March 2016

News

Wyoming State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

Wyoming State Board of Pharmacy • 1712 Carey Ave, Suite 200 • Cheyenne, WY 82002
http://pharmacyboard.state.wy.us

Research Behind Community Pharmacy Counseling

By Muriah Kayser, PharmD Candidate

The Omnibus Budget Reconciliation Act of 1990 (OBRA) required that states, as a condition of participation in Medicaid, establish requirements that "the pharmacist must offer to discuss with each individual receiving benefits," or the individual's caregiver, matters that in the exercise of the pharmacist's professional judgment "are deemed significant." The Wyoming Pharmacy Act (WPA) states that "Pharmacists shall offer to and shall counsel patients if requested, concerning and in conjunction with drugs dispensed pursuant to a new prescription." In Chapter 2, Section 4 of Wyoming's pharmacy rules, the definition of patient counseling includes "oral communication by the pharmacist of information, to the patient or caregiver, in order to improve therapy by ensuring proper use of drugs and devices. Patient counseling may be supplemented with printed materials." As a reminder, printed communication should not be a substitute for oral counseling because patients may not read or understand the information provided.

Evidence suggests that counseling patients helps to ensure that patients understand the optimal use of their medications, which in turn improves their overall quality of life. Although there are not exact guidelines on what information to include when counseling patients, OBRA offers suggestions to pharmacists of what could be discussed. Pharmacists have the unique ability to use their professional judgement to individually tailor their counseling to the patient's understanding, culture, feelings, and cognitive abilities. When patients are asked by a pharmacist, "Do you have any questions?" they are likely to decline the offer because they may see this as a closed-ended question and may be unaware of their needs for additional information. **Only a pharmacist or pharmacy intern can make the offer to counsel.**

As patients come into the pharmacy to pick up new prescriptions, they are more likely to receive counseling than those collecting repeat medications. Many patients may refuse refill counseling, but pharmacists have the ability to detect drug-related problems and minimize the incidence of adverse effects. Simulated-patient methods appear to be the most reliable research design for evaluating counseling practices. When simulated patients went into pharmacies picking up a new prescription, moderate correlations were found when pharmacists handed the medication to the patient, a more private area for the consultation was available, the pharmacist was the only one working in the prescription area, and the patient was the only person waiting in the prescription area. There was no association found between the pharmacist handing the medication to the patient and the strictness of state regulations specifying whether pharmacists must conduct patient counseling.

Patients who were asked about the information they received from the pharmacist stated that the information included directions for use, but did not address side effects. Although pharmacists may try to avoid side effects or make them appear "less severe or rare," patients have shown that they would like to receive that information. Interestingly enough, when pharmacists were counseling on antibiotics, the side effects of taking them with other medications were addressed more often.

Overall, pharmacists have fulfilled the minimum requirement of the legislation by providing information on medicine administration, including the name of the medication, indications, dose, and directions for use. Safety aspects of medicine information, such as side effects, precautions, interactions, contraindications, and storage, were less likely to be given. It is important for pharmacists to realize that they are the last person in the health care chain a patient sees before taking his or her medication, and are the ones who have **the last opportunity to make an impact.** Counseling patients plays a key role in compliance, helps reduce errors, and safeguards their dignity, autonomy, and informed consent. Also, the patient-advocate model of pharmacy practice implies a commitment to patient counseling, since one of the best ways to promote the interests of patients is to provide them with the information they require to make responsible and effective decisions. Lastly, pharmacy practice implies a strong commitment to counseling since it plays an important role in establishing and maintaining trust between pharmacists and patients.

CPR for Health Care Professionals Course Now Available Online

The CPR course, offered by the International CPR Institute, includes an immediate certificate and wallet card, with a hard copy wallet card mailed within 24 hours. The course has been updated with the latest guidelines from the American Heart Association. The pharmacist can return any time to review the course material and updates. The course's cost is $19.95. Course information is available at *https://www.icpri.com.*

Mailing Prescriptions to 'Snow Birds' in Other States?

As the weather turned colder and some of your patients headed south for the winter, remember that your pharmacy must be licensed in any state to which you might consider mailing prescriptions to your customers. The Wyoming State Board of Pharmacy has been contacted by other states regarding such illegal activities, including Arizona and Oregon. Patients should be aware that they may need to transfer their prescriptions to a pharmacy near where they will be staying.

Discontinue Use of Chen Shwezin Sterile Drug Products, FDA Warns

In October 2015, the United States Food and Drug Administration (FDA) issued a statement alerting health care providers and patients not to use drug products intended to be sterile that were made and distributed by Chen Shwezin, Inc, dba Park Compounding Pharmacy of Westlake Village, CA, because of lack of sterility assurance. Following an FDA inspection during which investigators observed unsanitary conditions, including poor sterile production practices, FDA recommended that Park Compounding Pharmacy cease sterile operations and recall all of its non-expired sterile drug products. However, the company had refused to recall its products, according to an FDA safety alert.

At this time, FDA has not received reports of any adverse events associated with the use of products from Park Compounding Pharmacy. FDA recommends that health care providers check their medical supplies, quarantine any sterile drug products from Park Compounding Pharmacy, and not administer them to patients.

More information is available in the FDA safety alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm465582.htm.*

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

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.*

This is the final article of a three-part series on seven persistent safety gaffes of 2014.

6) Compounded Pain Creams: High Profit Margin and Danger

Some compounding pharmacies have been heavily marketing compounded pain creams directly to consumers via unsolicited calls, suggesting that the creams are more effective and safer than oral or injectable pain medications. Many of the creams contain drugs that can cause central nervous system depression or adverse cardiac effects, and most have not been FDA-approved for use in combination with each other or for topical use. Patients are charged per ingredient, with many creams containing numerous, expensive medications. Toxicity from the creams has been reported to poison control centers, including cases of accidental child exposures and intentional use for multiple family members. Patients are often unaware of the dangers with using the creams, which include unsafe packaging in containers without child-resistant closures. ISMP is specifically concerned about some statements that may be unproven, such as the products' safe use with children. Compounded pain creams need prominent warnings on labels that describe the potential for toxicity, and physicians and pharmacists who prescribe and dispense the creams must provide patients with instructions about possible adverse effects, safe storage, and proper use. ISMP believes regulatory or licensing oversight is necessary.

7) Clear Care: Still Causing Severe Eye Injuries Five Years Later

Since early 2010, ISMP has received scores of reports of painful eye injuries from patients using CLEAR CARE® Cleaning & Disinfecting Solution for contact lenses by Alcon (formerly CIBA VISION), a Novartis company, and similar store-brand products. Hundreds more can be found on Internet listservs. Located on store shelves near other lens disinfectants and solutions, these disinfecting products differ from other commonly used solutions in that they must be used with a special lens case in order to neutralize the 3% hydrogen peroxide component of the solution over at least six hours before putting the lenses back into the eyes. However, many patients have inadvertently used the solution to soak their lenses in a standard lens case, or thought the solution was saline and instilled it directly into their eyes. This has caused severe eye burning, leading many to seek out emergency medical care for corneal burns. In 2012, Alcon made a label enhancement to warn customers to use the special lens case, but the label change has been ineffective. Neither the company nor FDA's Medical Devices division have been persuaded to make effective label improvements before permanent eye injury or blindness occurs. If the labeling and packaging cannot be improved to reduce the harm being reported, perhaps these products should be pulled from the market or available only behind the pharmacy counter.

Risk of Dose Confusion and Medication Errors With Avycaz, FDA Cautions

Confusion about the drug strength displayed on the vial and carton labels has led to some dosing errors with the intravenous antibacterial drug Avycaz™ (ceftazidime and avibactam), warned FDA in September 2015. The agency explained that Avycaz was initially approved with the vial and carton labels displaying the individual strengths of the two active ingredients (2 g/0.5 g); however, the product is dosed based on the sum of the active ingredients (2.5 g). To prevent medication errors, FDA revised the labels to indicate that each

vial contains Avycaz 2.5 g, equivalent to ceftazidime 2 g and avibactam 0.5 g, according to an FDA safety alert.

As of September 2015, FDA had received reports of three medication error cases related to confusion on how the strength was displayed on the Avycaz vial and carton labels. Two cases stated that the errors occurred during preparation of the dose in the pharmacy. The third case described concern about the potential for confusion because the strength displayed for Avycaz differs from how the strength is displayed for other beta-lactam/beta-lactamase drugs. Based on the information provided in the reports, FDA is aware that at least one of the patients received a higher-than-intended dose of Avycaz. As of September 2015, no adverse events were reported.

More details are included in the FDA safety alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463595.htm.*

US Compounding, Inc, Recalls All Lots of Sterile Compounded Products

In September 2015, US Compounding, Inc, of Conway, AR, issued a voluntary recall of all lots of sterile products aseptically compounded and packaged by the company, and that remain within expiry, because of a lack of sterility assurance. The affected sterile products were distributed nationwide to patients, providers, hospitals, and clinics between March 14, 2015, and September 9, 2015. The recall does not apply to any nonsterile compounded medications prepared by US Compounding. Providers are advised to discontinue use of the products, quarantine any unused product, and contact US Compounding to arrange the return of any unused sterile compounded products using the information provided in the FDA press release, available at *www.fda.gov/Safety/Recalls/ucm464071.htm.*

The company issued this recall out of an abundance of caution. Providers who have dispensed any sterile product distributed by US Compounding should contact patients to whom product was dispensed and notify them of this recall. A list of all sterile compounded products that have been recalled is provided on FDA's website at *www.fda.gov/Safety/Recalls/ucm464072.htm.*

FDA Investigates the Risks of Using Pain Medicine Tramadol in Young Patients

As of September 2015, FDA is investigating the use of the pain medicine tramadol in young patients because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in patients treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. Tramadol is not FDA-approved for use in patients aged 17 years or younger; however, data show it is being used "off-label" in the pediatric population, according to the safety alert on FDA's website, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463499.htm.*

FDA is evaluating all available information and will communicate final conclusions and recommendations to the public when the review is complete. Health care providers are encouraged to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Decreased Potency Reported in Drugs Stored in Becton-Dickinson Syringes

In September 2015, FDA expanded its alert regarding compounded or repackaged drugs stored in Becton-Dickinson (BD) general use syringes to include certain additional syringe sizes including 1 mL, 10 mL, 20 mL, and 30 mL BD syringes, and BD oral syringes. FDA's original alert applied to compounded or repackaged drugs that have been stored in 3 mL and 5 mL BD syringes. The agency expanded the alert based on BD reports that an interaction with the rubber stopper in certain lots of these syringes can cause some drugs stored in these syringes to lose potency if filled and not used immediately. BD reports that the following drugs in particular can be affected by the stoppers, but it does not know whether other drugs can be affected: fentanyl, rocuronium, neostigmine, morphine, midazolam, methadone, atropine, hydromorphone, cisatracurium, and remifentanil. This safety alert does not pertain to BD prefilled, prefillable, heparin flush, saline flush, or insulin syringes, indicates BD in an alert notice. Further, BD's alert notice also has a search tool to assist customers in determining if their lots are affected. FDA advises hospital pharmacies and staff to contact any outsourcers to determine if affected lots of BD syringes were used for compounded or repackaged products. Hospital pharmacies and staff should not administer compounded or repackaged drugs that have been stored in any of these syringes unless there is no suitable alternative available. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program.

More details are included in the FDA Safety Alert, available at *www.fda.gov/Drugs/DrugSafety/ucm458952.htm.*

MediStat Pharmacy Issues Recall of Sterile Drug Products

MediStat Pharmacy, a 503B outsourcing facility in Foley, AL, has initiated a national recall of all sterile injectable products distributed between November 1, 2014, and September 3, 2015. The recall is based on the identification of various pathogens within the compounding environment. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from MediStat, and not administer them to patients. FDA has received reports of several adverse events that are potentially associated with the drug products made by MediStat. MediStat voluntarily ceased sterile compounding operations in September 2015. FDA asks health care providers and patients to report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program.

More details are included in an FDA press release, available at *www.fda.gov/Safety/Recalls/ucm461939.htm.*

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50-Year Pharmacists

The Board congratulates the following pharmacists for achieving 50 years of continuous licensure in Wyoming: Wyo J. Brown (1669), Sara B. Hunter (1665), Donald A. Porter (1666), Edward F. Reynolds (1683), Robert F. Rubaha (1706), Daniel N. Schreiner (1685), Raymond A. Valdez (1681), and Grant H. Wilford (1670). They will be honored at the Wyoming Pharmacy Association Convention to be held June 24-26, 2016, in Casper, WY.

Point-of-Care Testing in Community Pharmacy

By Matthew Robison, PharmD Candidate

"Pharmacy" typically is not a patient's first thought when he or she thinks of getting tested for influenza or strep throat, but soon it might be. Point-of-care testing brings the patient directly to the pharmacy to receive appropriate and timely detection of common health concerns that would have otherwise necessitated multiple visits between a physician's office and the pharmacy to get medication. Some national education programs train pharmacists on the hardware, specimen collection techniques, and appropriate counseling points for managing these and other conditions, and incorporate the patient's provider into the picture to provide increasingly patient-centered health care.

In a 2012 survey of 194 licensed pharmacists from 40 different states, 85% of respondents were unaware that their state practice acts allow them to conduct these types of tests. Specifically, WPA Rules, Chapter 2, Section 4 currently state that medication therapy management (MTM) encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's scope of practice. Without necessitating a collaborative practice agreement, it may include ordering or performing laboratory assessments and evaluating the response of the patient to therapy as it directly relates to MTM, provided the pharmacy service is certified under the Clinical Laboratory Improvement Amendments (CLIA) as a clinical laboratory, or the tests do not otherwise require a physician's order, and that the pharmacist is qualified to direct the laboratory.

In order to be federally compliant and able to do laboratory testing, a facility must be CLIA-waived. CLIA regulates all laboratory testing performed on humans in the United States. Any testing must be approved and ordained by this component of Centers for Medicare & Medicaid Services. In total, CLIA currently covers more than 250,000 entities that meet this standard. According to the Centers for Disease Control and Prevention, as of March 16, 2015, Wyoming currently has 19 CLIA-waived pharmacies.

An important question about point-of-care testing is "What do I do with this information?" It is recommended that direct relationships with prescribers and primary care providers be implemented in response to these tests. For example, one out of every 20 patients may have a positive rapid group A strep test, but how do pharmacists go about procuring an antibiotic prescription for them? These types of questions must be addressed before implementation either by standing order, collaborative practice agreements, or referral systems.

Quality care is paramount, but patient satisfaction is also crucial. A key reason that point-of-care testing works in various practice models is that a patient knows the up-front cost, expectations, and approximate waiting time when he or she walks up to a pharmacy counter and asks for a strep test. Long-term analysis includes patients at a bare minimum receiving laboratory testing and getting a negative result, thus keeping them out of the provider office and freeing up the provider to spend more time with other patients. As a result of lack of primary care physicians, rising costs, and fewer appointments available for patients who need to be seen, community pharmacies are in a very good position to step in and help treat these patients at an easily accessible, professionally trained, and CLIA-waived facility.

Point-of-care testing could be crucial for a parent of three with a child with flu-like symptoms at 7:45 PM on a Friday night who otherwise might have a very sick child all weekend. By quickly running the test and making a call to the primary care provider (or local emergency room doctor), the parent can pick up phoned-in prescriptions and go home. While point-of-care testing is still being slowly adopted throughout the country, it is important to remember that it is truly increasing patients' access to care, especially in rural areas such as most of Wyoming.

Board Meeting Schedule for 2016

- March 2-3 at 130 Hobbs Avenue, Suite A, Cheyenne, WY 82002
- June 22-23 at Wyoming Oil and Gas Conservation Commission, 2211 King Blvd, Casper, WY 82604
- September 6-7 at the Wyoming Board of Professional Geologists, 500 S 3rd Street, Laramie, WY 82070
- December 7-8 in Casper

The Board meetings begin at 1 PM on the first day and end by noon on the second day.

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® (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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