February 2020

Oregon State Board of Pharmacy News

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No. 622 Board Member Opportunities

There are often opportunities for interested persons to serve on the Oregon State Board of Pharmacy. This year, the Board will have two pharmacist member positions available for appointment and reappointment, effective July 1, 2020. For qualifications, more information, and how to apply, please visit the Board's website. The Board encourages all interested and qualified people to apply by March 1, 2020.

No. 623 Pharmacist CE Audit

Oregon Administrative Rule (OAR) 855-021-0005 states:

> (1) During the period from July 1 through June 30 of each biennial license renewal cycle, each pharmacist must have satisfactorily completed three (3) continuing pharmacy education units (CEU's) in an approved continuing pharmacy education program prior to submission of the license renewal. Ten contact hours equals 1 CEU. Fifty minutes equals 1 contact hour.

To ensure that licensees comply with the requirement to complete CEUs, the Board conducts random audits of completion after each license renewal cycle. The pharmacist license renewal application asks the applicant to attest that he or she has completed the required CEUs at the time of application. If a pharmacist attests to completion of the required CEUs but has not completed them at the time of application for renewal, the licensee may be subject to disciplinary action by the Board.

When conducting continuing education (CE) audits, the Board first reviews CPE Monitor® for the licensees selected for audit. If the CPE Monitor report for each person shows completion of the required CEUs, including required hours in specific topics, then that person will have passed the audit and will not be contacted by the Board. If the CPE Monitor database does not show completion of the required CEUs, the Board will contact the licensee to request documentation of CEU completion.

Use of CPE Monitor for tracking completed CEUs is encouraged and will save the licensee from having to submit documentation for an audit, if the CEU requirements are met. Prior to submitting the renewal application, a licensee can verify that the CPE Monitor database accurately reflects CEU activities completed and that it meets the requirements of Division 021.

For the 2019 pharmacist renewal audit, the Board was able to successfully audit over 500 pharmacist CE records (approximately 79% of those audited) through the use of CPE Monitor without any action or submission required by those individuals, and is pleased to announce that 95% of the pharmacists passed the audit.

Note: Oregon pharmacists and certified pharmacy technicians renew licensure every other year. The process described is applicable to technicians for the 2020 renewal.

No. 624 Reverse Overdose Oregon Campaign

In November 2019, the Oregon Health Authority (OHA) launched Reverse Overdose Oregon, a campaign to equip employers with naloxone and build a network of people who are trained and ready to respond to an overdose.

Pharmacists play an important role in this work by readily prescribing naloxone to individuals or entities in our communities, preparing people to appropriately respond to patients in crisis. Here is what you need to know about the campaign:

- Employers will get naloxone cases and training materials from the OHA.
- The case does not include the naloxone. Employers need to "complete the kit" by obtaining naloxone doses from a local pharmacy.
- OHA provides employers with a letter to bring to pharmacists when requesting a naloxone prescription.

As part of its efforts with Reverse Overdose Oregon, and in recognition of Senate Bill 910, OHA also provided a

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National Pharmacy Compliance News

February 2020

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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poster compliant with the new requirement for a pharmacy that provides naloxone services to "provide written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available" (see also OAR 855-041-2340). A pharmacy may choose to utilize this as a way to comply with regulations – feel free to print and display this poster at any hospital or retail pharmacy locations. For more information, contact Mary Borges at OHA via email at mary.l.borges@dhsoha.state.or.us.

No. 625 New PDMP Reporting Requirements for Oregon Pharmacies

In 2019, as a result of the Opioid Epidemic Task Force, Governor Kate Brown signed House Bill 2257 into Oregon law. Among new policy directives, it includes the requirements for Oregon pharmacies to report all gabapentin* prescriptions dispensed, the diagnosis code, and the reason for prescription to the prescription drug monitoring program (PDMP). The program's related administrative rules became effective January 1, 2020, and state that the ICD-10 code and reason for prescription are to be reported **when provided by the prescriber with the prescription.** This means that if the prescription issued by the prescriber does not include this information, the pharmacist is not responsible to retrieve the missing information. The Oregon PDMP has stated that missing ICD-10 and reason for prescription data will not be considered an incomplete record when submitted, and therefore will not be rejected or sent back for completion at this time.

*Note: At this time, gabapentin is not a controlled substance.

No. 626 Proper Storage of Drugs

All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements. Pharmacists understand the importance of drug storage conditions on physical and chemical stability and its impact on safety and effectiveness. Vaccines and other biological drugs are most susceptible to damage due to improper storage conditions, and other drug products are adversely affected when improperly stored.

The Board adopted comprehensive drug storage rules in 2016. Board inspectors continue to find Oregon pharmacies that have not appropriately implemented policies and procedures to manage drug storage according to requirements in OAR 855-041-1036. The most frequent observations include improper or no documentation of response to a temperature excursion (deviation from the manufacturer's recommended storage conditions), failure to quarantine products that have experienced an excursion, failure to conduct and document quarterly monitoring system validation, and failure to maintain adequate documentation of actions taken. Use of household-grade refrigeration equipment may be a cause of temperature excursions and investment in medical-grade equipment (with backup power) may help to minimize them.

All pharmacists, pharmacists-in-charge, and drug outlets have the responsibility to ensure proper drug storage conditions, including appropriate refrigeration or freezing and monitoring equipment, policies and procedures (including a written quality assurance process to avoid temperature excursions), and maintenance of records. Records of temperature monitoring, excursion response, and quarterly monitoring system validation must be retained for three years, **must be stored on site for at least one year,** and available during Board inspection.

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