March 2020

Wyoming State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

Wyoming State Board of Pharmacy • 1712 Carey Ave, Suite 200 • Cheyenne, WY 82002
https://pharmacyboard.wyo.gov.

Board Welcomes New Members

Thomas A. "Tom" Maertens, RPh

Thomas A. "Tom" Maertens was appointed to the Wyoming State Board of Pharmacy in March 2019 by Governor Mark Gordon. Tom is the pharmacist-in-charge at the Buffalo Prescription Shop. He graduated from the University of Wyoming School of Pharmacy in 1995 and went straight to work with his father, Roger Maertens, in their family-owned and -operated pharmacy. The family-owned business has served the pharmacy needs of Buffalo, WY, since 1973.

Patrick Fitzgerald, APRN

Patrick Fitzgerald was appointed to the Board in March 2019 by Governor Gordon. Patrick earned his bachelor of science degree in nursing from the University of Wyoming School of Nursing, and his master of science degree in nursing-family nurse practitioner from Western Kentucky University. He currently works at HealthWorks in Cheyenne, WY, caring for acute and chronically ill patients of all ages.

New Third-Party Logistics Provider License

The Board has added a new license, specific to third-party logistics providers (3PLs). All 3PLs that are currently licensed under the wholesale distributor license in Wyoming will be required to apply for the 3PL license, as their wholesale distributor licenses will not be renewed. The new 3PL license will carry each licensee through June 30, 2021.

The Innovative State of the Pharmacy Market

By Ben Heady, PharmD Candidate

The newly rebranded Amazon Pharmacy, PillPack, has been expanding since 2018. In addition to operating as an online pharmacy, PillPack may begin to provide additional products and services such as surgical and dental instruments, medical and veterinary preparations, and medical and pharmaceutical hygiene beauty products. This represents an expansion in both the quantity and types of services that PillPack may offer in the future. Amazon's purchase of PillPack in 2018 was seen as a step away from traditional pharmacies, and caused shares of Walgreens Boots Alliance, CVS Health, and Rite Aid to drop by 7%, 9%, and 11%, respectively, at open.

The appeal of PillPack lies in technological advancement and personalization. Members are offered presorted packaging and delivery from Amazon's massive distribution network. PillPack holds mail-order pharmacy licenses in all 50 states and has begun interfacing with insurance companies, identifying medication interactions and duplications, and allowing refill ordering. Blue Cross Blue Shield (BCBS) of Massachusetts has planned to integrate PillPack into its membership app, making PillPack the first to offer direct online pharmacy access. BCBS has indicated that its members will be able to switch directly to PillPack using the MyBlue app or website.

BCBS members who use PillPack will also have access to customized dose packaging, pharmacist assistance around the clock, and physician contact for gaps in care, all without additional fees. BCBS representatives believe that this integration with PillPack will offer ease of access for patients, which will ultimately increase patient care. Spokespeople from BCBS have reported that their internal data indicates a much higher customer satisfaction score with PillPack than with other pharmacies.

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National Pharmacy Compliance News

March 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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CVS appears to be pushing back on PillPack via the release of CVS CarePass, a program that will allow for one- to two-day home delivery of eligible prescriptions for a set fee of $5 per month or $48 per year. CVS has reported that this will increase its customer base by 20% in the first few phases, appealing primarily to millennials. This may represent the beginning of a shift in pharmaceutical care, spurred on by Amazon's shifting of the market.

CVS first sought innovation in the retail market in 2006 when it partnered with MinuteClinic to provide treatment for short-term illnesses like sinus infections. Today, these clinics offer a myriad of clinical services such as health screenings, vaccinations, injections, and physicals, as well as the treatment of skin conditions, sexually transmitted infections, minor illnesses, and wounds. This care is provided seven days a week, with no appointment necessary. As of 2018, CVS has expanded to include telehealth options for video visits with practitioners.

CVS is not the only pharmacy retailer to branch out into the clinical space. Walgreens began adding walk-in clinics to its pharmacies in the early 2000s with blood pressure testing services. In January 2020, Walgreens added health and weight loss services from Jenny Craig in 100 Walgreens locations. Kroger pharmacies are another example, having opened The Little Clinics in 2009, providing services to 2 million patients annually.

These businesses are attempting to make the most out of a patient's one-stop shop for health care. They are doing this by integrating health care services and eliminating barriers to access, such as appointments, wait times, and affordability. Although the innovation may be challenging our traditional view of pharmacy, there are ways to maintain competitiveness in this market, and they all revolve around differentiation. Whether providing exceptional customer service, specialized clinical services, or unique marketing, pharmacies will need to stand out in this innovative market.

One area of services for pharmacies to consider is medication therapy management (MTM). Pharmacists are trained and capable of providing MTM services for therapeutic duplication identification, immunization, pharmacogenomics, smoking cessation, blood pressure, cholesterol, and anticoagulation monitoring. Furthermore, pharmacists can conduct comprehensive medication reviews annually to identify prescription and over-the-counter gaps in care. Many retail pharmacies offer these services with reimbursement through MirixaPro and OutcomesMTM. Providing these services may maintain business through a deeper connection with patients and their care.

Pharmacists may also consider improving business by prioritizing patient-centered tasks, such as counseling and medication monitoring, to ensure that patients are getting the quality care they desire. Although this may require an expansion of the non-patient-centered tasks that pharmacy technicians perform, it may motivate patients, increase adherence, and improve patient outcomes.

One last way to stand out in this market is to find unique ways to reimburse your pharmacy services. Pharmacists are finding ways to be reimbursed for medication consultations, prior authorization management, behavioral health, anticoagulation, and oncology. Some pharmacists provide smoking cessation and weight loss therapy, charging employers a fee per patient managed. Others are providing on-site flu shot clinics for clubs, businesses, schools, and municipalities, billing directly for these services. Marketing and providing these services will allow for referrals from local providers and help generate business. One thing is for certain, the landscape of pharmacy is changing. Pharmacies are finding unique niches to capitalize on. It may be beneficial for pharmacists to incorporate differentiating services into their practice.

Compliance Corner: Focus of Inspections in 2020

By Board Compliance Officers Patrick Johnson and Keith Bennett

The focus of inspections in 2020 includes, but is not limited to, the following:

- A random audit of a Schedule III, IV, and/or V controlled substance (CS) in addition to the random Schedule II audit
- Physical inspection of prescription files, including non-CS
- Checking for outdated medications, vaccines, and compounding components
- Review of immunization protocol and comparison to emergency kit configuration
- Documentation of training and compounding competencies for compounding staff (sterile and nonsterile)
- Compliance with compounding record-keeping and labeling requirements (sterile and nonsterile)
- Review of facility certification reports to identify inconsistencies with industry standards; in an attempt to streamline the process of sterile compounding inspections, compliance officers will request certification reports in advance, prior to coming on site

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- Educating on the upcoming requirement for e-prescribing of all CS – starting January 2021 – and outcomes of the 2020 legislative session
- Educating and discussing pending rule updates to the Wyoming Pharmacy Practice Act and Controlled Substances Act
- Any issue identified during the previous inspection
- The Board will give the compliance officers direction regarding compliance with United States Pharmacopeia Chapters <797> and <800> and the Board staff will ensure that all pharmacies, pharmacists, and technicians are updated

Phishing Scam

The Board office has received reports that pharmacists are receiving calls that appear to come from the Board office's main phone number and that the caller identifies himself or herself as an agent with the Board. The caller is able to confirm some of the pharmacist's information, such as license number, National Provider Identifier number, and place of employment.

In some cases, the caller accuses the pharmacist of having committed a violation, that his or her license may be suspended or revoked, and that the pharmacist will be arrested if he or she does not answer the caller's questions. In some cases, the caller alleges that the pharmacist was involved in prescription drug trafficking. Some pharmacists have reported that the caller becomes aggressive and demanding, threatening to have the Federal Bureau of Investigation come and arrest the pharmacist if he or she does not comply.

The Wyoming State Board of Pharmacy will not contact or interact with you in this manner.

The Federal Trade Commission has useful consumer information for how to recognize and avoid phishing scams available at *https://www.consumer.ftc.gov/articles/how-recognize-and-avoid-phishing-scams.*

If you receive such a phone call, please call and report it to the Federal Communications Commission at 888/225-5322.

Update on Intent to Amend Rules

The Wyoming Secretary of State has accepted the Board's proposed rules and they are open for public comment. Requests for copies of the proposed amendments may be addressed to the Board's executive director at 1712 Carey Avenue, Suite 200, Cheyenne, WY, 82002, or to BOP@wyo.gov. The proposed amended rules and new chapters are posted on the Wyoming Secretary of State website at *http://rules.wyo.gov.* Comments may be submitted to the Board at the address above or to BOP@wyo.gov on or before 5 PM MDT March 20, 2020. The Board will address public comments at its upcoming March meeting.

The *Wyoming State Board of Pharmacy News* is published by the Wyoming State Board of Pharmacy 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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