October 2013

News

Washington State Pharmacy Quality Assurance Commission

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No. 1150 Pharmacies and Pharmacists – DUR Requirements

The Washington State Pharmacy Quality Assurance Commission wishes to remind pharmacies and pharmacists that WAC 246-875-040 requires that the pharmacist examine the patient's medication record upon receipt of a prescription. Drug utilization review (DUR) is the review of a patient's drug therapy in order to improve care. Conducting the DUR will help alert a pharmacist of a possible drug interaction, reaction, or therapeutic duplication. It can also make a pharmacist aware of improper utilization of the drug, which may also prompt a need to consult with the prescriber. Remember, the rule applies to all prescriptions (new and refills). Therefore, if pharmacies employ an automated patient medication record system, the system must have screening capabilities to comply with the rule (ie, the system should provide sufficient detail to identify clinically relevant DUR warnings). Part of the pharmacy inspection may include challenging your systems and noting deficiencies when a system fails to alert the pharmacist of therapeutic warnings when filling or refilling some prescriptions. The system, at minimum, should be robust enough to alert the pharmacist to interactions with existing drugs for newly identified medical conditions (eg, patient with hepatitis condition should present a warning in the system for statin drugs). In some situations, inspectors have found that the alert function is turned off or the pharmacist is unaware if the function exists within the system he or she is using. Please review your system's alert sensitivities or contact your software vendor for resolution.

No. 1151 Collaborative Drug Therapy Agreements

In the past, the Washington State Department of Health recorded collaborative drug therapy agreements (CDTAs) into its licensing system with the agreement linked to the business entity rather than the individual pharmacist. This process may have caused a misperception regarding CDTAs and the relationships they represent.

A recent CDTA proposal considered by the Commission was determined to be inconsistent with a pharmacist prescriptive authority authorized by law and rule (RCW 18.64.011 and WAC 246-863-100, 110). The proposal in question was an agreement among the pharmacy, a business entity, and the prescriber.

As a result, the Commission recently changed how CDTAs are processed. Each CDTA is owned by those who are party to the agreement (the pharmacist and the prescriber). It is an agreement between a pharmacist and an authorized prescriber, which allows the pharmacist to initiate or modify drug therapy on behalf of the patient. The most popular CDTAs are immunization protocols; however, other widely exercised protocols include travel medications, anticoagulation for patients needing blood thinner medications, and pharmacy medication refill programs.

Pharmacists who are party to a CDTA must understand and accept the responsibilities delegated to them by the participating prescriber. A business entity can help facilitate an agreement, but a CDTA is not an agreement between a business entity and a prescriber. Please contact Tim Fuller, pharmacist consultant, if you have questions regarding CDTAs.

No. 1152 Pharmacist and Pharmacy Professional Responsibilities

The Commission continues to receive complaints from prescribers and patients regarding pharmacies that require their pharmacists to contact prescribers about the validity of controlled substance (CS) prescriptions. In some cases, patients are being denied prescription services as a result.

As previously noted in the July 2013 *Newsletter,* Article 1146, Drug Enforcement Administration is not basing current enforcement actions on any new or revised regulations. Title 21 of the Code of Federal Regulations, Section 1306.04(a), states that the responsibility for proper prescribing and dispensing of a controlled substance prescription rests with the prescriber and that a "correspond-

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Enteric-Coated Aspirin Recalled for Potential Acetaminophen Mix-Up

In June 2013, Advance Pharmaceutical Inc initiated a voluntary recall of Rugby Laboratories label enteric-coated aspirin tablets, 81 mg (Lot 13A026; expiration date: January 2015) due to a complaint that a bottle labeled with this product name actually contained acetaminophen 500 mg tablets. This over-the-counter (OTC) product is packaged in bottles of 120 tablets with National Drug Code 0536-3086-41 and Universal Product Code 3 0536-3086-41 9. The affected lot was distributed nationwide by Rugby Laboratories to wholesalers and retailers. The manufacturer warns that inadvertently taking acetaminophen, 500 mg, instead of enteric coated aspirin, 81 mg, according to the directions on the label, can lead to an acetaminophen overdose and potential severe liver damage. The manufacturer indicates that consumers who take the dosage as indicated on the defective product labeling may be ingesting up to 24,000 mg of acetaminophen, which is about six times the maximum recommended daily dose of acetaminophen (4,000 mg).

Consumers who have bottles from the affected lot should stop using the product and return it to the pharmacy or store where it was purchased and should contact a health care provider if they are experiencing any problems that may be related to using the product. Food and Drug Administration (FDA) notes that any adverse reactions related to the use of the product should be reported to FDA's MedWatch Program. More information about this recall is available on the FDA Web site at *www.fda.gov/Safety/Recalls/ucm357909*.

Barcoding Technology for Community Pharmacy

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.*

Barcoding technology is well-established in industries outside of the health care sector and is now being used within health care to enhance efficiency and safety, and in pharmaceutical wholesale operations to improve supply chain inventory and efficiency. Numerous studies prove the effectiveness and cost benefits of using barcoding technology during the drug dispensing process. About 75% of wrong drug or wrong dose errors are captured and corrected using barcode technology[1] and there is sufficient evidence that barcode scanning is becoming the standard of practice in pharmacies.

Although barcoding technology is mature with abundant evidence regarding its effectiveness, a 2006[2] study showed that only half (53.5%) of United States community pharmacies utilize a barcode scanner for verification/identification of medications. The study also revealed significantly lower adoption in independent pharmacies (11.5%) compared to chain pharmacies (62.6%).

According to a survey conducted by ISMP in 2009, the most frequently reported reasons for implementing barcode scanning for product verification included a desire to improve the accuracy and safety of the dispensing process, the ease with which the technology fits with pharmacy workflow, improvement of staff efficiency and inventory control, and a belief that the technology was necessary to stay in business. The most common reasons for **not** implementing barcode scanning for product verification, other than cost, included uncertainty regarding the "right" vendor product, satisfaction with the current system (without barcode product verification), and perceptions that the technology would reduce staff efficiency.

ISMP has developed a tool, Assessing Barcode Verification System Readiness in Community Pharmacies, to help address the reasons why barcode scanning has not been implemented and to facilitate the adoption of this technology in an estimated 27,327 community pharmacies that do not currently utilize it for product verification.

Given the resource commitment to purchase barcoding systems and the potential for technology to have a profound effect upon the work environment, this tool will help community pharmacy managers and owners better understand the issues related to barcode product verification systems. It will also help managers assess the pharmacy's readiness for the technology, prepare for the selection of a system, and implement the technology effectively.

Barcode scanning to verify prescription products prior to dispensing improves the safety and quality of pharmacy care provided to patients and increases efficiency during the provision of pharmacy services. Although technology should not be seen as a panacea, it can be a useful tool when used appropriately and combined with other patient safety strategies.[3] Does your pharmacy use barcode technology for product verification? If not, please access this free tool, at *www.ismp.org/AHRQ/Default.asp?link=sa.*

[1]*Cochran GL, Jones KJ, Brockman J, Skinner A, et al. "Errors prevented by and associated with barcode medication systems." Joint Comm J Qual Pt Safety. 2007;33(5):293-301.*

Ukens C. "New study sheds light on medication errors." Drug Topics. 2002;146(21):33.

[2]*Skrepnek GH, Armstrong EP, Malone DC, Abarca J, et al. "Workload and availability of technology in metropolitan community pharmacies." J Amer Pham Assoc. 2006; 46(2):154-160.*

[3]*American Hospital Association, Health Research and Educational Trust, Institute for Safe Medication Practices. "Pathways for medication safety: assessing bedside bar-coding readiness." 2002. Accessed on October 15, 2010 at:* www.ismp.org/selfassessments/PathwaySection3.pdf.

ISMP Launches Medication Safety Alert! Newsletter Tailored for LTCFs

ISMP has launched a new *ISMP Medication Safety Alert!* publication, *Long-Term Care Advise-ERR,* as a means to provide medication error prevention information tailored to assist staff and providers in long-term care facilities (LTCFs).

With *ISMP Medication Safety Alert!* publications making a significant impact on preventing medication errors, ISMP is now providing this new resource tailored to LTCFs. ISMP notes that medication errors reported to ISMP Medication Errors Reporting Program include reports from LTCFs. More information and a link to subscribe to this new publication are available in the Newsletters section of the ISMP Web site at *www.ismp.org/newsletters/longtermcare.*

FDA Warns of Rare Skin Reactions in Patients Taking Acetaminophen

FDA has issued a consumer update that warns of rare but serious skin reactions that may occur in patients taking acetaminophen. These complications include three serious skin reactions: Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP). SJS and TEN can both be fatal, and usually require hospitalization. Patients suffering from AGEP commonly recover within a few weeks after they stop taking the medication that caused the reaction.

Symptoms of these conditions include skin rashes, blisters, and widespread damage to the surface of the skin. Patients taking acetaminophen or other compounds that contain acetaminophen should be advised to stop taking the medication if they experience such symptoms and should consult their health care providers or seek an emergency department immediately.

FDA emphasizes that this information should be viewed within the context of millions of patients who, over generations, have used and benefited from acetaminophen and stresses that severe allergic skin reactions are an extremely rare condition. Further, the agency notes that many medications can cause allergic reactions, and skin allergy warnings have already been added to the drug labels of other categories of OTC analgesics including ibuprofen and naproxen. "This new information is not intended to worry consumers or health care professionals, nor is it meant to encourage them to use other medications," said Sharon Hertz, MD, deputy director of FDA's Division of Anesthesia, Analgesia, and Addiction Products. "However, it is extremely important that people recognize and react quickly to the initial symptoms of these rare but serious side effects, which are potentially fatal." The full consumer update is available on the FDA Web site at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm363010.htm.*

Reminder to Purchase Drugs Only from Licensed Wholesalers, Including VAWD-Accredited Wholesale Distributors

To ensure that patients are receiving safe, FDA-approved medications, pharmacists and other health care providers should purchase prescription drugs either directly from the manufacturer or from wholesale drug distributors licensed in the US as advised by FDA. The agency provides a list of state agencies for assistance in verifying licensure at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm*.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws and NABP's VAWD criteria. NABP has recently revised the VAWD criteria to allow virtual manufacturers and virtual wholesale distributors – a growing segment of the pharmaceutical wholesale industry – to qualify for VAWD, as well as to implement other changes aimed to help to ensure that the drug supply chain remains secure.

The revised VAWD criteria responds to changing business models and helps safeguard drugs in distribution at a time when there is an increased risk of counterfeit and substandard drugs entering the legitimate US drug supply chain. In particular, the criteria have been revised to provide stronger assurance that drugs diverted from pharmacies and unlawful sources are prevented from entering into the supply chain.

For a listing of VAWD-accredited facilities, please visit *www.nabp.net/programs/accreditation/vawd.*

Voluntary Recall of Unexpired Sterile Products After Reports of Adverse Events

FDA has announced a voluntary recall of all lots of unexpired sterile products produced by Specialty Compounding, LLC, in Cedar Park, TX. FDA received reports of 15 adverse events at two hospitals (Corpus Christi Medical Center Doctors Regional and Corpus Christi Medical Center Bay Area) potentially related to the use of these sterile products. Affected patients received an intravenous infusion of calcium gluconate supplied by the company.

Patients who were administered the injectable drug products are at risk of life-threatening infections. The recall applies to all unexpired sterile compounded medications dispensed by the company, including all strengths and dosage forms. Recalled products were distributed directly to hospitals and physicians' offices in Texas, and to patients located nationwide (with the exception of North Carolina). No calcium gluconate was shipped outside the state of Texas. Health care providers and patients should stop using all recalled products and return them to Specialty Compounding.

Veterinarians Not Eligible for NPIs, CMS Clarifies

Centers for Medicare and Medicaid Services (CMS) has become aware of cases in which veterinarians are told, incorrectly, that they must provide a National Provider Identifier (NPI) number for prescriptions they have written to be dispensed. The agency has issued a clarification, stressing that veterinarians do not meet the regulatory definition of "health care provider," and thus may not obtain NPI numbers. The clarification also states that "Any entity that insists veterinarians obtain an NPI [is] attempting to require veterinarians to obtain NPIs fraudulently." CMS also notes that "if a veterinarian fulfills the definition of 'health care provider' in a profession other than furnishing veterinary services," such as if they are also a nurse practitioner, "the veterinarian would be eligible for an NPI but would select a Nurse Practitioner code (not a Veterinarian code) from the Healthcare Provider Taxonomy Code Set when applying for an NPI."

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ing responsibility" rests with the pharmacist who fills the prescription. The law states that a prescription for a CS must be issued for a legitimate medical purpose and within the scope of the prescriber's practice. While Title 21, Section 1306.04, does not further define a pharmacist's "corresponding responsibility," there are two basic elements of the prescription order that should be the focus of the pharmacist fulfilling his or her duty: (1) the prescription is issued for a legitimate medical purpose; and (2) it is within the scope of the prescriber's practice.

Pharmacists and pharmacies need to be aware of their professional responsibilities under WAC 246-863-095 (4) and 246-869-010 (4) respectively, concerning patient access to prescription drugs pursuant to lawfully written prescriptions. Both pharmacists and pharmacies may be subject to disciplinary or other enforcement action for (1) destroying an unfilled lawful prescription, (2) refusing to return unfilled lawful prescriptions, (3) violating a patient's privacy, (4) discriminating against patients or their agent in a manner prohibited by state or federal laws, or (5) intimidating or harassing a patient.

Anyone involved in the denial of medical care to a patient pursuant to WAC 246-863-095 or WAC 246-869-010 could be at risk for disciplinary action by the Commission.

No. 1153 Pharmacy Technician Continuing Education Reminder

This is a reminder that all active certified pharmacy technicians must complete 10 hours of continuing education (CE) related to pharmacy practice every year beginning with their 2014 renewals (eg, the pharmacy technician's birthday is February 16, 2014; the pharmacy technician will be required to certify that he or she has taken 10 hours of approved CE sometime during the 12 months prior to his or her birthday). Pharmacy technicians can take coursework required for a pharmacist or a pharmacy technician, but at least one of the 10 hours must be in pharmacy law.

CE credits must be earned through courses approved by the Accreditation Council for Pharmacy Education (ACPE) or the Commission. A list of providers whose courses are approved by ACPE can be found at *www.acpe-accredit.org/*. The Commission may also approve courses that meet the CE requirements. To submit a course to the Commission for approval, a Continuing Education Approval form must be completed and mailed within 20 days following the presentation.

CE requirements to maintain Washington State certification and national certification as a pharmacy technician are not the same. Washington State certification requires 10 hours every year, and national certification requires 20 hours every two years. The same CE can be used for both the state and national certification if at least 10 hours of the CE is earned during the 12 months prior to the pharmacy technician's birthday.

For more information, including paperwork retention requirements, please refer to WAC 246-861-050.

No. 1154 Prescription Monitoring Program – Promoting Patient Safety

"This program has changed my practice. No single thing in the last 10 years has had such a positive impact on my practice and my patients as this program, so thank you!" These words from a Washington State emergency room physician are typical of the feedback the Department of Health has received about a relatively new program called the Prescription Monitoring Program (PMP).

Another physician told the department, "I believe this program has literally saved the lives of several of my patients. I have been floored by the number of narcotics that dozens of teenage girls have been obtaining (1,500 to 2,000 pills in six months). I have now been able to have meaningful interventions with them and their families."

The Department of Health has established several prevention initiatives including the PMP. A main reason was to help combat drug overdose deaths due mostly to the misuse or abuse of prescription drugs, the leading cause of accidental deaths here in Washington State.

The program collects information on the purchases of pain medications and other potentially dangerous medicines. The information comes from pharmacies and health care providers. It is then used to help improve patient safety and reduce prescription drug misuse.

Actual data collection began in October 2011, and health care providers started requesting information in January 2012. By the end of June 2013, more than 9,000 prescribers and 2,900 pharmacists were using the program, which averages more than 900,000 records per month. It now holds more than 22.8 million prescription records. Pharmacists, prescribers, and prescriber delegates so far have made more than 700,000 patient history requests.

In 2012, more than 2.3 million Washingtonians filled at least one prescription for a CS. Hydrocodone/acetaminophen (the generic form of Vicodin®, a pain reliever) is the most dispensed CS and makes up roughly 25% of all the prescriptions the Department of Health collects. There were more than 156 million pills dispensed for this drug in 2012, enough for each person in the state to receive 23 pills.

Who Can Access Data

The law allows health care providers, patients, and others to view the prescription records for certain reasons. Prescribers and pharmacists can use the data to intervene with patients earlier than they might without the PMP data. They can also identify dangerous drug interactions, address issues of misuse, and recognize under-managed pain or the need for substance abuse treatment. Health professional licensing boards and law enforcement can view the records based on authorized investigations.

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What the Future Holds

The department is pleased with the success of the program so far. With additional grant funding recently received, there are plans for several improvements. The Department of Health plans to share data on patients filling prescriptions across borders, to connect with its health information exchange to provide more seamless access for providers, and to make other improvements.

A third physician shared with the department, "I really am grateful to have the PMP active. It is absolutely essential for any pain management practice and essential for any physician prescribing controlled substances."

You can find more information on the PMP, also known as Prescription Review, online *(www.doh.wa.gov/PMP)*. Contact Program Director Chris Baumgartner at 360/236-4806 for more information.

No. 1155 Announcing Appointment of New Pharmacist Investigations/ Inspections Supervisor

It is the Commission's distinct pleasure to welcome Mr Gordon MacDonald, RPh, to the Department of Health in his new capacity as pharmacist investigations and inspections supervisor. Mr MacDonald, a graduate of the University of Washington (UW) School of Pharmacy, has been a pharmacist since 1979, with broad experience in retail, compounding, specialty packaging, naturopathic, and home infusion pharmacy operations and extensive management and pharmaceutical industry experience. He has served as an affiliate faculty member in the Department of Pharmacy at UW, precepting dozens of pharmacy students from both UW and Washington State University.

Mr MacDonald recently became the proud grandfather of identical twin boys. He brings great vision and experience to the department.

No. 1156 Recognition of 50 Years of Licensure in Washington State

The Commission wishes to acknowledge and congratulate the following pharmacists for 50 years of licensure in Washington State: **Ralph Alexander,** Seattle, WA; **Perry Bell,** La Jolla, CA; **Lee Brashler,** Arlington, WA; **Lalee Burrill,** Camano Island, WA; **Louis Caldwell,** Lake Tapps, WA; **Charlie Crow,** Auburn, WA; **Adelle Drawbaugh,** Renton, WA; **Robert Elmer,** University Place, WA; **Janet Eltz,** Bainbridge Island, WA; **Michael Faulkner,** Everett, WA; **Alton Gienger,** Vashon, WA; **Robert Giesinger,** Chelan, WA; **Robert Hamilton,** Burien, WA; **William Hollingsworth,** Olympia, WA; **Nancy Horst,** Shoreline, WA; **Nancy James,** Spokane, WA; **Ronald Johnson,** Richland, WA; **Douglas King,** Vancouver, WA; **Malcolm McCallum,** Woodway, WA; **James McFadden,** Mercer Island, WA; **Kenneth Paskett,** Port Orchard, WA; **James Ramseth,** Renton; **Mickey Simonson,** Vancouver; and **Herman VanLoo,** Arlington.

No. 1157 Pharmacy Intern Registration

Students attending a Washington State school or college of pharmacy can register as a pharmacy intern upon acceptance into the program by filing an application and submitting the appropriate fee to the Department of Health. On or before the intern's first day of training, he or she **must** file an Internship Site and Preceptor Notification form with the Commission. The form serves as formal notice to the Commission, and prompts the department to advise the intern of the acceptability of the preceptor's certification.

The named pharmacist preceptor is solely responsible for overseeing the intern's experiential learning. The preceptor will guide and direct the intern's practical training to develop the skills, professional socialization, and judgment necessary to become a competent pharmacist. Together the intern and preceptor will seek a balance in the experiential training and the intern's course work and individual abilities.

Intern registrations expire each year on the credential holder's birthday. You may renew your credential up to 90 days before it expires. You should receive a courtesy renewal reminder six to eight weeks before your birthday. If you do not receive the notice within four weeks of your expiration date, please call 360/236-4700 or send an e-mail to hsqa.csc@doh.wa.gov. Pharmacy interns must sign a statement, found on the back of the renewal notice, attesting they are currently enrolled as a student of pharmacy in an accredited college (RCW 18.64.080) or otherwise authorized by the Commission for registration as a pharmacy intern. The attestation form is also available on the Commission's Web page.

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