

BY: Education, Health, and Environmental Affairs Committee

AMENDMENTS TO HOUSE BILL NO. 351

(Third Reading File Bill)

AMENDMENT NO. 1

On page 1, strike in its entirety line 2 and substitute “Public Health - Medical Laboratories - Inspection, Information Sharing, and Whistleblower Protection”.

On pages 1 and 2, strike beginning with “prohibiting” in line 3 on page 1 through “of” in line 4 on page 2 and substitute “requiring that certain inspections of certain medical laboratories be unannounced; authorizing the Secretary of Health and Mental Hygiene to conduct announced inspections under certain circumstances; authorizing certain employees to disclose certain information to the Secretary under certain circumstances; prohibiting a medical laboratory from taking certain actions against certain persons; authorizing certain persons to institute a certain civil action; requiring a certain civil action under this Act to be brought within a certain period of time; authorizing a court to award certain remedies for certain violations of this Act; prohibiting the Secretary from disclosing the identity of certain persons; requiring the Secretary to develop and disseminate a certain document; requiring the document to include certain information; requiring a medical laboratory to post the document in a conspicuous place; authorizing the Secretary to grant a certain waiver to the requirement to post the document; requiring the Secretary to enter certain agreements with certain accrediting organizations; requiring certain agreements to include certain information; providing for certain penalties for certain violations; altering the duties and membership of a certain Laboratory Advisory Committee; requiring a certain annual report; and generally relating to the inspection, information sharing, and whistleblower protections for”.

On page 2, after line 4, insert:

“BY repealing and reenacting, without amendments,

Article - Health - General

Section 17-202(a)

Annotated Code of Maryland

(Over)

(2000 Replacement Volume and 2004 Supplement)”;

in line 7, strike “and” and substitute “(b) and (c).”; in the same line, after “17-216” insert “, and 17-217”; and strike in their entirety lines 12 and 13 and substitute “Section 17-202.2, 17-202.3, and 17-202.4”.

AMENDMENT NO. 2

On pages 2 and 3, strike in their entirety the lines beginning with line 25 on page 2 through line 8 on page 3.

On page 3, strike in their entirety lines 15 through 25, inclusive.

On page 4, strike in their entirety lines 1 through 20, inclusive, and substitute:

“(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

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

in line 23, after “(B)(1)” insert “(II)”; and in line 29, after “organization” insert “ON AN UNANNOUNCED BASIS”.

On pages 4 through 6, strike in their entirety the lines beginning with line 33 on page 4 through line 14 on page 6 and substitute:

“17-202.2.

(A) A PERSON WHO WORKS IN A MEDICAL LABORATORY MAY DISCLOSE INFORMATION TO THE SECRETARY THAT THE PERSON REASONABLY AND IN GOOD

FAITH BELIEVES EVIDENCES:

(1) A SUBSTANTIAL AND SPECIFIC DANGER TO PUBLIC HEALTH OR SAFETY; OR

(2) A VIOLATION OF THE STANDARDS AND REQUIREMENTS FOR MEDICAL LABORATORIES IN THE STATE.

(B) A MEDICAL LABORATORY MAY NOT TAKE AN ADVERSE EMPLOYMENT ACTION INCLUDING DISCRIMINATION OR RETALIATION AGAINST A PERSON WHO WORKS IN THE MEDICAL LABORATORY BECAUSE THE PERSON DISCLOSES THE INFORMATION UNDER SUBSECTION (A) OF THIS SECTION OR HAS AGREED TO COOPERATE WITH AN INVESTIGATION OF THE MEDICAL LABORATORY.

(C) (1) A PERSON WHO IS SUBJECT TO AN ADVERSE EMPLOYMENT ACTION IN VIOLATION OF SUBSECTION (B) OF THIS SECTION MAY INSTITUTE A CIVIL ACTION IN THE COUNTY WHERE:

(I) THE ALLEGED VIOLATION OCCURRED;

(II) THE PERSON RESIDES; OR

(III) THE MEDICAL LABORATORY MAINTAINS ITS PRINCIPAL OFFICE IN THE STATE.

(2) THE ACTION SHALL BE BROUGHT WITHIN 1 YEAR AFTER THE ALLEGED VIOLATION OF SUBSECTION (B) OF THIS SECTION OCCURRED.

(D) IN AN ACTION UNDER THIS SECTION A COURT MAY:

(1) ISSUE AN INJUNCTION TO RESTRAIN CONTINUED VIOLATION OF SUBSECTION (B) OF THIS SECTION;

(2) REINSTATE THE PERSON TO THE SAME OR AN EQUIVALENT

POSITION HELD BEFORE THE VIOLATION OF SUBSECTION (B) OF THIS SECTION;

(3) REMOVE ANY ADVERSE PERSONNEL RECORD ENTRIES BASED ON OR RELATED TO THE VIOLATION OF SUBSECTION (B) OF THIS SECTION;

(4) REINSTATE FULL FRINGE BENEFITS AND SENIORITY RIGHTS;

(5) REQUIRE COMPENSATION FOR LOST WAGES, BENEFITS, AND OTHER REMUNERATION;

(6) AWARD THE COSTS OF LITIGATION AND REASONABLE ATTORNEY'S FEES TO THE PREVAILING PERSON; AND

(7) AWARD ANY OTHER APPROPRIATE DAMAGES AND RELIEF.

(E) IF A REPORT MADE UNDER THIS SECTION IS MADE ANONYMOUSLY, THE SECRETARY MAY NOT DISCLOSE THE IDENTITY OF THE PERSON MAKING THE REPORT TO A MEDICAL LABORATORY.

17-202.3.

(A) THE SECRETARY SHALL DEVELOP AND DISSEMINATE A DOCUMENT THAT INFORMS PERSONS WHO WORK IN A MEDICAL LABORATORY OF THE MANNER IN WHICH TO REPORT INSTANCES OF NONCOMPLIANCE OR OTHER VIOLATIONS OF THE STANDARDS AND REQUIREMENTS FOR MEDICAL LABORATORIES IN THE STATE.

(B) THE DOCUMENT DEVELOPED UNDER SUBSECTION (A) OF THIS SECTION SHALL INCLUDE:

(1) THE NAME AND CONTACT INFORMATION OF THE STATE AGENCY TO WHOM TO REPORT;

(2) THE TYPES OF REPORTABLE OFFENSES INCLUDING VIOLATIONS RELATING TO TESTING, QUALITY, AND INADEQUATELY TRAINED PERSONNEL;

(3) A DESCRIPTION OF THE RIGHTS AND PROTECTIONS AVAILABLE UNDER § 17-202.2 OF THIS SUBTITLE; AND

(4) A TOLL-FREE TELEPHONE NUMBER, OPERATED BY THE DEPARTMENT, THROUGH WHICH A PERSON MAY REPORT.

(C) SUBJECT TO SUBSECTION (D) OF THIS SECTION, A MEDICAL LABORATORY SHALL POST THE DOCUMENT DEVELOPED UNDER SUBSECTION (A) OF THIS SECTION IN A CONSPICUOUS PLACE.

(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.

17-202.4.

THE SECRETARY SHALL ENTER AN INFORMATION SHARING AGREEMENT WITH AN APPROVED ACCREDITING ORGANIZATION TO ENSURE ONGOING COMMUNICATION THAT INCLUDES INFORMATION SHARING REGARDING:

(1) A DISCOVERY OF NONCOMPLIANCE OR OTHER VIOLATION OBTAINED UNDER § 17-202(B) OR (C) OF THIS SUBTITLE;

(2) DISCLOSURE MADE BY A PERSON WHO WORKS IN A MEDICAL LABORATORY OBTAINED UNDER § 17-202.2 OF THIS SUBTITLE; 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.”.

On page 6, in line 16, before “A” insert “(A) (1)”; and in line 19, after “provision.” insert:

(Over)

“(2)”.

On pages 6 through 8, strike in their entirety the lines beginning with line 21 on page 6 through line 21 on page 8 and substitute:

“(B) (1) THIS SUBSECTION DOES NOT APPLY TO AN ANNOUNCED INSPECTION CONDUCTED UNDER § 17-202(B)(3) OF THIS SUBTITLE.

(2) IN ADDITION TO ANY OTHER PENALTIES PROVIDED BY LAW, THE SECRETARY MAY IMPOSE A CIVIL PENALTY NOT EXCEEDING \$2,000 ON A PERSON WHO NOTIFIES, OR CAUSES TO BE NOTIFIED, A MEDICAL LABORATORY OF THE TIME OR DATE ON WHICH AN INSPECTION UNDER § 17-202(B) OR (C) OF THIS SUBTITLE IS SCHEDULED TO BE CONDUCTED.

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;
- (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 FREESTANDING 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.]

SECTION 2. AND BE IT FURTHER ENACTED, That, on or before December 15 of each

(Over)

year, the Secretary of Health and Mental Hygiene shall report to the Governor, the Senate Education, Health, and Environmental Affairs Committee, and the House Health and Government Operations Committee regarding:

- (1) the number of licensed medical laboratories in the State;
- (2) the number of discoveries made as a result of investigations conducted under § 17-202(b) or (c) of the Health - General Article;
- (3) the number of reports received under § 17-202.2 of the Health - General Article;
- (4) the steps taken to correct any discoveries or reports identified under items (2) and (3) of this section; and
- (5) the number of actions taken under § 17-216 of the Health - General Article.”.

On page 8, in line 22, strike “2.” and substitute “3.”; and in line 23, strike “October” and substitute “July”.