January 2020

News

Washington State Pharmacy Quality Assurance Commission

Published to promote compliance of pharmacy and drug law

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No. 1336 Message From the New Executive Director – Lauren F. Lyles-Stolz, PharmD

I am elated to be in the "Evergreen State," and I am committed to working with you in order to keep our population healthy and safe. Pharmacists play a momentous role in enhancing patient access and in optimizing patient care. This is true yesterday, today, and tomorrow. As health care transitions to this emerging – and in some places current – concept of value-based care, I, along with my team, hope to lead us into tomorrow by ensuring quality and safety, while promoting innovation and collaboration to advance our common mission for population health and safety. In order to achieve this goal, we must encourage partnerships and respect and trust among all, because our patients' outcomes depend on it. I wish you all a happy New Year, and look forward to making 2020 the "Year of Optimism and Opportunity" for pharmacy and the people we serve.

Thank you all again for your commitment to optimal patient care in all of your respective health care settings.

No. 1337 Rule Rewrite Update

After more than two years of meetings and discussion about the draft rule language for the rule rewrite project, the Washington State Pharmacy Quality Assurance Commission authorized staff members to move forward with the second phase of filing.

The rewrite project goal was to update the rules and to improve ease of access to them. Current pharmacy rules regulating the practice of pharmacy, facilities, production, distribution, and drugs covered more than 34 chapters. Many of these chapters are outdated, overly prescriptive, and limit the ability of licensees to adapt to changes in practice and technological advances.

By creating this new chapter, the Commission is repealing all previous Washington Administrative Code (WAC) rules under the Commission's jurisdiction. The proposed new rules incorporate current, amended, and newly created WAC rules. The proposed new rules incorporate current practice while allowing for flexibility as the practice evolves. The proposed new rules will update outdated practices, eliminate redundancies, and allow for professional judgment while still ensuring patient safety and access to quality care.

Staff members are working on finalizing all the necessary documents to file the CR-102 (proposal) by mid-January. The public and stakeholders will receive notice through GovDelivery and by publication in the state registry. The notice will include draft language and the significant analysis, as well as information regarding the official public comment period and public rules hearing date, tentatively scheduled for March 5, 2020. The hearing will be at the Department of Health, Town Center Two, Room 166/167, 111 Israel Road SE, Tumwater, WA 98501. The anticipated effective date of the new rules will be July 1, 2020.

No. 1338 CLOUD – Curated Library About Opioid Use for Decision-Makers

Check out a new web-based library known as Curated Library about Opioid Use for Decision-makers (CLOUD). Find resources and learn how to submit your materials for inclusion in the CLOUD web-based library at *https://www.opioidlibrary.org.*

Funding for CLOUD is provided by a grant from the Consumer and Prescriber Education Grant Program and the Center for Evidence-based Policy at Oregon Health & Science University, which administers the library. The mission is to provide high-quality evidence-based resources in one place related to opioid use or opioid-related issues such as alternative treatments for pain, addiction treatment, harm reduction, and prevention.

The focus audience includes those working to address the opioid crisis, patients, practitioners, and caregivers. All materials are publicly available without restrictions and remain the property of the original creators. The library includes

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National Pharmacy Compliance News

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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.

DEA Proposes New Regulations to Address Opioid Epidemic

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulation would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorney generals and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulations are available in the October 23, 2019, *Federal Register* announcement at *https://www.federalregister.gov/documents/2019/10/23/2019-21989/management-of-quotas-for-controlled-substances-and-list-i-chemicals*.

FDA Issues Report on Root Causes and Solutions to Drug Shortages

Food and Drug Administration (FDA) has released a new report, *Drug Shortages: Root Causes and Potential Solutions,* which identifies root causes for drug shortages and recommends three "enduring solutions" to address the shortages. These recommendations include:

- creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
- developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- promoting sustainable private sector contracts (eg, with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.

In addition to these recommendations, the report outlines the agency's ongoing initiatives to mitigate drug shortages and legislative proposals in President Donald J. Trump's Fiscal Year 2020 budget. FDA also highlighted the need for international action, including global implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH's) *ICH Guideline Q12: Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management,* which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process.

"We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers," FDA stated. "In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need."

FDA's full statement is available at *https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages*.

HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use

The United States Department of Health and Human Services (HHS) has published a new guide for clinicians intended to provide guidelines for tapering or discontinuing long-term opioid use. The guide, titled *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, covers important issues to consider when changing a patient's chronic pain therapy. The guide also lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs

of each patient," said ADM Brett P. Giroir, MD, assistant secretary for health in a press release. "This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction."

FDA Releases Draft Best Practice Document for Postmarket Drug Surveillance

As part of FDA's efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, *Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff*. The draft document outlines FDA's approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

"Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field," FDA said in a statement announcing the document's release. "By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public."

The full draft document can be accessed at *https://www.fda.gov/media/130216/download*.

FDA Issues Revised Draft Guidance on Regulation of Homeopathic Products, Withdraws 1988 Compliance Policy Guide

FDA is taking two new steps to clarifying their approach to regulating drug products labeled as homeopathic: revising draft guidance previously published in 2017, and withdrawing the Compliance Policy Guide (CPG) 400.400 issued in 1988. These moves were announced in a statement published on the FDA website. Homeopathic products are often marketed as natural alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Homeopathic products, however, are marketed without FDA review and may not meet modern standards for safety, effectivity, quality, and labeling. FDA uses a risk-based approach to monitor these products and to evaluate reports of adverse events.

The revisions to the 2017 draft guidance provide further information about FDA's approach. The guidance details a risk-based enforcement policy prioritizing certain categories of homeopathic products that could pose a higher risk to public health. These include products with particular ingredients and routes of administration, products for vulnerable populations, and products with significant quality issues. FDA has invited public comment on the guidance before it is finalized. The full guidance and instructions for providing comment are available in the *Federal Register* announcement.

CPG 400.400, Conditions Under which Homeopathic Drugs May be Marketed, is being withdrawn due to inconsistency with the agency's risk-based approach to regulatory and enforcement action and is therefore being withdrawn. Specifically, FDA states that it has encountered multiple issues with homeopathic drug products posing significant risk to patients, even though the products, as labeled, appeared to meet the conditions of CPG 400.400.

DEA Warns of Increase in Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of a legitimate investigation or legal action is always made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

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infographics, one- and two-page summary documents, policy reports, program evaluations, patient and provider educational materials, tool kits, government documents including relevant legislation and regulations, clinical practice guidelines, and links to videos and external websites.

No. 1339 2020 Legislative Session

The 2020 legislative session starts on January 13 and goes through March 12. This is a short session, so it will move quickly. The Commission does not have any requests for legislation but staff members will monitor bills to see whether any may affect its licensees. The Commission will hold weekly legislative calls by webinar to discuss bills and to invite public comments. Invitations to attend legislative calls will be sent through GovDelivery.

Find more information on prefiled bills and other legislation on the Washington State Legislature web page.

No. 1340 Commission Meeting Dates in 2020

The Commission will continue to hold two-day meetings in 2020. The Commission filed its 2020 calendar with the Code Reviser's Office on October 22, 2019, under Washington State Register 19-21-167. The Tumwater meeting location has changed to Town Center Two, Room 166/167, 111 Israel Road SE, Tumwater, WA 98501.

- January 30-31, 2020 – Tumwater
- March 5-6, 2020 – Tumwater
- April 16-17, 2020 – Tumwater
- May 28-29, 2020 – Des Moines, WA
- July 16-17, 2020 – TBD
- August 27-28, 2020 – Des Moines
- October 1-2, 2020 – Des Moines
- December 3-4, 2020 – Des Moines

Sign up to join the Friday business meetings by webinar (ID# 825-024-203). Register once and attend when you are available. You can also view meeting materials on the web.

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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