



State of Ohio Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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From the Director's Desk

Dear Ohio Pharmacist,

At its August meeting, the State of Ohio Board of Pharmacy welcomed some new faces and changes to the Board's structure. Beginning on July 1, 2018, Fred M. Weaver, BS, RPh, of Elyria, OH, became the Board president for state fiscal year 2019, and Shawn C. Wilt, RPh, of Toledo, OH, will now serve as the Board vice president for state fiscal year 2019. Both are members of the Ohio Pharmacists Association (OPA), and I look forward to continuing to work with them.

In June, D. Rich Miller III, BS, RPh, of Blacklick, OH, was appointed by Governor John Kasich to serve as a professional pharmacist member of the Board. A member of OPA, he brings over 10 years of experience in a retail pharmacy setting.

Other updates from the August meeting include the approvals of the following resolutions:

- ◆ The following pharmacy practice-specific specialty certification programs may now satisfy the continuing pharmacy education requirements for licensed pharmacists:
 - ◇ Board of Pharmacy Specialties in Cardiology Pharmacy
 - ◇ Board of Pharmacy Specialties in Compounded Sterile Preparations Pharmacy
 - ◇ Board of Pharmacy Specialties in Infectious Diseases Pharmacy
- ◆ The pharmacy technician training program requirement for programs to receive accreditation from the American Society of Health-System Pharmacists (ASHP)/Accreditation Council for Pharmacy Education (ACPE) was extended. This extension allows all programs to apply by February 15, 2019, to be considered compliant with Ohio Administrative Code (OAC) 4729:3-3-02. This rule requires all

pharmacy technician training programs to receive ASHP accreditation. ASHP accreditation is not required for programs that are employer-based, part of military training, or Ohio Department of Education-approved for high schools. All programs must be notified of their accreditation award no later than July 31, 2019.

If you have any questions about these changes, 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

Changes to Pharmacist CE Reporting Requirements

Effective September 16, 2018, [OAC 4729:1-5-02](#) updates the required minimum continuing education units (CEUs) pharmacists are required to obtain and aligns the reporting period to the biennial renewal cycle.

Specifically, pharmacists are required to obtain a minimum of 4 CEUs (40 hours) every two years prior to license renewal. Every pharmacist, no matter the license number, will be on the same reporting cycle beginning with the 2019 renewal.

Note: Only ACPE-accredited courses and continuing education (CE) from accredited in-state providers (law and provision of volunteer health care services) are accepted. Some examples of courses that are not accepted include continuing medical education and continuing legal education.

Important: Any CE credit that was granted **prior to September 16, 2018**, will still be accepted by the Board.

More information including CE requirements by reporting cycle can be found by visiting www.pharmacy.ohio.gov/ce.

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>.

Changes to Reporting Suspected Elder Abuse in Ohio

Effective September 29, 2018, Ohio Revised Code (ORC) 5101.63 will significantly expand the list of individuals mandated to report suspected elder abuse in Ohio.

The new individuals **mandated** to report suspected elder abuse in Ohio will now include:

- ◆ Pharmacists
- ◆ Employees of a home health agency, outpatient health facility, hospital, nursing home, residential care facility, health department, community mental health agency, fire department, emergency medical services organization, coroner, or county humane society.

The full list of who is required to report can be found by reviewing [ORC 5101.63](#).

To support these individuals in their new responsibilities, the Ohio Department of Job and Family Services developed training materials specifically for medical professionals on identifying and reporting elder abuse, and a general guide for Ohioans.

Understanding Elder Abuse: A Guide for Medical Professionals can be found [here](#).

Second and Third Quarter – Rule Update

The Board has posted a second and third quarter rule update guidance document, which can be found [here](#). Additionally, anyone can subscribe to the Board's website updates [here](#).

Use of Key Boxes by First Responders

It has come to the Board's attention that some fire departments around the state are utilizing "key boxes," commonly referred to as a "knox box," on structures that are occupied by Ohio-licensed pharmacies. The key boxes have been placed at these locations to give immediate access to the pharmacy when it is necessary in emergency situations.

The Board would like to clarify that, in certain situations, the use of key boxes conflicts with Ohio laws and rules governing the supervision and control of dangerous drugs in a pharmacy.

Please be advised that if your pharmacy does not secure dangerous drugs in its possession in a physical space or cabinet that can be accessed only by a pharmacist, and you are utilizing the key box system, you must immediately

discontinue the use of a key box system. The pharmacy key must be removed from the key box and returned to the pharmacy's responsible person. This includes pharmacies that do not have a physical space or barrier separating drug stock from store front (ie, "open air").

If your pharmacy has dangerous drugs secured with a barrier and lock system separately, and the drug stock cannot be accessed by anyone entering the pharmacy via the key box, then the use of a key box is permitted.

To review the full guidance document issued by the Board, please visit the Board's website [here](#).

OARRS Update

Ohio's colleges and universities now have access to a new training program designed to simulate the use of the state's prescription drug monitoring program, Ohio Automated Rx Reporting System (OARRS), with the release of OARRS Academy, a demonstration system designed to educate students in the health care professions on the process and value of including OARRS in the professional decision-making process.

OARRS Academy is the first of its kind in the country and will provide Ohio students with an opportunity to simulate the use of OARRS in the classroom setting. The simulation comes preloaded with data for a variety of sample patients and allows for the creation of additional sample patients. This tool is available at no cost to all Ohio colleges and universities engaged in the training of pharmacists and prescribers.

To assist faculty and students in utilizing OARRS Academy, the Board has developed the following website: www.oarrsacademy.ohio.gov. This site includes resources and downloads to maximize the use of the system and instructions on how to obtain access.

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