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Iowa Board of Pharmacy News

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400 SW 8th St, Suite E • Des Moines, IA 50309-4688 • Tel: 515/281-5944
Fax: 515/281-4609 • Website: *https://pharmacy.iowa.gov*

Technician Product Verification

During the 2018 legislative session, the Iowa Administrative Code (IAC) was amended to allow technician product verification (TPV) programs in community pharmacies. TPV programs essentially replace programs currently known as tech-check-tech programs but will be expanded to the community setting for the purpose of redirecting pharmacists' time to patient clinical activities. The legislation followed a multi-year pilot program by the Iowa Pharmacy Association in which TPV was utilized and studied to ensure patient safety and effectiveness in increasing pharmacist clinical activities. The Iowa Board of Pharmacy is currently in the process of promulgating rules to set the minimum standards for such programs. Anyone interested in any of the Board's proposed rules may review and submit comments at *https://rules.iowa.gov*.

Statewide Protocols

Also during the 2018 legislative session, the IAC was amended to allow pharmacists to order and administer certain medications based on a statewide protocol developed by the Board in collaboration with the Iowa Department of Public Health (IDPH). The pharmacy services allowed to be handled by a pharmacist under such protocols include naloxone, nicotine replacement tobacco cessation therapy, and immunizations.

Rules relating to such protocols have been published as "Notice of Intended Action," and comments received will be considered prior to the Board's consideration for adoption.

Only once the protocols are approved by the Board and the final rules are adopted and effective will pharmacists be authorized to practice pursuant to the protocols. Check the Board's website for updates at *https://pharmacy.iowa.gov*.

- **Naloxone –** The Board's statewide protocol **will not** replace or supersede the current statewide standing order issued by Dr Caitlin Pedati, IDPH medical director and state epidemiologist. The IAC section authorizing Dr Pedati's order remains current and effective. Pharmacists may continue to practice under that order in accordance with Board rules. The Board's statewide protocol will be a second option for pharmacists to dispense naloxone to interested individuals who are not able to get a patient-specific prescription from a practitioner.
- **Nicotine replacement tobacco cessation therapy –** This protocol is being drafted, and updates will be on the Board's website as they are available.
- **Immunizations –** During the 2018 legislative session, the IAC section authorizing pharmacists to administer immunizations under a physician-signed protocol was repealed, effective July 1, 2019. Pharmacists may continue, only until July 1, 2019, to practice under a physician-signed protocol. Once the Board's statewide protocol is approved and rules are adopted and effective, pharmacists will be able to practice under the Board's protocol.

PMP Changes in the Pipeline

House File (HF) 2377, commonly referred to as the "Opioid Bill," was signed into law on July 1, 2018, and numerous provisions of the bill require specific action be taken by the Board's prescription monitoring program (PMP). As a result, the Board's Rules Committee has drafted an entire revision to IAC 657 – Chapter 37: Iowa Prescription Monitoring Program to accommodate the bill requirements and update aging information. The proposed chapter revision will begin its way through the rulemaking process before the end of 2018, yet the rules would not be officially effective until late March 2019. Nevertheless, to ensure future compliance with and comprehension of new requirements and anticipated changes, it is important to be apprised of the following:

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National Pharmacy Compliance News

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NABPF
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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.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants,* which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at *www.samhsa.gov*.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.*

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at *www.ema.europa.eu.*

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids,* with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services,* describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.*

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability,* FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at *www.fip.org/news_publications.*

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017," can be accessed at *http://dx.doi.org/10.15585/mmwr.mm6709e1.*

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- Opioid antagonists dispensed by a pharmacy pursuant to a prescription or standing statewide protocol must be reported to the PMP.
- The record of each reportable prescription submitted to the PMP by a pharmacy or dispensing practitioner must include the patient's **legal** first and last names. Nicknames and familiar names are not acceptable.
- Pharmacists involved in patient care will be required to obtain a PMP user account.
- The cap of six delegate users per practitioner will be lifted and changed to allow an "adequate number of health care professionals that actively work with the practitioner" to be approved.
- If patients believe information within their PMP record is false or erroneous they are to notify the pharmacy that submitted the information and the pharmacy must correct any errors that are validated.
- Proactive notifications may be disseminated by the Board to practitioners, both prescriber and dispensers, involved in the care of a patient who meets or exceeds identified threshold values that commonly correlate to prescription abuse or misuse.

HF 2377 also mandates that any prescriber who prescribes, administers, or dispenses controlled substances (CS) must maintain a PMP user account and query the PMP prior to issuing an opioid prescription. Each professional board that licenses CS prescribers is tasked with drafting and implementing administrative rules that specifically define the requirement to query the PMP. The *Iowa Administrative Bulletin* (IAB) is published on a biweekly basis and contains all proposed and adopted changes to the rules in the IAC. The IAB can be accessed at *www.legis.iowa.gov/law/administrativerules/bulletinsupplementlistings.*

Additionally, you can receive email updates on selected rulemaking documents or agency chapters or rules by subscribing to "Bills and Rules Watch" at *www.legis.iowa.gov/subscribe.*

Online License and Registration Renewals

The Board has converted its legacy licensing database to iGov Solutions, LLC's licensing and enforcement management system, also known as iLEMS. You may now log on to *https://iowa.igovsolution.com/iboponline/user_login.aspx* and create a user profile. Through this portal individuals can manage personal information online, including updating addresses and employment information.

A cornerstone to this solution includes the provision for licensees and registrants to renew and pay for licenses and registrations online through their respective user profiles. This functionality is now active and live for **all** licenses and registrations.

Please visit the Board's website at *https://pharmacy.iowa.gov/licensureregistration* for additional online services, including license verification and to check the status of pending applications. Online capabilities will be extended to new applicants beginning in the first quarter of 2019.

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Andrew Funk, PharmD - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Amy Suhajda - Communications Manager