Institutional Pharmacy and Facility Rules - Effective 12/1/2021

Effective December 1, 2021, new rules for institutional pharmacies and facilities (Chapter 4729:5-9 of the Administrative Code) go into effect. This guide applies only to locations licensed as terminal distributor of dangerous drugs that meet the following definition of an “institutional pharmacy” or “institutional facility” in rule 4729:5-9-01 of the Ohio Administrative Code.

To assist licensees in complying with the new rule chapter, the Board recently published an institutional inspection guide that can be accessed using the following short link: www.pharmacy.ohio.gov/IPFinspect. It is also accessible via the Board’s TDDD licensing page: https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx.

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.

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 20, 2021. 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 institutional pharmacy/facility inspection guide may be sent to: RuleComments@pharmacy.ohio.gov

Request for Comments – COVID-19 Waivers

To address the COVID-19 pandemic, the State of Ohio Board of Pharmacy authorized operational waivers for licensees. With the removal of Ohio’s emergency order in June, the Board is currently reviewing the waivers to determine when/if they should be rescinded.

To assist in this process, the Board is asking its licensees to review the list of waivers and determine which waivers licensees would like to maintain or even make permanent. Please be advised that some waivers were omitted from the list because: they are based on a federal action, the Board is already proceeding with a rule to make the waiver permanent (e.g., remote technician entry), or the waiver had already expired.

All comments on the waivers should be sent to RuleComments@pharmacy.ohio.gov by COB 8/6/2021.

The comments should include the following:

- Name of licensee (or an organization representing licensees);
- Identification of the waiver; and
- Rationale for extending or making it permanent (including suggestions for improvement if recommending it be made permanent).

As a reminder, to allow for licensees to adjust business operations accordingly, the State of Ohio Board of Pharmacy shall provide a minimum of 30 days’ notice prior to the rescission of any resolutions or waivers issued due to the COVID-19 pandemic. The 30-day notice requirement does not apply to any resolution that is based upon authorization of a federal agency or the Governor of the State of Ohio.

Inspection Guide Updates

The following inspection guides were recently updated by the Board:
Prescriber Compounding ([www.pharmacy.ohio.gov/PrescriberComp](http://www.pharmacy.ohio.gov/PrescriberComp))

Outpatient Pharmacy ([www.pharmacy.ohio.gov/OPinspect](http://www.pharmacy.ohio.gov/OPinspect))

To review updates, please see the update history section at the end of each document.

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### Updated Pharmacy Naloxone Patient Counseling Brochures

The patient counseling brochure for pharmacies dispensing naloxone has been updated to reflect newer formulations and also includes additional treatment referral resources. The updated brochure is only available in English but is being translated into several other languages. As a reminder, the patient brochure and other naloxone resources are available here: [www.pharmacy.ohio.gov/naloxone](http://www.pharmacy.ohio.gov/naloxone)

As a reminder, copies of the patient counseling brochure are available free-of-charge from the Board by sending a request with all of the following information to contact@pharmacy.ohio.gov:

- Name of Requestor
- Pharmacy Name
- Mailing Address
- Phone Number
- Quantity Requested (there is a 250 pamphlet limit but additional requests can be made if the pharmacy is running low)

Please allow 7-10 days for delivery from the date of the request.

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### Pharmacist and Pharmacy Intern Renewal Began on July 17th

License renewal began on Saturday, July 17, 2021. Any license renewed after the expiration date of September 15, 2021, will be assessed a late fee.

More information about renewal can be found here:

- Pharmacist License Renewal
- Pharmacy Intern License Renewal

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### Ohio Physicians Health Program (OPHP) Survey

The Ohio Physicians Health Program (OPHP) is conducting a statewide COVID-19 well-being survey. The purpose of this study is to gather the perspectives of health care professionals on the types of services needed to support well-being and the infrastructure needed to provide easy accessibility. Your insight will not only benefit the current system of support for health care professionals, but also better equip Ohio for future crises.

OPHP provides an environment for health care professionals to receive confidential services to improve their health and well-being. Understanding the current status of stress, burnout, compassion fatigue, and physical exhaustion for health care professionals is critical. It is necessary to gain a better understanding of what types of supportive services are most desired and how to help those services be more accessible and less stigmatized. OPHP has partnered with the evaluation team at Mighty Crow to design this survey and analyze the results. This survey is being funded through a grant from the Federation of State Medical Boards.

Your input is greatly appreciated. Your answers will help better inform OPHP and its partners as they work to improve services for health care professional health and well-being. The survey will take approximately 10 minutes to complete.

Please complete the survey by August 5. The survey can be found [here](http://example.com).

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### Participate in National State-based Pharmacy Workplace Survey

APhA and the National Alliance of State Pharmacy Association (NASPA) have developed a national state-based pharmacy workplace survey that is open to all pharmacy personnel. The survey is anonymous and takes only 10 minutes. The deadline to complete the survey is August 31.

The survey can be found [here](http://example.com).

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### Reminder: 2021 Virtual Law Reviews and Responsible Person Roundtables


Join the State of Ohio Board of Pharmacy for a presentation to learn about the latest developments in pharmacy law and rules.

Law Review topics will include:
- New requirements for terminal distributors of dangerous drugs
- New outpatient pharmacy rules and inspection guide
- State of Ohio Board of Pharmacy COVID-19 response efforts
- Pharmacy compounding rules & implementation plan

Responsible Person Roundtable topics will include:
- Duties of a responsible person
- General provisions applicable to a terminal distributor of dangerous drugs
- Duty to report requirements
- Additional compliance resources

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

More information can be found [here](#).

Please note that if you choose to unsubscribe from receiving emails, this unsubscribes you from all emails that are sent by the State of Ohio Board of Pharmacy, including renewal reminders. If you believe you have unsubscribed in error, please email contact@pharmacy.ohio.gov for assistance. If you would like to change the email address, please log into your eLicense Ohio account to update the email address on file.