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THE GENERAL ASSEMBLY OF PENNSYLVANIA

# HOUSE BILL

## No. 2033 Session of 2003

INTRODUCED BY FRANKEL, BEBKO-JONES, BELFANTI, CORRIGAN, CURRY, DeLUCA, DeWEESE, FABRIZIO, GOODMAN, GRUCELA, HORSEY, JAMES, JOSEPHS, KIRKLAND, ROSS, WANSACZ, WASHINGTON AND YOUNGBLOOD, SEPTEMBER 29, 2003

REFERRED TO COMMITTEE ON PROFESSIONAL LICENSURE, SEPTEMBER 29, 2003

AN ACT

Amending the act of September 26, 1951 (P.L.1539, No.389), entitled, as amended, "An act defining clinical laboratory; regulating the operation of the same; requiring such laboratories to obtain permits, and to be operated under the direct supervision of qualified persons; imposing certain duties upon the Department of Health; and providing penalties," providing for the use of home tests by physicians.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. The act of September 26, 1951 (P.L.1539, No.389), known as The Clinical Laboratory Act, is amended by adding a section to read:

Section 11.2. Use of FDA-approved and Clinical Laboratory Improvement Act (CLIA) Waived Point-of-care and At-home Testing Equipment by Physicians.--(a) Notwithstanding any other provision of law, a private physician may utilize in his office laboratory any FDA-approved and CLIA-waived point-of-care testing equipment, including cholesterol profile testing,

glucose testing and prothrombin time testing or at-home testing equipment that is available to a patient if all of the following conditions are met:

(1) The physician's office laboratory must be licensed by the Bureau of Laboratories and directed by a physician.

(2) The personnel of the physician's office laboratory must be trained according to manufacturer's recommendations to use the equipment.

(3) The physician's office laboratory may perform testing only on the patients of the physician or those of the practice and may not receive specimens from other offices or laboratories.

(4) The physician's office laboratory shall use materials that are in date and are stored and used according to the manufacturer's directions.

(5) The physician's office laboratory shall have written procedure manuals or follow supplemental package inserts supplied by the equipment manufacturer.

(6) All quality control tests conducted by the physician's office laboratory shall be done in accordance with manufacturer's directions and recorded in a quality control log book.

(7) All results of the laboratory tests of a patient shall be entered in the patient's chart.

(b) The Bureau of Laboratories may perform an onsite examination of the physician's office laboratory when point-of-care or at-home testing is initiated and every two years thereafter or in lieu of the onsite examination, a self-evaluation questionnaire may be sent to the physician's office laboratory which shall be completed by the physician's office

laboratory and returned to the Bureau of Laboratories.

Section 2. This act shall take effect in 60 days.