



State of Ohio Board of Pharmacy

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From the Director's Desk

Dear Ohio Pharmacist,

At its June 2020 meeting, the State of Ohio Board of Pharmacy made several updates to previously issued waivers. Updates can be found starting on page five of the COVID-19 Response Efforts document, located at www.pharmacy.ohio.gov/COVID.

The updated waivers include:

- ◆ Authorizing temporary compounding of certain alcohol-based hand sanitizer products. As a reminder, compounders are not permitted to add other active or inactive ingredients, such as ingredients to improve the smell or taste due to the risk of accidental ingestion in children (eg, the use of essential oils).
- ◆ Mailing or delivery of non-controlled dangerous drugs personally furnished by prescribers. The updated guidance can be found by visiting www.pharmacy.ohio.gov/ncpf.
- ◆ Additional delay of drug distributor due diligence requirements. The Board has delayed all drug distributor due diligence requirements until November 29, 2020.

As a reminder, the full list of coronavirus disease 2019 (COVID-19)-related waivers can be found by visiting www.pharmacy.ohio.gov/COVID.

At this time, Board staff will continue to work remotely until further notice. Please be advised that it may take longer than usual to receive a response. If you have any questions, please do not hesitate to contact the Board via email at contact@pharmacy.ohio.gov, or by phone at 614/466-4143.

On behalf of the members of the Board, thank you for your ongoing efforts and care for the citizens of the state during this unprecedented public health event.

Sincerely,

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

Expansion of Pharmacy Personnel Testing Authority During COVID-19 – Updated May 27, 2020

On May 27, 2020, the Board issued an updated guidance on pharmacy personnel conducting COVID-19 testing. Specifically, it clarifies that pharmacists can order COVID-19 testing per guidance issued by the United States Department of Health and Human Services. To access the updated guidance, visit www.pharmacy.ohio.gov/COVIDtest.

Mailing or Delivery of Non-Controlled Dangerous Drugs Personally Furnished by Prescribers – Updated June 8, 2020

Authorizes a licensed terminal distributor of dangerous drugs (TDDD) to mail or deliver non-controlled drugs to patients who have been personally furnished by a prescriber who is employed or contracted by the terminal distributor. This guidance can be accessed [here](#).

Updates to Non-Pharmacy Inspection Guides

Recently, the Board issued updates to the following non-pharmacy inspection guides to include a new policy guidance that was issued at the June 2020 Board meeting:

- ◆ **Pain Management Clinics** – www.pharmacy.ohio.gov/PMCinspect

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National Pharmacy Compliance News

August 2020



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.

NABPF

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of Pharmacy Foundation

FDA Releases MOU on Human Drug Compounding Regulation and Oversight

Acknowledging the vital role states play in reducing the risks associated with compounded drugs, Food and Drug Administration (FDA) has made available a [Final Standard Memorandum of Understanding \(MOU\) Addressing Certain Distributions of Compounded Human Drug Products](#), intended to be entered into between the agency and the states. The release of the MOU is required as part of its [submission to the Office of Management and Budget](#) for review and clearance under the Paperwork Reduction Act of 1995. The MOU was developed in close [consultation with the National Association of Boards of Pharmacy® \(NABP®\)](#), as described in the Federal Food, Drug, and Cosmetic Act. The agency also engaged with states, pharmacies, associations, pharmacists, and other stakeholders.

Among the issues addressed in the MOU is the definition of the statutory term “inordinate amounts,” which refers to compounded drugs that are distributed interstate. In addition, the MOU includes the risk-based oversight model from the 2018 revised draft MOU. States that sign the document agree to identify pharmacy compounders that distribute inordinate amounts (greater than 50%) of compounded drug products interstate, as well as report certain information to FDA about those compounders. FDA also provided clarity in the MOU on state investigations of complaints associated with compounded drugs distributed out of state. States that enter into the MOU will investigate complaints about drugs compounded at a pharmacy within their state and distributed outside of the state and advise FDA when they receive reports of serious adverse drug experiences or serious product quality issues, like drug contamination.

To help states to better investigate these issues, FDA has also announced an agreement with NABP to make an information sharing network available to the states. Through this network, states will be able to obtain information from pharmacies in their states and transmit that information to FDA.

“We anticipate the final MOU, once signed, will help to facilitate increased collaboration between the FDA and the states that sign it,” said Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, in an [FDA Voices](#) article. “Working together, we can

help promote quality compounding practices and better address emerging public health concerns that may affect patients.”

FDA Clarifies Compounding Rules, Offers Flexibility to Help Ease Drug Shortages During COVID-19 Pandemic

FDA noted it will use discretion in enforcing certain standards related to 503A and 503B compounding in an effort to ease drug shortages during the coronavirus disease 2019 (COVID-19) pandemic. During an American Pharmacists Association (APhA) webinar on April 30, 2020, the agency clarified it will “look to 503B compounders to grapple with drug shortages” and “turn to 503A compounders to fill in the gaps.”

In addition, the agency clarified that medications on the FDA drug shortage list are effectively considered “not commercially available,” which frees 503A and 503B compounding facilities from limits on compounding drugs that are “essentially a copy” of a product already available on the market. FDA also does not intend to take action if a 503A facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

In April 2020, FDA issued a temporary guidance that granted flexibility for pharmacists to compound certain necessary medications under 503A for nonspecific patients hospitalized due to COVID-19. In addition, a temporary guidance was issued that granted enforcement flexibility for 503B outsourcing compounding facilities for drugs in shortage for patients hospitalized during the COVID-19 public health emergency. The guidance documents stipulate the conditions compounders must meet and are available at <https://www.fda.gov/media/137125/download>.

More information on these compounding rule clarifications is available in a May 5, 2020 press release on the [APhA website](#).

CMS Allows Pharmacies to Temporarily Enroll as Clinical Diagnostic Laboratories for COVID-19 Testing

Centers for Medicare & Medicaid Services (CMS) has released a document detailing a process that allows pharmacies to temporarily enroll as independent clinical diagnostic laboratories. This process will allow those

facilities to seek Medicare reimbursement for COVID-19 tests, making it easier for them to provide that service during the pandemic.

“Up until this point in time, most pharmacies could only offer this as a cash service because they were not considered providers through CMS, and really a lot of the third-party payers really didn’t have an interest in a fee-for-service type model,” said Michael E. Klepser, PharmD, FCCP, pharmacy professor at Ferris State University, in an interview with *Bloomberg Law*. “The fact that CMS is saying we’re now authorizing or allowing pharmacists to get reimbursed for these is a great door opening at the federal level and that’s a huge, huge thing.”

Chain pharmacies such as CVS, Walgreens, and Rite Aid are offering drive-through testing at many pharmacies throughout the country.

FDA Issues Updated Guidance for Compounding Pharmacies Experiencing PPE Shortages

FDA has issued an update for its guidance to pharmacy compounders that may experience shortages of personal protective equipment (PPE) during the COVID-19 pandemic. As compounders typically utilize PPE when performing sterile compounding, the updated guidance clarifies that the drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom. This policy has been adopted to ensure patients continue to have access to medicines they need during the pandemic, and to reduce the risks of compounding when standard PPE is not available.

In addition to FDA guidance, United States Pharmacopeial Convention has previously issued an informational document for compounders regarding garb and PPE shortages during the pandemic. The document includes recommendations for conserving garb and PPE and what steps might be considered in the case of shortages of garb and PPE used for both sterile and nonsterile compounding.

The updated guidance can be accessed through FDA’s website by visiting www.fda.gov/media/136841/download.

HHS Expands Telehealth Access in Response to COVID-19

In an effort to prevent and respond to the COVID-19 pandemic, the US Department of Health and Human

Services (HHS) has awarded \$20 million to increase telehealth access and infrastructure for health care providers and families. The funds, which are awarded through the Health Resources and Services Administration (HRSA), will increase capability; capacity and access to telehealth and distant care services for providers, pregnant women, children, adolescents, and families; and assist telehealth providers with cross-state licensure.

“This new funding will help expand telehealth infrastructure that is already being used during the pandemic to provide essential care, especially to the most vulnerable, including pregnant women and children with special health care needs,” said HHS Secretary Alex Azar in a press release. “This funding will also help clinicians use telehealth nationally by streamlining the process to obtain multi-state licensure.”

HRSA’s Maternal and Child Health Bureau awarded a total of \$15 million to four recipients; each award supports a key area in maternal and child health, including pediatric care, maternal health care, state public health systems, and family engagement for children with special health care needs. HRSA’s Federal Office of Rural Health Policy awarded a total of \$5 million to two recipients through the Licensure Portability Grant Program, which will assist telehealth clinicians nationally on licensure and credentialing to meet emerging needs related to COVID-19.

Criminals Found Posing as CDC Representatives to Steal Money and Information

Centers for Disease Control and Prevention (CDC) is warning the general public of a new type of phone and phishing scam by criminals posing as CDC representatives, often requesting donations. According to CDC, most of these fraudulent activities are being conducted by phone, utilizing software to “spoof” phone calls to make them appear as if they are coming from phone numbers that may look familiar. CDC advises consumers to avoid answering calls from numbers they do not recognize, and to avoid sharing personal information over the phone. In addition, CDC notes that no federal agency will request donations from the general public. Suspicious phone calls may be reported to the Federal Communications Commission.

More information on the scams is available on the CDC website at <https://www.cdc.gov/media/phishing.html>.

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- ◆ **First Aid Departments** – www.pharmacy.ohio.gov/FAinspect
- ◆ **Animal Shelters** – www.pharmacy.ohio.gov/ASinspect
- ◆ **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/OTPininspect
- ◆ **Non-limited Facilities** – www.pharmacy.ohio.gov/NLFinspect
- ◆ **Limited Facilities** – www.pharmacy.ohio.gov/LFinspect

Licensees are reminded that all updates to the guides are included in the “Update History” page located at the end of each guide.

Important Notice to All Licensees Regarding Fraudulent Prescriptions

The Board has been made aware of an increasing number of fraudulent prescriptions for promethazine/codeine being dispensed at this time.

These fraudulent prescriptions are generated using two primary techniques.

- ◆ **Phone-in prescriptions:** Suspects will download apps to generate VoIP phone numbers, which are then used to impersonate prescribers and fictitious patients. The suspects then call pharmacies and order promethazine/codeine, accompanied with a non-controlled substance (CS) such as Flonase®, an inhaler, prednisone, or an antibiotic. The suspect provides a Drug Enforcement Administration (DEA) number, a National Provider Identifier number, and in many instances, a diagnosis code. The caller also provides a generated number for the “patient.” Unsuspecting pharmacies then call the “patient” once the prescription is filled, and the “patient” typically tells the pharmacy that a relative will pick it up. Pharmacies sometimes call the number left for the prescriber to verify that the prescription is valid, and they end up speaking with the suspect again.

- ◆ **Paper prescriptions:** Suspects may produce fraudulent prescriptions on valid Rx paper.

To help combat these fraudulent prescriptions, it is recommended that pharmacies verify promethazine/codeine prescriptions with the practitioner’s office by means other than the phone numbers provided on the prescriptions.

Pharmacies and/or pharmacists should report all incidents of prescription fraud to the Board, and they must report such activity to local law enforcement.

Reports to the Board may be filed online by visiting www.pharmacy.ohio.gov/complaint.

Temporary Authorization to Move Dangerous Drugs in the Event of an Emergency – Updated June 1, 2020

To address emergency situations where a TDDD is unable to maintain the security of its drug stock, the Board has issued guidance authorizing the temporary movement of drug stock to another in-state location.

The guidance has been updated to remind Board licensees who are also registered with US DEA that they must also notify the local DEA field office of any situations involving the security of CS or the temporary relocation of any CS to another location.

To access the updated guidance, visit www.pharmacy.ohio.gov/TempMove.

Outpatient Pharmacy Inspection Guide Request for Comments on Outpatient Inspection Guide

On December 1, 2020, new rules for outpatient pharmacies (Chapter 4729:5-5 of the Administrative Code) go into effect.

To assist licensees in complying with the new rule chapter, the Board recently published an outpatient inspection guide that may be accessed using the following short link: www.pharmacy.ohio.gov/OPinspect.

The inspection guide aligns with internal guidance used by Board inspectors and allows licensees to conduct self-inspections to ensure compliance. The guide also includes links to the new rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board.

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To provide further guidance to licensees, the Board has opened a comment/question period for the inspection guide. This comment period will be open until **August 21, 2020**. Following the conclusion of this comment period, the Board will review all comments and attempt to address or clarify any issues within the guide.

Comments/questions on the outpatient pharmacy inspection guide may be sent to RuleComments@pharmacy.ohio.gov.

Outpatient Inspection Guide Continuing Education Opportunity

To assist with the implementation of the new rules, the Board has developed a one-hour jurisprudence quiz. The quiz is intended to test the participant's knowledge of the new outpatient pharmacy rules and provides one contact hour of (0.1 CEU) Board-approved jurisprudence (for pharmacists and registered pharmacy technicians). For more information, visit www.pharmacy.ohio.gov/OPquiz.

Temporary Extension of Basic Life-Support Requirements – Updated July 28, 2020

To address limited access to basic life-support training recertification, the Board has adopted the following guidance regarding certifications maintained by Ohio pharmacists and pharmacy interns.

Pharmacists and pharmacy interns whose basic life-support training certification is set to expire on or after

March 1, 2020, will be permitted to continue to administer immunizations and dangerous drugs in accordance with section 4729.41 under the following conditions:

- ♦ The pharmacist or intern maintains documentation demonstrating their basic life-support training certification expired on or after March 1, 2020.
- ♦ The pharmacist or intern obtains recertification **no later than December 1, 2020 (formerly July 29, 2020)**.

Important: Unless circumstances warrant, the Board **does not** expect to extend this requirement past the new December 1, 2020 deadline. Licensees should plan to have their basic life-support training recertification current by December 1, 2020.

A copy of this updated waiver can be accessed by visiting <http://www.pharmacy.ohio.gov/BLS2020>.

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