
By: **Senator Hollinger (Chair, Education, Health, and Environmental Affairs Committee) and Senators Britt, Brochin, Colburn, Conway, Dyson, Greenip, Grosfeld, and Pinsky** Pinsky, Harris, and Kittleman

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Assigned to: Education, Health, and Environmental Affairs

Committee Report: Favorable with amendments

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CHAPTER _____

1 AN ACT concerning

2 **Public Health - Medical Laboratories - Inspection, Information Sharing, and**
 3 **Whistleblower Protection**

4 FOR the purpose of requiring that certain inspections of certain medical laboratories
 5 be unannounced; authorizing the Secretary of Health and Mental Hygiene to
 6 conduct announced inspections under certain circumstances; authorizing certain
 7 employees to disclose certain information to the Secretary of ~~Health and Mental~~
 8 ~~Hygiene~~ under certain circumstances; prohibiting a medical laboratory from
 9 taking certain actions against certain ~~employees~~ persons; authorizing certain
 10 ~~employees~~ persons to institute a certain civil action; requiring a certain civil
 11 action under this Act to be brought within a certain period of time; authorizing
 12 a court to award certain remedies for certain violations of this Act; prohibiting
 13 the Secretary from disclosing the identity of certain ~~employees~~ persons;
 14 requiring the Secretary to develop and disseminate a certain document;
 15 requiring the document to include certain information; requiring a medical
 16 laboratory to post the document in a conspicuous place; authorizing the
 17 Secretary to grant a certain waiver to the requirement to post the document;
 18 requiring the Secretary to provide certain notice to certain entities regarding
 19 certain discoveries and certain reports; requiring the Secretary to develop a
 20 certain format and certain method of transmission of information; requiring the
 21 Secretary to enter certain agreements with certain accrediting organizations;
 22 requiring certain agreements to include certain information; providing for
 23 certain penalties for certain violations; altering the duties and membership of a
 24 certain Laboratory Advisory Committee; requiring a certain annual report; and
 25 generally relating to the inspection, information sharing, and whistleblower
 26 protections for medical laboratories.

1 BY repealing and reenacting, without amendments,
 2 Article - Health - General
 3 Section 17-202(a)
 4 Annotated Code of Maryland
 5 (2000 Replacement Volume and 2004 Supplement)

6 BY repealing and reenacting, with amendments,
 7 Article - Health - General
 8 Section 17-202(b) and (c) ~~and 17-216, 17-216, and 17-217~~
 9 Annotated Code of Maryland
 10 (2000 Replacement Volume and 2004 Supplement)

11 BY adding to
 12 Article - Health - General
 13 Section 17-202.2, 17-202.3, and 17-202.4
 14 Annotated Code of Maryland
 15 (2000 Replacement Volume and 2004 Supplement)

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

18 **Article - Health - General**

19 17-202.

20 (a) (1) The Secretary shall adopt regulations that set standards and
 21 requirements for medical laboratories.

22 (2) The regulations shall contain the standards and requirements that
 23 the Secretary considers necessary to assure the citizens of this State that medical
 24 laboratories provide safe and reliable services.

25 (b) (1) To assure compliance with the standards and requirements adopted
 26 in regulations pursuant to this subtitle, the Secretary shall:

27 (1) Conduct an ~~UNANNOUNCED~~ inspection of each medical
 28 laboratory for which a license to operate is sought; and

29 (2) Conduct an ~~UNANNOUNCED~~ inspection periodically of each
 30 medical laboratory for which a license has been issued.

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

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

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

3 (II) THE SECRETARY DETERMINES THAT AN ANNOUNCED
 4 INSPECTION IS WARRANTED.

5 (c) (1) A medical laboratory accredited by an organization approved by the
 6 Secretary shall be deemed to meet the:

7 (i) State's inspection requirements under subsection ~~(b)(2)~~ (B)(1)(II)
 8 of this section; or

9 (ii) State's standards under this subtitle if the Secretary
 10 determines the standards of the accrediting organization equivalent to the State's
 11 requirements.

12 (2) The medical laboratory shall submit the report of the accrediting
 13 organization to the Secretary within 30 days of its receipt.

14 (3) The Secretary may inspect a medical laboratory accredited by an
 15 organization ON AN UNANNOUNCED BASIS for the purpose of a complaint
 16 investigation or to validate findings of the accrediting organization.

17 17-202.2.

18 (A) ~~AN EMPLOYEE OF A PERSON WHO WORKS IN A MEDICAL LABORATORY~~
 19 ~~MAY DISCLOSE INFORMATION TO THE SECRETARY THAT THE EMPLOYEE PERSON~~
 20 ~~REASONABLY AND IN GOOD FAITH BELIEVES EVIDENCES:~~

21 ~~(1) AN ABUSE OF AUTHORITY, GROSS MISMANAGEMENT, OR GROSS~~
 22 ~~WASTE OF MONEY;~~

23 ~~(2)~~ (1) A SUBSTANTIAL AND SPECIFIC DANGER TO PUBLIC HEALTH OR
 24 SAFETY; OR

25 ~~(3)~~ (2) A VIOLATION OF THE STANDARDS AND REQUIREMENTS FOR
 26 MEDICAL LABORATORIES IN THE STATE.

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

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

36 (I) THE ALLEGED VIOLATION OCCURRED;

1 (II) THE ~~EMPLOYEE PERSON~~ RESIDES; OR

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

4 (2) THE ACTION SHALL BE BROUGHT WITHIN ~~2 YEARS~~ 1 YEAR AFTER
5 THE ALLEGED VIOLATION OF SUBSECTION (B) OF THIS SECTION OCCURRED ~~OR~~
6 ~~WITHIN 2 YEARS AFTER THE EMPLOYEE FIRST BECAME AWARE OF THE ALLEGED~~
7 ~~VIOLATION.~~

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

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

11 (2) REINSTATE THE ~~EMPLOYEE PERSON~~ TO THE SAME OR AN
12 EQUIVALENT POSITION HELD BEFORE THE VIOLATION OF SUBSECTION (B) OF THIS
13 SECTION;

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

16 (4) REINSTATE FULL FRINGE BENEFITS AND SENIORITY RIGHTS;

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

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

21 (7) AWARD ANY OTHER APPROPRIATE DAMAGES AND RELIEF.

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

25 17-202.3.

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

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

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

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

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

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

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

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

14 17-202.4.

15 ~~(A) THE SECRETARY SHALL PROVIDE NOTICE TO ANY ORGANIZATION THAT~~
16 ~~THE SECRETARY DETERMINES HAS OVERSIGHT AUTHORITY OVER MEDICAL~~
17 ~~LABORATORIES IN THE STATE OF~~ ENTER AN INFORMATION SHARING AGREEMENT
18 WITH AN APPROVED ACCREDITING ORGANIZATION TO ENSURE ONGOING
19 COMMUNICATION THAT INCLUDES INFORMATION SHARING REGARDING:

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

22 (2) ~~A REPORT OF NONCOMPLIANCE OR OTHER VIOLATION DISCLOSURE~~
23 MADE BY A PERSON WHO WORKS IN A MEDICAL LABORATORY OBTAINED UNDER §
24 17-202.2 OF THIS SUBTITLE; AND

25 (3) A COMPLAINT FILED BY A CONSUMER OF SERVICES OF A MEDICAL
26 LABORATORY, A FAMILY MEMBER OF A CONSUMER, A FAMILY MEMBER OF A PERSON
27 WHO WORKS IN A MEDICAL LABORATORY, OR OTHER SOURCE.

28 ~~(B) THE SECRETARY SHALL DEVELOP A STANDARD FORMAT AND METHOD OF~~
29 ~~TRANSMISSION OF INFORMATION FOR THE IMPLEMENTATION OF THIS SECTION.~~

30 17-216.

31 (A) (1) A person who violates any provision of this subtitle is guilty of a
32 misdemeanor and on conviction is subject to a fine not exceeding ~~\$100~~ \$5,000 for the
33 first offense and not exceeding ~~\$500~~ \$10,000 for each subsequent conviction for a
34 violation of the same provision.

35 (2) Each day a violation is continued after the first conviction is a
36 subsequent offense.

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

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

8 17-217.

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

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

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

15 (b) The Advisory Committee shall consist of:

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

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

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

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

21 (iv) 1 member of the American Society of Clinical Pathologists; and

22 (v) 1 member of the American College of Pathology; and

23 (2) 1 representative of the Health Industry Manufacturers Association]

24 (1) 1 REPRESENTATIVE FROM THE DEPARTMENT;

25 (2) 1 PATHOLOGIST FROM A HOSPITAL LABORATORY;

26 (3) 1 PATHOLOGIST FROM A FREE-STANDING INDEPENDENT
27 LABORATORY;

28 (4) 1 PHYSICIAN FROM A LABORATORY THAT CONDUCTS FEWER THAN
29 25,000 TESTS PER YEAR;

30 (5) 3 MEDICAL TECHNOLOGISTS THAT WORK IN A MEDICAL
31 LABORATORY;

1 (6) 1 REPRESENTATIVE FROM EACH APPROVED ACCREDITING
2 ORGANIZATION; AND

3 (7) 2 CONSUMERS, 1 OF WHOM THE SECRETARY SHALL APPOINT TO
4 SERVE AS THE CHAIR OF THE ADVISORY COMMITTEE.

5 (c) The Secretary may appoint any other individuals or representatives at the
6 Secretary's discretion.

7 (d) The chairman of the Advisory Committee shall be designated by the
8 Secretary every 2 years.]

9 SECTION 2. AND BE IT FURTHER ENACTED, That, on or before December
10 15 of each year, the Secretary of Health and Mental Hygiene shall report to the
11 Governor, the Senate Education, Health, and Environmental Affairs Committee, and
12 the House Health and Government Operations Committee regarding:

13 (1) the number of licensed medical laboratories in the State;

14 (2) the number of discoveries made as a result of investigations conducted
15 under § 17-202(b) or (c) of the Health - General Article;

16 (3) the number of reports received under § 17-202.2 of the Health - General
17 Article;

18 (4) the steps taken to correct any discoveries or reports identified under items
19 (2) and (3) of this section; and

20 (5) the number of actions taken under § 17-216 of the Health - General
21 Article.

22 SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect
23 July 1, 2005.