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News



Washington State Pharmacy Quality Assurance Commission

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No. 1257 Rules Rewrite Project

At the May 12, 2017 special meeting of the Washington State Pharmacy Quality Assurance Commission, the Commission discussed its rules workload and the work needed to bring the rules up to date. After a presentation from staff members regarding the amount of outdated rules, the Commission voted to start a rules rewrite project. This rewrite will entail multiple stakeholder meetings to discuss strategy and prioritization. The Commission wants to make rules that provide general direction and patient safety, but that are flexible for future changes in technology and services. The first rules workshop is tentatively scheduled for the September 2017 business meeting. The time, location, and additional information on this project will be announced through GovDelivery.

No. 1258 GovDelivery

The Commission has migrated its interested parties list to GovDelivery. The new GovDelivery communication platform allows people to self-select content that interests them, as well as when and how they want to receive it. The Commission would like to remind licensees that the *Newsletter* and email notices often contain information on required law and rule changes that are necessary for licensure compliance.

The Commission currently has four topic lists:

- ◆ Pharmacy Commission Meeting and Agenda
- ◆ Pharmacy Commission Newsletter
- ◆ Pharmacy Commission Rules
- ◆ Rx Fraud Alert

Licensees may subscribe using the direct [GovDelivery](#) link or by clicking on the green Subscribe button at the bottom of all health profession web pages on the Washington State Department of Health (DOH) website. All current subscribers to the listserv were migrated to GovDelivery, so no further action on their part is needed.

No. 1259 Legislative Summary

The 2017 Washington State legislative session ended on April 23, 2017. The following bills affecting the practice of pharmacy passed and were signed into law:

Engrossed Substitute House Bill (ESHB) 1427 – Concerning Opioid Treatment Programs. This law requires certain disciplining authorities to update opioid prescribing rules by January 1, 2019, expands access to the prescription monitoring program (PMP), and requires the DOH to provide provider and other information at least quarterly to entities who use the PMP for quality improvement and other purposes. This law also requires the DOH to annually report, beginning November 15, 2017, to the governor and legislature on the number of facilities, entities, and provider groups that have integrated their electronic health records with the PMP.

Substitute House Bill 1765 – Concerning Donations to the Prescription Drug Donation Program. This law makes changes to Chapter 69.70 Revised Code of Washington (RCW), which allows the donation of prescription drugs under the professional judgment of a pharmacist. The law previously required patient-donated medications to be equipped with time temperature indicators. With the exception of controlled substances (CS), the law allows all medications to be donated as long as the patient or patient's representative completes and signs the [Medication Donation Form](#), a donor form certifying that the drugs have never been opened, used, adulterated, or misbranded. Participation by pharmacists and pharmacies is voluntary.

Substitute Senate Bill 5035 – Concerning Patients' Access to Investigational Medical Products. This law permits patients who are suffering from a serious or immediately life-threatening disease to use investigational medical products that have been partially tested by Food and Drug Administration, but that are not available for patient use. The patient's health insurance plan is not required to provide coverage for the investigational medical product or for harm caused to the patient because of product use.

No. 1260 Suicide Prevention Training

ESHB 1424 recently modified RCW 43.70.442, which now requires suicide prevention training for health care providers to include pharmacists. The Commission has recently adopted rules specific for pharmacists under Washington

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WHO Launches Global Patient Safety Challenge on Medication Safety

To reduce severe, avoidable medication-associated harm in all countries by 50% over the next five years, the World Health Organization (WHO) has launched a worldwide initiative, the Global Patient Safety Challenge on Medication Safety. Medication errors cause at least one death every day and injure approximately 1.3 million people every year in the United States. In addition, low- and middle-income countries are estimated to have similar rates of medication-related adverse events as high-income countries.

The Global Patient Safety Challenge on Medication Safety aims to make improvements in each stage of the medication use process including prescribing, dispensing, administering, monitoring, and use. WHO intends to provide guidance and develop strategies, in addition to plans and tools to ensure that the medication process has the safety of patients at its core in all health care facilities.

Previous WHO Global Safety Challenges have included the Clean Care is Safer Care challenge on hand hygiene in 2005 and the Safe Surgery Saves Lives challenge in 2008. Additional information is available in the WHO press release available at <http://who.int/mediacentre/news/releases/2017/medication-related-errors/en>.

Continuous Quality Improvement and Patient Safety Organizations

 *This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.*

Data from the ISMP Medication Errors Reporting Program reveals that medication-related problems are repetitive in nature. An incident of misuse in one setting is likely to repeat itself in another. Most importantly, the system changes that are necessary to prevent errors are similar, and a growing body of literature is available to guide these efforts. Tragically, too many organizations and individual providers do not believe similar incidents could happen to them. They fail to use information about errors occurring elsewhere as a roadmap for improvement in their own organization or practice. It is not until a serious error hits home that aggressive prevention efforts are implemented. With so much evidence-based information about error prevention at hand, there is little excuse for reacting to errors after they happen instead of preventing them.

The development and implementation of continuous quality improvement (CQI) efforts should be the highest priority in all pharmacies. Such efforts must be aimed specifically at preventing

well-known and repetitive dispensing errors. Pharmacies should seek out medication safety information and use it proactively to prevent medication errors. At the same time, safety issues recognized internally and/or reported by patients should be documented and analyzed, with a process to determine the best strategies to prevent future problems and methods to ensure implementation. An annual survey to assess consumer perceptions of the quality of pharmaceutical products and professional services could supply additional information upon which to base improvement strategies. For more information on CQI programs, visit Section 7 of Model Rules for the Practice of Pharmacy in *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*.

Informational tools like the *ISMP Medication Safety Alert!* publication, or ISMP's *Quarterly Action Agenda*, which is a readily available list of medication problems compiled from the nation's reporting programs, can be a backbone of any CQI effort. The very purpose of the ISMP Medication Errors Reporting Program – indeed the purpose of any type of safety reporting program and the expert recommendations that stem from it – is to guide the implementation of quality improvement initiatives by practitioners and organizations.

It is important that certain information from the CQI proceedings and records of review be protected from discovery. Patient safety organizations (PSO) are organizations that share the goal of improving the quality and safety of health care delivery. Patient Safety Work Product (PSWP) is the information protected by the privilege and confidentiality protections of the Patient Safety Act and Patient Safety Rule. PSOs serve as independent, external experts who can collect, analyze, and aggregate PSWP locally, regionally, and nationally to develop insights into the underlying causes of patient safety events, thus improving quality by identifying and reducing the risks and hazards associated with patient care. Communications with PSOs are protected to allay fears of increased risk of liability because of collection and analysis of patient safety events.

For more information on PSOs, visit <https://www.pso.ahrq.gov/faq>.

NCPDP Releases Guide to Ensure Patients Get Their Medications During a Disaster

The National Council for Prescription Drug Programs (NCPDP) released the *NCPDP Emergency Preparedness Information* guide to assist pharmacists and other health care providers during a declared emergency. Prepared by the NCPDP Emergency Preparedness Committee, the guide provides resource information for eligibility and claims processing affecting displaced individuals. The guide is available at www.ncdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation_v1_4.pdf. Additional information for pharmacists about emergency preparedness is available on the NCPDP website at www.ncdp.org/Resources/Emergency-Preparedness.

FDA Warns of Illnesses and Deaths in Pets Exposed to Fluorouracil

Food and Drug Administration (FDA) is alerting pharmacists that patients' pets are at risk of illness and death when exposed to the topical cancer medication fluorouracil cream USP 5% (5-FU) that is intended for use in people. Fluorouracil may also be marketed under the brand names Carac®, Efudex®, and

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

Fluoroplex®. Very small amounts could be dangerous to household pets; thus, patients should use care when applying and storing the medication. FDA has received reports of five dogs that became ill and died after accidentally ingesting the topical cream, notes a Center for Veterinary Medicine Update available at www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm537434.htm.

Although FDA has not received any reports involving cats to date, cats are also expected to be extremely sensitive to fluorouracil cream. For instance, if an owner applies fluorouracil cream to an afflicted area and touches his or her cat, the cat may accidentally ingest the medication when grooming itself and suffer adverse events.

FDA advises that pharmacists who fill these prescriptions should advise patients with pets to prevent exposing their pet to the medication. Adverse events may be reported to FDA using the Form FDA 1932a, which may be obtained at www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm.

FDA Revises Final Guidance Documents on Bulk Drug Substances Used in Compounding

In January 2017, FDA issued revised versions of two final guidance documents regarding the use of bulk drug substances in compounding.

- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act
- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act

FDA clarified that the policies described in the guidances do not apply to inactive ingredients. Inactive ingredients are not included in the definition of a “bulk drug substance” and can be used in compounding without appearing on the bulk drug substances lists developed under sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act, if all applicable conditions are met.

As indicated on its website at www.fda.gov/Drugs/DrugSafety/ucm502075.htm, FDA will also provide regular updates to the categories of bulk drug substances described in the guidances. FDA previously stated that it would not evaluate new nominations for placement in one of the three categories until after it completed its review of substances already nominated with adequate supporting information.

Now, the guidances state that FDA will determine after submissions are received whether new nominations, including renominations of substances with additional supporting information, have sufficient information for FDA to review them. After making that determination, FDA will place nominated substances in the appropriate category on FDA’s website. FDA intends to update the categories with any new nominations the first business day of each month. This revised policy will further minimize unnecessary disruptions to patient treatment while FDA develops the lists of bulk drug substances for use in compounding.

The guidances are available online at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf and www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf.

APhA Resource Guide Applies JCPP Pharmacists’ Patient Care Process to Immunization Services

The American Pharmacists Association (APhA) published a resource guide that applies the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists’ Patient Care Process to pharmacy-based immunization services. The components of the Pharmacists’ Patient Care Process to collect, assess, plan, implement, and follow-up should be implemented as routine practice along with the National Vaccine Advisory Committee Standards for Adult Immunization Practice, as noted in the resource guide, *Applying the Pharmacists’ Patient Care Process to Immunization Services*. “[P]harmacists and other vaccine providers need to strive to constantly improve collaboration, communication, and documentation,” indicates the APhA guide. For more information, visit the APhA Immunization Center at www.pharmacist.com/immunization-center.

CPE Training on Older Adult Fall Prevention Available Online

Developed in collaboration with the Centers for Disease Control and Prevention (CDC) and the APhA, the Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative is offering continuing pharmacy education (CPE) training for pharmacists to prevent falls in adults 65 and older. The training will provide strategies to help pharmacists screen older adults for fall risk, conduct medication review and management, and offer patient education. To participate in the free online training, “STEADI: The Pharmacist’s Role in Older Adult Fall Prevention,” visit the CDC website at www.cdc.gov/steadi/training.html for more information.

New FDA Drug Info Rounds Training Video Addresses the Combat Methamphetamine Epidemic Act

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, “Combat Methamphetamine Epidemic Act,” pharmacists discuss the legal requirements for the sale of over-the-counter drug products that contain pseudoephedrine. Drug Info Rounds was developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

FDA Presents Series of CE Webinars for Students and Clinicians

FDA’s Division of Drug Information in the CDER 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 FDA’s role in medication error prevention and prescription drug labeling. The webinars and presentation slides can be accessed on FDA’s website at www.fda.gov/DDIWebinars.

Administrative Code (WAC) 246-861-105. Effective January 1, 2017, all pharmacists must complete a one-time, minimum three-hour training in suicide assessment. The training must include suicide screening and referral, assessment of issues related to imminent harm by lethal means, treatment, and management from a qualified suicide prevention-training program. A summary includes the following key points:

- ◆ Training is required for each pharmacist before the end of his or her full continuing education (CE) reporting cycle, which begins on the pharmacist's birthday in 2017. (Example: Pharmacist's birthday falls on February 4; that pharmacist has until February 3, 2018, to complete the one-time suicide prevention training.)
- ◆ Beginning July 1, 2017, the required training course must be from one of the DOH-approved courses located on the [model list](#). The course selected must meet the required elements for a pharmacist.
- ◆ Training on suicide prevention obtained before July 1, 2017, is acceptable as long as it includes appropriate content about imminent harm by lethal means, treatment, and management.
- ◆ If the pharmacist has just received initial licensure, the suicide prevention training is required during the first full CE reporting period following initial licensure.
- ◆ No pharmacists are exempt from the required suicide training, regardless if the pharmacist does or does not have direct contact with patients. The risk of suicide is seen in all areas.
- ◆ Suicide training may be included toward the 15 hours of required annual CE.
- ◆ Pharmacists will not need to provide proof of training unless selected for a random audit of CE credits.

Find more information on the DOH's web page on [suicide prevention](#) training for health care providers.

No. 1261 Schedule II Prescriptions – New Partial Fill Allowance

The following article has been adapted from the February 2017 issue of the Oregon State Board of Pharmacy Newsletter.

In July 2016, the Comprehensive Addiction and Recovery Act (CARA) was signed into law. One of the provisions of the law amended the Controlled Substances Act to allow a pharmacist to partially fill a prescription for a Schedule II CS for ambulatory patients under certain circumstances. Previously, this was permissible only if the pharmacist was unable to supply the full quantity as issued on the original prescription, and the pharmacist was required to complete the balance within 72 hours. Partial filling has been allowed for nursing home patients in a nursing home setting and for terminally ill patients.

CARA allows for the partial filling of a Schedule II drug if the following conditions are met:

- ◆ It is not prohibited by state law. (Neither the RCW nor the WAC prohibit this. However, please note that RCW 69.50.308 does prohibit refills of Schedule II CS.)

- ◆ The prescription is written and filled in accordance with federal and state law;
- ◆ The partial fill is requested by the patient or the practitioner who wrote the prescription; and
- ◆ The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

The new law requires that the remaining portion(s) of a partially filled Schedule II prescription may be filled no later than 30 days after the date on which the prescription was written (original date).

Visit www.congress.gov/bill/114th-congress/senate-bill/524 for additional information. Per Drug Enforcement Administration, the Code of Federal Regulations did not reflect this change until the new edition was issued in April 2017.

Though the intent of the law is to decrease the amount of unwanted and unused prescription opioid medications in households across the country, the law change is applicable to all Schedule II prescriptions. Leftover prescription medications being diverted continues to be a major issue with drug overdoses and abuse. This law change creates the opportunity for increased dialogue with practitioners and enhanced patient care and safety.

No. 1262 Epinephrine Autoinjectors

RCW 70.54.440 went into effect in June 2016. This statute refers to epinephrine autoinjectors, guidance on prescribing to certain entities, training requirements, liability, and incident reporting procedures.

The law permits an authorized health care provider to prescribe epinephrine autoinjectors in the name of an authorized entity. An authorized entity can be a restaurant, recreation camp, sports league, or others as defined in the statute. Pharmacists, advanced registered nurse practitioners, and physicians may dispense epinephrine autoinjectors if they have a prescription issued in the name of the authorized entity.

An employee or representative of the authorized entity must complete an anaphylaxis and epinephrine autoinjector training. That person, while on the premises of the authorized entity, may administer or provide an epinephrine autoinjector for self-administration to an individual. The employee, representative, or another person may do so regardless of whether the individual has a prescription for an epinephrine autoinjector or was previously diagnosed with an allergy. The employee, representative, or another person must simply believe, in good faith, that the individual is experiencing anaphylaxis.

The DOH determined that the American Red Cross' anaphylaxis and epinephrine autoinjector training meets the requirement of this statute and includes all the elements required in the law (techniques, storage and administration, emergency follow-up, and provision of a certificate upon completion).

For more information, visit the DOH's [web page](#).

No. 1263 Contraceptive Sign

The 64th Legislature passed [RCW 18.64.008](#), which tasked the Commission with increasing public awareness around access to self-administered contraceptives. With assistance from stakeholders, the Commission approved a sign that pharmacies may display wherever pharmacists are available to initiate or modify drug therapy related to self-administered contraception. Pharmacies may reproduce the [contraceptive sign](#) for posting as a window cling or as a sign in the pharmacy.

No. 1264 New Commission Members Appointed by Governor Jay Inslee

Katherine (“Kat”) Wolf Khachatourian, PharmD, is the vice president of pharmacy services and strategy for Qualchoice Health Plan Services, Inc, overseeing multiple regional Medicare contracts.

Dr Wolf spent the first 11 years of her pharmacy career working in a retail pharmacy chain as a pharmacy technician and pharmacy intern. After receiving her doctorate of pharmacy from Mercer University in Atlanta, GA, she completed her managed care pharmacy practice residency with Group Health Cooperative in Seattle, WA. Dr Wolf earned her master of business administration at the University of Washington in June 2017.

In addition to leading her professional team, Dr Wolf serves as a mentor for the University of Washington Academy of Managed Care Pharmacy (AMCP) student chapter, a local pharmacy and therapeutics competition judge, and a speaker at student events in support of pharmacy practice. Dr Wolf further expands knowledge and practice of managed care through her roles as an AMCP committee member, an AMCP Washington State advocacy coordinator, and as a participant, and contributor to AMCP initiatives locally and nationally, most recently in the Partnership for Pre-Approval Information Exchange development and congressional briefings.

Dr Wolf spends her free time with her husband and three dogs in Seattle and enjoys traveling domestically and internationally.

Michael Sieg, MBA, PharmD, is the director of pharmacy services at Confluence Health, based in Wenatchee, WA. In his role, Dr Sieg is responsible for all hospital pharmacy departments, infusion centers, retail locations, anticoagulation clinics, and an expanding ambulatory care department. In all of these departments, the pharmacy services work to serve the rural communities throughout North Central Washington. Dr Sieg received his doctor of pharmacy degree from St Louis College of Pharmacy and a master’s in health care administration from New England College. He has been a Washington-licensed pharmacist since 2007.

Uyen Thorstensen, CPhT, is employed at the University of Washington Medical Center as a part-time oncology technician and as full-time tenured faculty at North Seattle College. She received her pharmacy certification at North Seattle College in 1996 and has been nationally certified since 1996. Ms Thorstensen has two bachelor’s degrees, in French and microbiology. She speaks English and Vietnamese (and “some Norwegian, Japanese, and Spanish, but not enough to brag about, just enough to eavesdrop”).

Ms Thorstensen is a current member of the American Pharmacists Association. Additional accomplishments include authoring several technician book reviews and American Society of Health-Systems Pharmacists accreditation in 2011 and 2017.

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