January 2018

News

Washington State Pharmacy Quality Assurance Commission

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No. 1272 Rules Rewrite Project

The Washington State Pharmacy Quality Assurance Commission continues with the work to rewrite the pharmacy-related rules. The Commission has undertaken this project to make sure that the pharmacy rules protect not only patient safety, but also support the contemporary and changing health care delivery system. The Commission wants rules that allow for innovation, support collaboration, and provide guardrails for safe patient care. The Commission is looking at rules that provide flexibility, support a pharmacist's professional judgment, and are outcome-focused.

The first group of rules the Commission is working on is General Licensing. This started at the December 2017 meeting and will continue at the February 1, 2018 meeting. The Commission may also look at the Regulatory Framework-related rules at the February meeting. Operational Business Practices will be considered at the March, April, and June meetings. These may change, so please visit the Commission's web page on the Washington State Department of Health website for current meeting schedules and resources. The best way to stay informed is to subscribe to the Commission's email notice system, called GovDelivery, which can be accessed by clicking the green "Subscribe" button at the bottom of every Department of Health/Commission web page.

No. 1273 Pharmaceutical Firms Enforcement Process

The Commission is changing its procedure for enforcement action against pharmaceutical firms.*

A 2009 Court of Appeals of Washington, Division 1 determination in *Seymour DDS v. Washington State Department of Health Dental Quality Assurance Commission* (DQAC) found that the authority to launch an investigation belongs to DQAC. After the ruling, all boards and commissions changed their process to a three-member board or commission panel to authorize and charge under the Uniform Disciplinary Act (UDA), Chapter 18.130 Revised Code of Washington (RCW).

The interpretation at that time extended the panel of three Commission members under the UDA to authorize and charge pharmaceutical firms licensed and disciplined under the authority of the Pharmacy Quality Assurance Commission.

In August 2017, the Commission was advised that using the Administrative Procedure Act (APA) for pharmaceutical firm enforcement more closely reflects the governing statutes' language. The Commission has requested transparency in implementing the change and to inform stakeholders by developing a communication plan and posting the procedure on the internet.

The Commission will use APA, RCW 34.05, when taking enforcement action against a pharmaceutical firm. This allows a quorum of the Commission (minimum of eight members) to pursue enforcement action in cases involving a pharmaceutical firm. The Commission will continue to use UDA, RCW 18.130, for enforcement action in cases related to the credential of an individual licensee. The UDA allows the use of a three-member panel.

The Commission regulates the practice of pharmacy and the distribution, manufacturing, and delivery of pharmaceuticals within and into the state. The Commission protects and promotes public health and safety by responding to complaints or reports of unprofessional conduct or law and rule violations. When the Commission receives a complaint or report of a violation, it has a process to determine whether the complaint or report warrants investigation and then whether the outcome of the investigation warrants enforcement action. The flow charts that can be found in the link provided on page 4 outline the processes that the Commission uses when assessing, investigating, and taking enforcement action based on a complaint or report. One chart sets out the process for pharmacists, pharmacy interns, and ancillary staff. The other chart sets out the process for pharmaceutical firm applicants, pharmaceutical firm licensees, or pharmaceutical firm certificate holders.

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National Pharmacy Compliance News

January 2018

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy,* applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA's website at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.*

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC's *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report,* "Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015," can be accessed on the CDC website at *www.cdc.gov/mmwr/index.html* in the Weekly Report section.

AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient's family member or close friend, which may be found in the August 2017 document, "AMA Opioid Task Force naloxone recommendations," available on the AMA opioid microsite at *https://www.end-opioid-epidemic.org.*

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for

minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found in an FDA Drug Safety Communication announcement at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015,* found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. "Some counties have 13 pharmacies per capita, while others have none," said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit *https://doi.org/10.1371/journal.pone.0183172.* The UIC news release is available at *https://today.uic.edu/access-to-pharmacies-limited-to-some-patients.*

Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.*

FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA's website may be found at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.*

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch/report.*

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- Pharmaceutical firms enforcement process – flow charts (pdf)
- Definitions used in the flow chart (pdf)

*Pharmaceutical firm is defined as: "Applicants or holders of facility licensees or registrations issued to facilities under RCW 18.64 that includes, but is not limited to: pharmacies, manufacturers, wholesalers, nonresident pharmacies, health care entities, and hospital pharmacy associated clinics."

No. 1274 Mandatory Reporting

Many licensees are not aware of the mandatory reporting rules found in Chapter 246-16 Washington Administrative Code (WAC), titled Standards of Professional Conduct. Mandatory reporting is required to protect the public and to address patient safety. License holders are required to self-report and to report other license holders under certain circumstances, outlined below. Employers of license holders are required to report as well. The following are examples of when reporting is required:

- When a patient has been harmed;
- When there is an inability to practice with reasonable skill and safety because of a mental or physical condition; or
- When unprofessional conduct has occurred (defined in RCW 18.130.180).

Who Is Required to Report?

1. Each license holder is required to **self-report** when any of the following has occurred:
   - Any conviction, determination, or finding that he or she has committed unprofessional conduct;
   - Information that he or she is unable to practice with reasonable skill and safety because of a mental or physical condition; or
   - Any disqualification from participation in the federal Medicare or Medicaid program.
2. Each license holder is required to report other license holders for circumstances similar to the self-reporting requirements. WAC 246-16-235 lists exceptions to these reporting requirements.
3. The chief administrator or executive officer or designee of health care institutions is required to report when:
   - A license holder's services are terminated or restricted because a license holder has harmed or placed at unreasonable risk of harm a patient or client; or
   - A license holder poses an unreasonable risk of harm to patients or clients because of a mental or physical condition.
4. Employers of license holders are required to report when the employed license holder's services have been terminated or restricted based on a final determination or finding that the license holder:
   - Has committed an act or acts that may constitute unprofessional conduct; or
   - May not be able to practice his or her profession with reasonable skill and safety because of a mental or physical condition.

The rules in this chapter do not limit reporting from any person who has a concern about a license holder's conduct or ability to practice safely.

How to Report?

Reporting must be submitted to the Department of Health. The Department will give the report to the appropriate disciplining authority for review, possible investigation, and further action.

You may choose any of the following ways to submit a report:

1. Complaint Intake Unit phone: 360/236-2620; Complaint Intake Unit fax: 360/236-2626
2. Mail via United States Postal Service (USPS): Health Systems Quality Assurance, Complaint Intake Unit, PO Box 47857, Olympia, WA 98504-7857
3. Email: HSQAComplaintIntake@doh.wa.gov
4. Online Complaint Form: You may submit online or print, complete form, and submit via fax or USPS

No. 1275 Consultants' Corner

- The Commission has been adopting several interpretive and policy statements, which are viewable on the Commission's Policies and Procedures web page. Please note that these are considered guidance documents to assist with compliance. They have not been legislatively mandated, nor have they been adopted into rule. Any guideline, interpretive statement, or policy statement issued is not a RCW or WAC and is not enforceable under current law or rule.
- Many pharmacy students contact the Commission staff requesting assistance studying for the North American Pharmacist Licensure Examination® (NAPLEX®) or the Multistate Pharmacy Jurisprudence Examination® (MPJE®). The Commission recommends the following resources while preparing for the NAPLEX and/or Washington State MPJE as a refresher on laws and rules:
  1. Download the NAPLEX/MPJE Registration Bulletin from the National Association of Boards of Pharmacy® website for current competency statements and sample questions
  2. Washington State Online Laws and Rules (there is no longer a printed version in book format). Please note that for additional assistance, on pages 833-834 of the Washington Law Book, there is information on how

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to study for the MPJE as well as Federal Law Study References created by a Commission member.

3. Drug Enforcement Administration's Pharmacist's Manual
4. Title 21 Code of Federal Regulations Part 1300 to 1400

No. 1276 Rx Fraud Alert

A joint six-month pilot project was started on April 15, 2015, between the Commission and the Washington prescription monitoring program (PMP). The intent was to allow a health care provider who becomes aware of a fraudulent prescription to complete a web-based form with specific information regarding the prescription and submit it to the Department of Health. The Department would then make that information available to the pharmacies that registered with the public email alert system by subscribing to the Rx Fraud Alert reports through GovDelivery. The reports are distributed to subscribers and posted to the Commission's web page, as well as in the PMP system. The hope was that this tool would help prevent additional fraudulent prescriptions from being filled.

The Department determined this system to be effective, and current resources have allowed this project to continue. While the Rx Fraud Alert pilot project continues, many licensees are unaware of this service. Please sign up to receive the Rx Fraud Alert information. Visit the following web page for more information regarding the web-based reporting form, the Rx Fraud Alert reports, and subscription to the email delivery system to receive the Rx Fraud Alert reports: *https://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/PharmacyCommission/RxFraudAlerts.*

No. 1277 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 that can be found in the drop-down list of Health Systems Quality Assurance after you sign in:

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

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

No. 1278 Improving Access to PMP for Pharmacy Professionals

By Gary Garrety, PMP Operations Manager

Washington's PMP allows health care providers (HCP) access to their patients' controlled substances prescription history. The information is an important tool when providing medical or pharmaceutical care to ensure proper prescribing and safe patient use. The PMP has taken the following steps to improve access for pharmacy professionals:

- Access to prescribing history reports on the PMP for pharmacists with prescriptive authority.
- Ability for pharmacies that use electronic health care record (EHR) systems to access PMP data when the EHR is integrated with the state's Health Information Exchange.
- Authority for PMP delegate account access for pharmacy ancillary staff (pharmacy assistants and pharmacy technicians) and pharmacy interns.

Pharmacy systems will need information technology resources with access to email and phone lines for identity authentication through SecureAccess Washington for quick and easy access to the PMP. Access by pharmacy staff to the PMP is essential to ensure patient safety. Accidental drug overdoses have killed more people each year in our state than traffic accidents since 2008. More information on connection and integration is found on the program's main page, as well as medication disposal resources and helpful information for opioid misuse. For questions or assistance, PMP staff may be reached at prescriptionmonitoring@doh.wa.gov.

No. 1279 Distinguished Young Pharmacist of 2017

Congratulations to Commission Member Dr Michael Sieg on being named 2017's Distinguished Young Pharmacist of the Year by the Washington State Pharmacy Association. Well done!

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® (NABPF®) 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 NABPF or the Board unless expressly so stated.

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