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News



State of Ohio Board of Pharmacy

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From the Director's Desk

Dear Ohio Pharmacist,

Registered pharmacy technician renewal began in January 2020. As part of the renewal process, a registered pharmacy technician will be required to complete a total of 10 contact hours (1.0 CEU) of continuing pharmacy education (CPE) during the 24 months preceding the expiration date of a registered technician's registration (ie, April 1, 2018, to March 31, 2020).

It is important that registered pharmacy technicians maintain their registration and complete their required CPE. By failing to renew a registration, both the registered pharmacy technician and the pharmacy may face administrative action if the employee continues to practice as a technician. The State of Ohio Board of Pharmacy will be conducting audits of registered pharmacy technicians to determine if CPE requirements have been met. Certificates and other documented evidence of participation only need to be submitted to the Board when requested.

All registered pharmacy technicians must obtain a free CPE Monitor[®] account from the National Association of Boards of Pharmacy[®]. This account will be used to report and monitor the successful completion of Accreditation Council for Pharmacy Education-accredited CPE.

The Board has also created a guidance document that can be found by visiting: www.pharmacy.ohio.gov/techCE.

Certified pharmacy technician renewal will begin in August 2020, with more information to be published this spring. As part of the renewal process and as a condition of maintaining a valid Ohio registration, a certified pharmacy technician is required to maintain a national pharmacy technician certification, obtained by passing either the Exam for the Certification of Pharmacy Technicians (ExCPT) or the Pharmacy Technician Certification Board (PTCB) exam.

As of January 2020, the Board began verifying that certified technicians have a valid ExCPT or PTCB

certification. A certified technician must meet the CPE requirements for his or her pharmacy technician certification (ExCPT or PTCB). Any certified technician who holds a valid certification is not required to complete the 10 contact hours that are required for a registered pharmacy technician. Failure to maintain an ExCPT or PTCB certification may result in disciplinary action by the Board. Therefore, all Ohio-certified technicians should have obtained valid certifications prior to January 2020. If a certified pharmacy technician no longer wishes to maintain his or her ExCPT or PTCB certification, the applicant will be required to reapply as a registered pharmacy technician.

If you have any questions, please do not hesitate to contact the Board via contact@pharmacy.ohio.gov or 614/466-4143. Sincerely,

Steven W. Schierholt, Esq
Executive Director
State of Ohio Board of Pharmacy

Reminder: Important Notice to All Licensees Regarding Extortion Scam

Licensees should be on alert for a scam that has been targeting Ohio health care providers.

Scammers have been calling and faxing prescribers and pharmacists saying that they are being investigated by Drug Enforcement Administration (DEA) and that their DEA registration will be revoked or suspended or they will be arrested if they do not agree to pay a fine immediately via phone or fax.

Additionally, individuals posing as Board of Pharmacy or state medical board agents are also contacting health care providers by phone and/or fax in an attempt to obtain payment to resolve a disciplinary matter.

Please be aware that if the Board of Pharmacy or state medical board is conducting an investigation and that

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National Pharmacy Compliance News

February 2020



NABPF
National Association of Boards
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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 organiza-

nizations) 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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individual faces action against his or her license, he or she will receive an official notice of opportunity for a hearing either via certified mail or by personal service.

If you are unsure of whether the individual claiming to be a Board agent or inspector is legitimate, you may call the Board office at 614/466-4143 and ask to speak to the Compliance and Enforcement department.

DEA is also aware of the extortion scam and has published more information on its website, https://www.deadiversion.usdoj.gov/pubs/pressreleases/extortion_scam.htm, including how to notify DEA.

Non-Pharmacy Terminal Distributor Rules – Effective March 1, 2020

Effective March 1, 2020, the following terminal distributor rule chapters go into effect:

- ◆ Pain Management Clinics – 4729:5-11
- ◆ First Aid Departments – 4729:5-13
- ◆ Animal Shelters – 4729:5-15
- ◆ Laboratories – 4729:5-16
- ◆ Office-based Opioid Treatment Facilities – 4729:5-18
- ◆ Clinics and Prescriber Offices – 4729:5-19
- ◆ Veterinary Clinics – 4729:5-20
- ◆ Opioid Treatment Programs – 4729:5-21
- ◆ Non-limited Facilities – 4729:5-22
- ◆ Limited Facilities – 4729:5-23

Reminder: The above rule chapters **do not apply** to pharmacies, emergency medical services (EMS) agencies, drug distributors (wholesalers, manufacturers, etc), and institutional facilities.

To assist licensees in complying with the new rule chapters, the Board recently published inspection guides for each license type. The inspection guides align with internal guidance used by Board inspectors and allow licensees to conduct self-inspections to ensure compliance.

Guides also include links to the new rule chapters, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board.

The guides are available on the terminal distributor licensing page and can also be accessed using the short links below:

- ◆ Pain management clinics – www.pharmacy.ohio.gov/PMCinspect
- ◆ First aid departments – www.pharmacy.ohio.gov/FAinspect
- ◆ Animal shelters – www.pharmacy.ohio.gov/ASinspect

- ◆ Laboratories – www.pharmacy.ohio.gov/LABinspect
- ◆ Office-based opioid treatment facilities – www.pharmacy.ohio.gov/OBOTinspect
- ◆ Clinics and prescriber offices – www.pharmacy.ohio.gov/CPOinspect
- ◆ Veterinary clinics – www.pharmacy.ohio.gov/VETinspect
- ◆ Opioid treatment programs – www.pharmacy.ohio.gov/OTPinspect
- ◆ Non-limited facilities – www.pharmacy.ohio.gov/NLFinspect
- ◆ Limited facilities – www.pharmacy.ohio.gov/LFinspect

Additional guides for other license types (pharmacies, EMS, institutional, etc) will be published by early next year.

Reminder: Duty to Report Rules Effective December 1, 2019

Effective December 1, 2019, Rule 4729:1-4-02 of the Ohio Administrative Code requires Ohio-licensed pharmacists to report to the Board certain types of conduct of which the licensed pharmacist has knowledge.

The new rule requires pharmacists to report the following to the Board:

- ◆ Conduct indicating an individual licensed or registered by the Board is addicted to or is suspected to be abusing alcohol, drugs, or other chemical substances, or is impaired physically or mentally to render the individual unfit to carry out his or her professional duties
- ◆ Violations, attempts to violate, or aiding and abetting in the violation of any of the provisions of Ohio Revised Code (ORC) Chapters [4729](#) (Pharmacy Practice Act), [4752](#) (Home Medical Services), [3715](#) (Pure Food and Drug Law), [3719](#) (Controlled Substances), [3796](#) (Medical Marijuana Control Program), [2925](#) (Drug Offenses), and [2913](#) (Theft and Fraud) or any rule adopted by the Board under those provisions by an individual or entity licensed or registered by the Board
- ◆ Conduct by a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician, pharmacy intern, or pharmacist that constitutes unprofessional conduct or dishonesty

A pharmacist is not required to report an error in dispensing or a prescription error except when the error is the result of reckless behavior or unprofessional conduct and meets any of the following per the National Coordinating Council for Medication Error Reporting and Prevention's *Index for Categorizing Medication Errors*. Per section

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4729.23 of the ORC, the identity of the pharmacist making a report in accordance with this rule will remain confidential.

The rule also requires a pharmacist to self-report to the Board any of the following:

- ◆ Any criminal conviction within 10 days after the date of conviction except for minor traffic violations, or if the pharmacist is convicted, plead guilty to, or is subject to a judicial finding of eligibility for intervention in lieu of conviction. The conviction must be reported regardless of whether the case has been expunged or sealed or the equivalent thereof.
- ◆ Entry into a diversion program, deferred prosecution program, or equivalent within 10 days after the individual is granted entry into a program.
- ◆ Any arrest for a felony within 10 days after the arrest.
- ◆ Any disciplinary licensing or registration action taken by another state against the licensee within 10 days of the notice action.

More information on duty to report can be found at www.pharmacy.ohio.gov/PharmReport.

DATA 2000 Prescriber Training for Medication-Assisted Treatment

(Permission was given to use the article content below from the Ohio Department of Mental Health and Addiction Services)

The 21st Century Cures Act enacted by Congress in December 2016 recognized that states need significant help to combat the opioid epidemic.

Ohio is receiving federal funds over two years to focus on developing a skilled workforce that can prescribe buprenorphine for medication-assisted treatment (MAT). MAT has been recognized as a critical component in the treatment of people with opioid use disorder. Currently, buprenorphine availability is limited in Ohio because it is the only form of MAT that requires prescribers (ie, physicians, physician assistants, or advanced nurse practitioners) to have a unique DEA license (also known as a DATA 2000 waiver). Prescribers must take additional training to obtain this license through one eight-hour course and then apply for a DATA 2000 waiver through the Substance Abuse and Mental Health Services Administration.

Ohio Department of Mental Health and Addiction Services has designed a training agenda that will allow any medical professional with prescribing privileges to freely obtain the DATA 2000 waiver to meet the growing need of Ohio's patients with opioid use disorder.

More information and training dates can be found [here](#).

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