CHAPTER 73

(House Bill 343)

AN ACT concerning

Department of Health and Mental Hygiene – Laboratories – Letter of Exception

FOR the purpose of altering a certain definition that relates to the circumstances under which the Secretary of Health and Mental Hygiene is required to issue a letter of exception from certain State licensing requirements for laboratories; and generally relating to exceptions from State licensing requirements for laboratories.

BY repealing and reenacting, with amendments,

Article – Health – General

Section 17–205

Annotated Code of Maryland

(2005 Replacement Volume and 2006 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article - Health - General

17-205.

- (a) A person shall hold a license issued by the Secretary before the person may:
- (1) Offer or perform medical laboratory tests or examinations in this State;
- (2) Offer or perform medical laboratory tests or examinations on specimens acquired from health care providers in this State at a medical laboratory located outside this State; or
- (3) Represent or service in this State a medical laboratory regardless of the laboratory's location.

- (b) The Secretary shall issue a letter of exception to a laboratory that:
- (1) Performs only limited medical laboratory tests or examinations; and
- (2) Meets the exception requirements in regulations adopted by the Secretary pursuant to this subtitle.
- (c) For the purposes of this section, "limited medical laboratory tests or examinations" means [simple] medical laboratory procedures as defined in regulations adopted by the Secretary pursuant to this subtitle.
- (d) If preliminary screening procedures are performed by an operator who is trained under § 17–214(k) of this subtitle, an employer:
- (1) Is not required to obtain a permit or to obtain a letter of exception from the Secretary under this section to perform testing; but
- (2) Is required before performing preliminary screening procedures, as defined under 17–214(a) of this subtitle, to register with the Secretary in accordance with requirements adopted in regulations by the Department of Health and Mental Hygiene.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2007.

Approved by the Governor, April 10, 2007.