your score or certificate, **please contact Adherence Inc at 513/794-1642.**

Final CE Reminder

This is a final reminder to those pharmacists whose license numbers begin with 03-3. This is the year for you to report your continuing education (CE). Your CE statement will be due to the Pharmacy Board office **no later than May 15, 2012.** The CE report notice should be arriving in your mail sometime early in March with the instructions on the reporting process. Your license renewal instructions will not be arriving until mid-summer. If you have not received your CE report notice by the end of March, please notify the Board office so we can get you a replacement.

You will need to attest to a total of 6 CEUs (60 hours) of CE credit. **0.3 CEUs (3 hours) of those must be in**

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FDA Recommends Use of Sterile Needle and Syringe for Administration of Inactivated Influenza Vaccines

Food and Drug Administration (FDA) recommends that health care providers use a sterile needle and syringe to administer inactivated influenza vaccines. The recommendation was released in response to questions regarding the use of jet injector devices to administer inactivated influenza vaccines. FDA advises that "inactivated influenza vaccines that are approved by FDA have information in their labeling stating how the vaccines should be administered, such as, by intramuscular (IM) or intradermal (ID) administration." Further, FDA clarifies its October 21, 2011 communication "to inform the public that inactivated influenza vaccines labeled for IM injection are intended for administration using a sterile needle and syringe. There is one inactivated influenza vaccine labeled for ID administration, this vaccine is supplied in its own pre-filled syringe. The live attenuated influenza vaccine is given through the nose as a spray; the sprayer is not a jet injector." FDA also notes the following:

- Currently, there is only one vaccine, Measles, Mumps, and Rubella (MMR), that is approved and specifically labeled for administration by jet injector.
- Safety and effectiveness information that would support labeling inactivated influenza vaccines for delivery by jet injector have not been submitted to FDA.
- At this time, there are no inactivated influenza vaccines that are approved and specifically labeled by FDA for administration by jet injector.

FDA recommends that all approved vaccines, including influenza, be administered in accordance with their approved labeling, and FDA advises that if a vaccine has been approved for administration with a jet injector, information specifically addressing vaccine use with a jet injector will appear in the vaccine labeling. Additional background information is available in the communication posted on the FDA Web site at *www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm276773.htm.*

The Centers for Disease Control and Prevention continues to encourage people to get vaccinated throughout the flu season, which can begin as early as October and last as late as May. For information about the flu vaccine visit *www.cdc.gov/flu.*

'Tell Back' Works Best to Confirm Patient Understanding

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.*

In the past few years, multiple studies have demonstrated that patients often leave medical encounters with a poor understanding of their health conditions and recommended treatment. One recent study on this subject demonstrates the low level of understanding patients have about follow-up care and medication therapy upon discharge from the emergency department (Engel KG et al. Patient Comprehension of Emergency Department Care and Instructions: Are Patients Aware of When They Do Not Understand? Ann Emerg Med. Available on the journal Web site).

Given the importance of patient understanding of medical information, there are surprisingly few studies that point out how to approach this task. However, a study published in 2008 offers some insight into what approach to assessing understanding of medical information patients most prefer and perceive to be the most effective (Kemp EC, et al. Patients Prefer the Method of "Tell Back-Collaborative Inquiry" to Assess Understanding of Medical Information. J Am Board Fam Med 2008;21(1):24-30). Researchers tested three types of inquiry about the patient's understanding:

- Yes-No
- Tell Back-Directive
- Tell Back-Collaborative

The Yes-No approach asked closed-ended questions to assess patient understanding. (Example: "I've given you a lot of information. Do you understand?") The Tell Back-Directive method used open-ended questions that were physician-centered and paternalistic in that it was clear authority and control still remained with the physician. (Example: "It's really important that you do this exactly the way I explained. What do you understand?") The Tell Back-Collaborative approach used open-ended questions that were patient centered, making it clear that power and responsibility were shared between the health care provider and patient. (Example: I imagine you are really worried about your blood pressure. I've given you a lot of information. It would be helpful to me to hear your understanding about your clot and its treatment.)

Patients showed a significant preference for the Tell Back-Collaborative inquiry over other tested approaches. Because of the potential for embarrassment if patient misunderstandings are exposed, one might anticipate health care providers' reluctance to put patients "on the spot" with open-ended questions. But a collaborative approach to Tell Back allows the patient to save face for misunderstandings by acknowledging the large amount of information being provided. Patients might also view the request for Tell Back as evidence of the health care provider's care and concern for them personally, or evidence of the provider's attention to detail and competence. So, when counseling patients about their medications, instead of asking "Do you have any questions?" or "Do you understand?" ask them to restate their understanding of the information you provided in their own words within a shame-free, blame-free environment.

DEA Clarifications on Certification Process for Audits of EPCS Software

Drug Enforcement Administration (DEA) emphasizes that third-party audits of software applications for Electronic Prescriptions for Controlled Substances (EPCS) must encompass all applicable requirements in DEA regulations, including security, and must address "processing integrity" as set forth in the regulations. Further, DEA recommends that where questions or gaps may arise in reviewing a particular applica-

tion, federal guidelines set forth in National Institute of Standards and Technology Special Publication 800 – 53A should be consulted. DEA has also announced the first DEA-approved certification process for EPCS. Certifying organizations with a certification process approved by DEA pursuant to the regulations are posted on DEA's Web site at *www.deadiversion.usdoj.gov/ecomm/e_rx/thirdparty.htm#approved*. Detailed background information is provided in the Federal Register Notice, available for download at *www.gpo.gov/fdsys/pkg/FR-2011-10-19/pdf/2011-26738.pdf*.

'Script Your Future' Provides Tools and Outreach to Encourage Medication Adherence

United States Surgeon General Regina Benjamin called upon pharmacists, physicians, nurses, and other health care providers to talk with their patients about the importance of taking medications as directed to help prevent serious health complications at the recent launch of the national campaign, "Script Your Future." Benjamin also "encouraged patients with chronic conditions to speak with their health care professionals about their medication" as noted in a press release. A survey released by the National Consumer League, the organization that developed Script Your Future, indicates that "patients who do not always take their medication as directed are less likely to have received a full explanation of the consequences of their condition, and are less convinced of the importance of adherence." The Script Your Future campaign is targeting six regional areas with outreach activities and advertising, and more information is available at *www.ScriptYourFuture.org*. The campaign brings together "stakeholders in health care, business, and government to offer practical tools for patients to help them better adhere to their medication, and to help health care professionals better communicate with patients." More information about the campaign is available in a press release at *www.prnewswire.com/news-releases/us-surgeon-general-joins-baltimore-launch-of-the-national-script-your-future-campaign-to-highlight-importance-of-taking-medication-as-directed-133077423.html*.

FDA Releases 'Use Medicines Wisely' Video

FDA Office of Women's Health has released a new public service announcement (PSA) video titled, "Use Medicines Wisely," to help raise awareness about safe medication use. As stated in an FDA news release, "Millions of people benefit from FDA approved medications and are living longer productive lives. However, when medications are used incorrectly, they can cause serious injuries, even death. Many of these injuries can be prevented."

The video shows simple steps women can take to use medications wisely. Viewers are reminded to:

- Make a list of the medications they take
- Keep their medication list with them at all times
- Know the name of each medication, why they are taking it, how much to take, and when to take it
- Talk with their doctor, nurse, or pharmacist to find out how to safely use their medications

In addition to the video, a medications record-keeper, fact sheets, and other safe medication use resources are available on the FDA Web site.

Training Video Provides Tips on Preventing Pharmacy Robbery

Rx Pattern Analysis Tracking Robberies and Other Losses (RxPATROL) has released a training video discussing pharmacy robbery and how to prevent it. The video features a pharmacist and law enforcement liaison as they tour a pharmacy, evaluating security measures and discussing additional steps that can be taken to prevent robbery. RxPATROL is an initiative designed to collect, collate, analyze, and disseminate pharmacy theft intelligence to law enforcement throughout the nation. RxPATROL is designed to gather and disseminate critical information to help protect pharmacists, guard against potential robberies, and assist law enforcement in their efforts to successfully apprehend and prosecute those involved in controlled substance pharmacy crime. The training video can be accessed on the RxPATROL Web site at *http://rxpatrol.org/TrainingVideos.aspx*.

Nearly 20 Products Marketed as Natural Supplements Contain Sibutramine, FDA Warns

FDA has posted public warnings regarding 19 products, frequently marketed as natural supplements, and found to contain sibutramine, a controlled substance that was removed from the US market in October 2010 for safety reasons. These products pose a threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. These products may also interact in life threatening ways with other medications a consumer may be taking. FDA warnings included products marketed as "Slender Slim 11," "Dream Body Slimming Capsule," "Acai Berry Soft Gel ABC," and 16 other product names. The products included in the warnings are being sold on Web sites and in some retail stores. FDA advises consumers not to purchase or use the products listed in the warnings. Consumers who have purchased any of these products should stop use immediately. And if consumers have experienced any negative side effects from using these products, they should consult a health care provider as soon as possible. The complete list of warnings is available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm234592.htm*.

2012 Survey of Pharmacy Law Now Available

Serving as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2012 *Survey of Pharmacy Law* is now available and can be purchased online for $195 by visiting the NABP Web site at *www.nabp.net/publications*.

The *Survey,* produced in a CD format, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 17, Wholesale Distributor Licensure Requirements, asks which state agency has regulatory authority over medical device distributors. In addition, a newly added question in Section 22, Electronic Transmission of Prescriptions: Computer-to-Computer, asks whether the state allows electronic prescribing of controlled substances.

Updates for the 2012 *Survey* were graciously provided by the state boards of pharmacy. In addition to the boards' support, NABP requested data from relevant health care associations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25, and laws pertaining to the possession of non-controlled legend drugs and possession of controlled substances in Sections 26 and 27.

All final-year pharmacy students receive the *Survey* free of charge through the generous grant of Purdue Pharma L.P.

For more information on the *Survey,* please contact Customer Service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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Board-approved jurisprudence. Please make sure that the jurisprudence courses are Board approved. The approved list is on the Board's Web site. There are a large number of courses coded as law that are not approved by the Board for use in meeting this requirement. 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 (ACPE) provider number or has an Ohio State Board of Pharmacy CE provider number.

You may use certificates dated on or after March 1, 2009, that you did not use when reporting in 2009. In addition, **please be sure that you have the certificates in hand before you certify your compliance with the CE requirements.** Every year, we have a few pharmacists who submit the form attesting that 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 your CE form with the Board, **any certificates dated after the date you filed the CE form 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 report form, you should have no problem with this reporting period. If you fail to submit a CE form in a timely manner, 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.

What About the New CE Process With NABP?

I am sure most of you are aware of the new CPE Monitor™ service, a collaborative effort by NABP, ACPE, and ACPE providers. The Board recommends that you create an NABP e-Profile to electronically track your continuing pharmacy education (CPE) by registering online at *www.MyCPEmonitor.net*. This is a painless online registration that will give you an NABP e-profile ID number, which will be connected to your Ohio pharmacist license number. It is anticipated that by the end of 2012, all ACPE-accredited CPE providers will require licensees to provide their NABP e-Profile ID and date of birth (MMDD) in order to obtain CPE credit. Eventually when CPE Monitor is in full effect (capturing all CPE from ACPE-accredited providers as well as all non ACPE-accredited in-state Ohio CE providers), it will provide real time auditing for all boards of pharmacy, as well as reporting capabilities to the pharmacists for tracking of completed CPE. This will eventually impact Ohio's auditing process of CE; however, this will most likely not change for at least a few years until the new NABP process has been fully active for a complete three-year CE cycle.

Updated Rule 4729-5-20 – Effect of HB 93 on Pharmacy Practice

As you know, the new Board rules for the "Pill Mill Bill," HB 93, went into effect October 27, 2011. For the link to the Board's new rule, please visit *http://pharmacy.ohio.gov/Rule-changes-effective-10-27-11-showing-changes.pdf* or visit the Board's home page at *www.pharmacy.ohio.gov.* Click on "What's New" and then on "Rules Changes Effective 10-27-2011 – Summary – Showing Changes," and finally reference 4729-5-20 (D) of the OAC. Also HB 93 required that the Medical Board, Nursing Board, and Dental Board promulgate rules for their respective agencies to address this bill. The Medical Board's Ohio Automated Rx Reporting System (OARRS) rule went into effect on November 30, 2011, and can be referenced at *www.med.ohio.gov/pdf/rules/4731-11-11%20FAQs.pdf*. Also, the Nursing and Dental Boards are both completing rules that should be out by spring 2012.

What's Been the Impact of this Rule to the Board's Licensing and OARRS Departments?

HB 93's impact to the licensing department was dramatic due to the nature of the license required. This bill requires that a prescriber's practice must be licensed as a pain management clinic with a TDDD license if the majority of his or her patients are being treated for pain or chronic pain with controlled substances. It is the only type of prescriber practice license that requires a TDDD license independent of drug purchase or storage. It is required solely based on the type of practice. Also, it is the first type of license that requires coordination with the Medical Board prior to licensing a facility in some cases. To date, the Board of Pharmacy has had about 250 pain management applications in Ohio from this bill. Sixty were fully credentialed per the law, which allowed the Board of Pharmacy to license them without Medical Board review. Thus about 75% were grandfathered and require Medical Board review for minimal standards prior to licensure. The Board of Pharmacy is currently working with legislature and Ohio Department of Alcohol and Drug Addiction Services to communicate these facts and measure the effectiveness of the bill and its impact on the illegal prescription drug problem in Ohio.

Also, the OARRS department has been dramatically impacted due to HB 93 and the Board of Pharmacy rule that mandates all pharmacists check OARRS (and thus be registered with OARRS) if the prescription exceeds 12 weeks of continuous treatment of a controlled substance or if "red flags" arise during the prescription fill for the patient. The Medical Board's rule also mandates that prescribers review OARRS. As you can imagine, the OARRS user applications jumped tremendously increasing from 4,250 pharmacist OARRS applications prior to the bill, to 5,739 OARRS applications by the end of December. Or another way to

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analyze this is prior to this bill the Board of Pharmacy averaged less than 100 pharmacist applications per month, and it now receives about 100 per day. The application percentage makeup is mostly prescribers, followed by pharmacists, and finally law enforcement. Ohio has about 12,500 active in-state licensed pharmacists and 45,000 prescribers! So as you can imagine the Board of Pharmacy is expecting the number of applicants to explode in volume. The Board of Pharmacy is continually updating its system, processes, and staff to keep up with this demand.

Carisoprodol (Soma) Now a Schedule IV Controlled Substance

On December 12, 2011, Drug Enforcement Administration (DEA) published a final rule making carisoprodol (Soma®) a Schedule IV controlled substance with an effective date of January 11, 2012. This means that several things must occur:

1. On or before January 11, 2012, every registered/licensed location possessing carisoprodol must have taken an inventory of the stocks on hand. From then on, carisoprodol must be a part of every controlled substance inventory.
2. Any location possessing carisoprodol that is not currently registered with DEA must have applied for a DEA registration prior to January 11, 2012. If they did, they may continue their activities until DEA acts on the application. Alternatively, those locations not wishing to seek DEA registration must have removed all carisoprodol from their possession prior to January 11, 2012.
3. All current prescriptions for carisoprodol must be treated as controlled substance prescriptions on and after January 11, 2012.
4. All new prescriptions received on or after January 11, 2012, are to be treated as Schedule IV controlled substances.
5. Commercial containers of carisoprodol must bear the CIV designation on or after June 11, 2012. Until then, current stock not bearing the CIV designation may be sold and dispensed, but the products are to be handled as you would a Schedule IV controlled substance.

For more information, please review the *Federal Register* publication by visiting the link below.

www.gpo.gov/fdsys/pkg/FR-2011-12-12/pdf/2011-31542.pdf.

Again, the Importance of Your E-mail

If you have not been receiving the e-mails sent by the Board, please make sure that your system is not blocking Board 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. You should receive a notice at the beginning of February, May, August, and November notifying you that the state Board *Newsletter* is available on the Board's Web site. In addition, the Board occasionally sends out other e-mails, such as the one sent at the end of December to alert everyone to the schedule change in carisoprodol to a Schedule IV drug. Please try to ensure that you are able to receive the Board's messages when they are sent. It is also important that you keep your address and employer up to date, as this is required per rule 4729-5-06 of the OAC. This also drives the renewal mailings for your pharmacist license. The Board still receives many calls from pharmacists stating they never received their renewal and it is usually because an address change was not submitted to the Board.

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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