No. 529: Executive Director Retires

Oregon State Board of Pharmacy Executive Director Gary Schnabel has announced his retirement effective November 30, 2013. Gary joined the agency as compliance director in 1994 and was appointed executive director in 1999. Gary has overseen many changes in the profession, the industry, and the Board in his 19 years with the agency. Under Gary’s leadership and tenure, the agency has been recognized nationally for innovation and excellence, and for its commitment to serving the citizens of Oregon. Steering the Board through controversy became his passion, including addressing such topics as veterinary drug outlets, pharmacy technician registration and licensing, patient counseling, collaborative drug therapy, pharmacy technician duties, technician ratios, Oregon Death with Dignity Act, methamphetamine precursor laws, foreign drug importation, pharmacy compounding, practitioner dispensing, and pharmacy working conditions. These issues provided him many challenging and rewarding opportunities in his service to the Board and to all Oregonians.

Working closely with the Governor’s Office, Gary also found ways to shepherd the Board through 10 legislative sessions including preparation and presentation of the biennial operating budget, drafting and presenting bills, and representing the Board in front of legislative committees and individual legislators. Further, he has helped monitor and move the profession and the industry forward on a wide range of issues and has helped shape the profession in the broader interest of public health and safety as 2009-2010 president and 2010-2011 chairperson of the National Association of Boards of Pharmacy®. The members of the Board and agency staff are saddened to see him leave the agency, but wish him all the best for his well-earned retirement.

The Chief Human Resources Office at the Department of Administrative Services has begun the process to recruit and select Gary’s replacement. The Board is seeking public input on the recruitment for the new executive director. The position description and timeline was discussed at the October Board meeting. Public comment and input are encouraged. Comments may also be e-mailed via the “Contact Us” section of the Board Web page or to pharmacy.board@state.or.us. The Board has posted the job announcement and is working to have a new candidate in place early in 2014.

The link to the position announcement has been posted on the Board Web site and disseminated via the listserv.

No. 530: Immunizations for Public Health Emergency

By Jennifer Scovell, 2014 PharmD Candidate

With the signing of 2013 Oregon Senate Bill 167, effective January 1, 2014, the governor can authorize pharmacists to administer vaccines to patients three years of age and older without a prescription when declaring a public health emergency. Also under this new bill, the Oregon Office of the State Public Health Director can do the same during events such as infectious disease outbreaks. These are opportunities for pharmacists to expand patient accessibility to treatment and to better protect the public’s health. Pharmacists who immunize will be notified of such an event by the Board through e-mail, phone, and/or fax messages. Information or alerts of a public health emergency will be distributed to the Board by the Oregon Health Authority (OHA). By being involved in this network of communication, the Board can relay information to allow pharmacists to act quickly and be a resource for the public if the need arises. Pharmacists employed by corporate chains will be alerted by their respective management offices with details on how to proceed in this kind of event.

One way for pharmacists to be more aware of these types of emergencies is by signing up with the Oregon Health Alert Network (HAN). The Oregon HAN is funded by the Centers for Disease Control and Prevention (CDC) and managed by the OHA – Public Health Division. It is designed to send out alerts to inform health systems, emergency responders, and public health personnel of health emergencies and/or hazards. If you would like to personally sign up to receive alerts from the Oregon HAN and/or the CDC HAN, you may visit www.han.oregon.gov and www.emergency.cdc.gov/han for more information.

No. 531: Frequently Asked Questions About Immunization in a Declared Emergency

1. Who can declare a state of emergency or public health emergency?
   a. The governor or the public health officer of Oregon.
   b. The president of the United States or other designated federal official.
   c. A signatory to the Pacific Northwest Emergency Management Arrangement (Alaska, Idaho, Oregon, Washington,
Enteric-Coated Aspirin Recalled for Potential Acetaminophen Mix-Up

In June 2013, Advance Pharmaceutical Inc initiated a voluntary recall of Rugby Laboratories label enteric-coated aspirin tablets, 81 mg (Lot 13A026; expiration date: January 2015) due to a complaint that a bottle labeled with this product name actually contained acetaminophen 500 mg tablets. This over-the-counter (OTC) product is packaged in bottles of 120 tablets with National Drug Code 0536-3086-41 and Universal Product Code 3 0536-3086-41 9. The affected lot was distributed nationwide by Rugby Laboratories to wholesalers and retailers. The manufacturer warns that inadvertently taking acetaminophen, 500 mg, instead of enteric coated aspirin, 81 mg, according to the directions on the label, can lead to an acetaminophen overdose and potential severe liver damage. The manufacturer indicates that consumers who take the dosage as indicated on the defective product labeling may be ingesting up to 24,000 mg of acetaminophen, which is about six times the maximum recommended daily dose of acetaminophen (4,000 mg).

Consumers who have bottles from the affected lot should stop using the product and return it to the pharmacy or store where it was purchased and should contact a health care provider if they are experiencing any problems that may be related to using the product. Food and Drug Administration (FDA) notes that any adverse reactions related to the use of the product should be reported to FDA’s MedWatch Program. More information about this recall is available on the FDA Web site at www.fda.gov/Safety/Recalls/ucm357909.

Barcoding Technology for Community Pharmacy

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 regulatory agencies, 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-FDA-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.

Barcoding technology is well-established in industries outside of the health care sector and is now being used within health care to enhance efficiency and safety, and in pharmaceutical wholesale operations to improve supply chain inventory and efficiency. Numerous studies prove the effectiveness and cost benefits of using barcoding technology during the drug dispensing process. About 75% of wrong drug or wrong dose errors are captured and corrected using barcoding technology1 and there is sufficient evidence that barcode scanning is becoming the standard of practice in pharmacies.

Although barcoding technology is mature with abundant evidence regarding its effectiveness, a 20062 study showed that only half (53.5%) of United States community pharmacies utilize a barcode scanner for verification/identification of medications. The study also revealed significantly lower adoption in independent pharmacies (11.5%) compared to chain pharmacies (62.6%).

According to a survey conducted by ISMP in 2009, the most frequently reported reasons for implementing barcode scanning for product verification included a desire to improve the accuracy and safety of the dispensing process, the ease with which the technology fits with pharmacy workflow, improvement of staff efficiency and inventory control, and a belief that the technology was necessary to stay in business. The most common reasons for not implementing barcode scanning for product verification, other than cost, included uncertainty regarding the “right” vendor product, satisfaction with the current system (without barcode product verification), and perceptions that the technology would reduce staff efficiency.

ISMP has developed a tool, Assessing Barcode Verification System Readiness in Community Pharmacies, to help address the reasons why barcode scanning has not been implemented and to facilitate the adoption of this technology in an estimated 27,327 community pharmacies that do not currently utilize it for product verification.

Given the resource commitment to purchase barcoding systems and the potential for technology to have a profound effect upon the work environment, this tool will help community pharmacy managers and owners better understand the issues related to barcode product verification systems. It will also help managers assess the pharmacy’s readiness for the technology, prepare for the selection of a system, and implement the technology effectively.

Barcode scanning to verify prescription products prior to dispensing improves the safety and quality of pharmacy care provided to patients and increases efficiency during the provision of pharmacy services. Although technology should not be seen as a panacea, it can be a useful tool when used appropriately and combined with other patient safety strategies.3 Does your pharmacy use barcode technology for product verification? If not, please access this free tool, at www.ismp.org/AHRQ/Default.asp?link=sa.


ISMP Launches Medication Safety Alert! Newsletter Tailored for LTCFs

ISMP has launched a new ISMP Medication Safety Alert! publication, Long-Term Care Advise-ERR, as a means to provide medication error prevention information tailored to assist staff and providers in long-term care facilities (LTCFs).

With ISMP Medication Safety Alert! publications making a significant impact on preventing medication errors, ISMP is now providing this new resource tailored to LTCFs. ISMP notes that medication errors reported to ISMP Medication Errors Reporting Program include reports from LTCFs. More information and a link to subscribe to this new publication are available in the Newsletters section of the ISMP Web site at www.ismp.org/newsletters/longtermcare.
FDA Warns of Rare Skin Reactions in Patients Taking Acetaminophen

FDA has issued a consumer update that warns of rare but serious skin reactions that may occur in patients taking acetaminophen. These complications include three serious skin reactions: Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exantheomatic pustulosis (AGEP). SJS and TEN can both be fatal, and usually require hospitalization. Patients suffering from AGEP commonly recover within a few weeks after they stop taking the medication that caused the reaction.

Symptoms of these conditions include skin rashes, blisters, and widespread damage to the surface of the skin. Patients taking acetaminophen or other compounds that contain acetaminophen should be advised to stop taking the medication if they experience such symptoms and should consult their health care providers or seek an emergency department immediately.

FDA emphasizes that this information should be viewed within the context of millions of patients who, over generations, have used and benefited from acetaminophen and stresses that severe allergic skin reactions are an extremely rare condition. Further, the agency notes that many medications can cause allergic reactions, and skin allergy warnings have already been added to the drug labels of other categories of OTC analgesics including ibuprofen and naproxen.

“This new information is not intended to worry consumers or health care professionals, nor is it meant to encourage them to use other medications,” said Sharon Hertz, MD, deputy director of FDA’sDivision of Anesthesia, Analgesia, and Addiction Products. “However, it is extremely important that people recognize and react quickly to the initial symptoms of these rare but serious side effects, which are potentially fatal.” The full consumer update is available on the FDA Web site at www.fda.gov/ForConsumers/Consumer Updates/ucm363010.htm.

Reminder to Purchase Drugs Only from Licensed Wholesalers, Including VAWD-Accredited Wholesale Distributors

To ensure that patients are receiving safe, FDA-approved medications, pharmacists and other health care providers should purchase prescription drugs either directly from the manufacturer or from wholesale drug distributors licensed in the US as advised by FDA. The agency provides a list of state agencies for assistance in verifying licensure at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD certification are in compliance with state and federal laws and NABP’s VAWD criteria. NABP has recently revised the VAWD criteria to allow virtual manufacturers and virtual wholesale distributors — a growing segment of the pharmaceutical wholesale industry — to qualify for VAWD, as well as to implement other changes aimed to help to ensure that the drug supply chain remains secure.

The revised VAWD criteria responds to changing business models and helps safeguard drugs in distribution at a time when there is an increased risk of counterfeit and substandard drugs entering the legitimate US drug supply chain. In particular, the criteria have been revised to provide stronger assurance that drugs diverted from pharmacies and unlawful sources are prevented from entering into the supply chain.

For a listing of VAWD-accredited facilities, please visit www.nabp.net/programs/accreditation/vawd.

Voluntary Recall of Unexpired Sterile Products After Reports of Adverse Events

FDA has announced a voluntary recall of all lots of unexpired sterile products produced by Specialty Compounding, LLC, in Cedar Park, TX. FDA received reports of 15 adverse events at two hospitals (Corpus Christi Medical Center Doctors Regional and Corpus Christi Medical Center Bay Area) potentially related to the use of these sterile products. Affected patients received an intravenous infusion of calcium gluconate supplied by the company.

Patients who were administered the injectable drug products are at risk of life-threatening infections. The recall applies to all unexpired sterile compounded medications dispensed by the company, including all strengths and dosage forms. Recalled products were distributed directly to hospitals and physicians’ offices in Texas, and to patients located nationwide (with the exception of North Carolina). No calcium gluconate was shipped outside the state of Texas. Health care providers and patients should stop using all recalled products and return them to Specialty Compounding.

Veterinarians Not Eligible for NPIs, CMS Clarifies

Centers for Medicare and Medicaid Services (CMS) has become aware of cases in which veterinarians are told, incorrectly, that they must provide a National Provider Identifier (NPI) number for prescriptions they have written to be dispensed. The agency has issued a clarification, stressing that veterinarians do not meet the regulatory definition of “health care provider,” and thus may not obtain NPI numbers. The clarification also states that “Any entity that insists veterinarians obtain an NPI [is] attempting to require veterinarians to obtain NPIs fraudulently.” CMS also notes that “if a veterinarian fulfills the definition of ‘health care provider’ in a profession other than furnishing veterinary services,” such as if they are also a nurse practitioner, “the veterinarian would be eligible for an NPI but would select a Nurse Practitioner code (not a Veterinarian code) from the Healthcare Provider Taxonomy Code Set when applying for an NPI.”
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the Province of British Columbia, and Yukon) requesting assistance during a civil emergency.

d. A signatory to Emergency Management Assistance Compact requesting assistance during a civil emergency.

2. How long does a state of emergency last?

a. When these rules are authorized by any one of the officials listed above, they are in effect to the extent necessitated by the scope of the declaration.

3. What are examples of public health emergencies?

a. Some examples of a public health emergency are natural disasters and severe weather, chemical attack, accidental chemical release, nuclear attack or nuclear accident, bioterrorism, biological toxin considered highly contagious, epidemic of a communicable disease, etc.

4. During a declared emergency or a public health emergency, the rules under Chapter 855 Division 7 apply to:

a. All persons licensed or registered with the Board under OAR Chapter 855; and

b. Any persons acting under the authority of the Oregon State Public Health Division; or

c. Any other state agency, local or county health department, emergency manager, or to any such person acting in preparation for a public health emergency.

5. In a declared emergency, may I dispense medications without a prescription? If so, what medications may I dispense?

a. A pharmacist may dispense a refill without a valid prescription, not to exceed a 30-day supply, without a practitioner’s authorization.

b. A pharmacist may also, after consultation with any authorized prescriber, initiate or modify any drug therapy, and dispense an amount of the drug to meet the patient’s health care needs until that patient can be seen by a health care practitioner, provided that:

i. The pharmacist acts in accordance with currently accepted standards of care

ii. In the professional judgment of the pharmacist, the drug is essential to the maintenance of the patient’s health or the continuation of a current drug therapy regimen

iii. The pharmacist records all relevant information to a form and indicates that a drug therapy has been initiated or modified, and that this is an emergency prescription

iv. The pharmacist informs the patient or his or her agent at the time of dispensing that the drug is being provided in the absence of a valid patient-prescriber relationship but that a prescriber was consulted, pursuant to emergency protocols, regarding the appropriateness of the drug therapy

v. The pharmacist informs the patient or his or her agent that a prescriber authorization is required for any refill.

6. May I administer medications?

a. Yes, pharmacists may administer vaccines and other medications and may be called upon to do so during a declared emergency.

7. Do I still have to complete drug utilization reviews and counsel?

a. Yes.

8. Do I still have to maintain records?

a. Yes. Initiation of a drug therapy during a declared emergency is not necessarily pursuant to a traditional prescription. State and federal emergency preparations authorize alternative prescribing methods, including forms such as individual data collection forms, intake forms, etc. Pharmacists are expected to maintain a record of the drugs and vaccines dispensed and/or administered along with all relevant information.