

Andy Beshear Governor

KENTUCKY BOARD OF PHARMACY

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OPINION AND DECLARATORY RULING: TECHNICIAN AUTHORITY TO PERFORM POINT-OF-CARE TESTING

Issued on: March 22, 2023

The Kentucky Board of Pharmacy issues this declaratory ruling to clarify the role of pharmacy technicians in assisting pharmacists with point of care testing in the pharmacy setting. The Board of Pharmacy is authorized to issue Opinion and Declaratory Judgments pursuant to KRS 13A.130(3) and 13A.010(2)(b). A declaratory ruling does not create a new law or modify an existing one. Board of Pharmacy declaratory rulings are not binding, and are only offered as a guideline to licensees, permit-holders and registrants who wish to engage in a safe practice of pharmacy that promotes, preserves and protects public health, safety and welfare of the citizens of the Commonwealth.

The Kentucky Board of Pharmacy is authorized by Kentucky Revised Statute (KRS) 315 to regulate pharmacies, pharmacists, pharmacist interns, pharmacy technicians, manufacturers, wholesalers, outsourcing facilities and third-party logistics providers within the Commonwealth of Kentucky or transacting business within the Commonwealth of Kentucky in order to promote, preserve, and protect public health, safety and welfare of the citizens of the Commonwealth.

The Kentucky Board of Pharmacy has been asked the following regarding the role of pharmacy technicians in performing CLIA-waived point-of-care testing: Can pharmacy technicians perform point-of-care testing used in Board authorized protocols? Additionally, there are other CLIA waived testing that may be performed at a pharmacy not involving Board authorized protocols, such as blood pressure, cholesterol, and blood glucose. If the technician is properly trained, may the technician perform the tests under supervision?

Pharmacy technicians are authorized under KRS 315 to assist a pharmacist in the practice of pharmacy under pharmacist supervision. KRS 315.135(1). Pharmacists are authorized to order lab tests pursuant to Collaborative Care Agreements (CCAs) (201 KAR 2:220) and board authorized protocols (201 KAR 2:380) under the name of the prescriber that signed the CCA or board authorized protocol so long as the criteria of the CCA or protocol have been met. Pursuant to KRS 333.040, pharmacists may perform screenings using CLIA-waived tests that are in stock and on the shelf without a prescription if the pharmacy has a CLIA certificate.

The administration of point-of-care tests is not a professional task, and therefore can be completed under the supervision of a pharmacist. The Board expects any pharmacy personnel conducting such tests to be properly trained. The interpretation of the point-of-care test or any action taken as a result of the test is a professional task and should only be completed by a pharmacist.

APPLICABLE LAW

KRS 333.040 Medical laboratories not subject to law. This chapter applies to all medical laboratories within the State of Kentucky, except: (5) Medical laboratories operated by facilities holding a permit pursuant to KRS 315.035 and holding a valid certification issued pursuant to the Clinical Laboratory Improvement Act of 1988 (CLIA), as amended, solely and exclusively in connection with assisting a patient with the use of CLIA-waived tests available from the facility's stock or inventory, and in connection with testing and treatment of patients covered under collaborative care agreements established under KRS 315.010 and other applicable laws. If any referred work is received or performed by these medical laboratories, all provisions of this chapter shall apply.

KRS 315.135 Registration as pharmacy technician required to assist in the practice of pharmacy -- Exemptions. (1) Effective April 1, 2009, a person shall not assist in the practice of pharmacy unless he or she is duly registered as a pharmacy technician under the provisions of this chapter or is exempt under subsection (2) of this section.

201 KAR 2:220(4) A collaborative care agreement shall comply with KRS 315.010(4) and contain the following information:

- (1) Protocol, criteria, standing orders, or other method by which services are authorized;
- (2) The method established for the assessment of patient outcomes, if appropriate; and
- (3)Lab tests that may be ordered.

201 KAR 2:380 A pharmacist may initiate the dispensing of noncontrolled medications, over-the-counter medications, or other professional services...

Sincerely,

Christopher Harlow, Executive Director Kentucky Board of Pharmacy

