

Department of Legislative Services
Maryland General Assembly
2010 Session

FISCAL AND POLICY NOTE

Senate Bill 1053 (Senator Klausmeier)
Education, Health, and Environmental Affairs

Health Occupations - Pharmacists - Laboratory Tests

This bill permits a pharmacist to perform laboratory tests that are waived from the requirements of the federal Clinical Laboratory Improvement Amendments (CLIA).

Fiscal Summary

State Effect: None. This change does not directly affect governmental finances.

Local Effect: None.

Small Business Effect: Minimal.

Analysis

Current Law/Background: “Practice pharmacy” includes:

- providing pharmaceutical care;
- compounding, dispensing, or distributing prescription drugs or devices;
- compounding or dispensing nonprescription drugs or devices;
- monitoring prescriptions for prescription and nonprescription drugs or devices;
- providing information, explanation, or recommendations to patients and health care practitioners about the safe and effective use of prescription or nonprescription drugs or devices;
- identifying and appraising problems concerning the use or monitoring of therapy with drugs or devices;

- acting within the parameters of a therapy management contract;
- administering vaccinations for influenza, pneumococcal pneumonia, or herpes zoster, or any vaccination that has been determined by the State Board of Pharmacy, with the agreement of the State Board of Physicians and the State Board of Nursing, to be in the best health interests of the community;
- delegating a pharmacy act to a registered pharmacy technician, pharmacy student, or an individual engaged in a board-approved pharmacy technician training program;
- supervising such a delegated pharmacy act; or
- providing drug therapy management in accordance with the Maryland Health Maintenance Organization Act.

Currently, pharmacists in the State are not authorized to perform any laboratory testing.

In 1988, CLIA established standards for all laboratory testing to ensure accuracy, reliability, and timeliness of patient test results regardless of where a test is performed. Tests may be waived from regulatory oversight if they meet certain requirements established by the amendments. In February 1992, regulations were published to implement CLIA, which waived tests that:

- were defined as simple laboratory examinations and procedures that are cleared by the U.S. Food and Drug Administration for home use;
- employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
- pose no reasonable risk or harm to the patient if the test is performed incorrectly.

Examples of testing waived from regulations include glucose monitoring devices for home use; dipstick or tablet reagent urinalysis for specified testing including hemoglobin, pH, and protein; and fecal occult blood tests to detect colon cancer.

The State Board of Pharmacy advises that 46 states permit pharmacists to perform laboratory testing waived from CLIA regulations.

Additional Information

Prior Introductions: None.

Cross File: HB 1089 (Delegates Rudolph and Elliott) - Health and Government Operations.

Information Source(s): Department of Health and Mental Hygiene, U.S. Food and Drug Administration, Department of Legislative Services

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Analysis by: Erin McMullen

Direct Inquiries to:
(410) 946-5510
(301) 970-5510