



Washington State Pharmacy Quality Assurance Commission

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No. 1265 Pharmacy Inspection Rules

At a public rules hearing on September 14, 2017, the Washington State Pharmacy Quality Assurance Commission adopted proposed rule language updating the inspection process for pharmacies. The adopted rules amend Washington Administrative Code (WAC) 246-869-040 and 190. The new inspection rules support continuous quality improvement by removing the point scores and moving to an annual self-inspection and plan of correction for all deficiencies identified during a Commission inspection. The rules require pharmacies to perform and complete a self-inspection worksheet in March of each year. The Commission will post the worksheet on the [Pharmacies Applications and Forms](#) web page and review the form for updates annually. A new self-inspection form is also required within 30 days of a change in a pharmacy's responsible manager.

WAC 246-869-190 was amended by adding language outlining the changes to the current rule from a point-based system to a notice of deficiency and plan of correction system. The adopted rule specifically requires that all deficiencies are identified at the end of an inspection and noted on the inspection report/notice of deficiency. The pharmacy must remedy deficiencies promptly. The licensees must submit a plan of correction to the Commission for review. The Commission or its designee will notify the licensee if the plan of correction adequately addresses the deficiencies. Finally, the rule removes the requirement to post an inspection certificate in the pharmacy.

Additionally, the adopted rule makes changes to WAC 246-869-040 regarding new pharmacy registrations, revising the language concerning what type of inspection needs to occur before an applicant will receive a new pharmacy license, rather than an achieved score, while framing the scope of services. The rules are effective 31 days after filing with the Washington State Office of the Code Reviser.

No. 1266 Rules Rewrite Project

The Commission held a two-day workshop on September 13 and 14, 2017, to discuss and start work on a complete pharmacy rules rewrite. The Commission is considering

a move to broad and flexible rules that provide for patient safety but allow for innovation and flexibility as health care technology and delivery change. The Commission is also looking at identifying patient care outcomes while allowing for judgment of the pharmacist on duty for the best process given the practice setting. Just more than 100 people attended and participated in small group discussions on what topics were most important to regulate the practice of pharmacy. At the end of the workshop, the Commission decided, with input from stakeholders, on four overarching categories in which to bucket its rules:

- ◆ Regulatory Framework/General Provisions
- ◆ General Licensing
- ◆ Professional Standards
- ◆ Operational Business Practices

The rules rewrite project will take place during the next 18 to 24 months. The Commission anticipates holding workshops in conjunction with its regularly scheduled business meetings. The Commission will discuss a more detailed timeline at its October meeting. If you would like to submit comments or ideas for this project, please attend future workshops or email the Commission at PharmacyRules@doh.wa.gov. The Commission will post updates to its [Rules in Progress](#) web page.

No. 1267 Opioid Prescribing Rules and Schedule II Partial Fill

The Washington boards and commissions for medicine, osteopathic medicine, podiatry, dentistry, and nursing have begun to develop opioid prescribing rules. The Pharmacy Commission is a nonvoting member of this panel. The first stakeholder meeting was held September 20, 2017, with additional meetings scheduled throughout the state on October 19, November 15, and December 12 in 2017, and on January 8, 2018. February and March 2018 meetings have not been set. Visit the Washington State Department of Health website for [House Bill 1427 implementation information](#).

The Commission continues to get questions about the partial fill of Schedule II controlled substances (CS). With

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.Pharmacy Domain Signals Safety on the Web



With only 4% of websites selling prescription drugs online following United States pharmacy laws and practice standards, consumers seeking medications online are faced with the daunting task of finding a safe site. To assist consumers and those legitimate pharmacies with an online presence, NABP has streamlined its website verification programs. As of September 1, 2017, NABP is only offering the .Pharmacy Verified Websites Program and the Verified Internet Pharmacy Practice Sites® (VIPPS®) program, providing an easy choice for safety-minded consumers and pharmacies alike. The .Pharmacy Program, which was launched in 2014, enables qualified pharmacies and pharmacy-related businesses to register a web address with the .pharmacy domain. A .pharmacy domain (pronounced “dot pharmacy”) is part of a website’s address like “.com” or “.biz”: *www.safe.pharmacy*. It enables people to identify an online pharmacy or pharmacy-related website as safe and legitimate. Since .pharmacy is a verified domain, websites are evaluated against a set of safety standards before an applicant is approved to register the domain.

In addition to showing patients that they operate a safe website, the .pharmacy domain allows pharmacies and related entities to advertise online through Google, Bing, and Yahoo! The .Pharmacy Program replaces the e-Advertiser Approval™ and Veterinary-VIPPS® programs for those entities that are not eligible to apply for VIPPS but want to advertise with the search engines.

For more information about the .Pharmacy Program, including the application and domain name registration process and fees, visit *www.safe.pharmacy/apply*.

Quality Processes, Risk Management, and Culture: HR-Related Policies That Conflict With a Just Culture

*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*.*

As health care organizations move toward a “Just Culture,” one of the areas potentially overlooked is human resource (HR)-related policies and procedures. Because these policies and procedures typically describe staff expectations, individual accountability, and disciplinary processes, they must be reviewed and often revised to ensure alignment with the tenets of a Just Culture. Otherwise, the journey will be long and unsuccessful if the policies are in conflict with a Just Culture.

In a Just Culture, HR-related policies and procedures regarding safety should hold all individuals equally accountable for the quality of their behavioral choices and should not focus on errors (which are not a behavioral choice), except for the expectation to report them. Policies and procedures should reflect a tone that is proactive toward risk identification, rather than reactive to errors and adverse outcomes. They should define human error as inadvertent, with a response of consoling individuals and conducting an investigation to determine how to redesign systems to prevent errors or detect them before reaching the patient. Policies and procedures should describe how to investigate a procedural violation to determine its causes and scope, and how to coach staff who have engaged in at-risk behaviors under the mistaken, but good faith, belief that the risks were insignificant or justified. For outcome-based duties related to a business code of conduct, such as arriving to work on time and wearing identification badges, policies should be clear about expectations and the actions that will be taken when they are not met. When describing reckless behavior (actions involving a conscious disregard of what an individual knows is a substantial and unjustifiable risk), remove any reference to “negligent” or “criminal” conduct as the basis for disciplinary action. Regrettably, mere human error can result in legal action (criminal negligence), but human error is never reckless behavior. Also ensure that event reporting and investigation policies and procedures support the tenets of a Just Culture.

While HR-related policies and procedures cannot guarantee that the desired actions will be realized in practice, they are a critical step for building an organizational foundation for success. Old punitive policies risk slipping back into an unjust culture. As organizations align actual practice with a Just Culture, they also need to align supporting policies and procedures.

AMA Task Force to Reduce Opioid Abuse Promotes Safe Storage, Disposal of Opioids

The American Medical Association (AMA) Task Force to Reduce Opioid Abuse released a resource document that urges physicians and other health care providers to promote safe storage and disposal of opioids and all medications. The AMA document indicates physicians and other providers need to:

- ◆ educate patients about safe use of prescription opioids;
- ◆ remind patients to store medications out of children’s reach in a safe place; and
- ◆ talk to patients about the most appropriate way to dispose of expired, unwanted, and unused medications.

The AMA resource document and additional information can be found at *www.ama-assn.org/opioids-disposal*. Options for disposing of medications safely are available in the Initiatives section of the NABP website at *www.nabp.pharmacy* under AWAR_xE®.

CDC Guide Shows Importance of Physicians, Pharmacists Working Together

Collaborative care by at least two practitioners working together with the patient to accomplish shared goals has been shown to improve hypertension control and cholesterol management, especially when the team involves a physician or nurse and a pharmacist, notes a new guide developed by the Centers for Disease Control and Prevention (CDC) Division for Heart Disease and Stroke Prevention, in collaboration with the American Pharmacists Association and AMA. The guide,

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

Creating Community-Clinical Linkages Between Community Pharmacists and Physicians, discusses the importance of community-clinical linkages specific to community pharmacists and physicians and provides a framework for how community pharmacists and physicians might approach the development of a link to help patients. In addition, the guide provides examples of existing community-clinical linkages between community pharmacists and physicians and discusses common barriers to and potential solutions for creating community-clinical linkages. The guide is available at www.cdc.gov/dhbsp/pubs/docs/ccl-pharmacy-guide.pdf.

FIP Report Shows Value of Pharmacists' Role in Consumers' Self-Care

Support from pharmacists will assist consumers in better health maintenance and greater health system efficiency, indicates a recently released report from the International Pharmaceutical Federation (FIP). The report, *Pharmacy as a gateway to care: Helping people towards better health*, discusses the various factors involved in individual self-care and the evidence that pharmacists can increase value for those individuals through many opportunities because informed, engaged, and educated consumers will play a greater and critical role in caring for themselves. The definition of self-care this report adopts is that of the World Health Organization: "the ability of individuals, families and communities to promote health, prevent disease, and maintain health, and to cope with illness and disability with or without the support of a health care provider."

The report is available at www.fip.org/files/fip/publications/2017-04-Pharmacy-Gateway-Care.pdf.

FDA Restricts Use of Codeine and Tramadol Medicines in Children; Recommends Against Use in Breastfeeding Women

As of April 2017, Food and Drug Administration (FDA) is restricting the use of codeine and tramadol medicines in children. FDA is also recommending against the use of these medicines in breastfeeding mothers due to possible harm to their infants. Codeine and tramadol medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in this age group. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults.

As indicated in the FDA Drug Safety Communication available at www.fda.gov/Drugs/DrugSafety/ucm549679.htm, FDA is requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond their 2013 restriction of codeine use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids. FDA is now adding:

- ◆ A *Contraindication* to the drug labels of codeine and tramadol, alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- ◆ A new *Contraindication* to the tramadol label, warning against its use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids.
- ◆ A new *Warning* to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and

18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.

- ◆ A strengthened *Warning* to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants.

FDA urges health care providers to report side effects involving codeine- and tramadol-containing medicines to the FDA MedWatch program at www.fda.gov/safety/medwatch.

AVMA Warns Pharmacists and Pet Owners About Xylitol Pharmaceutical Products

Pharmaceutical products containing xylitol may be dangerous and fatal to dogs, warns the American Veterinary Medical Association (AVMA). Xylitol stimulates an insulin release that can result in severe hypoglycemia and fatal liver damage. Pharmacists and pet owners need to be aware of and protect against xylitol toxicoses, indicates AVMA. FDA-approved gabapentin capsules and tablets do not contain xylitol, but the liquid form does. In addition, xylitol-containing media might be used in compounding products if the pharmacist is uninformed about not using it.

AVMA urges pharmacists to not use xylitol-containing products when compounding for canine patients and to contact the veterinarian if a prescribed product contains xylitol. The veterinarian may be unaware that this sweetener is in the product. AVMA also encourages pet owners and caretakers to verify with the pharmacist when picking up their dog's medication at a human pharmacy that the medication does not contain xylitol. Xylitol-containing peanut butter should not be used to help a dog take its medication.

For more information, visit atwork.avma.org/2017/05/30/eliminate-xylitol-from-canine-prescriptions.

CDC Publishes Guide to Help Pharmacists Initiate CPAs With Prescribers

CDC published a guide that provides pharmacists with information and resources to empower them to initiate collaborative practice agreements (CPAs) with collaborating prescribers. The guide, *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team*, contains a sample CPA and sample language that can be customized by pharmacists and prescribers using their specific state laws to create a CPA. The guide includes an overview of state laws, including which states currently allow CPAs. The guide is available at www.cdc.gov/dhbsp/pubs/docs/CPA-Team-Based-Care.pdf.

DEA Releases New Edition of Drugs of Abuse Resource Guide

Drug Enforcement Administration (DEA) released the 2017 edition of *Drugs of Abuse, A DEA Resource Guide*, which serves as a resource on the most commonly abused and misused drugs in the US. The latest edition, which is an update to the 2015 publication, describes the consequences of drug use, a drug's effects on the body and mind, overdose potential, origin, legal status, and other key facts. It also includes the most current information on new and emerging trends in drug misuse and abuse, including fentanyl, other opioids, and synthetic drugs. The 2017 edition can be found at www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf.

the passing of the federal Comprehensive Addiction and Recovery Act (CARA) in 2016, this is allowed if not prohibited by the state. (Visit www.congress.gov/bill/114th-congress/senate-bill/524 for more information about CARA.) At the May 2017 Commission meeting, it was determined that while Revised Code of Washington 69.50.308(3)(d) prohibits Schedule II refills, a partial fill following the CARA provisions is not prohibited. See the Pharmacist Consultants Corner scenarios below in this *Newsletter* and article No. 1261 in the July 2017 *Newsletter*.

No. 1268 Pharmacist Consultants Corner – Frequently Asked Questions

Scenario A: Out-of-State Naturopathic Physician

Pharmacists in Washington State receive prescriptions written for Washington patients by naturopaths licensed and residing in Oregon.

Question: Is a prescription from an out-of-state naturopath valid?

Answer: A prescription from an out-of-state naturopath is valid in Washington under the following conditions:

1. The naturopath must possess an active Washington State license; and
2. The naturopath must be prescribing within his or her scope of practice for Washington State.

Scenario B: Pharmacist/Technician Ratio

The Commission voted at its May 11, 2017 business meeting to open up rulemaking regarding the pharmacist to pharmacy technician ratio (WAC 246-901-130). The Commission is considering updating the rule to change the pharmacist to pharmacy technician ratio to reflect current practice.

Question: Does this mean pharmacies can now have four or five pharmacy technicians per pharmacist and are not required to follow the 1:3 pharmacist to pharmacy technician ratio as stated in WAC 246-901-130?

Answer: No. Although the Commission is examining WAC 246-901-130 for potential rulemaking, the current rule is still in effect and enforceable until such time that a new rule is adopted and codified with the Office of the Code Reviser. The process to create, amend, or adopt a new rule can take up to 18 to 24 months.

Scenario C: Schedule II Partial Fill – Prescriber/Patient Request

A patient comes into the pharmacy after a minor procedure with a prescription for 60 tablets of a Schedule II medication. On the face of the prescription, the prescriber instructed the pharmacist to initially dispense only 20 of the 60 tablets.

Question: May the pharmacist provide a partial fill of the prescription?

Answer: Yes. CARA aims to address unused medications by allowing for the partial fill of prescriptions and supporting the efficient disposal of medications no longer needed by patients. According to CARA, a prescription for a CS in Schedule II may be partially filled if:

1. It is not prohibited by state law;
2. The prescription is written and filled in accordance with this title, regulations prescribed by the attorney general, and state law;
3. The partial fill is requested by the patient or the practitioner who wrote the prescription; and
4. The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

The remaining portions of a partially filled prescription for a CS in Schedule II:

1. May be filled; and
2. Shall be filled within **30 days** from the date on which the prescription is written.

Scenario D: Schedule II Partial Fill – Emergency

A physician phones in an emergency oral prescription for 60 tablets of Schedule II medication. The pharmacy has only 40 tablets in stock.

Question: If available from its wholesaler, may the pharmacy order more tablets of the Schedule II medication and provide a partial filling of the prescription?

Answer: Yes. The partial filling of a prescription for a CS listed in Schedule II is still permissible when the pharmacist is unable to dispense the full quantity called for in an emergency oral prescription. The pharmacist must make a notation of the quantity dispensed on the written record of the emergency oral prescription. The remaining portion of the prescription may be **dispensed within 72 hours** of the first partial filling; however, if the remaining portion is not or cannot be filled within 72 hours, the pharmacist shall notify the prescriber. **No further quantity of the medication may be dispensed beyond 72 hours without a new prescription.** (Reference: §1306.13 Partial filling of prescriptions.)

No. 1269 GovDelivery – Stay Informed and Get Involved

Why join [GovDelivery](#)? GovDelivery is the new communication platform that allows you to self-select content that interests you. It lets you determine when and how you receive information. Do not miss out! Get updates from the Commission to stay compliant with the latest changes in rules and laws, as well as opportunities for you to share your voice in all things pharmacy. Have the *Newsletter* delivered straight to your personal or business email inbox. You can change or cancel your subscription at any time. The Commission currently has four topic lists:

- ◆ Pharmacy Commission Meeting and Agenda
- ◆ Pharmacy Commission Newsletter
- ◆ Pharmacy Commission Rules
- ◆ Rx Fraud Alert (notices of potential fraud or stolen prescriptions reports)

GovDelivery provides options to subscribe to other Department of Health topics, including health professions discipline news releases, Department rulemaking activities, and other organizations.

No. 1270 Recognition of 50 Years of Licensure in Washington State

The Commission wishes to acknowledge and congratulate the following pharmacists for 50 years of licensure in Washington State. Thank you for your dedication to your profession and the practice of pharmacy. The Washington State Pharmacy Association will award certificates of service at its annual meeting in November 2017.

Randolph Collins	Aldon Oscarson
Darrel Koistinen	Eldon Riggle
Jeannette Longstreth	Michael Rosati
Janis McDermid	Kirmit Sheker
James Movick	Duane Schoeppach

No. 1271 Commission Meeting Dates 2018

- ◆ February 1-2 – Tumwater, WA
- ◆ March 15-16 – Des Moines, WA
- ◆ April 26-27 – TBD
- ◆ June 7-8 – Tumwater
- ◆ July 26-27 – Des Moines
- ◆ September 6-7 – Des Moines
- ◆ October 18 – Des Moines
- ◆ December 13-14 – Des Moines

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