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News

Washington State Pharmacy Quality Assurance Commission

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No. 1198 Long-Term Care Prescriptions

The Washington State Pharmacy Quality Assurance Commission office is receiving an increasing number of inquiries from long-term care facilities and the pharmacies that serve them regarding what information is required for prescriptions transmitted electronically. Washington Administrative Code (WAC) 246-870-030 states:

> The electronic transfer of prescription information includes the communication of prescription information by computer, fax, or other electronic means. It includes the transfer of original and refill prescriptions and the transfer of prescription information from one pharmacy to another pharmacy.
>
> Transmission of original prescriptions must include:
>
> (1) Prescriber's name and the physical address of the prescriber;
>
> (2) Prescriber's Drug Enforcement Administration Registration number where required for controlled substance prescriptions;
>
> (3) Date of issuance;
>
> (4) Patient's name and address;
>
> (5) Drug name, dose, route, form, directions for use, quantity;
>
> (6) Electronic, digital, or manual signature of the prescriber;
>
> (7) Refills or renewals authorized, if any;
>
> (8) A place to note allergies and a notation of purpose for the drug;
>
> (9) Indication of preference for a generic equivalent drug substitution;
>
> (10) Any other requirements consistent with laws and rules pertaining to prescription content and form, RCW 69.41.120 and 21 Code of Federal Regulations Part 1300; and
>
> (11) Identification of the electronic system readily retrievable for board of pharmacy inspection.
>
> Transfer of prescription information from pharmacy to pharmacy by facsimile, or verbally, must include:
>
> (a) All elements of the original prescription;
>
> (b) Date of transfer maintained in records at each site;
>
> (c) Number of refills remaining and the date of last refill;
>
> (d) State and federal required information for controlled substances;
>
> (e) No further refills may be issued by the transferring pharmacy unless the pharmacies use a common electronic database for prescription filling which provides an audit trail to document each refill and limits refills to the number authorized.

The Commission encourages pharmacies not following the requirements of WAC 246-870-030, ie, accepting electronic transmission of prescriptions that contain incomplete prescription information such as missing drug quantity and refill information, to work with prescribers to ensure compliance.

No. 1199 Sterile Compounding Update

More than 25 people submitted comments on the first draft of the sterile compounding rules that were available for public input through mid-February. The Commission's compounding subcommittee and staff members are reviewing those comments. When they complete the review, the Commission will prepare and distribute a second working draft for additional comment. The second draft should be available in late spring 2015 for another round of comments. At the close of the comment period, the Commission will again review and consider all comments it receives. It will make changes as deemed necessary and potentially approve proposed rule language for filing with the Washington State Office of the Code Reviser. The official public comment period begins upon filing the proposed rules (CR-102). The public rules hearing may be held within 33 days of the CR-102 filing.

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*.

No. 1200 Pharmacy Technician Training Program Updates

For the past six months, the Washington State Department of Health has been implementing a new credential type for all active pharmacy technician training programs. Approved programs are entered in the Integrated Licensing and Regulatory System for tracking and automated renewal notices. Because of this new process, an application form (PDF) was created to collect the necessary demographic information.

In April, the Commission will send letters to all active and recently expired programs to update its records and verify the program's status. If you are interested in implementing a technician training program (on-the-job or academic), please refer to the *Guidelines for the Implementation of a Washington Pharmacy Technician Training Program* (PDF) form for guidance or contact Irina Tiginyanu, pharmacy technician analyst, at 360/236-4827 or by email at Irina.Tiginyanu@doh.wa.gov.

No. 1201 Prescription Fraud Alert Project

After an eightfold increase during the previous decade, the prescription drug overdose rate in Washington has declined by 29% between 2008 and 2013. The decline in deaths due to prescription drug overdoses seems to be leveling off – there were 381 of these deaths reported in 2013, down by seven from 2012. While the trend is encouraging, too many people are still dying due to misuse of these medications.

To address this epidemic, the Department of Health has been working on several efforts, including pain management rules and a prescription monitoring program. While working on this issue, the Commission often gets calls from health care providers who have become aware of fraudulent prescriptions through forgery or theft of prescription pads. To try to address this piece of the issue, the Department of Health would like to pilot an alert system.

This system would allow a health care provider who becomes aware of a fraudulent prescription to fill out a web-based form with specific information regarding the prescription and submit it to the Department of Health. The Department of Health would then make that information available to the pharmacies registered with the public listserv DOH-RX-FRAUD-ALERT, on the Commission's web page, and in the prescription monitoring system. The hope is that this tool will help prevent additional fraudulent prescriptions from being filled.

The form is available online. The Commission hopes you, as a valued partner, make it and this communication available to your members. The pilot will start on April 15, 2015, and end October 15, 2015.

During the next six months, the Department of Health will determine if the system is effective and whether current resources will allow it to continue.

The Commission appreciates your continued efforts to work with its staff to address prescription drug misuse. Please let the Commission know if you have any comments or questions about this pilot. The Commission looks forward to implementing and evaluating it with you.

Pharmacies can sign up to receive alert notices via email by providing a pharmacy site-specific email address to DOH-RX-FRAUD-ALERT.

No. 1202 Dextromethorphan

On July 1, 2015, a law (Chapter 69.75 RCW) becomes effective that requires retailers of finished drug products containing any quantity of dextromethorphan (DXM) to verify that the purchaser is at least 18 years old or meets exemptions in the law. It is unlawful for a commercial entity to knowingly sell or trade DXM-containing products to people under the age of 18. Proof of age includes any document issued by a governmental agency that contains a description or photo of the person and that gives the person's date of birth, including a passport, military identification, or driver's license. This restriction does not apply to products containing DXM sold by prescription.

The law does not require a retailer to document the proof of identification or to restrict physical access by consumers to over-the-counter products containing DXM.

Before July 1, the Commission will post a list of products containing DXM. The list, provided by the trade association representing manufacturers of dextromethorphan, will be updated annually.

No. 1203 Commission Seeks New Members

The Commission is looking to fill positions for two professional members and a public member. The positions will become vacant on the Commission in January 2016.

Public member applicants may not have any affiliation with any aspect of pharmacy. Professional members must have been duly licensed as pharmacists in Washington State for five consecutive years immediately preceding their appointment. The Commission is looking for people interested in participating in state government and in advancing the Commission's mission and vision.

Members of the Commission are appointed by the governor and confirmed by the Washington State Senate. People interested in appointment must be citizens of the United States and residents of this state. To apply, visit Governor Jay Inslee's web page. For more information on qualifications, please contact the Commission office at 360/236-4834 or at wspqac@doh.wa.gov. Recruitment closes August 1, 2015.

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