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Pharmacy Issues

Is the Correct Name of the Prescribing Practitioner on the Record?

Submitted by Samantha Nettesheim, RPh, Pharmacist Administrator

The Delaware State Board of Pharmacy/Office of Controlled Substances (OCS) recently was contacted by a practitioner accusing a patient of obtaining fraudulent controlled substance (CS) prescriptions under the physician's name and Drug Enforcement Administration (DEA) number. Records generated from the Delaware Prescription Monitoring Program (PMP) indicated multiple CS prescriptions dispensed under this physician's name. Prior to reporting the patient to law enforcement, our office contacted the dispensing pharmacies to investigate the fraudulent prescriptions. What did they find? **The pharmacy chain dispensing software system had the wrong physician's name and address linked to the physician's DEA number. All of the prescriptions had been entered using the physician's DEA number, which resulted in the prescriptions being dispensed with the wrong physician's name and address. No fraudulent prescriptions or diversion had occurred.**

This is an example of an increasing number of complaints of prescriptions that are dispensed and mislabeled with incorrect prescriber information. To add to the dilemma, in order to expedite the dispensing process, pharmacy dispensing software is designed to default to the last provider name used on the patient profile, increasing the chances of selecting the incorrect provider during data entry. Prescribers retire; prescribers lose or surrender their DEA registrations; and incorrect prescriber data is frequently entered and stored in the pharmacy dispensing software prescriber profile. What can be done to reduce this type of error? Pharmacists can request that their pharmacy dispensing software vendor disable the provider default option during the data entry process. Additionally, **pharmacists should verify that both the DEA number and the physician name on the prescription label match the DEA number and physician name on the prescription.**

In the next few months, prescribers will have the ability to review and check their own provider prescribing history through the PMP. The purpose of the provider prescribing history is to enable providers to identify fraudulent use of their DEA number and to view their CS prescribing habits. The Board/OCS anticipates that the volume of complaints against pharmacies and pharmacists for mislabeling prescriptions with incorrect prescriber names and DEA numbers will increase once prescribers have access to their provider prescribing history.

Pharmacists-in-charge, staff pharmacists, and/or pharmacy owners are responsible for proper maintenance of all prescription records and prescription dispensing software systems. Dispensing pharmacists are accountable for the information in the record of the prescriptions they have verified.

Controlled Substance Issues

Drug Diversion Case Reporting

The Delaware State Police (DSP) has a full-time group of sworn agents, referred to as the Drug Diversion Unit (DDU), whose primary mission is to investigate crimes related to prescription drug diversion. In the terminology of the United States DEA, "diversion" refers to the use of prescription drugs for other than legitimate medical purposes. The term comes from the "diverting" of drugs from their original purposes. Drug diversion cases are handled much in the same way any other incident is investigated. Officers review the initial report and then attempt to identify the responsible person(s) by looking for clues and analyzing evidence. In many cases, the success of the investigation relies heavily on how quickly all relevant details are relayed to law enforcement. How is this done?

Initial reports of investigation can be done in one of two ways. The first way is to call the DDU unit supervisor at

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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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302/365-8397. The caller should leave his or her contact information and a brief description of the incident. The other option involves making an online submission via the DSP website at *www.dsp.delaware.gov.* Select the link titled Report Suspicious Activity, then click Drug Diversion Unit Complaint Submission Form, fill in the pertinent information, and click Submit. The benefits of this new reporting method are as follows:

- ♦ No login required, and the form can be filled in by anyone.
- ♦ Reports can be made any time of the day or night and will be reviewed the very next business day.
- ♦ The information submitted is shared with all members of the DDU, thus possibly linking cases together.
- ♦ Online submissions can be made via any computer or mobile device, including cell phones and tablets.
- ♦ The online submission form can be accessed via the DSP website at *www.dsp.delaware.gov.*

Regardless of how the information is reported, the DDU unit supervisor will review the details provided, identify potential solvability factors, and assign the case for follow-up investigation by a drug diversion agent. All cases handled by the DDU may be reviewed with the Delaware Attorney General's Office, as well as other health care and pharmaceutical regulatory agencies.

Questions about this initiative can be directed to Sergeant Jeff Whitmarsh of the DSP DDU at 302/365-8397 or jeff.whitmarsh@state.de.us.

Newly Licensed Pharmacists

20 Issued From January 1, 2015 to March 31, 2015

Robert Joseph Mullen – A1-0004714; Jennifer Defnet – A1-0004715; Amy Floerke – A1-0004716; Madhurima Agumamidi – A1-0004717; Paul J. Danielraj – A1-0004718; Meyyappan Ramanathan – A1-0004719; Deanna Marie Rowe – A1-0004720; Lakshmi Veerareddy – A1-0004721; Abby Gayle Horseman – A1-0004722; Kristina M. Riley – A1-0004723; Paulette Rhoden – A1-0004724; Sharona-Stephanie Mahta Wasserman – A1-0004725; Arti Patel – A1-0004726; Ha Na Kim – A1-0004727; Andrew Gene Gibson – A1-0004728; Andrew B. Clayborne – A1-0004729; John P. Dolan – A1-0004730; Virbala A. Patel – A1-0004731; Michelle Patricia Bauer – A1-0004732; Alex L. Keller – A1-0004733

Distributor Permits

35 Issued From January 1, 2015 to March 31, 2015

Sanofi-Aventis US, LLC – A4-0001184; Midwest Veterinary Supply, Inc – A4-0001346; ProVen Pharmaceuticals, LLC – A4-0001743; Sigma-Aldrich, Inc – A4-0001770; RemedyRepack, Inc – A4-0001982; ProPharma Distribution, LLC – A4-0002153; Walgreen Co – A4-0002154; Perrigo Pharmaceuticals Company – A4-0002155; Owen Laboratories, Inc – A4-0002156; Independent Pharmaceutical, LLC – A4-0002157; Halyard Sales, LLC – A4-0002159; Atlantic Biologicals Corp – A4-0002160; DSC Logistics, Inc – A4-0002163; Exel, Inc – A4-0002164; DPT Lakewood, LLC – A4-0002165; McKesson Medical-Surgical, Inc – A4-0002166; Blen Pharmacal, Inc – A4-0002167; H.D. Smith, LLC – A4-0002168; Huvepharma, Inc – A4-0002169; Haemonetics Corporation – A4-0002170; Genco I, Inc – A4-0002172; Genco I, Inc – A4-0002173; AirGas Merchant Gases, LLC – A4-0002174; Argon Medical Devices – A4-0002175; Perrigo Pharmaceuticals Company – A4-0002176; Perrigo Pharmaceuticals Company – A4-0002177; Incyte Corporation – A4-0002178; Fisher Bioservices, Inc – A4-0002179; Reckitt Benckiser, LLC – A4-0002180; The Procter & Gamble Distributing, LLC – A4-00002181; The Procter & Gamble Distributing, LLC – A4-00002182; The Procter & Gamble Distributing, LLC – A4-00002183; Healix Infusion Therapy, Inc – A4-0002184; Southern Anesthesia & Surgical, Inc – A4-0002185; Questcor Pharmaceuticals, Inc – A4-0002186

In-State Pharmacy Permits

Three Issued From January 1, 2015 to March 31, 2015

Meds Your Way, Inc – A3-0000980; PRMC Home Scripts Millsboro – A3-0000981; Progressive Health Services, LLC – A3-0000982

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David W. Dryden, JD, RPh - State News Editor
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