

January 2017

News



# 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](http://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/PharmacyCommission.aspx)

## **No. 1244 Election of Officers**

The Washington State Pharmacy Quality Assurance Commission re-elected Tim Lynch, PharmD, MS, as chair and elected Cheryl Adams, PharmD, as vice chair at the November 10, 2016 business meeting for 2017. Governor Jay Inslee appointed Dr Lynch in November 2013 to the newly named Pharmacy Quality Assurance Commission. Dr Adams was appointed in May 2015; she chairs the Pharmacy Inspection Committee. Both members are serving their first terms, which end on January 19, 2018, and January 19, 2020, respectively. In addition, the Commission would like to thank Nancy Hecox, PharmD, CDP, for her last year of service as vice chair. Dr Hecox will continue on the Commission.

## **No. 1245 Suicide Awareness and Prevention Training**

During the 2016 legislative session, [RCW 43.70.442](#) was amended (ESSHB 2793) to include pharmacists as one of the professions that require a one-time suicide awareness and prevention training. The Commission is proposing to add a new section to the continuing education (CE) rules: Washington Administrative Code (WAC) 246-861-105 Suicide Prevention Education. According to the [Washington State Suicide Prevention Plan](#), suicide is a serious problem in Washington State. The state's suicide rate is almost 11% higher than the national rate. On average, three people die by suicide every day. Nineteen percent of Washington State suicide deaths are by poisoning. Why is this training important for pharmacists? Given pharmacists' frequent and long-term relationship with patients and their families, the CE will increase awareness of the risk factors and signs to help prevent suicide.

Beginning January 1, 2017, pharmacists must complete a one-time training in suicide assessment, treatment, and management. The training for pharmacists must include content related to the assessment of issues related to imminent harm via lethal means. Note that this may not be available in the three-hour courses until after July 1, 2017.

Pharmacists will have their first full renewal period following January 1, 2017, to complete the training. For example, if your next birthday and renewal period is March 2017, you would proceed with your renewal as normal with your regular CE hour submission. Then, sometime between March 2017 and February 2018,

you would need to obtain the three hours of suicide prevention training. These three hours will also count toward your 15 hours of total CE for that renewal period year.

By July 1, 2017, the Washington State Department of Health will post on its website a model list of approved training that will fulfill the suicide education requirement. The Department has suicide prevention experts evaluating and approving training for the model list, which will show courses approved specifically for pharmacists and include content related to the assessment of issues related to imminent harm via lethal means. After July 1, 2017, CE must be from the model list. If possible, pharmacists are encouraged to use one of the pharmacy-specific courses on the model list after July 1, 2017. When you complete your suicide education, retain the certificate of completion with your other CE records for two years. This will provide proof of training if you should be randomly audited on CE credits.

## **No. 1246 New Rule – Continuity of Care Refills During a Proclaimed Emergency**

The Commission has proposed a new rule to address patients' access to their current medications during a governor-proclaimed emergency. The rule would allow licensed pharmacists to use their professional judgment while providing prescription refills for legend drugs, maintenance medications, and certain controlled substances (CS) to patients who are displaced and whose access to their medications is disrupted in a declared emergency such as an earthquake, flood, landslide, tsunami, or wildfire.

In 2014, the Commission by policy allowed pharmacists to provide patients with temporary prescription refills in areas hard hit by wildfires that resulted in evacuations of all or parts of some towns. In 2015, wildfires in Washington State again displaced entire communities and forced the evacuation of at least one hospital in eastern Washington.

Under an existing rule, WAC 246-869-100, pharmacists may dispense a 72-hour supply of medications if the patient's prescription is expired or if refill authorization cannot be obtained from the prescriber. This rule does not address refills when patients are displaced from their homes or pharmacy services for longer periods during a major declared emergency such as an earthquake, flood, landslide, tsunami, or wildfire.


*Continued on page 4*

## FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at [www.ecfr.gov](http://www.ecfr.gov).

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at [www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf](http://www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf). FDA provides more information online at [www.fda.gov/Drugs/DrugSafety/ucm524320.htm](http://www.fda.gov/Drugs/DrugSafety/ucm524320.htm).

## Selected Medication Risks to Manage in 2017

 *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](http://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](http://www.ismp.org). Email: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

### Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.<sup>1</sup> Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been

taken to increase staff awareness of the problem or improve the lighting.<sup>1,2</sup> This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.<sup>1,2</sup>

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.<sup>3,4</sup> Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.<sup>4</sup> Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.<sup>4</sup> Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.<sup>4</sup> Medication rooms should provide illumination at 100 fc.<sup>4</sup> Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy<sup>3</sup> and should be used on mobile medication carts (including those used with bar code medication verification systems)<sup>4</sup> and near ADCs.

### References:

1. Chaudhury H, Mahmood A, Valente M. The effect of environmental design on reducing nursing errors and increasing efficiency in acute care settings: a review and analysis of the literature. *Environ Behav.* 2009;41(6):755-786.
2. Graves K. *Nurses' Decision Making Processes About Lighting During Medication Administration* [dissertation]. Denton: Texas Woman's University College of Nursing; 2014.
3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
4. United States Pharmacopeial Convention. Chapter <1066> Physical environments that promote safe medication use. *Revision Bulletin.* October 1, 2010;2-6. [www.ismp.org/sc?id=1664](http://www.ismp.org/sc?id=1664).

### DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

News to a particular state or jurisdiction can only be ascertained  
such state or jurisdiction.

of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at [www.dea.gov/divisions/hq/2016/hq100416.shtml](http://www.dea.gov/divisions/hq/2016/hq100416.shtml) and in the final order available at <https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf>.

### **New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose**

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, “Pharmacists: On the Front Lines,” offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at [www.cdc.gov/drugoverdose/pdf/pharmacists\\_brochure-a.pdf](http://www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf).

### **FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines**

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA’s news release indicates the changes are part of the agency’s Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm).

### **FDA’s Division of Drug Information Offers CE Webinars for Students and Clinicians**

FDA’s Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information presents a series of continuing education (CE) 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. Previous webinar topics have included an overview of drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA’s website at [www.fda.gov/DDIWebinars](http://www.fda.gov/DDIWebinars).

### **FDA Approves Labeling Changes for All Prescription Testosterone Products**

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will “alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse.” In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at [www.fda.gov/Drugs/DrugSafety/ucm526206.htm](http://www.fda.gov/Drugs/DrugSafety/ucm526206.htm).

### **Latest FDA Drug Info Rounds Training Videos Available**

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, “Extortion Scam,” pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA’s 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](http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm).

As a result, a new emergency rule, WAC 246-869-105, was drafted and adopted in September 2015. Subsequently, the same emergency rule has been readopted three additional times, in December 2015, May 2016, and August 2016.

The Commission determined that rulemaking was needed to provide consistent and enforceable standards and that a permanent rule would alleviate the need to adopt emergency rules each time patients are displaced from their medications and usual pharmacy services during a governor-proclaimed emergency. The new permanent rule, WAC 246-869-105, would be activated automatically when there is a governor-declared emergency that displaces patients from their usual community pharmacy services. The emergency rule previously adopted on this subject is under its fourth revision and will remain in force until the permanent rule goes into effect.

At the September 29, 2016 Commission meeting, a public hearing was held and the Commission finalized the permanent rule, WAC 246-869-105. The permanent rule, WAC 246-869-105 Continuity of care refills in proclaimed emergencies, is effective as of December 31, 2016.

### **No. 1247 Pharmacy Assistant Registration and Fee Rule Amendments**

Pharmacy assistants may perform certain duties not reserved for the pharmacist or a pharmacy technician. These duties include, but are not limited to, filing, bookkeeping, and stocking. Pharmacy assistants must be registered with the Department of Health.

As this article goes to production, the Commission is proposing amendments to a specific section of existing pharmacy assistant rules to implement and conform to recent legislation. Senate Bill (SB) 5549 became effective June 28, 2016, and amended portions of Chapter 18.64A RCW that affect registration and discipline of pharmacy assistants, adding them to the Uniform Disciplinary Act. The proposed rule removes the timing of pharmacy assistant registration renewal, removes reference to the fees that are currently included in the pharmacy ancillary personnel fee, and establishes registration fees for pharmacy assistants. Fee rules consistent with SB 5549 are being adopted under separate rulemaking and should be in place before the next *Newsletter*.

The Commission will hold a public hearing on January 5, 2017, and anticipates the rule to become effective in March 2017. Beginning in March, pharmacy assistants will see their renewal notice includes the registration fee for pharmacy assistants. This fee will be \$25 for a new applicant and \$25 for each annual renewal.

### **No. 1248 Hospital Pharmacy Associated Clinics**

Legislation enacted in March 2016 created a new emergency rule requirement for allowing individual practitioner offices and multipractitioner clinics owned and operated by a hospital to be added to the hospital pharmacy license. This legislation directed the Commission to set regulatory, inspection, and investigation standards appropriate for the level of risk and type of services provided at these clinic sites. The legislation also required that any rules written by the Commission be adopted under the emergency rulemaking process in RCW 34.05.350, and that when the

Commission begins the process of adopting permanent rules, it must do so while the emergency rules are in place and the emergency rules remain in effect until permanent rules are in place.

The first emergency rule regulating hospital pharmacy associated clinics went into effect on September 8, 2016. The first stakeholder meeting for permanent rulemaking occurred on November 28, 2016, and stakeholder comments from previous stakeholder meetings were reviewed and addressed. Permanent rules are in the drafting stage process, factoring in stakeholder comments received at the November meeting and existing emergency rule language. Additional stakeholder meetings are planned for early 2017.

### **No. 1249 PMP Update**

The prescription monitoring program (PMP) staff would like to remind all dispensing pharmacies about the changes to data submission requirements that were implemented on October 1, 2016. The new changes are: dispensing records must be submitted within one business day, “zero” reporting is required when no CS are dispensed for a day, and submission of additional data fields is required. When available to the dispenser, the following data fields are now required: the National Provider Identifier and phone numbers for both the prescriber and the dispenser, species code, and partial fill. The reporting requirements for veterinarian dispensers are not affected by these changes. Refer to WAC 246-470-035 for the veterinarian dispenser data submission requirements.

Starting in January 2017, pharmacies that do not meet these new requirements or provide the required information on a consistent basis may be subject to Department follow-up.

A reminder that if your pharmacy does not dispense CS to Washington State residents, you can certify this by completing the Certification of No Dispensing of Controlled Substances form online and thereby not have to report to the PMP. Please contact the PMP staff at [prescriptionmonitoring@doh.wa.gov](mailto:prescriptionmonitoring@doh.wa.gov) if you have further questions.

### **No. 1250 Monitoring and Commenting on Rules**

The Commission has several rules open. These rules affect inspection, long-term care, electronic prescribing, donation of drugs, and other areas. The Commission welcomes input by pharmacists, patients, and other interested parties in person, via webinar, or through submitted comments. Rules adopted by the Commission are published in the Washington State Register. Please see the [Pharmacy Commission Rules in Progress](#) web page on the Department of Health website for updates on these and other rule writing projects. Please visit the [LISTSERV 16.0 – PQAC-RULES list at LISTSERV.WA.GOV](#) to join the listserv and receive current rule updates.