

Mike DeWine, Governor Jon Husted, Lt. Governor Steven W. Schierholt, Executive Director

Rules for Stakeholder Comment

Issue Date: 1/22/2025 Comments Due: 2/7/2025

In accordance with Chapter 119. of the Revised Code, the Ohio Board of Pharmacy proposes the adoption of the following rules:

Rule Number / Title	Type of Rule Change
Rule 4729:1-3-01 Pharmacist administration of diagnostic	No Change
tests	
Rule 4729:2-3-05 Pharmacy intern administration of	No Change
diagnostic tests	
Rule 4729:3-3-05 Certified pharmacy technician	No Change
administration of diagnostic tests	

Comments on the proposed rules will be accepted until close of business on **Friday, February 7, 2025**. Please send all comments to the following email address: <u>rulecomments@pharmacy.ohio.gov</u>.

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Rule 4729:1-3-01 | Pharmacist administration of diagnostic tests.

(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.

(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.

(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.