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WORx Works!

By Angela Wilde PharmD Candidate

WORx is Wyoming's online prescription database program that is expected to roll out soon and streamline the process of the current prescription drug monitoring program (PDMP). The PDMP has had much success since the program began in 2004. The program monitors patients' prescriptions of controlled substances in Schedules II, III, and IV from all community pharmacies licensed with the state of Wyoming. Community pharmacies that dispense less than 25 controlled substance prescriptions per month may request a waiver to become exempt from transmitting the Wyoming State Board of Pharmacy this information. The goal of this program is to reduce the inappropriate use of prescription drugs. There are two types of reports distributed through this program that include both unsolicited profiles and solicited profiles. Unsolicited profiles are generated by WORx when a predefined threshold has been met for a patient due to use of controlled substances. A copy of this report is then sent out to each practitioner and each pharmacy listed within the patient profile. A solicited report can be generated by appropriate parties who provide care for the patient and the reports are then faxed or mailed to the solicitor. Appropriate parties include any practitioner licensed in the state of Wyoming to prescribe controlled substances, current licensed pharmacists who dispense controlled substances, any federal, state, or local law enforcement agency, and any state licensing or regulatory boards. These agencies must request reports via facsimile.

Also, any patient who receives a controlled substance can request a report of his or her own profile. In order for a patient to place a request, the request must be made in person at the Wyoming State Board of Pharmacy and the person must have a proof of identification. Data collection from this program has shown the importance of a PDMP within the state of Wyoming. Patients that have met the predefined threshold, or "doctor shoppers," were mapped according to zip codes with populations greater than 1,000. According to this chart, the areas with the highest rates of doctor shoppers include Gillette, Wright, Cheyenne, Laramie, and Star Valley. The number of solicited profiles has more than doubled since 2008, which means that those requesting profiles have understood the importance of PDMP and the impact it can have on patient health and safety. Meanwhile, the number of unsolicited profiles has slightly decreased since 2008, meaning that fewer patients have crossed the doctor shopping threshold for a report to be generated. This may mean that practitioners are soliciting reports and using that information to deter patients from the inappropriate use of prescription medications.

The Wyoming Board of Medicine **strongly** encourages physicians to use the program when beginning any controlled substance treatment for a patient. Currently reports generated from the PDMP are available Monday through Friday, 8 AM to 5 PM. The move of PDMP to the online version, WORx, will streamline the process and allow solicitors almost instant access to the PDMP program at any time, day or night. As WORx continues to increase in utilization and as practitioners recognize the importance of the program, hopefully the amount of unsolicited profiles and the rates of doctor shoppers will continue to decline.

Fifty-Year Wyoming Pharmacists

The following pharmacists will receive recognition for their 50 years of service at the Wyoming Pharmacy Association banquet on June 23, 2012, in Sheridan, WY:

Joan Anderson #1534 issued on April 15, 1961, **Rudy Anselmi #1536** issued on May 1, 1961, **James Christian #1532** issued on February 6, 1961, **Mary Hamilton #1624** issued on February 8, 1961, **Marian Jansen #1529** issued on February 6, 1961, and **Charles Knowlton #1537** issued on June 2, 1961.

Inhaler Safety Hint

School nurses have requested to have the patient label placed on the inhaler itself instead of on the box. Children may not be allowed to have inhalers at school if they are unlabeled. Be careful to check when dispensing an inhaler in case a labeled inhaler is put back into stock (always check the actual inhaler, not the box).

Keeping Prescribers in the Loop

By Jeremy Wagner, PharmD Candidate

Wyoming Pharmacy Act 33-24-148(b) states,

> Except as limited by W.S. 33-24-149(b) or when the practitioner has clearly indicated substitution is not permitted, a pharmacist may substitute a drug product with the same generic name in the identical strength, quantity, dose and dosage form as the prescribed drug, provided the substituted drug meets all requirements specified in W.S. 33-24-147(a)(ii).

Recently the Board of Pharmacy has received complaints from patients about pharmacies dispensing different medications than what they had been taking previously or what the prescriber had told them. Due to the increasing number of drug shortages many pharmacists have to substitute a higher strength or lower strength of the same medication and revise the directions accordingly to maintain the proper dose. When performing these necessary switches it is paramount that the prescriber stay in the loop for patient safety. The prescriber might have a reason why a particular strength is given and they might oppose a change in the strength that is given to the patient. The prescriber should be consulted on the change and this consultation should be documented on the prescription and/or in the patient profile. Most importantly the patient should be counseled on the change so that he or she is taking the dose that the prescriber intended and not using the directions that

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DEA Provides Information Regarding Carisoprodol Prescriptions

A Drug Enforcement Administration (DEA) announcement provides information regarding the scheduling of carisoprodol, effective as of January 11, 2012. The DEA Final Rule making the drug a Schedule IV controlled substance was published December 12, 2011, and states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with DEA regulations. Specifically, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met:

- the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 CFR §1306.04);
- the prescription contains all the information required by 21 CFR §1306.05; and
- the number of refills authorized by the prescribing practitioner is five or less (21 USC §829(b)).

The full text of the notice is available on the DEA Web site at *www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html.*

Pfizer Recalls Several Lots of Two Oral Contraceptive Products

Pfizer Inc recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) tablets and 14 lots of norgestrel and ethinyl estradiol tablets (generic) due to potential for inexact count and out-of-sequence tablets. A Pfizer investigation found that some blister packs of the affected products may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. Food and Drug Administration (FDA) advises that patients who have the affected product should notify their physician and return the product to the pharmacy. A Pfizer press release includes a list of the affected products with the National Drug Code (NDC) number, lot number, and expiration date for each, and is available at *www.fda.gov/Safety/Recalls/ucm289770.htm.*

Changes in Medication Appearance Should Prompt Investigation by Pharmacists and Patients

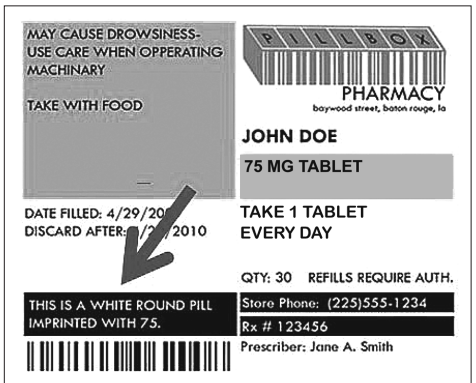
This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and 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.*

As the numbers of generic products continue to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

Your pharmacy may be providing an important patient safety tool on the prescription label that may be overlooked by patients and their caregivers: a description of the shape, color, and imprint code of the medication that should be inside. This information can help ensure accuracy since it's based on the NDC number. Teach patients to look for this description and question any differences. In addition, the patient needs to know if the medication name on the pharmacy generated label is the medication he or she was expecting to receive. Even if the generic manufacturer is different each time the prescription is renewed, the description on the label should match the NDC number and thus the product inside.



With so much information on prescription labels such as patient and doctor name, drug name, instructions, and warnings – this added information can easily be missed. But it's important, so look for it and put it to use!

FDA Reminder: Purchasing Unapproved Injectable Cancer Medications Threatens Patient Safety

FDA is reminding health care providers to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the United States. FDA explains that "current shortages of injectable cancer medications may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply, which could result in

serious harm to patients." FDA reports that the agency is aware of promotions and sales of unapproved injectable cancer medications directly to clinics in the US and that the medications were likely administered to patients. Examples of products include unapproved versions of FDA-approved medications such as Faslodex® (fulvestrant), Neupogen® (filgrastim), Rituxan® (rituximab), and Herceptin® (trastuzumab). FDA stresses the risks to patients when such unapproved medications are used. The agency outlines several steps health care providers should take to ensure patient safety:

1. Obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the US. An FDA Web page, *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* provides the online resource for each state for verifying that a wholesale distributor is appropriately licensed.
2. Determine if the medication you have received is FDA-approved by checking the Orange Book or searching the Drugs@FDA database.
3. Question whether a price sounds too good to be true. Deep discounts may be offered because the product is stolen, counterfeit, or unapproved.
4. Carefully inspect the product and packaging and be alert for signs that the product is not FDA approved, such as if the packaging looks different or the dosing recommendations are unfamiliar.

FDA also notes that if a health care provider receives multiple complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

FDA reminds health care providers that in certain circumstances the agency may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the US through a controlled network, and would not be sold in direct-to-clinic solicitations. If FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available in the Drug Shortages section of the FDA Web site, *www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm.*

Additional details are provided in an FDA Drug Safety Communication, available at *www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf.*

Insulin Pens Should Not Be Used for Multiple Patients, Stresses CDC

Centers for Disease Control and Prevention (CDC) issued a notice, reminding health care providers that insulin pens are intended for use by a single patient, and should never be used on more than one patient. CDC indicates that the agency has become "increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV)." The notice explains that regurgitation of blood into the insulin cartridge can occur after injection, creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed. CDC provides the following recommendations to help protect patient safety:

- Insulin pens containing multiple doses of insulin are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- Insulin pens should be clearly labeled with the person's name or other identifying information to ensure that the correct pen is used only on the correct individual.
- Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

The notice may be downloaded from the CDC Web site at *www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf.*

US Public Health Service Report Supports Maximizing the Scope of the Pharmacist as Part of Health Care Team

Presenting an evidence-based discussion of the comprehensive patient care services that pharmacists currently provide, a new government report calls for expanded support for such pharmacist-delivered patient care models. The report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice,* prepared by the Office of the Chief Pharmacist, US Public Health Service (PHS), is organized into four focus points as follows:

- Focus point 1 discusses how pharmacists are integrated in many practice settings as health care providers, such as through collaborative practice agreements, and provides data showing interprofessional support for such models.
- Focus points 2 and 3 support recognition of pharmacists as health care providers and compensation models that will allow pharmacists to continue to improve patient and health care system outcomes.
- Focus point 4 presents a review of numerous peer-reviewed studies that demonstrate favorable outcomes from pharmacist-delivered care.

RADM Scott Giberson, chief professional officer, PHS Pharmacists, and the primary author of the report, stated that "one of the most evidence-based and cost-effective decisions we can make as a nation is to maximize the expertise and scope of pharmacists, and minimize expansion barriers to successful health care delivery models." The report may be downloaded from the US PHS Web site at *www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf.*

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were previously taken or discussed. This may seem like a nuisance for the prescriber and the pharmacist for most occasions where a change is made, but it is the one prescription that should not be changed that makes consulting the prescriber a necessary routine.

Disciplinary Actions

Note: All fines are payable to the county treasurer where the action occurred for the credit of the public school fund in that county pursuant to Wyoming Statute §33-24-113(f).

A.O. Pharmacy Technician License #2033T. Worked as a technician-in-training after the permit expired. Ordered to pay an administrative penalty of $500 and complete additional hours of continuing education (CE) pertaining to pharmacy law.

T.T. Pharmacist License #3375. Conviction of misdemeanor larceny and four felonies regarding possession and diversion of controlled substances to a minor. License voluntarily surrendered.

J.A. Pharmacist License #3078. Board order following a hearing to reinstate pharmacist license with certain conditions.

10-55563 Non-Resident Pharmacy. Administrative penalty of $2,000 based on a disciplinary action in its resident state.

Honing in on Compounding Regulations

By Calvin Culver, PharmD Candidate

Pharmacy compounding is the art and science of preparing personalized medication for patients. Compounding is the result of individual ingredients mixed, prepared, or assembled together in the exact strength and dosage form required by the patient. A compound provides the patient a unique product that is tailored for his or her individual need.

Producing a compound is an art; however, every compounding pharmacy must comply with the regulations set forth by the Wyoming State Board of Pharmacy. Wyoming Pharmacy Act 33-24-114 states, "To secure and retain a license, a pharmacy shall be equipped with facilities, apparatus, utensils, and stock of drugs and medicines sufficient to permit the prompt and efficient compounding of prescriptions and shall be maintained in a sanitary and orderly manner." Therefore, if a pharmacy is equipped to produce a compound then there are important regulations to abide by.

Practicing within the scope of the regulations requires proper written and recorded policies and procedures for everything from compounding controls to the facility. Essential documentation that may easily be overlooked is the requirement for pharmacy employees. According to Wyoming Pharmacy Act, Rules and Regulations Chapter 13, Section 4, Subsection (b), the "competency and proficiency in the art of compounding for all pharmacists shall be evaluated, documented, and maintained in the files of the pharmacy by the Pharmacist-in-Charge (PIC)." The PIC should determine what would be appropriate for his or her staff pharmacists.

Ensuring the competencies of pharmacy technicians is required. Wyoming Pharmacy Act, Rules and Regulations Chapter 10, Section 3(c) states, "The PIC shall certify competency of the pharmacy technician prior to allowing a pharmacy technician to assist the pharmacist in compounding, and annually thereafter." A minimum checklist of competencies for pharmacy technicians can be found in Wyoming Pharmacy Act, Rules and Regulations, Chapter 10, to help the PIC determine some necessary items to include on the checklist. Technicians-in-training may not compound.

Remember as you ensure all the proper documentation of your staff that the records and reports shall be retained for a minimum period of two years from the date of last activity and be available for inspection by the Board.

Board Meeting Schedule 2012

- **June 20-21, 2012:** Sheridan, WY, at the Sheridan Best Western.
- **September 12-13, 2012:** Cheyenne, WY, at 6920 Yellowtail Road.
- **December 5-6, 2012:** Casper, WY, at an address to be determined.

CPE Monitor

Visit *www.MyCPEmonitor.net* to create your National Association of Boards of Pharmacy® (NABP®) e-Profile and register for CPE Monitor™. Once you have completed this you will receive your e-Profile ID, which is necessary for obtaining CE credit. In the near future your CE will be tracked and recorded in your NABP e-Profile through the CPE Monitor service and the Board's audits will be done online. Keep track of your e-Profile ID. Both pharmacists and pharmacy technicians will be required to provide their e-Profile ID, along with their date of birth (MMDD), when registering and completing any CE accredited through Accreditation Council for Pharmacy Education. To ensure that your CE is accurately recorded, it is important that you submit the correct e-Profile ID and date of birth to the provider when registering for a CE activity.

The *Wyoming State Board of Pharmacy News* is published by the Wyoming 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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