February 2012

News

Oregon State Board of Pharmacy

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No. 497: New Board Member

The Oregon State Board of Pharmacy recently added a new member to its ranks, Corvallis, OR, pharmacist Penny Reher. Penny began her term as of July 1, 2011, and attended her first Board meeting in August 2011. She has a variety of pharmacy practice experience spanning more than 30 years. Penny is currently chief pharmacy officer at Samaritan Health Services in Corvallis. Her prior experience includes community pharmacy, hospital pharmacy, home infusion, anticoagulation, and residency practice settings. While at Good Samaritan Regional Medical Center, she established a nationally accredited pharmacy residency program.

In addition to her pharmacy activities, Penny served as a member on the board of the Corvallis Caring Place, a not-for-profit assisted living facility in Corvallis. She has served on the boards of the Corvallis Chamber of Commerce and Crescent Valley High School Booster Club. She has also served on her church council and numerous committees. Penny has earned the respect of her peers and is a welcome addition to the Board.

The other current Board members include pharmacist Ann Zweber of Corvallis, pharmacist Dianna Pimlott of Florence, OR, pharmacist Larry Cartier of Lake Oswego, OR, pharmacist Ken Wells of Junction City, OR, and public member Christine Chute of Dallas, OR. One public member position is currently vacant.

No. 498: Carisoprodol Inventory

Carisoprodol has been a controlled substance in Oregon for many years. The requirement for annual controlled substance inventory is well established based upon the Oregon Uniform Controlled Substances Act and the State Schedule of Controlled Substances. The United States Drug Enforcement Administration issued a final rule to place carisoprodol into Schedule IV of the federal Controlled Substances Act, effective January 11, 2012. Oregon pharmacists need to be aware that an inventory of carisoprodol must have been taken on January 11, to establish an initial quantity. Even though the federal inventory requirement is every two years, Oregon requires an annual controlled substance inventory.

No. 499: Pharmacist Renewal Cycle and Other Important Reminders

1. Reminder to Oregon licensed pharmacists, the annual renewal cycle is rapidly approaching and the renewal notices will be issued soon. The plan is to mail them out in the first week of April so you should receive your notice with plenty of time to complete the online renewal process well before the deadline. Remember, renewals are done online as they were last year and a delinquent fee applies to applications received on or after June 1, 2012.
2. To all Oregon pharmacists and pharmacy technicians regarding the Board's listserv notification service, the Board has developed a listserv, which is designated for providing notices to all Board of Pharmacy licensees. If you are interested in subscribing to the service please visit the Board of Pharmacy's Web site and sign up. You can always "unsubscribe" if you no longer wish to be included on the list. To subscribe, visit the Board of Pharmacy Web site and click on "Sign Up Now!" under "Topics of Interest." A second listserv has been developed for notices directed specifically for the pharmacist-in-charge (PIC).
3. To all Oregon pharmacists and pharmacy technicians, remember to update your address and contact information with the Board. Often the Board receives renewal applications returned as undeliverable or discovers address changes or employer changes on the annual renewal form months after the fact. OAR 855-019-0205(7) and OAR 855-025-0020(7) require that pharmacists and pharmacy technicians must notify the Board within 15 days of any change of address or change of employer. Failure to comply with this reporting requirement may be grounds for disciplinary action or civil penalty.
4. To all Oregon PICs, this reminder after the fact hopefully is not necessary and will not catch any PIC off guard. Each PIC should have completed the pharmacy's self-inspection form by February 1, 2012. The form was made available online on January 4, 2012, and the annual inspection cycle normally begins February 1. If you are a PIC you have the month of January to complete the annual self-inspection form and prepare for your inspection. A new PIC has 15 days from assuming the PIC position in which to complete the self-inspection. The PIC is not required to complete the annual self-inspection form personally but is responsible for making sure the self-inspection is completed and available for review by

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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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the Board during the on-site inspection. However, a new PIC must personally complete the self-inspection form within 15 days of assuming PIC responsibilities, keep it on file, and make it available to the Board upon request.

5. Pharmacists should remember that allowing a pharmacy technician whose license has expired to perform the duties of a technician in a pharmacy may be grounds for discipline against the technician, supervising pharmacist, the PIC, and the pharmacy. Likewise, allowing a pharmacist to work in a pharmacy whose license has expired may be grounds for discipline against the pharmacist, the PIC, and the pharmacy. Employers must make sure that licensed employees have current licenses on file.
6. To all Oregon pharmacists and pharmacy technicians, this is a reminder that you have a duty to report **suspected violations** of ORS Chapter 689, the Oregon Pharmacy Act, or Chapter 475, the Oregon Controlled Substances Act to the Board of Pharmacy under ORS 689.455. Also, a pharmacy must report the termination of a pharmacy technician to the Board. ORS 689.497 states in part,

   (1) A pharmacy that terminates a pharmacy technician shall report the termination to the State Board of Pharmacy. In the sole discretion of the pharmacy, the pharmacy may report the reason for the termination.

   (2) A pharmacy reporting the termination of a pharmacy technician under subsection (1) of this section shall provide the pharmacy technician an opportunity to issue a statement accompanying the report of termination. The statement of the pharmacy technician may include any mitigating factors or other information the pharmacy technician deems relevant to the termination.

All of the pharmacy laws and rules in Chapters 689 and 475 can be found on the Board's Web site at *www.pharmacy.state.or.us*.

No. 500: Reminder for Pharmacy Technicians and CPTs

This is a reminder for pharmacy technicians and certified Oregon pharmacy technicians. Remember that performing the duties of a pharmacy technician or a certified pharmacy technician (CPT) without a current license is grounds for discipline. Also please remember, the certified Oregon pharmacy technician license is not the same as the national CPT certification. The Oregon license is renewable annually while the CPT national certification has a two-year cycle. Certification is not the same as a license. Do not let your license lapse. Pharmacy technicians should receive a notice from the Board several months before expiration of their one-year pharmacy technician license as a reminder to complete one of the national certification examinations and become certified in addition to renewing the Oregon certified pharmacy technician license if they want to continue working as a technician in Oregon.

No. 501: Discontinuing Prescriptions When Orders Change

One very important aspect of the Drug Utilization Review (DUR) performed by a pharmacist upon receipt of a prescription is to first determine whether the prescription represents a new prescription, a refill of an existing prescription, or a change in an existing prescription. Certain requirements are determined based upon the outcome of that first assessment. A new prescription requires counseling. A refill requires counseling unless the pharmacist determines in his or her judgment that counseling is not appropriate. Upon receipt of a new prescription that changes an existing prescription the pharmacist must determine whether the existing prescription is to be discontinued. Part of the pharmacist's DUR responsibility is to make sure that inadvertent duplication of therapy does not occur due to his or her failure to discontinue medications following the prescribed change in therapy. If it cannot be determined by reviewing the prescription and profile, the pharmacist should discuss this with the patient and, if necessary, contact the prescriber to confirm.

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Gary A. Schnabel, RN, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Communications Manager

National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056

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