



Washington State Pharmacy Quality Assurance Commission

Published to promote compliance of pharmacy and drug law

Dept. of Health • PO Box 47852 • Olympia, WA 98504-7852

www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/PharmacyCommission.aspx

No. 1165 Hospital Inspections

Washington administrative rules state that all pharmacies shall be subject to periodic inspections to determine compliance with the laws regulating the practice of pharmacy ([WAC 246-869-190\(1\)](#)). Pharmacies are reinspected on a 24-month rotation. All inspections are unannounced. Because of the complicated nature of hospital pharmacy inspections, all large pharmacy operations will involve two pharmacist investigators. This process will help the Washington State Pharmacy Quality Assurance Commission to be more efficient and to minimize the effect of the inspection process on normal workflow, allowing for fewer time-consuming inspections and less distraction to pharmacy staff members.

Below is a list of some of the most common documents pharmacist investigators may ask to review during a routine inspection of hospital pharmacies:

- ◆ Policies and procedures manual, including but not limited to, nursing unit inspections, controlled substance (CS) distribution records, CS losses, emergency outpatient medications, emergency access to the pharmacy, quality assurance (QA)/coordinated quality improvement programs (CQI), IV preparation, and drug recall.
- ◆ Two randomly selected surgery patient charts or access via electronic means.
- ◆ Two randomly selected general inpatient charts or access via electronic means.
- ◆ Copies of the most recent Joint Commission and Department of Health hospital survey reports.
- ◆ QA summary reports for the past year (eg, incident reports, adverse drug reactions, drug utilization evaluations, drug use evaluation, CQI).
- ◆ Pharmacy and Therapeutics Committee minutes for the past few meetings.
- ◆ Nursing unit inspection reports for the past 12 months.
- ◆ Copies of any prescriptive authority protocols and resulting QA reports.
- ◆ Pharmacy assistant/technician utilization plans.
- ◆ Technician training records and IV recertification training records including, but not limited to, end product testing, glove fingertip sampling, etc.
- ◆ Drug Enforcement Administration (DEA) biennial inventory and Schedule II CS perpetual inventory books.
- ◆ CS loss reports for past 24 months.
- ◆ Copies of completed DEA Form 222 orders or access to Controlled Substance Ordering System for retrievable reports for the past few months.
- ◆ Power-of-attorney forms.

- ◆ Sterility and environmental testing reports of any ISO classed space, certification reports, volumetric air samples, etc (eg, hoods, ante room, buffer area).
- ◆ Any investigational drug use protocols.
- ◆ Refrigerator and freezer temperature logs.
- ◆ Emergency room dispensing logs.
- ◆ Drug references.
- ◆ A list of all pharmacy employees and verification of license/credentials.

Ensuring that all pharmacy staff members know the location of pertinent pharmacy records, policies, and procedures will minimize interruptions for your staff during the inspection process.

No. 1166 Commission Rules Update

Rules on sterile compounding continue to progress as a draft document is being reviewed and revised internally. The Commission hopes to distribute the document to stakeholders and to the Commission in May 2014, for review and direction on the next steps.

In addition, the Commission will file emergency rules amending [WAC 246-873-060](#), Emergency Outpatient Medications. The rule affects rural hospitals without 24-hour pharmacy services. The emergency rule will be effective once it is filed with the Office of the Code Reviser and will remain in effect for 120 days. During this time, the Commission will engage in permanent rulemaking on this issue and will convene stakeholder workgroups. Updates on this and other rulemaking activities will be distributed through the [newsletter distribution list](#).

No. 1167 2013-2014 Legislative Session

March 13, marked the end of the 2014 legislative session. The Washington State Legislature passed several bills related to health care. The following laws relate specifically to the practice of pharmacy and to the business of the Commission. The complete bill history is available by using the search function on the [Bill Information](#) web page of the Washington State Legislature.

- ◆ **SHB 2105** – Requires a public agency with a governing body to make the agenda of each regular meeting of the governing body available online no later than 24 hours in advance of the published start time of the meeting. Excludes an agency that does not have a website or if it employs fewer than 10 full-time employees. Effective 90 days after the last day of session.
- ◆ **ESSB 6137** – Requires pharmacy benefit managers to register with the Washington State Department of Revenue and to adhere to certain standards when conducting audits related to insurance claims; how those audits are conducted and what is and is not allowed in that process; a specific appeals process; reporting criteria to the pharmacy being audited; and provide a much-needed path

Continued on page 4



New USP Webpage Answers Common Questions About USP Chapters <795> and <797>

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at www.usp.org/support-home/frequently-asked-questions/compounding. Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

Only You Can Prevent Look-Alike Sound-Alike Drug Names

 *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.*

VESicare/Vesanoid Mix-Up. A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESicare**® (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid**® (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESicare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

Benazepril Confused With Benadryl. A pharmacist reported a mix-up between benazepril (**Lotensin**®) and **Benadryl**® (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazapryl." The pharmacist who received the fax interpreted

it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

Your Help Is Needed With Product Safety Testing. If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit www.med-errs.com and click on "Become a Reviewer."

FDA Issues Alert on Acetaminophen Products

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)



can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at www.fda.gov/Safety/Recalls/ucm382076.htm.

FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm.

New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- ◆ The preliminary application and first state transfer fee will increase from \$350 to \$375
- ◆ Each additional state transfer will increase from \$50 to \$75
- ◆ Change of states will increase from \$50 to \$75
- ◆ Time extensions will increase from \$50 to \$75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at www.nabp.net. Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at nwatson@nabp.net.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

Continued from page 1

for pharmacies to challenge audit practices. Effective 90 days after the last day of session.

- ◆ **2 SHB 2163** – Requires a person making a retail sale of a finished drug product containing any quantity of dextromethorphan to require and get proof from purchasers that they are 18 years of age or older before completing the sale. People under the age of 18 may purchase dextromethorphan products if they are actively enrolled in the military and present a valid military identification card at time of sale or if they are emancipated and are able to provide proof of emancipation. The trade association representing manufacturers of dextromethorphan must supply to the Commission, as well as to requesting licensed retailers, a list of products containing dextromethorphan that its members market. Effective July 1, 2015.

No. 1168 Scope of Practice Prescriptions

Regularly, Commission staff members answer questions about pharmacists refusing to fill prescriptions based on what the pharmacist perceives to be beyond the practitioner's scope of practice. The Commission has concerns that this may create unnecessary barriers for patients accessing their medication. Pharmacists must remember that physicians, nurse practitioners, and physician assistants are not licensed by their specialty. Unless restricted by law, rules, or regulations, a prescriber's specialty should not be a consideration for determining the scope in which he or she has the authority to practice.

For example, a prescription written by a dental resident of an oral and maxillofacial surgery (OMS) residency program is denied because the prescription is seen as beyond the scope of practice. An OMS resident is a doctor of dental surgery and OMS is a specialty of dentistry. The Commission encourages pharmacists to work with all practitioners and practitioners in residency programs to ensure they are not creating unnecessary challenges to patient care.

No. 1169 Workplace Survey Coming Soon

Coming soon, the Commission will conduct a workplace survey of all registered pharmacists to help the Commission better understand pharmacy workplace concerns. Be looking for a letter and prepaid return postcard in your mailbox very soon.

No. 1170 Pharmacy License Customer Satisfaction Survey

The Commission continues to encourage feedback from license holders regarding the pharmacy license inspection process. The Commission has recently added a link to its website that allows you to complete the [Customer Satisfaction Survey online](#). The survey is voluntary, anonymous, and will not affect your current or future inspection results.

No. 1171 The Complaint Process

The Commission's mission is to protect the people of Washington. When the Commission receives a complaint regarding a health care provider or facility it licenses, a panel of Commission members reviews the complaint to decide if the incident or event is a violation of law and if the Commission has legal authority to take action. If these two conditions are not met, the complaint is closed as being below threshold for not meeting the legal requirements for the Commission to investigate.

If the Commission determines an allegation might be a violation, and there is legal authority to take action, an investigation is authorized and conducted. Each case is managed throughout the process and involves investigators, staff attorneys, and the Office of the Attorney General to identify violations and to evaluate evidence. If the evidence does not support the complaint, then the complaint is closed. If violations are found, a panel of Commission members considers the case for approval to take action.

Procedures for the complaint and disciplinary process are described in the Administrative Procedure Act under [Chapter 34.05 RCW](#).

The disciplinary actions that may be taken against a health care provider are described in the Uniform Disciplinary Act under [RCW 18.130.160](#). Actions include, but are not limited to, fines, counseling, retraining, practice limitations, or suspension from practice. Both

the Commission and the Washington State Department of Health are responsible to ensure the public is protected and to rehabilitate the provider.

Disciplinary files are public records. However, public record law provides that some records will not be released. For example, medical records and the names of patients will be removed before other documents are released.

No. 1172 Frequently Asked Questions

- Q. Is there a law or direction by the Commission on how a pharmacy must store prescriptions received electronically?
 - A. The Commission issued a directive on January 8, 2008, stating that electronic storage of prescriptions is permitted and approved if it complies with patient medication record system requirements and is readily retrievable by the Commission, or its agent, for inspection. Hard copy and CS prescriptions must be stored in their original form and not electronically.
- Q. My collaborative drug therapy agreement (CDTA) is expired. I have heard the processing requirements are under review by the Commission. How do I renew?
 - A. Immediately submit your CDTA according to the current processing requirements established on August 1, 2013. Each pharmacist must submit to the Commission an authorizing CDTA document signed both by the pharmacist and a prescriber. If standardized protocols are used, a list of protocols may be added to that authorizing document.
- Q. May I dispense an out-of-state prescription written by a physician? What if the prescription is for oxycodone 360?
 - A. Washington state law allows the filling of out-of-state CS prescriptions, provided they are from authorized providers ([RCW 69.50.101\(dd\)\(3\)](#)). The pharmacist must determine if the prescription is for a valid medical condition, based upon the corresponding responsibilities outlined in [Title 21 CFR Part 1306.04](#).
- Q. I heard that the federal DEA has filed proposed rulemaking to reschedule hydrocodone combination products from Schedule III to Schedule II. If that happens, what do I do with the stock I have on hand?
 - A. Once DEA adopts regulations to reschedule hydrocodone combination products, you must take an inventory of all stock on hand and maintain a perpetual inventory just as you would for all products that are Schedule II CS.

No. 1173 New Pharmacist Investigator – Eleanor Carbett

The Commission and the Washington State Department of Health take great pleasure in welcoming Eleanor Carbett in her new position as pharmacist investigator for Region 4 in eastern Washington. Eleanor is a graduate of the University of New Mexico (UNM) College of Pharmacy, where she earned her doctor of pharmacy degree. During her studies, Eleanor received the Pharmacy Summer Research Fellowship, the UNM Health Sciences and Informatics Award of Excellence, the New Mexico Pharmacists Association Scholarship, and the Norman and Lila Levit Radiopharmaceutical Science Memorial Scholarship. Eleanor has experience working in community retail, compounding, nuclear, and long-term care settings. Her most recent position was at the Medicine Shoppe Pharmacy in Deer Park, WA. She is licensed as a pharmacist in both Washington and Idaho.

Page 4 – April 2014

The *Washington State Pharmacy Quality Assurance Commission News* is published by the Washington State Pharmacy Quality Assurance Commission 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.

Chris Humberson, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor
& Executive Editor
Deborah Zak - Communications Manager