



STATE OF OHIO BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

From the Director's Desk

In July 2022, the National Suicide Prevention Lifeline (1-800/273-8255) transitioned to the 988 Suicide & Crisis Lifeline. Ohioans who are experiencing a mental health or addiction crisis, and their family members, can call, chat, or text the 988 number to reach a trained counselor who can offer help and support.

Moving to the easy-to-remember, three-digit number will provide greater access to lifesaving services. The Ohio Department of Mental Health and Addiction Services has been planning for this transition over the last 18 months to ensure that Ohio is ready for 988.

The new 988 direct line builds on the existing National Suicide Prevention Lifeline system and provides 24/7, free, and confidential support to Ohioans in a behavioral health crisis. It is a direct connection to compassionate, accessible care and support for anyone experiencing mental health-related distress – whether that is thoughts of suicide, mental health or addiction concerns, or any other kind of emotional distress.

Research shows that most calls to the Lifeline can be managed and resolved through a consultation on the phone; however, if a person needs an emergency, in-person response, 988 counselors are trained to connect the person in crisis with a mobile response team, which may be a behavioral health team or first responder team (or a combination of both) who will meet the person at their place of crisis. For more information, please visit www.pharmacy.ohio.gov/988.

National Pharmacy Compliance News

A Service of the National Association of Boards of Pharmacy Foundation (NABPF)

Visit NABP's website for the latest regulatory updates and news from FDA, USP, NABP, and more.

[Read National News](#)

On behalf of the State of Ohio Board of Pharmacy, all pharmacists are encouraged to take care of their mental health and make use of these important resources.

Sincerely,

Steven W. Schierholt, Esq

Executive Director

State of Ohio Board of Pharmacy

Pharmacists Dispensing Nicotine Replacement Therapy

Pharmacists are now permitted to dispense nicotine replacement therapy (NRT) pursuant to a physician-approved protocol. NRT is defined in the Ohio Revised Code (ORC) as “a drug, including a dangerous drug, that delivers small doses of nicotine to an individual for the purpose of aiding in tobacco cessation or smoking cessation,” as well as the cessation of alternative nicotine delivery systems, such as e-cigarettes.

A pharmacist must successfully complete a course on NRT in order to dispense NRT. Unless otherwise approved by the Board, training courses must be taught by a provider accredited by the [Accreditation Council for Pharmacy Education](#).

For more information, please visit www.pharmacy.ohio.gov/NRT.

Free Law Continuing Education Activity – Dispensing Naloxone in Ohio Without a Prescription: What Pharmacy Personnel Need to Know

The continued opioid epidemic across the United States has made it more important than ever to destigmatize opioid addiction and make naloxone products readily available to people in need. This continuing education (CE) activity focuses on basic information on the dispensing of naloxone products in pharmacies by registered pharmacists or pharmacy interns in the state of Ohio without a prescription pursuant to a physician-authorized protocol. This CE activity provides one contact hour (0.1 CEU) of CE in jurisprudence (law) for pharmacists and registered pharmacy technicians. For more information, visit www.pharmacy.ohio.gov/naloxonereview.

Nonresident Compounding Pharmacy and Outsourcing Facility Responsible Person Requirements

Responsible pharmacists listed on a license application for a nonresident compounding pharmacy or outsourcing facility are now required to hold an Ohio pharmacist license in active status prior to the issuance of the terminal distributor or outsourcing facility license.

Because of delays in background check processing, if a responsible pharmacist on a nonresident compounding pharmacy license submits a completed application for reciprocity, they are considered to be compliant with the extended June 1 deadline.

For more information on nonresident compounding pharmacy requirements and pharmacist licensure via reciprocity, visit www.pharmacy.ohio.gov/NRPcompound.

Drug Shortage Guidance

Because of supply chain issues, hospitals, clinics, and other health care facilities may experience shortages of drugs necessary to care for patients. The Board has developed a [guidance document](#) to assist licensees in obtaining drugs that may not be commercially available from manufacturers or wholesalers from Ohio-licensed outsourcing facilities.

CE Opportunities in Cultural Competency for Pharmacy Professionals

Although it can be defined in numerous ways, cultural competency in pharmacy practice is generally a complex integration of knowledge, attitudes, and skills that promotes effective communication and appropriate interactions with patients from various ethnic and/or cultural groups.

Cultural competency can foster a greater understanding and appreciation of diverse patient populations, giving pharmacy professionals additional information to enrich patient care. The skills developed with cultural competency allow health care providers to understand and respect a patient's cultural identity.

The Board has developed a [guidance document](#) to assist pharmacy professionals in locating existing CE courses addressing cultural competency. While there is no requirement to complete CE related to this subject, the Board strongly encourages its licensees to consider these important learning opportunities.

Healthcare Distribution Alliance's Pharmaceutical Cargo Security Coalition Warning on Fraud Incidents

Healthcare Distribution Alliance's Pharmaceutical Cargo Security Coalition (PCSC) issued a warning to the pharmacy industry earlier this year regarding product ordering/recall fraud incidents, several of which have resulted in losses. PCSC recently issued an updated [warning](#) to inform licensees of current trends. While there continue to be attempts at fraud, law enforcement and corporate security investigations into these incidents continue on multiple levels as well.

Please note the following trends related to the schemes:

- The perpetrators continue to convince distribution representatives (both in wholesale and retail environments, as well as over the phone and electronically) that they are making legitimate inquiries about drug shipments.
- The credentials the perpetrators are supplying are real, having obtained them through a variety of social engineering techniques.
- A fair number of retail pharmacies are now receiving telephone calls from individuals identifying themselves as being from a state board of pharmacy or a state health department. In these scenarios, the person calling (who is almost always female) asks the pharmacy representative for specific routine and disarming information, such as address, hours of operation, phone numbers, principal contacts, etc.

- The names used by the female callers to identify themselves include “Julie McNeil,” “Cynthia,” “Beth,” “Beth Walton,” and “Danielle.”
- The caller eventually asks questions about the names of the pharmacy’s primary and secondary wholesalers, the type(s) and cadence of their business interactions with their wholesalers, and, in some instances, account numbers.
- On some calls, the perpetrator uses the excuse that the board of pharmacy needs such information because it is responsible for notifications of recalls.

If a licensee receives such an inquiry, PCSC suggests the following:

1. do not answer any questions;
2. indicate to the caller that someone will call them back;
3. try to get a name and callback number;
4. hang up; and
5. immediately contact the pharmacy’s known principal contact at the board of pharmacy or health department to report the incident.

Additionally, PCSC requests that these instances be reported to cforsaith@hda.org so they can be shared with law enforcement.

2022 Law and Responsible Person Review Virtual Presentations

The Board announced dates for the 2022 Law and Responsible Person Review Virtual Presentations, which will highlight the latest developments in pharmacy laws and rules.

These presentations will count for 1 credit hour toward pharmacy jurisprudence CE. To register, please visit this [link](#). You will need to provide your name, license type and number, presentation date, NABP e-Profile ID number, phone number, and employer.

2022 law review topics will include:

- Updated state laws and regulations for terminal distributors of dangerous drugs
- Pharmacy technician updates
- Board coronavirus disease 2019 (COVID-19) response efforts
- Pharmacy compounding rules

Responsible person roundtable topics will include:

- Duties of a responsible person
- General provisions of a terminal distributor of dangerous drugs
- Duty to report
- Know your resources

Who should attend?

- Pharmacists, pharmacy interns, registered or certified pharmacy technicians, and pharmacy compliance staff employed in outpatient/community-based pharmacies.

ASHP Launches Recruitment for Well-Being Ambassadors

The American Society of Health-System Pharmacists (ASHP) Well-Being Ambassador Program is a grant-funded, curriculum-based, virtual learning community that empowers local action, particularly in tribal, rural, and underserved areas, to mitigate occupational burnout in the pharmacy profession and support local implementation of well-being strategies.

The program consists of pharmacists, pharmacy technicians, pharmacy residents, and pharmacy students. Members complete a professional certificate to inform local strategies that foster well-being and resilience to create a network of ambassadors and expert implementation coaches to support local cultures of well-being.

To learn more or sign up for the ASHP Well-Being Ambassador Program, visit wellbeing.ashp.org.

CDC Requires Use of Digital Data Logger to Monitor Temperatures in Units That Hold COVID-19 Vaccine

On May 10, 2022, the Centers for Disease Control and Prevention (CDC) sent a communication indicating that provider locations enrolled in the COVID-19 Vaccination Program **must** use a digital data logger (DDL) to monitor temperatures in all storage units that hold COVID-19 vaccines; this includes units used for transport of COVID-19 vaccines.

All COVID-19 vaccination providers should obtain a DDL if they have not already done so. Because of supply chain delays and shortages, allowances were made in 2021 for COVID-19 Vaccination Program providers having difficulty obtaining DDLs. However, at this time, DDL supply chain issues should be resolved, and all COVID-19 vaccination providers are required by the CDC to obtain a DDL per storage unit.

DDLs are the gold standard for temperature monitoring and help to ensure that all vaccines are stored according to the manufacturer recommendations. This adds confidence that all COVID-19 doses being administered in Ohio are viable and effective in providing vaccine recipients with protection against COVID-19 disease.

DDLs should have the following features:

- Detachable probe that best reflects vaccine temperatures (eg, a probe buffered with glycol, glass beads, sand, or Teflon)
- Alarm for out-of-range temperatures
- Low-battery indicator

- Current, minimum, and maximum temperature display
- Recommended uncertainty of +/-0.5°C (+/-1°F)
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes
- A current and valid Certificate of Calibration Testing

More information about DDLs for COVID-19 vaccines can be found in the [CDC Vaccine Storage and Handling Toolkit](#).

Guidance Document Information for DEA Registrants

Drug Enforcement Administration (DEA) released information regarding DEA's use of guidance documents, specifically why DEA is utilizing guidance documents, where to find DEA's guidance documents, and the status of certain policy directives or regulatory interpretations issued by DEA prior to the establishment of its [Guidance Document Portal](#).

For more information regarding DEA's Diversion Control Division, please visit <https://www.deadiversion.usdoj.gov>. Please contact the Diversion Control Division, Policy Section at 571/362-3260 if you seek additional assistance regarding this issue or any other matter involving DEA.

Dispensing of an Emergency Refill of Medication Without a Prescription

[Section 4729.281 of the ORC](#) authorizes a pharmacist to dispense medications without a prescription under certain conditions. On June 1, 2022, this law was further amended to make the following changes:

- Increases from one to three the number of times that a pharmacist may dispense certain refills without a prescription to a specific patient within a 12-month period.
- Requires a health insurer to cover prescription drugs dispensed under the act if those drugs are already covered under the insurer's health benefit plan and prohibits the insurer from imposing a cost-sharing requirement that is greater than that imposed on a drug dispensed with a prescription.

For questions regarding the dispensing of an emergency refill, please review the [guidance document](#) posted on the Board's website.

Update: Pharmacist Workload Advisory Committee

In 2021, the Board created the Pharmacist Workload Advisory Committee (PWAC) to ensure compliance with the following Ohio laws and rules:

- [Section 4729.55 of the ORC](#), which states: "Adequate safeguards are assured that the applicant will carry on the business of a terminal distributor of dangerous drugs in a manner

that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner.”

- Rules [4729:5-5-02](#) and [4729:5-9-02.1](#) of the Ohio Administrative Code, which state: “The pharmacy shall be appropriately staffed to operate in a safe and effective manner pursuant to section 4729.55 of the Revised Code.”

The PWAC began meeting in October 2021 to review potential options to improve working conditions in pharmacies with the goal of protecting the health and safety of Ohioans.

During the initial meetings, committee members were asked to provide actionable policy recommendations that would be reviewed by the committee. For more information on this process, visit www.pharmacy.ohio.gov/PWACdraft.

As a result of the recommendations, the Board distributed a policy survey to Ohio pharmacists. The results of this survey can be accessed using the following links:

- [Pharmacist Survey Responses - PWAC Policy Options by Practice Type](#)
- [Pharmacist Survey Responses - PWAC Policy Options](#)

The Board is currently analyzing the results of the survey responses to develop policies that support Ohio’s pharmacy personnel. For more information on the work of the PWAC, visit www.pharmacy.ohio.gov/PWAC.

Mandatory Electronic Prescribing of Schedule II CS

On **September 23, 2022**, Ohio [House Bill 193](#) went into effect. This law establishes the requirement that a prescriber issue an electronic prescription when prescribing a Schedule II CS, but also allows for issuance of a written prescription in specified circumstances.

To assist licensees in complying with the provisions of this law, the Board developed a [frequently asked questions document](#) that can be found on the Board’s website.

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Steven W. Schierholt, Esq - State News Editor

Lemrey “Al” Carter, PharmD, MS, RPh - National News Editor & Executive Editor

Megan Pellegrini - Publications and Editorial Manager

77 S High St, 17th Floor | Columbus, OH 43215-6126 | Tel: 614/466-4143 Fax: 614/752-4836 | www.pharmacy.ohio.gov
