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News

Washington State Pharmacy Quality Assurance Commission

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No. 1174 Change of Responsible Pharmacist Manager or Consultant Pharmacist

Washington Administrative Codes (WAC) 246-863-060, 246-869-070, and 246-904-030 require all pharmacies and health care entities to designate a responsible pharmacist manager or consultant pharmacist. The Washington State Pharmacy Quality Assurance Commission must be notified of any changes in the designated pharmacist-in-charge. Both the pharmacist and the non-licensed proprietor of a pharmacy or pharmacies are required to report. The Change of Responsible Pharmacist Manager or Consultant Pharmacist form is available on the Commission's website and should be faxed or e-mailed to the number or e-mail listed on the form.

Pharmacists are advised that they may be held responsible for actions occurring in a pharmacy where they are no longer functioning as a designated pharmacy manager if they have not notified the Commission that they have stepped down from that position.

No. 1175 CDTA Process Update Approved by the Commission

The Collaborative Drug Therapy Agreement (CDTA) Subcommittee reported its recommendation for the current process to the full Commission during the May 2014 Commission meeting in Spokane, WA.

The current method of processing CDTAs began in August 2013, after Commission concern that CDTAs had become agreements not between pharmacists and providers, but between business entities and providers. Further, the Commission was concerned that some pharmacists, in exercising their agreement, were restricted from directly contacting the prescriber who provided their prescriptive authority.

The subcommittee, formed in January 2014, conducted several stakeholder meetings to review concerns with the issues raised and came to recommend the following proposal for the full Commission to consider at its July 2014 business meeting.

CDTA Subcommittee Recommendations

1. A CDTA is permitted to include a single pharmacist or a group of pharmacists exercising prescriptive authority under the delegation of a practitioner authorized to prescribe.
   a. The authorizing prescriber shall determine the appropriate number of pharmacists authorized to prescribe under the prescriber's authority.
   b. The authorizing prescriber shall determine the scope of practice delegated and shall set any limitations of the prescribing that has been delegated.
2. A CDTA shall be filed with the Commission in the following formats:
   a. A document listing a single prescriber and a single pharmacist with both parties' signatures, or
   b. A document listing a single prescriber and multiple pharmacists with the prescriber and multiple pharmacists' signatures.

   An electronic or "wet" signature of the prescriber must be dated after every pharmacist has signed and dated the agreement.
3. Upon filing the CDTA with the Commission, each pharmacist will be assigned a unique CDTA identifier.
4. A CDTA:
   a. Shall be continually updated to reflect all current pharmacists covered by the agreement. This includes both additions and deletions of pharmacists.
   b. A change in the authorizing prescriber will require that a new CDTA be filed.
   c. A new pharmacist may be added to the agreement during the two-year period the agreement is on file by submitting to the Commission a document signed by the authorizing prescriber and the pharmacist, and a copy of the CDTA previously filed.
   d. The addition or deletion of a pharmacist(s) does not extend the Commission's assigned expiration date.
5. Employers may facilitate the filing and management of a CDTA on behalf of a pharmacist(s) and prescriber; however,
   a. A CDTA is an agreement between a pharmacist and a prescriber.
   b. It is not an agreement between a corporation or an employer and a prescriber.
   c. Employers may not restrict or impose limitations on communication between the pharmacist(s) and the authorizing prescriber.
6. When a CDTA is facilitated by an employer:
   a. The employer may coordinate the quality assurance program or systems that support WAC 246-863-100(2)(d) used to provide the authorizing prescriber with documentation of decisions, communication, and feedback.
   b. An employer, through policy, may limit the implementation of a pharmacist's CDTA within the employer's setting.

New Educational Video for Pharmacists Addresses Prescription Drug Abuse

The National Association of Boards of Pharmacy® (NABP®) and the Anti-Diversion Industry Working Group (ADIWG), a consortium of pharmaceutical manufacturers and distributors of controlled substances (CS), have released an educational video for pharmacists to help them identify the warning signs of prescription drug abuse and diversion when dispensing CS prescriptions. The video, entitled "Red Flags," encourages pharmacists to help combat this national problem by exercising their professional judgment to ensure that the prescriptions they dispense were written for a legitimate medical purpose, and to act upon any unusual behavior they observe.

Drug Enforcement Administration and various state pharmacy boards have described "red flags" as circumstances surrounding the presentation of a CS prescription that should raise reasonable suspicion about the validity of that prescription. The video highlights a number of these potential warning signs, some of which are not easy to spot, by weaving personal narratives with interactions between pharmacists and customers.

The video is available in the Pharmacists section of the AWAR$_X$E® Prescription Drug Safety website at *www.AWARERX.ORG/pharmacists*.

Root Causes: A Roadmap to Action

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 Error Reporting Program Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

Errors are almost never caused by the failure of a **single** element in the system. More often, there are **multiple** underlying system failures that lead to an error, many of which can be identified when the involved health care providers take the time to uncover them.

Consider the following error: A doctor sent a hand-written order for car**bam**azepine 400 mg twice daily for an adult patient with a history of seizures.

The pharmacist entered the medication into the profile of a four-year-old child with the same last name as the adult patient for whom the medication had been prescribed.

The pharmacist failed to notice that the patient was a child, as age was not in a prominent location on the order entry screen. The nurse failed to recognize that the dose was too high and administered 400 mg of car**bam**azepine to the child. She also never thought to question why the pharmacy would send oral tablets for a four-year-old child, considering that the drug is available in chewable tablets and as a liquid suspension.

The nurse **assumed** that the child was receiving the medication because he had a history of seizures. However, the nurse did not check the patient's medical record. In fact, the child did **not** have a history of seizures.

The parents had a very limited understanding of English, so they were unable to intervene to correct the erroneous seizure history.

The error was finally detected after the child became lethargic and developed nausea and vomiting. At the time of discovery, the child's car**bam**azepine level was 18 mcg/mL; levels greater than 12 in pediatric patients are supratherapeutic.[i]

It may be discouraging to see how many things go wrong when a medication error reaches a patient. However, a thorough root cause analysis (RCA) can uncover the latent failures and produce an action plan to avoid future errors.

ISMP, through a generous grant from the National Association of Boards of Pharmacy Foundation™, has developed the *Root Cause Analysis Workbook for Community/Ambulatory Pharmacy.* The workbook is designed to assist community pharmacy personnel in completing RCA for a sentinel event that may have occurred in their pharmacy. The RCA workbook uses a specific set of steps and associated tools to identify the primary causes of the **sentinel event.**

The goal of the RCA is to create an action plan framework, including risk-reduction strategies, communication and implementation strategies, and measurement of effectiveness.

RCA for **sentinel events** is required in the Center for Pharmacy Practice Accreditation's standards developed by NABP, American Pharmacists Association, and American Society of Health-System Pharmacists Association, as well as by several boards of pharmacy in conjunction with their continuous quality improvement regulations.

This ISMP RCA workbook is suitable for use in community pharmacy, mail-order pharmacy, or other ambulatory pharmacy practice settings that need to investigate a **sentinel event.** For more information and to access the **free** workbook, visit *www.ismp.org/tools/rca/.*

[i] *http://pediatrics.aappublications.org/content/113/2/406.abstract*

FDA Withdraws Approval of Some High Dose Acetaminophen Products

Food and Drug Administration (FDA) is withdrawing approval of 108 abbreviated new drug applications (ANDAs) for prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit. For the 108 ANDAs, the manufacturers asked to withdraw their applications, as announced in the March 27, 2014 *Federal Register* notice. A second *Federal Register* notice addresses the applications of six manufacturers who have discontinued marketing their products, but who have not withdrawn their applications. The notice also announces FDA's intention to begin the process of withdrawing approval of those applications.

In light of these announcements, and to protect patients from inadvertent acetaminophen overdose, NABP advises that pharmacies no longer dispense combination drugs containing more than 325 mg of acetaminophen per dosage unit. NABP also advises that pharmacists consult with prescribers to discuss alternative products with lower acetaminophen doses.

FDA asked manufacturers to voluntarily withdraw these products from the market to reduce the risk of severe liver injury from inadvertent acetaminophen overdose. In January 2014, FDA recommended that providers consider prescribing acetaminophen products containing 325 mg or less per dose. The original announcement may be found in the Drug Safety and Availability section of FDA's website at *www.fda.gov/Drugs/DrugSafety*.

NCPDP Recommends Standardized Metric Measurements on Oral Liquid Medication Labels

The National Council for Prescription Drug Programs (NCPDP) has issued new recommendations and guidance for standardizing the dosing designation used on prescription container labels of oral liquid medications dispensed by community pharmacies in order to reduce dosing errors. NCPDP notes that such errors have been "a source of concern for many years," and that dosing errors involving young children are of particular concern because they may be more susceptible to harm from measurement errors and overdoses. The paper outlines the following recommendations for the dosing designation on prescription container labels for oral liquid medications:

- The millimeter (mL) should be used as a standard unit of measurement.
- Dose amounts should always use leading zeros before decimal points for amounts less than one and should not use trailing zeros after a decimal point.
- Dosing devices with numeric graduations and units corresponding to the container label should be made easily and universally available. For example, a device should be included with each dispensed medication.

The white paper was developed following a meeting with stakeholders representing 27 participants, including NABP. In addition to its general recommendations, the white paper also issued calls to action for relevant stakeholders, including government agencies, standards organizations, pharmacists and pharmacy technicians, pharmacy leadership, and health care associations. The white paper, *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* is available for download from the NCPDP website at *http://ncpdp.org/Education/Whitepaper*.

USP Proposes New General Chapter Addressing Compounding of Hazardous Drugs

In an effort to protect health care providers and personnel who handle hazardous drugs, United States Pharmacopeial Convention (USP) has proposed new General Chapter <800> Hazardous Drugs–Handling in Healthcare Settings. The new proposed chapter addresses standards that apply to all personnel who compound hazardous drug preparations and all places where hazardous drugs are prepared, stored, transported, and administered. The new chapter also covers standards for receiving, storing, compounding, dispensing, administering, and disposing of nonsterile and sterile products and preparations. The proposed chapter applies to all personnel who are involved in handling hazardous drugs, including health care providers and staff, occupational health and safety specialists, and human resources. General Chapter <800> was published in the May/June issue of *Pharmacopeial Forum,* and may currently be viewed on the USP website at *www.usp.org/usp-nf*. Comments will be accepted until July 31, 2014.

No. 1176 Veterinary-Pharmacy Relationships

With the recent adoption of a National Association of Boards of Pharmacy® resolution at its 110th Annual Meeting in Phoenix, AZ, in May 2014, in regard to encouraging veterinary pharmacy education (Resolution 110-5-14), the Commission encourages all pharmacists with an interest in this specialty to reach out to colleges of pharmacy to support the adoption of veterinary pharmacology education opportunities in collaboration with schools of veterinary medicine. As more prescriptions are being provided by pharmacists, those dispensing medications for veterinary patients must possess the competence and have access to resources necessary to appropriately dispense and counsel on pertinent medications. By pursuing broader education in this area, pharmacists can partner with the veterinary community to improve outcomes for our non-human patients.

No. 1177 Common Pharmacy Inspection Violations

WAC 246-875-020(1)(i) and WAC 246-875-030(1)(g) require that the pharmacist maintain an up-to-date patient profile of any patient allergies, idiosyncrasies, or chronic conditions that may relate to drug use. Failure to maintain an up-to-date patient profile of drug allergies and chronic conditions is the most common violation found in pharmacy inspections. The Commission reminds pharmacists that maintaining accurate patient profiles is a required component of ensuring that patients receive safe and appropriate medication therapy.

WAC 246-869-150(2) and (6) require that all merchandise that has exceeded its expiration date be removed from stock and that all drugs be stored in accordance with United States Pharmacopeia (USP) standards and protected from excessive heat or freezing, except as those drugs that must be frozen in accordance with the requirements of the label. If drugs are exposed to excessive heat or frozen when not allowed by the requirements of the label, they must be destroyed. Pharmacists must remove all expired drugs from the pharmacy inventory shelves and quarantine them until they can be removed from the pharmacy. All drugs that have been exposed to temperatures outside USP standards must immediately be removed from stock and quarantined until destroyed.

No. 1178 Commission Seeks Public Members

The Commission is looking to fill two public member vacancies on the Commission. Public member applicants may not have any affiliation with any aspect of pharmacy. The Commission is looking for people interested in participating in state government and in advancing its mission and vision.

All Commission members are appointed by the governor and confirmed by the Senate. People interested in appointment must be citizens of the United States and residents of this state. To apply, visit Governor Jay Inslee's webpage at *www.governor.wa.gov/boards/application/default.aspx*. For more information on qualifications, please contact the Commission office at 360/236-4834 or at wspqac@doh.wa.gov. Recruitment closes in August.

No. 1179 How and When to Get on the Commission's Agenda

The Commission encourages members of the public, the pharmacy profession, or other interested parties to bring issues of concern or consideration to the Commission's attention. Anyone wanting to appear on a Commission agenda should contact the Commission office by phone at 360/236-4946, by e-mail at wspqac@doh.wa.gov, by fax at 360/236-4626, or by mail to PO Box 47852, Olympia, WA 98504.

The request should specify the topic to be presented, including any materials the person making the request wishes the Commission to review. The request should clearly state if any action is requested of the Commission. Please include contact information, the title or affiliation of the person making the request, and Washington State credential number(s) and addresses if applicable.

Requests must be received at least six weeks before the business meeting for which the person making the request wishes to appear. All requesters will receive notice whether their presentation is added to the agenda, and if so, the date and time of the presentation. Reasonable efforts are made to accommodate requested meeting dates, but people making requests are strongly encouraged to identify one or two alternate meeting dates.

Many specialty practices require Commission approval, as specified in WAC. Others require Commission consideration when the practice is not specifically authorized in rule or law. For clarification, contact the Commission office before implementing a specialty practice (eg, telepharmacy, remote order entry, exceptions to pharmacist-to-technician ratios, and use of automated drug distribution devices).

No. 1180 Washington's Oldest Drug Stores

In 1877, Crazy Horse and his warriors fought their last battle with the US Cavalry in northwest Nebraska. In 1877, Thomas Edison demonstrated his hand-cranked phonograph. In addition, in 1877, La Conner Drug Store in La Conner, WA, was established.

The Commission would like to recognize five of the oldest drug stores still in business today. Some may be under different ownership, but they continue to serve their communities.

	Name	Location	Date Established
1	La Conner Drug Store	La Conner	1877
2	Tallman Drug Co	Walla Walla, WA	1880
3	Cheney Owl Pharmacy	Cheney, WA	1882
4	Pomeroy Pharmacy	Pomeroy, WA	1885
5	Sumner Pharmacy	Sumner, WA	1885

No. 1181 Tim Fuller Retires

After 22 years of service to the Washington State Board of Pharmacy and Washington State Department of Health, Tim Fuller, MS, BS, RPh, FASHP, retired in June 2014. Tim began working for the pharmacy board in July 1992. Over the course of his service, Tim was involved in several unique pharmacy board programs, including collaborative drug agreements, automated drug device and telepharmacy guidelines, patient counseling regulations, and medication take-back program guidelines. He also worked with the Centers for Disease Control and Prevention on national stockpiles and the Department of Health H1N1 workgroup, and on several rules affecting pharmacy and other health care professions. Tim's contributions to pharmacy practice in Washington State have been substantial, and the Commission wishes him the best in his retirement.

No. 1182 New Pharmacy Consultant

The Commission is pleased to announce that Lisa Roberts, PharmD, RPh, is joining the Commission as the new pharmacy consultant starting on July 1. Lisa has experience in both hospital and retail pharmacy, and was most recently the pharmacy director at Willapa Harbor Hospital in South Bend, WA. Lisa is a graduate of the University of Washington School of Pharmacy. Welcome to the team, Lisa!

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