February 2014

Oregon State Board of Pharmacy News

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No. 532: Interim Director's Report on Staff and Board Member News

Gary Miner, RPh, has been appointed the Oregon State Board of Pharmacy's interim executive director until a new director has been chosen, which is expected to occur in the early months of 2014. Gary has served as the Board's compliance director since 2004 and will continue in that role after the appointment of the new executive director.

Dianna Pimlott, RPh, has served the Board for two four-year terms beginning July 2006. Her current term ends in June 2014. Dianna's participation has been instrumental with regard to her contributions to the hospital rule rewrite, the implementation of the Technician Checking Validation Program regulations, and ongoing advocacy for rural Oregon. Dianna's passion is patient safety and ensuring that the Board meets its mission. Her wisdom will be missed!

If you are interested in becoming a pharmacist Board member, candidates can be nominated by Oregon pharmacy associations or may apply directly to the Governor's Office. Forms and instructions are available on the Governor's Office website at *www.oregon.gov/gov/pages/boards.aspx.*

The Board welcomes a new inspector to its team. Her name is Laura Elvers and she came on board as a member of the Board's compliance staff in March 2013. Her primary inspection area of focus is within the tri-county area: Multnomah, Clackamas, and Washington counties. Laura graduated from the University of Wisconsin-Madison School of Pharmacy in 1997, and immediately moved to Portland, OR, to avoid ever needing to shovel snow again. She hails from an extensive background in community pharmacy.

The Board also welcomes Fiona Karbowicz, RPh, as the newly hired pharmacist consultant. This position had been eliminated due to budget cuts but it has been reinstated. Fiona will be transitioning out of her current role as inspector/investigator over the upcoming months and looks forward to working with the Board, staff, and the new executive director on projects involving rule writing, continuing education (CE), research, and analysis that require pharmacist expertise.

No. 533: Antibiotic Resistance in Community Settings: a Cause for Health Care Providers

National pharmaceutical data suggest that outpatient antibiotic prescription rates are lower in Oregon than in many states, but unnecessary antibiotic use does occur. The Oregon Alliance Working for Antibiotic Resistance Education (AWARE), based in the Oregon Public Health Division, reviewed data from Oregon's all-payer all-claims database and found that broad-spectrum drugs were used in 55% of upper respiratory infections in 2011. The worst offenders: 90% of patients treated for bronchitis and 66% of patients receiving antibiotics for the common cold – two infections that rarely require antibiotics – received broad-spectrum antibiotics. The likelihood a person would be inappropriately prescribed these types of antibiotics increases with age. Only 34% of children aged five and younger in Oregon received broad-spectrum antibiotics for upper respiratory tract infections, compared to 40% of children aged five to 17 and 72% of persons aged 18 to 64.

Oregon AWARE encourages health care providers to:

- **Prescribe appropriately**
  - When antibiotics are prescribed, ensure that the narrowest spectrum drug possible is used.
  - Optimize dosage and timing (such as using high dose amoxicillin).
  - Avoid unnecessary double coverage.
  - Make use of continuing medical education and CE opportunities such as Oregon's recently released *Judicious Use of Antibiotics* guide and stay up to date on antibiotic resistance patterns in Oregon.
- **Collaborate with providers and patients**
  - Engage your patients in a discussion of side effects of antibiotics and the potential for developing a resistant infection when they request antibiotics for likely viral infections.
  - Enlist your colleagues to counsel patients on appropriate antibiotic use, antibiotic resistance, and adverse effects.
  - Utilize materials from professional organizations or Oregon AWARE such as educational brochures or fact sheets for patients.

For more information, please contact Oregon AWARE at:
The Oregon Alliance Working for Antibiotic Resistance Education
800 NE Oregon St, Suite 772, Portland, OR 97232
Telephone: 1-971/673-1111
E-mail: oregon.aware@state.or.us
Web: *www.healthoregon.org/antibiotics*

Changes to Fentanyl Pain Patch Warnings Required by FDA

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

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

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

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

Here are a few excerpts from a recent issue.

Immediate Vs Extended Release Error

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

Errors Occur During Transitions of Care

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

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

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

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

FDA Recommends Schedule II Classification for Hydrocodone Combination Products

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

New FDA Drug Info Rounds Training Videos Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest two Drug Info Rounds videos, pharmacists discuss the review and approval of new drug names and the review of marketing and advertising materials for new drugs. The videos can be viewed at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm368620.htm* and *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm371785.htm,* respectively. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information.

CPPA Developing Specialty Pharmacy Accreditation Program

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

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

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

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No. 534 Workplace Environment Update

By Angie Chau, 2014 PharmD Candidate

The primary function of the Board of Pharmacy is to preserve and protect the public health, safety, and welfare by ensuring high standards in the practice of pharmacy and by regulating the quality, manufacture, sale, and distribution of drugs. The Board is not the entity for professionals to look to or rely upon to "promote," "enhance," or "propel" the profession of pharmacy – that is the responsibility of the local, state, and national professional associations.

Licensees should realize and understand this distinction and be involved with a professional organization to advance the profession. Additionally, licensees should comprehend and practice with the mindset that the rules are written as **minimum standards to exceed and not as a best practice to achieve.**

In June 2012, the Board adopted regulations regarding "Unprofessional Conduct for the Outlet." The Board adopted these rules in response to safety concerns expressed by pharmacists in a 2011 Working Conditions Survey conducted by the Board. Please refer to the November 2012 *Newsletter*.

Some folks have inquired as to whether and how this rule has impacted current practice. In the time since the rule's inception, pharmacy practice has seen some immediate changes. For example, the prohibition of the use of coupons and gift cards to incentivize patients to repeatedly transfer prescriptions resulted in a swift discontinuation of this practice and the recognition of patient safety at the forefront. The Board believes that such prohibition, at a minimum, has resulted in fewer incomplete profiles.

Other impacts of this rule are more subtle and require invocation of the investigatory process. Allegations regarding an outlet's use of productivity or production quotas and failure to provide sufficient personnel and appropriate opportunities for uninterrupted meal and rest periods have been reported to the Board. However, many outlets have changed procedures in order to provide for uninterrupted meal and rest periods and, in some situations, outlets have procedures for these breaks that pharmacists may not be aware of or are not following.

The Board reviews all complaints on a case-by-case basis and determines if a violation has occurred and whether to propose disciplinary action. Licensees must understand a few critical tenets of administrative law and perhaps the investigatory process itself. In order to have a solid case that exhibits the violation of a law or rule, one must have concrete evidence. Evidence in a case alleging drug outlet misconduct may include such things as documentation of communication between a pharmacist and his or her supervisor. For example, if a pharmacist determines that staff is working at an unsafe rate, he or she must request additional personnel in the pharmacy department and document the response and what steps were taken to maintain patient safety. Documentation is crucial and may be reviewed by an administrative law judge (ALJ) at a hearing. It may compel the ALJ to determine that the outlet failed to provide a working environment that protects the health, safety, and welfare of a patient due to failure to provide sufficient personnel and/or adequate time for a pharmacist to complete professional duties.

This type of investigation takes time and the long-term outcomes of this regulation may not occur as immediately as the changes described above. The Board is keenly aware of the reality of the environment in which many community pharmacists currently work as exhibited by the data collected in the initial and 2013 follow-up Working Conditions Survey. Remember, the Board has a mission to keep patients safe, not to protect pharmacists, but there may be instances where keeping patients safe means "protecting" pharmacists from unsafe working conditions.

Pharmacists must maintain standards of professionalism and not take shortcuts in their practice or attempt to practice at a rate that is not safe. Pharmacists want to remind themselves that they have a license that permits them to practice. It is the pharmacist's responsibility to take the steps necessary to practice safely and not act in a manner that jeopardizes patient safety and may result in discipline.

Speak with your supervisor if you have a concern of an outlet conduct violation and find out if there is a current procedure in place to address your concern (eg, lunch break procedure) that is not being followed. Document the interaction and specifics of date, time, and who was involved. Remember that pharmacists, interns, and technicians have a duty to report and the Board may not be able to take action if a suspected violation is not reported.

The *Oregon State Board of Pharmacy News* is published by the Oregon State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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