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Counseling Revisited

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Omnibus Budget Reconciliation Act (OBRA) of 1990. Since 1990, counseling regulations have been in effect and lawmakers have been aware of the importance of counseling in the prescription filling process. In fact, counseling is considered so important in [Wyoming] that it is **mandatory** on all new prescriptions, as you all should be aware. A pharmacist **must** counsel, and if the patient refuses to listen, that refusal must be made **to the pharmacist.** A technician cannot ask whether a patient wants counseling and take that refusal.

Quality of Counseling. Consider the following actual case: A prescription is written for clomi**phene** (a fertility drug), then entered incorrectly into the computer system by a technician as clomi**pramine** (an antidepressant). A pharmacist verifies the prescription as correct and it is filled by the technician. A second pharmacist then verifies that what is on the label is what is in the bottle, which it was, but **it is the wrong drug!** The second pharmacist argues at his hearing that this is okay because his job in this process is to compare the drug to the label, regardless of whether the drug in the bottle is the correct one. It makes no sense that verifying a wrong drug is acceptable; maybe that system needs to be reexamined to have a meaningful check at this point as well. Regardless, we still have the counseling piece, which is the pharmacist's last chance at getting it right. The counseling pharmacist then proceeds to counsel based on what is on the label and what is actually in the bottle (the clomi**pramine**), which is totally wrong. One can only wonder what he discussed with that patient. She is to take a fertility drug and supposedly is counseled by the pharmacist on an antidepressant – what did they talk about? Did he inform her that this was an antidepressant and inquire about her depression? It makes no sense! The patient took the clomi**pramine** thinking it would help her get pregnant; she got sick instead.

One of the most basic of all counseling goals is to ensure that the patient receiving a medication knows what the drug is and what it is to treat. The most complete counseling on the wrong drug is not only useless but dangerous. Some tips:

1. Compare the drug to the hard copy (or image) at all points of the filling process. It is senseless to verify a wrong drug simply because it is wrongly printed on a label.
2. **Open the bottle!** "Show and tell" is considered by the [Wyoming State Board of Pharmacy] to be an integral part of counseling and it does prevent injury.
3. Ask the patient to describe the intended use of the medication.
4. Ask the patient to read back to you the name of the drug and directions for use.

In a recent court case *(Oleckna v. Daytona Discount Pharmacy),* the opinion released stated: "A pharmacy owes a customer a duty of reasonable care. Pharmacists are required to exercise that degree of care that an ordinarily prudent pharmacist would under the same or similar circumstances." In other words, as opined by David Brushwood from the University of Wyoming, "Duty is not determined by a list of tasks that must be completed. It is determined by the nature of the relationship and expectations (individual and social) that are created by that relationship."

Proper counseling (including a final check that the correct drug is in the bottle) ensures that everyone in that often fragmented filling process got it right. Take it seriously; you owe it to your patients!

Correction to 2016 Board Meeting Dates

- June 22-23 at 2211 King Blvd, Casper, WY
- September 7-8 at 500 S 3rd Street, Laramie, WY
- December 7-8 in Casper

DSCSA Product Tracing Requirements

Do the Drug Supply Chain Security Act (DSCSA) product tracing requirements related to transaction history, transaction information, and transaction statements apply when pharmacies transfer/sell product to another pharmacy? Section 582(d)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) states the following (emphasis added).

> A dispenser . . . prior to, or at the time of, each transaction in which the dispenser transfers ownership of a product (but not including dispensing to a patient or returns) shall provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product, except that the requirements of this clause **shall not apply to sales by a dispenser to another dispenser to fulfill a specific patient need.**

Section 581(19) of the FD&C Act defines **"specific patient need" as the transfer of a product from one pharmacy to another to fill a prescription for an identified patient.** Section 581(19) further states that this term does not include the transfer of a product from one pharmacy to another for the purpose of **increasing or replenishing stock in anticipation** of a potential need.

FDA Approves Naloxone Nasal Spray to Prevent Opioid Overdose Deaths

Food and Drug Administration (FDA) has approved Narcan® Nasal Spray (also known as naloxone), a life-saving medication that can stop or reverse the effects of an opioid overdose. Prior to this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector, explains FDA in a news release.

Narcan Nasal Spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, which can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan Nasal Spray should seek further immediate medical attention on the patient's behalf. The use of Narcan Nasal Spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. Narcan Nasal Spray is distributed by Adapt Pharma, Inc, of Radnor, PA. The FDA news release is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm.*

Selected Medication Safety Risks to Manage in 2016

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.*

It is a nearly impossible task to list all the risks associated with medication use that could lead to harmful medication errors. So where do health care professionals start to improve medication safety? Most people frequently resort to playing "whack-a-mole," addressing risks only after they pop up and become visible after an adverse event.

Listed below are two serious medication safety risks that might fall off the radar screen unless an adverse event happens to draw attention to them. Additional serious risks will be published in future issues of the National Association of Boards of Pharmacy® *National Pharmacy Compliance News.*

Patient Information – Placing Orders on the Wrong Patient's Electronic Health Record

A potentially hidden vulnerability that can lead to serious errors is placing orders on the wrong patient's electronic health record. A recent study published in the *Journal of the American Medical Informatics Association* identified and quantified close calls that would have resulted in wrong-patient errors. According to this study, about 14 wrong-patient electronic orders are placed every day in a large hospital system with approximately 1,500 beds, or about 68 wrong-patient errors per 100,000 medication orders. By this measure, one in 37 hospitalized patients will have an order placed for them that was intended for another patient.[1]

These errors are sometimes due to juxtaposition but more often caused by interruptions and having more than one patient's electronic health record open.

Multiple studies have demonstrated ways to reduce these events. Requiring verification of the patient's identity has reduced errors by 16% to 30%, and requiring re-entry of the patient's identification has reduced errors by 41%.[1,2] Prompting clinicians for an indication when certain medications are ordered without an indication on the patient's problem list has intercepted errors at a rate of 0.25 per 1,000 alerts.[3] In one study, most emergency department (ED) staff (81%) felt a room number watermark on the patient's electronic health record would eliminate most wrong-patient orders in the ED.[4]

Communication About Drug Therapy – Confusing the Available Concentration as the Patient's Dose on Electronic Records

Another risk deals with how home medications appear on computer screens. For example, a physician accidentally ordered 100 units of Lantus® (insulin glargine) instead of the correct dose of six units because the list of medications used at home displayed the concentration right next to the drug name on the first line, and the patient's dose below it on the second line: "Insulin glargine (Lantus) 100 units/mL," followed on the next line with "6 units subcutaneous daily every evening."

Now that insulin is available in 100 units/mL, 200 units/mL, 300 units/mL, and 500 units/mL concentrations, the risk

of receiving an overdose of insulin is high if the presentation of the order lists the product's concentration before the patient's dose. ISMP's recommendation is to list the drug name, patient-specific dose, and directions for use on the first line of the electronic medication administration record and patient medication lists, and the available concentration and any directions on how to measure the patient's dose below it.

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3. Galanter W, Falck S, Burns M, Laragh M, Lambert BL. Indication-based prescribing prevents wrong-patient medication errors in computerized provider order entry (CPOE). *J Am Med Inform Assoc*. 2013; 20(3):477-481.
4. Yamamoto LG. Reducing emergency department charting and ordering errors with a room number watermark on the electronic medical record display. *Hawaii J Med Public Health*. 2014; 73(10):322-328.

FDA Provides Training Videos on MedWatch Resources and Breakthrough Therapy

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. In the January 2016 Drug Info Rounds video, "MedWatch Tips and Tools," pharmacists discuss reporting adverse events to FDA's MedWatch Safety Information and Adverse Event Reporting Program and the resources available for health care professionals to report safety information. In the December 2015 Drug Info Rounds video, "Breakthrough Therapy," pharmacists discuss the breakthrough therapy designation program, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Reading Medicine Labels Helps Reduce Acetaminophen Overdoses

The Acetaminophen Awareness Coalition (AAC) reminds pharmacists and other health care providers to encourage patients to properly read medicine labels to avoid unintentional acetaminophen overdoses. The coalition also encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use.

AAC's "Know Your Dose" campaign reminds patients to take these four steps to avoid acetaminophen overdose:

(1) Always read and follow the medicine label.
(2) Know if their medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.
(4) Ask their health care provider about any questions.

Additionally, pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website at *www.knowyourdose.org.*

Over-the-Counter Children's Medicine Recalled Due to Incorrect Dose Markings

In January 2016, Perrigo Company voluntarily recalled two lots of children's guaifenesin grape liquid cough medicine (100 mg/5 mL) and three lots of children's guaifenesin DM cherry liquid cough medicine (100 mg guaifenesin and 5 mg dextromethorphan HBr/5 mL) sold in 4 oz bottles. The recall was initiated because some packages contain an oral dosing cup with incorrect dose markings. The affected products were sold by distributors nationwide and distributed through retail stores. The recalled lots and store brands are available in the Perrigo press release posted on the company's website, *www.perrigo.com,* under "Investors." To date, the company has not received reports of overdose. Distributors and retailers that have the affected lots should stop distribution and return the product using the information provided in the press release.

Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch.*

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information, CDER, presents a series of continuing education webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Past topics have included "Introduction to FDA's MedWatch Adverse Reporting Program" and "An Overview of the FDA's Breakthrough Therapy Designation Program." Upcoming webinars, previous webinars, and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

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PRN Prescriptions Are Good for Two Years

A non-controlled substance (CS) prescription that is written for *pro re nata* (abbreviated PRN, meaning "when necessary") refills is good for two years in Wyoming as listed in Wyoming Statute 33-24-101(b)(iv)(F), which defines "unprofessional conduct" as "filling a prescription which is more than two (2) years old . . . " The prescriber from out of state may think Wyoming has a one-year rule for PRN refills, so he or she should be contacted to clarify if there is any question. Many third-party payers will only allow one year on such prescription refills, which is their policy, not the law. When the prescription is transferred, the number of refills remaining must be clear. Board members have discussed this part of the statute and feel that in this rural state, allowing a prescription to be refilled PRN for two years is appropriate for routine medications (eg, antihypertensives, antihyperlipidemics, antidiabetics).

Biologics, A Wave of Change

By Brian Hughes, 2016 PharmD Candidate

We have all heard of biologics and the amazing potential that they possess for pharmacy, but the comments usually stem from a research standpoint, ie, something that we can look forward to with anticipation but not really interact with. Well, our anticipation is now a reality, with an estimated 60-70% of all drugs in clinical trials being biologics. Biologics are effective, proven safe, and have excellent use in many conditions, but does this mean anything to patient care if pharmacists are not ready to store and understand them and counsel on their safe use? The list of patient-administered injectables was historically restricted to diabetes management, anticoagulation, and rare conditions and forms of cancer, but the face of medicine is quickly changing. One such instance of this change is the breakthrough cholesterol medication alirocumab, which has been proven to vastly reduce cholesterol beyond the ability of statins. Many patients may have never even seen a needle outside of a clinic, least of all in their own hand. As pharmacists, we carry the legal requirement to offer counseling, including safe handling, disposal, and storage guidance.

Beyond patient use, most of these new biologics are antibodies that require refrigeration; some even specify that they need to be protected from accidental freezing. Many of these medications are also excessively expensive, which means that their correct storage is necessary along with loss prevention measures in the event of power outages. Some of the refrigerators in pharmacies already contain medications totaling in the tens of thousands of dollars. Are pharmacies going to trust their growing inventory to daily logs and the hope of reliable electricity? Under Chapter 2, Section 7(a) of the Wyoming Pharmacy Act Rules and Regulations, the acceptable temperature ranges for both refrigerators and freezers are outlined, but there is no mention of the size of those facilities or backup requirements. If the trend continues, there may be a need for larger and more trustworthy equipment for every pharmacy.

Lastly, the difficult subject of "biosimilars" has already turned some heads. We have all heard of the "Orange Book," but what about the "Purple Book?" As of now, only one biosimilar has been approved, but the list will quickly grow upon Food and Drug Administration approval. The Purple Book is a compilation of approved biologics and their approved biosimilars. The questions asked by many are: 1) "Will biosimilars be any less expensive than the brand-name products they resemble?"; and 2) "Will therapeutic equivalence be completely guaranteed in light of the complex processes required to develop monoclonal antibodies?" Wherever the future of biologics puts pharmacy, it will certainly be an interesting and challenging time for patients and health care professionals.

Recent Disciplinary Actions

P.H., Pharmacist License #2042: Revocation of pharmacist license due to the conviction of a high misdemeanor involving moral turpitude, which constituted unprofessional conduct.

M.M., Pharmacist License #2667: Voluntary relinquishment and subsequent revocation of pharmacist license due to noncompliance with conditions on the license.

How Does an Ambulance Service Obtain Schedule II CS for Stock?

An ambulance service would need to obtain Schedule II CS via a Drug Enforcement Administration (DEA) Form 222. The transfer is from a DEA registrant (pharmacy) to a DEA registrant (medical director).

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