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News

Oregon State Board of Pharmacy

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No. 548: Warning From the Board: Phantom PIC Solicitation

Be sure that you and your license are protected! Recently, pharmacists with Oregon licenses have been solicited by out-of-state pharmacies to serve as what is becoming known as "phantom PICs." By rule, an out-of-state pharmacy shipping prescriptions into the state of Oregon must have a pharmacist who holds an Oregon license and is registered with the Oregon State Board of Pharmacy as a pharmacist-in-charge (PIC) who works to ensure that the pharmacy is compliant with Oregon law. Unscrupulous pharmacies are offering pharmacists positions in which the pharmacist is never required to physically be in the pharmacy, or even the same state, but to serve as PIC in name only. New graduates have been a target group of solicitation for these pharmacies.

Be advised that in the state of Oregon, PIC responsibilities include the following:

(a) An inventory of all controlled substances must be taken within 15 days before or after the effective date of change of PIC, and must be dated and signed by the new PIC. This inventory must be maintained in the pharmacy for three years and in accordance with all federal laws and regulations;

(b) Verifying, on employment and as appropriate, but not less than annually, the licensure of all pharmacy personnel who are required to be licensed by the Board;

(c) Conducting an annual inspection of the pharmacy using the PIC Annual Self-Inspection Form provided by the Board by February 1 each year. The completed self-inspection forms must be signed and dated by the PIC and maintained for three years from the date of completion;

(d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;

(e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs;

(f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such training should include an annual review of the PIC Self-Inspection Report; and

(g) Implementing a quality assurance plan for the pharmacy.

Source: OAR 855-019-0300(5)

PICs are responsible for oversight and compliance within their pharmacy; therefore, when an outlet is disciplined, the PIC's license may be subject to discipline as well. Oregon PIC laws are currently under review and propose to specify a minimum requirement of number of hours physically present in the pharmacy to clarify the intent of the pharmacist facilitating the lawful practice of pharmacy according to Oregon regulations. Open comment will be from May 1 through May 28, 2015, at 4:30 PM. In the meantime, be cautious of these types of offers and report them to the Board for investigation.

No. 549: Disaster Preparedness and Volunteers in Oregon

By DeWayne Hatcher, SERV-OR Systems Coordinator

What is the State Emergency Registry of Volunteers in Oregon (SERV-OR)? SERV-OR is part of a nationwide network of state programs designed to verify the qualifications of health care providers in advance, thereby creating a volunteer pool capable of assisting in disasters, public health emergencies, and public health improvement initiatives at the local and state level. The Oregon SERV-OR program is federally funded through the United States Department of Health and Human Services (HHS). HHS works with all states to establish common credentialing standards. SERV-OR operates and is organized within the Oregon Health Authority, Public Health Division, Health Security, Preparedness and Response program.

SERV-OR volunteers are able to serve as they choose; within their community or state or, if needed, across state lines. Currently in Oregon there are 74 volunteer pharmacists registered in SERV-OR. During a governor's declared disaster or public health emergency, registered SERV-OR volunteers deployed by the state of Oregon are covered for liability and workers compensation.

SERV-OR is divided into two major divisions. The first division is the State Managed Volunteer Pool (SMVP). These SMVP volunteers are unaffiliated and operate as individual provider resources for the state of Oregon. The second division is the county-based Medical Reserve Corps organizations. A volunteer can belong to one or both of these volunteer divisions. In Oregon there are nearly 2,500 health care volunteers made up of licensed or certified health care providers.

Why pre-register? Taking advantage of a volunteer's time and capabilities presents a major challenge during an emergency response, and we have learned much from recent large disasters in the US. It is common for large groups of people

continued on page 4

FDA's New Database Simplifies Searching for Guidance Documents

Food and Drug Administration (FDA) has released a new database that houses most FDA guidance documents for regulatory professionals. The guidance documents for nearly all FDA-regulated professions and industries are available in a searchable database that allows users to enter keywords that update automatically as they are typed. Search results may also be narrowed by product, date, document type, and other terms. The database also indicates whether there is an open comment period and the deadline for submitting comments.

The database can be accessed at *www.fda.gov/RegulatoryInformation/Guidances/default.htm*.

2014-2015 Targeted Medication Safety Best Practices for Hospitals

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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

The purpose of the Targeted Medication Safety Best Practices (TMSBP) for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices on specific medication safety issues that continue to cause fatal and harmful errors in patients despite repeated warnings in ISMP publications. These best practices are realistic practices, already adopted by many organizations, upon which hospitals can focus their medication safety efforts. The best practices are applicable to all types of hospitals including, but not limited to, critical access hospitals, cancer hospitals, and children's hospitals. They may also be applicable to other health care settings, as well as non-inpatient areas of hospitals and hospital systems. These best practices have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the *ISMP Medication Safety Alert!* are referenced after each best practice.

Recurrent Issue of Serious Harm

Oral methotrexate for non-oncological indications administered daily instead of weekly or twice weekly is a recurrent issue and one of the six TMSBPs.

ISMP has published this error in seven *ISMP Medication Safety Alert!* issues from 1996 to 2013. Although dosed daily for oncology purposes, it is used weekly or twice weekly to treat a variety of autoimmune diseases (eg, psoriasis, severe rheumatoid arthritis). Error reports point to inadvertent ordering and/or entering as daily instead of weekly or twice weekly, and lack of patient education/understanding of medication dosing schedule. To minimize the risk of error, **Best Practice 2** calls for hospitals to:

a) Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.
b) Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.

Question: Does the best practice of a weekly frequency default for oral methotrexate apply to a specialty cancer hospital?

Answer: The intent of this best practice is to reduce errors when methotrexate is prescribed as a weekly regimen for non-oncologic or oncologic indications. Even when used for oncologic purposes, oral methotrexate is sometimes prescribed as a weekly regimen, not daily. Thus, this best practice applies to all patient care settings, including specialty cancer hospitals.

Teaching Points (Both Verbal and Written)

- Explain the weekly dosing schedule.
- Explain that taking extra doses is dangerous.
- Have the patient repeat back the instructions.
- Provide the patient with the free ISMP high-alert medication consumer leaflet on methotrexate (found at *www.ismp.org/AHRQ/default.asp)*.

To read all of the best practices, visit *www.ismp.org/Tools/BestPractices/default.asp.*

ACPE Releases Updated Definition of CPE and Guidance on CPD

The Accreditation Council for Pharmacy Education (ACPE) has released two documents that provide guidance and support for continuing pharmacy education (CPE) and continuing professional development (CPD). The two documents, approved by the ACPE board of directors, are described below.

- The revised *Definition of Continuing Education for the Profession of Pharmacy* defines the quality of CPE required by ACPE and the competencies required for CPE activity content. The *Definition* document will assist providers of CPE in planning activities that will be applicable to the professional development of pharmacists and certified pharmacy technicians.
- The *Guidance on Continuing Professional Development (CPD) for the Profession of Pharmacy* incorporates feedback from a broad survey of the pharmacy profession that was conducted in July 2014. The *Guidance* document provides details on the learning activities that may contribute to the professional development of both pharmacists and pharmacy technicians beyond CPE, and also "provides a process for pharmacists and pharmacy technicians to meet and maintain defined competencies in areas relevant to their respective professional responsibilities."

Additional information, including links to the documents, is available in a press release on the ACPE website at *www.acpe-accredit.org/pdf/ACPEAdvancesCPE-CPDforPharmacists.pdf*.

Hospira Issues Recall for Multiple Lots of Ketorolac Tromethamine Injection Due to Potential Contamination

Hospira, Inc, of Lake Forest, IL, has issued a voluntary recall of ketorolac tromethamine injection, USP in the United States and Singapore due to potential particulate matter. The presence of particulate was confirmed through a customer report of visible floating particulate that was identified as calcium-ketorolac crystals. If in-

jected, medications contaminated with particulate matter may cause localized inflammation, allergic reaction, granuloma formation, or microembolic effects. Multiple lots are impacted by this recall and are listed in a press release posted to the FDA website at *www.fda.gov/Safety/Recalls/ucm433857.htm*. The lots were distributed from February 2013 to December 2014 in the US. To date, there have been no cases of adverse events associated with this medication. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

FDA Warns of Counterfeit Cialis Tablets Entering the US

Potentially dangerous, counterfeit versions of Cialis® 20 mg tablets were intercepted in the mail before reaching a US consumer, warns FDA. Laboratory analysis of the counterfeit product showed that it contained multiple active ingredients that could lead to adverse effects or harm if used, indicates an FDA Drug Safety Announcement. The agency reminds US consumers to only buy prescription medications from state-licensed pharmacies located in the US. FDA notes that it cannot confirm that the manufacturing, quality, storage, and handling of products ordered from unlicensed websites follow US standards because the products are from an unknown source.

To help consumers identify these counterfeit medications, FDA provides guidelines in the safety announcement. For example, these counterfeits list "AUSTR81137" on the front of the bottle and lack a National Drug Code number. Other possible identifiers include misspellings and unusual colors on the label, and a manufacturer listed as "112 Wharf Road, WEST RYDE, NSW 2114" on the side of the bottle.

To date, FDA is not aware of any adverse events associated with these counterfeit medications; however, consumers are encouraged to talk to a health care provider about their condition and options for treatment if a counterfeit product was received.

The National Association of Boards of Pharmacy® (NABP®) has reviewed more than 10,900 websites selling prescription drugs to patients in the US and found that nearly 97% are operating out of compliance with pharmacy laws and practice standards established to protect the public health. To help consumers in the US find the safest sources for purchasing medications online, NABP developed the Verified Internet Pharmacy Practice Sites® (VIPPS®) program. NABP encourages consumers to look for the VIPPS Seal and to check NABP's list of accredited sites on the AWAR$_X$E® Prescription Drug Safety Program website. In addition, consumers may soon watch for pharmacy sites using the newly launched .pharmacy Top-Level Domain; sites in the domain (with a website address ending in .pharmacy) will be reviewed by NABP and approved only if they are legitimate online pharmacies or pharmacy resources adhering to applicable pharmacy laws and best practices.

Additional details on the counterfeit Cialis are available in a Drug Safety Announcement posted to the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm431071.htm*. More information on VIPPS and other NABP programs is available in the Programs section of the NABP website, *www.nabp.net*.

New FDA Drug Info Rounds Training Videos Review Drug Disposal and REMS

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 decisions. The latest Drug Info Rounds videos are as follows.

- In "Disposal of Unused Medicines," pharmacists discuss how consumers can safely dispose of expired or unused medications to prevent abuse or misuse and accidental poisoning.
- In "REMS," pharmacists discuss the many components of Risk Evaluation and Mitigation Strategies (REMS) and how they can help manage a drug product with known or potential serious risks.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

FDA Issues New Drug Labeling Rules to Benefit Pregnant, Breastfeeding Women

FDA announced new prescription drug labeling requirements that will clarify how medications might affect women who are pregnant or breastfeeding and men and women of reproductive potential. The final "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling Rule" removes the previously used pregnancy letter categories – A, B, C, D, and X – and places information into three main categories:

- **Pregnancy:** Labor and delivery guidelines now fall under this category, which also now includes information for pregnancy exposure registries. Such registries track data on the effects of certain approved medications on pregnant and breastfeeding women.
- **Lactation:** Previously labeled "Nursing Mothers," this category provides information such as how much drug is secreted through breast milk and the potential effects on a breastfed infant.
- **Females and Males of Reproductive Potential:** This is a new category that includes information on how a certain medication might affect pregnancy testing, contraception, and infertility.

The new labeling changes go into effect on June 30, 2015. Over-the-counter medication labels will not be affected. The new rules are available for download through the *Federal Register* at *https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-28241.pdf*.

FDA Approves Zohydro ER With Abuse-Deterrent Properties

In February 2015, FDA approved a new formulation of Zohydro® ER with abuse-deterrent properties. The new formulation uses a technology that allows the drug to maintain its release properties when used as intended, according to a press release from Zogenix. The abuse-deterrent system, known as BeadTek, incorporates "pharmaceutical excipients" that create a viscous gel when the medication is crushed and dissolved in a liquid or solvent, thus making the product more difficult to abuse through methods that involve crushing, breaking, or dissolving the drug. In early 2014, Zohydro ER became the first extended-release, single-ingredient hydrocodone product to receive approval for use in the US. Approval of the drug came under criticism, with some organizations arguing that the potential for addiction, abuse, and misuse could outweigh therapeutic benefits, in part because the drug lacked abuse-deterrent properties. Zogenix indicates that transition to the new abuse-deterrent formulation will take place in second quarter 2015.

Additional information on the new formulation is provided in a press release available on the Zogenix website at *http://ir.zogenix.com/phoenix.zhtml?c=220862&p=irol-newsArticle&cat=news&id=2012326*.

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continued from page 1

to travel to a disaster zone to volunteer medical assistance. In most cases, authorities are unable to distinguish those who are qualified from those who are not – no matter how well intentioned. For example, during Hurricane Katrina, physical operations for the Louisiana Board of Pharmacy, State Board of Medical Examiners, and State Board of Nursing were limited or shut down. Registering and verifying the credentials of health professional volunteers on site immediately following a major disaster can be difficult or impossible. By registering in advance, valuable time is saved in emergency situations and questions regarding liability protections are resolved.

Most disasters, public health threats, and medical emergencies are dealt with at the local level. The SERV-OR program provides Oregon the ability to quickly identify, contact, and deploy health professional volunteers during disasters and public health emergencies, such as mass vaccination clinics. Statewide efforts and planning also address large emergency events, such as a Cascadia Subduction Zone earthquake.

If you are interested in registering for SERV-OR, have questions, or want more information, visit the SERV-OR website at *https://serv-or.org,* call 877/343-5767, or email serv.or@state.or.us. There is also direct link to SERV-OR on the Board web page.

No. 550: Compliance Corner

License Lookup and Verification is an online tool for pharmacists, technicians, and outlets for license status and Board action. Best practice would include verifying employees and vendors upon hire/initiation of service **and** on an annual and ongoing basis. Note that when awaiting licensing information, the online information is updated within an hour of a license being issued. Therefore, the use of the online tool is often a quicker verification. Be sure to print out and post the online verification to use temporarily while awaiting the official license by mail.

License Updates are required any time a licensee (pharmacist, technician, intern, outlet) changes information. Information needs to be submitted to the Board within 15 days if there is a change in address, phone number, email address, or location of employment; see OAR 855-025-0020 and OAR 855-019-0205. You can communicate easily with Board staff to report personal information changes using the following email: pharmacy.board@state.or.us.

Drug Utilization Review (DUR) has been a hot topic in pharmacy the past several years. As a reminder, DUR is required by a pharmacist on all new **and** refilled prescriptions. Pursuant to OAR 855-019-0220, the review includes (but is not limited to):

- Full name of the patient for whom the drug is prescribed;
- Address and telephone number of the patient;
- Patient's gender and age or date of birth;
- Chronic medical conditions and disease states of the patient;
- A list of all drugs or devices the patient is currently obtaining at that pharmacy showing the name of the drug or device, strength of the drug, the quantity and date received, and the name of the prescribing practitioner;
- Known allergies, adverse drug reactions, and drug idiosyncrasies;
- Pharmacist comments relevant to the individual's drug therapy, including any other information specific to that patient or drug; and
- Additional information, which may relate to DUR, or for the monitoring of the patient as appropriate, such as dose and timing.

The Board offers this reminder because it is obvious from the cases brought before the Board that the DUR process is either not a part of procedure within the pharmacy, or is being bypassed by the technician or pharmacist. **This is not simply relying on the computer to screen for the technician and the pharmacist to give override initials. This is an intentional, thoughtful process in which the medication expert (pharmacist) on the health care team is reviewing the medication records.** Build the DUR into pharmacy procedures and perform the DUR with each prescription fill. Remember, a proper DUR can prevent medication errors and promotes patient safety.

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™ (NABPF™) 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 NABPF or the Board unless expressly so stated.

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