April 2025 – Rules and Resolutions

Resolutions

NOTE: All resolutions that are starred (*) were initially authorized by the Board President pursuant to resolution R-2022-0128.

1) Extension of IV Fluid Hang Times Inside an ISO Class 5 PEC*

This resolution extends the time of a punctured conventionally manufactured product in an ISO Class 5 PEC for Ohio hospitals licensed as terminal distributors of dangerous drugs.

1. As used in this resolution, "a conventionally manufactured pharmacy bulk package" means a container of a sterile product for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program that are restricted to the sterile preparation of admixtures for infusion or, through a sterile transfer device (i.e., closed system transfer device or iv spike adapters with needle-free connection) for the filling of empty sterile containers.

2. The conventionally manufactured pharmacy bulk package must be entered or punctured only in an ISO Class 5 PEC and maintained within the PEC.

3. The conventionally manufactured pharmacy bulk package may be used up to 24 hours after initial entry or puncture, unless the manufacturer's instructions specifically permit a timeframe longer than 24 hours.

4. An Ohio hospital utilizing this resolution shall only do so to minimize supply disruptions of IV and peritoneal dialysis solutions.

This resolution was authorized by the Board President in accordance with a Board resolution adopted on May 5, 2020. It shall remain in effect until June 1, 2025, unless rescinded earlier by the Board.

2) Designating Hospice Programs as Institutional Facilities

Pursuant to OAC 4729:5-9-01 (A)(11), the Ohio Board of Pharmacy hereby designates all hospice care programs licensed in accordance with ORC 3712.04 as institutional facilities for the purposes of licensure and enforcement. Hospice programs may still operate under the Board's existing non-limited facility rules (OAC 4729:5-22) until as such proposed amendments are finalized in OAC 4729:5-22-01.

Rules – For Filing with CSI and JCARR

Rule 4729:5-5-01 Definitions - outpatient pharmacies. (AMEND)

(I)

(1) "Positive identification" means a method of identifying a person that does not rely on the use of a private personal identifier such as a password, but must use a secure means of identification that includes any of the following, as authorized under this chapter of the Administrative Code:

(a) A manual signature on a hard copy record;

(b) A magnetic card reader;

(c) A bar code reader;

(d) A biometric method;

(e) A proximity badge reader;

(f) A board approved system of randomly generated personal questions;

(g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who performed the action requiring positive identification. The printout must be maintained for three years and made readily retrievable; or

(h) Other effective methods for identifying individuals that have been approved by the board.

(2) A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier ~~for entry into a secure mechanical or electronic system~~.

Rule 4729:5-3-04 - Verification of licensure prior to sale or purchase. (AMEND)

…

(D) Paragraph (C) of this rule does not apply when a terminal distributor sells or distributes dangerous drugs at wholesale to any of the following:

…

(3) The sale, transfer, or distribution of dangerous drugs to an EMS organization from an institutional pharmacy or facility licensed as a terminal distributor of dangerous drugs that is owned or operated by a hospital for purposes of restocking an emergency medical services vehicle if the institutional pharmacy or facility conducts an annual query to ensure the EMS organization is properly licensed as a terminal distributor of dangerous drugs.

(4) An intracompany transfer made in accordance with rule 4729:5-3-09 of the Administrative Code, if the entity engaged in the transfer conducts an annual query to ensure each location is properly licensed as a terminal distributor of dangerous drugs.

Rule 4729:1-3-01 - Pharmacist administration of diagnostic tests. (NO CHANGE)

(A) A pharmacist may administer clinical laboratory improvement amendments (CLIA) waived diagnostic laboratory testing provided the following conditions are met:

(1) The pharmacy or facility licensed as a terminal distributor of dangerous drugs is certified by the United States department of health and human services (HHS), as a clinical laboratory through the CLIA;

(2) The pharmacy or facility licensed as a terminal distributor of dangerous drugs has obtained a CLIA certificate of waiver from HHS; and

(3) The responsible person of the terminal distributor of dangerous drugs and the terminal distributor of dangerous drugs ensures and documents that all pharmacists conducting CLIA waived tests pursuant to this rule receive appropriate training to conduct testing in a safe and effective manner.

(B) A pharmacist may evaluate the results of a test administered under this rule when advising a patient or a health care professional treating a patient if the test relates to the patient's drug therapy.

(C) This rule applies only to the administration and evaluation of laboratory testing by individuals licensed or registered in accordance with Chapter 4729. of the Revised Code.

Rule 4729:2-3-05 - Pharmacy intern administration of diagnostic tests. (NO CHANGE)

(A) A pharmacy intern under the direct supervision of a pharmacist may administer clinical laboratory improvement amendments (CLIA) waived diagnostic laboratory testing provided the following conditions are met:

(1) The pharmacy or facility licensed as a terminal distributor of dangerous drugs is certified by the United States department of health and human services (HHS), as a clinical laboratory through the CLIA;

(2) The pharmacy or facility licensed as a terminal distributor of dangerous drugs has obtained a CLIA certificate of waiver from HHS; and

(3) The responsible person of the terminal distributor of dangerous drugs and the terminal distributor of dangerous drugs shall ensure and document that all pharmacy interns conducting CLIA waived tests pursuant to this rule receive appropriate training to conduct testing in a safe and effective manner.

(B) A pharmacy intern under the direct supervision of a pharmacist may evaluate the results of a test administered under this rule when advising a patient or a health care professional treating a patient if the test relates to the patient's drug therapy.

(C) This rule applies only to the administration and evaluation of laboratory testing by individuals licensed or registered in accordance with Chapter 4729. of the Revised Code.

Rule 4729:3-3-05 - Certified pharmacy technician administration of diagnostic tests. (NO CHANGE)

(A) A certified pharmacy technician under the direct supervision of a pharmacist may administer clinical laboratory improvement amendments (CLIA) waived diagnostic laboratory testing provided the following conditions are met:

(1) The pharmacy or facility licensed as a terminal distributor of dangerous drugs is certified by the United States department of health and human services (HHS), as a clinical laboratory through the CLIA;

(2) The pharmacy or facility licensed as a terminal distributor of dangerous drugs has obtained a CLIA certificate of waiver from HHS; and

(3) The responsible person of the terminal distributor of dangerous drugs and the terminal distributor of dangerous drugs shall ensure and document that all certified pharmacy technicians conducting CLIA waived tests pursuant to this rule receive appropriate training to conduct testing in a safe and effective manner.

(B) This rule applies only to the administration and evaluation of laboratory testing by individuals licensed or registered in accordance with Chapter 4729. of the Revised Code.

Diagnostic Testing Rules – Initial Stakeholder Comments

Organization	Respondent	Response	Comment
N/a	Pharmacist	Proponent	I support the adoption of these rules. The benefit to patient care is significant and positive.
Mount Carmel Medical Group	Family Practice Physician	Opponent	Regarding Chapter 19 of the Revised Code, Rule 4729:1-3-01, Rule 4729:2-3-05, and Rule 4729:3-3-06 I have serious concerns with Pharmacists and Pharmacy texts performing CLIA waived tests without physician or advanced practitioner oversight. These tests must be performed in the context of an appropriate exam by a practitioner trained in evaluation, diagnosis, and management of disease. For the safety of my patients and our community, I oppose all three of these rules.
Curtis Rude	N/A	Opponent	While I support beneficial services provided to assist patients by pharmacy personnel, (i.e. pharmacists, interns, & technicians), the Ohio Pharmacy Board should both carefully monitor and mandate the additional **educational** requirements that will be necessary to order diagnostic tests for patients. It is also highly questionable in my view that consistent payments will be allocated by insurance carriers to pharmacies and pharmacy personnel for these services. That is the intention of these new rules in my mind. Diagnostic services have long been classified as a **" practice of medicine"** as well. There will be significant resistance from both nursing and medical groups against pharmacy

			personnel ordering diagnostic tests. Theses rules also cross the social and philosophical boundaries of the practice of medicine and they will be challenged by competing medical interest groups and the public as well.

4729:8-1-01 **Ohio automated ~~Rx~~rx reporting system - definitions.**

As used in division 4729:8 of the Administrative Code:

(A) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code and chapter 4729:9-1 of the Administrative Code.

(B) "Central fill pharmacy" has the same meaning as in rule 4729:5-5-19 of the Administrative Code.

~~(B)~~(C) "Distributor of dangerous drugs" or "drug distributor" means the following persons licensed in accordance with section 4729.52 of the Revised Code and division 4729:6 of the Administrative Code:

(1) Wholesale distributors of dangerous drugs, including virtual wholesalers.

(2) Manufacturers of dangerous drugs.

(3) Outsourcing facilities.

(D) "Designated representative" means the dispensary key employee responsible for acting in compliance with agency 3796 of the Administrative Code.

(E) "Dispense" means the final association of a drug with a particular patient pursuant to a prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for interpreting, preparing, compounding, labeling, and packaging a specific drug.

(F) "Dispensary" means a holder of a valid retail dispensary license in accordance with Chapter 3796. of the Revised Code.

(G) "Originating pharmacy" has the same meaning as in rule 4729:5-5-19 of the Administrative Code.

(H) "Opioid treatment program" has the same meaning as in Chapter 4729:5-21 of the Administrative Code.

~~(C)~~(I) "Outpatient" means any person who receives drugs for use outside of an institutional facility as defined in agency 4729 of the Administrative Code.

~~(D)~~(J) "Peer review committee" has the same meaning as in section 2305.25 of the Revised Code, except that it includes only a peer review committee of a hospital or a peer review committee of a nonprofit health care corporation that is a member of the hospital or of which the hospital is a member.

~~(E)~~(K) "Personally furnish" means the distribution of drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting.

~~(F)~~(L) "Pharmacy" has the same meaning as in section 4729.01 of the Revised Code.

~~(G)~~(M) "Prescriber" or "licensed health professional authorized to prescribe drugs" have the same meaning as in section 4729.01 of the Revised Code.

~~(H)~~(N) "Terminal distributor of dangerous drugs" or "terminal distributor" has the same meaning as in section 4729.01 of the Revised Code.

~~(I)~~(O) "Sale" and "sell" has the same meaning as in section 4729.01 of the Revised Code.

~~(J)~~(P) "Wholesale sale" and "sale at wholesale" have the same meaning as in section 4729.01 of the Revised Code. Wholesale sale also includes the following:

(1) An occasional sale conducted in accordance with section 4729.51 of the Revised Code;

(2) The sale of a sample or complimentary supply, as defined in rule 4729:6-3-08 of the Administrative Code, to a prescriber or terminal distributor;

(3) The transfer or sale of a non-patient specific dangerous drug to a prescriber or terminal distributor.

~~(K)~~(Q) ~~"Zero report" means a report documenting that none of the drugs listed in Chapter 4729:8-2 of the Administrative code were sold, dispensed or personally furnished during the required reporting period.~~"Zero report" means either:

(1) A report documenting that none of the drugs listed in Chapter 4729:8-2 of the Administrative Code were sold, dispensed, or personally furnished during the required reporting period; or

(2) For a dispensary, a report documenting that no medical marijuana was sold or dispensed.

4729:8-3-01 **Entities required to submit information.**

The following entities are required to submit the specified dispensing, personal furnishing, or wholesale sale information in accordance with this chapter of the Administrative Code to the state board of pharmacy for the operation of the drug database:

(A) All pharmacies located within this state and licensed as a terminal distributor of dangerous drugs shall report all drugs listed in Chapter 4729:8-2 of the Administrative Code that are dispensed to outpatients.

(B) All pharmacies located outside this state and licensed as a terminal distributor of dangerous drugs shall report all drugs listed in Chapter 4729:8-2 of the Administrative Code that are dispensed to outpatients residing in this state.

(C) Except as provided in rule 4729:8-2-02 of the Administrative Code, all licensed drug distributors and terminal distributors of dangerous drugs located within this state that sell at wholesale drugs listed in Chapter 4729:8-2 of the Administrative Code to prescribers or terminal distributors of dangerous drugs shall report those drug transactions in accordance with the wholesale reporting requirements of this chapter.

(D) Except as provided in rule 4729:8-2-02 of the Administrative Code, all licensed drug distributors and terminal distributors of dangerous drugs located outside this state that sell at wholesale drugs listed in Chapter 4729:8-2 of the Administrative Code to prescribers or terminal distributors of dangerous drugs located within this state shall report those drug transactions in accordance with the wholesale reporting requirements of this chapter.

(E) Except as provided in rule 4729:8-2-02 of the Administrative Code, all prescribers, except veterinarians, located within this state shall report all drugs listed in Chapter 4729:8-2 of the Administrative Code that are personally furnished to patients.

(F) A retail dispensary licensed under Chapter 3796. of the Revised Code in accordance with section 4729.771 of the Revised Code.

(G) An opioid treatment program licensed as a terminal distributor of dangerous drugs is exempted from the reporting requirements of this division.

(1) An opioid treatment program shall report patient information via the central registry established in rule 5122-40-08 of the Administrative Code.

(2) Reporting of patient information pursuant to paragraph (G)(1) of this rule shall be made in compliance with Title 42 CFR Part 2 (4/1/2025).

4729:8-3-03 **Electronic format required for the transmission of drug sales.**

(A) All prescription dispensing information or prescriber personally furnishing information required to be submitted to the board pursuant to rule 4729-8-3-02 of the Administrative Code must be transmitted in the following format specified by the "American Society for Automation in Pharmacy" (ASAP) for prescription monitoring programs:

(1) ASAP Version 5.0 Standard for Prescription Drug Monitoring Programs (4/1/2025); or

(2) Until July 1, 2026, ASAP Version 4.2A Standard for Prescription Drug Monitoring Programs (3/15/2017).

(B) The board's executive director or the director's designee may authorize up to a six-month extension to the implementation of ASAP Version 5.0 beyond July 1, 2026. Such extensions may only be considered if the pharmacy or prescriber has made all reasonable and prudent attempts to meet the deadline.

(C) In the event that a pharmacy or a prescriber cannot electronically transmit the required information pursuant to paragraph (A) of this rule, the pharmacy or prescriber may request a variance from the board’s executive director or the director's designee to submit drug sales information in a mutually acceptable format.

(D) All wholesale data required to be submitted to the board of pharmacy pursuant to rule 4729-8-3-02 of the Administrative Code shall be transmitted in the report format used when transmitting controlled substance data to the federal drug enforcement administration via the "Automation of Reports and Consolidated Orders System" (ARCOS) or other mutually acceptable format.

(E) In the event that a drug distributor or terminal distributor cannot electronically transmit the required information pursuant to paragraph (D) of this rule, the drug distributor or terminal distributor may request a variance from the board's executive director or the director's designee to submit drug sales information in a mutually acceptable format.

4729:8-3-04 **Frequency requirements for submitting drug database information.**

(A) A terminal distributor or prescriber that has been in possession of a drug listed in Chapter 4729:8-2 of the Administrative Code for dispensing or personally furnishing within the previous three years shall submit to the board of pharmacy, at least daily, either of the following:

(1) All information required to be submitted to the board of pharmacy pursuant to this division of the Administrative Code.

(2) A zero report, if a terminal distributor has no drug dispensing information or a prescriber has no personally furnishing information required to be submitted to the board of pharmacy pursuant to this division of the Administrative Code.

(B) The information required to be reported pursuant to paragraph (A) of this rule shall be consecutive and inclusive from the last date and time the information was submitted to the board of pharmacy and shall be reported no later than thirty-six hours after the last time reported.

(C) Any record of a dispensed or personally furnished drug listed in Chapter 4729:8-2 of the Administrative Code shall be reported to the board of pharmacy within twenty-four hours of being dispensed or personally furnished.

(D) Any terminal distributor or prescriber whose normal business hours are not seven days per week shall electronically indicate their normal business hours to the board and no zero report will be required for the terminal distributor or prescriber's non-business days.

(E) If a terminal distributor or prescriber ceases to dispense or personally furnish a drug listed in Chapter 4729:8-2 of the Administrative Code, the responsible person on the terminal distributor of dangerous drugs license or the prescriber shall notify the board of pharmacy in writing and request an exemption to reporting.

If at any time a terminal distributor or prescriber begins dispensing or personally furnishing drugs listed in Chapter 4729:8-2 of the Administrative Code, the exemption to reporting shall no longer be valid and the terminal distributor or prescriber shall start reporting in accordance with this rule.

(F) A drug distributor that has been in possession of a drug listed in Chapter 4729:8-2 of the Administrative Code for sale at wholesale within the previous three years shall submit to the board of pharmacy, at least monthly, either of the following:

(1) All information required to be submitted to the board pursuant to this division of the Administrative Code.

(2) A zero report, if a drug distributor has no drug sale information required to be submitted to the board of pharmacy pursuant to this division of the Administrative Code.

(G) All wholesale sale information required to be submitted to the board of pharmacy pursuant to this division of the Administrative Code shall be submitted at least monthly. The information shall be consecutive and inclusive from the last date and time the information was submitted and shall be reported no later than forty-five days after the date of the wholesale sale.

(H) If a drug distributor, prescriber, or terminal distributor cannot submit the required information at the required intervals specified in this rule, the drug distributor, terminal distributor or prescriber may request an extension from the ~~board's~~board's executive director or the ~~director's~~director's designee to submit the required information in a mutually acceptable time frame.

(I) A dispensary licensed in accordance with Chapter 3796. of the Revised Code shall submit information in accordance with rule 4729:8-5-01 of the Administrative Code.

4729:8-4-01 **Procedures for obtaining drug database information and access by peer review committees and fatality review committees.**

(A) Persons that are permitted pursuant to section 4729.80 of the Revised Code to obtain information from the drug database shall comply with all application procedures, requirements and acceptable use policies adopted by the board.

(B) An individual seeking the individual's own database information shall comply with the following:

(1) Complete a ~~notarized~~ request form giving such information as required by the board of pharmacy;

(2) Submit the completed form in person or by mail;

(3) Receive the information in person at the board of pharmacy office during normal business hours and show proof of identity with a current government issued form of identification that contains a picture such as a current state issued identification card, a current state issued driver's license, or a valid passport; and

(4) The person may be required to pay the cost of printing the document as determined by the board of pharmacy's current per page rate.

(C) Pursuant to section 4729.80 of the Revised Code, the board shall provide the following information to a designated representative of a peer review committee relating to a prescriber who is subject to the committee's evaluation, supervision, or discipline:

(1) A summary of the prescriber's prescribing record, if such a record is created by the board;

(2) Information from the database, in a format determined by the board, relating to a current or previous patient of the prescriber who is subject to the committee's evaluation, supervision, or discipline.

(D) An employee of the state board of pharmacy who has been appointed to an overdose fatality review committee or suicide fatality review committee may provide a drug database report to a person described in division (A)(5), (6), or (17) of section 4729.80 of the Revised Code.

(1) The employee may only provide the information for the purposes of the committee's review in accordance with Chapter 307 of the Revised Code.

(2) The employee shall verify that the person receiving the report has signed a written agreement specifying how the information is to be used and disseminated according to the laws of this state.