

BY: Education, Health, and Environmental Affairs Committee

AMENDMENTS TO SENATE BILL NO. 250

(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in the sponsor line, strike “and Pinsky” and substitute “Pinsky, Harris, and Kittleman”; in line 5, after “unannounced;” insert “authorizing the Secretary of Health and Mental Hygiene to conduct announced inspections under certain circumstances;”; in line 6, strike “of Health and Mental Hygiene”; in line 8, in each instance, strike “employees” and substitute “persons”; in line 12, strike “employees” and substitute “persons”; in line 14, after “place;” insert “authorizing the Secretary to grant a certain waiver to the requirement to post the document;”; strike beginning with “requiring” in line 14 down through “information;” in line 17 and substitute “requiring the Secretary to enter certain agreements with certain accrediting organizations; requiring certain agreements to include certain information;”; in line 18, after “violations;” insert “altering the duties and membership of a certain Laboratory Advisory Committee;”; and in line 28, strike “and 17-216” and substitute “, 17-216, and 17-217”.

AMENDMENT NO. 2

On page 2, in line 15, after “(b)” insert “(1)”; in lines 17 and 19, strike “(1)” and “(2)”, respectively, and substitute “(I)” and “(II)”, respectively; in lines 17 and 19, in each instance, strike “UNANNOUNCED”; after line 20, insert:

“(2) EXCEPT AS PROVIDED IN PARAGRAPH (3) OF THIS SUBSECTION, INSPECTIONS UNDER THIS SUBSECTION SHALL BE CONDUCTED ON AN UNANNOUNCED BASIS;

(3) THE SECRETARY MAY CONDUCT AN ANNOUNCED INSPECTION UNDER THIS SUBSECTION IF:

(I) THE TOTAL VOLUME OF TESTS CONDUCTED BY THE MEDICAL LABORATORY IS LESS THAN 25,000 PER YEAR; OR

(Over)

(II) THE SECRETARY DETERMINES THAT AN ANNOUNCED INSPECTION IS WARRANTED.”;

and in line 23, strike “(b)(2)” and substitute “(B)(1)(II)”.

AMENDMENT NO. 3

On page 3, in line 2, strike “AN EMPLOYEE OF” and substitute “A PERSON WHO WORKS IN”; in lines 3, 12, 19, and 28, in each instance, strike “EMPLOYEE” and substitute “PERSON”; in line 3, after “REASONABLY” insert “AND IN GOOD FAITH”; strike in their entirety lines 4 and 5; in lines 6 and 8, strike “(2)” and “(3)”, respectively, and substitute “(1)” and “(2)”, respectively; in line 11, strike “AN EMPLOYEE OF A” and substitute “A PERSON WHO WORKS IN THE”; in line 15, strike “AN EMPLOYEE” and substitute “A PERSON”; in line 22, strike “2 YEARS” and substitute “1 YEAR”; and strike beginning with “OR” in line 23 down through “VIOLATION” in line 24.

AMENDMENT NO. 4

On page 4, in line 2, strike “EMPLOYEE” and substitute “PERSON”; in line 5, strike “INDIVIDUAL” and substitute “PERSON”; in line 9, strike “THE EMPLOYEES OF” and substitute “PERSONS WHO WORK IN”; in line 21, strike “AN EMPLOYEE” and substitute “A PERSON”; in line 22, after “(C)” insert “SUBJECT TO SUBSECTION (D) OF THIS SECTION,”; after line 23, insert:

“(D) THE SECRETARY MAY WAIVE THE REQUIREMENTS OF SUBSECTION (C) OF THIS SECTION FOR A MEDICAL LABORATORY ACCREDITED BY AN ORGANIZATION APPROVED BY THE SECRETARY IF THE ACCREDITING ORGANIZATION HAS AN EQUIVALENT REQUIREMENT.”;

in line 25, strike “(A)”;

strike beginning with “PROVIDE” in line 25 down through “OF” in line 27 and substitute “ENTER AN INFORMATION SHARING AGREEMENT WITH AN APPROVED ACCREDITING ORGANIZATION TO ENSURE ONGOING COMMUNICATION THAT INCLUDES INFORMATION SHARING REGARDING”; in line 29, strike “AND”; in line 30, strike “REPORT OF NONCOMPLIANCE OR OTHER VIOLATION” and substitute “DISCLOSURE MADE BY A PERSON WHO WORKS IN A MEDICAL LABORATORY”; in line 31, after “SUBTITLE” insert “; AND

(3) A COMPLAINT FILED BY A CONSUMER OF SERVICES OF A MEDICAL LABORATORY, A FAMILY MEMBER OF A CONSUMER, A FAMILY MEMBER

OF A PERSON WHO WORKS IN A MEDICAL LABORATORY, OR OTHER SOURCE”;

and strike in their entirety lines 32 and 33.

AMENDMENT NO. 5

On page 5, in line 3, strike “\$100” and substitute “\$5,000”; in line 4, strike “\$500” and substitute “\$10,000”; in line 8, after “(B)” insert “(1) THIS SUBSECTION DOES NOT APPLY TO AN ANNOUNCED INSPECTION CONDUCTED UNDER § 17-202(B)(3) OF THIS SUBTITLE.

(2)”;

and after line 12, insert:

“17-217.

(a) The Secretary shall [establish] APPOINT a Laboratory Advisory Committee to advise AND MAKE RECOMMENDATIONS TO the Secretary REGARDING:

(1) [on matters] MATTERS relating to the implementation of [the provisions] § 17-202 of this subtitle; AND

(2) ISSUES RELATING TO QUALITY OF CARE AND SERVICES PERFORMED BY MEDICAL LABORATORIES IN THE STATE.

(b) The Advisory Committee shall consist of:

[(1) At least the following representatives appointed biennially from a list of eligibles submitted by the Medical and Chirurgical Faculty of Maryland:

(i) 1 member of the American Academy of Family Practitioners;

(ii) 1 member of the American Academy of Pediatricians;

(iii) 1 member of the American Society of Internal Medicine;

(Over)

- (iv) 1 member of the American Society of Clinical Pathologists; and
 - (v) 1 member of the American College of Pathology; and
 - (2) 1 representative of the Health Industry Manufacturers Association]
 - (1) 1 REPRESENTATIVE FROM THE DEPARTMENT;
 - (2) 1 PATHOLOGIST FROM A HOSPITAL LABORATORY;
 - (3) 1 PATHOLOGIST FROM A FREE-STANDING INDEPENDENT LABORATORY;
 - (4) 1 PHYSICIAN FROM A LABORATORY THAT CONDUCTS FEWER THAN 25,000 TESTS PER YEAR;
 - (5) 3 MEDICAL TECHNOLOGISTS THAT WORK IN A MEDICAL LABORATORY;
 - (6) 1 REPRESENTATIVE FROM EACH APPROVED ACCREDITING ORGANIZATION; AND
 - (7) 2 CONSUMERS, 1 OF WHOM THE SECRETARY SHALL APPOINT TO SERVE AS THE CHAIR OF THE ADVISORY COMMITTEE.
- (c) The Secretary may appoint any other individuals or representatives at the Secretary's discretion.
- (d) The chairman of the Advisory Committee shall be designated by the Secretary every 2 years.]”.