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

Introduced and read first time: January 26, 2005

Assigned to: Education, Health, and Environmental Affairs

A BILL ENTITLED

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 certain employees to disclose certain information
6 to the Secretary of Health and Mental Hygiene under certain circumstances;
7 prohibiting a medical laboratory from taking certain actions against certain
8 employees; authorizing certain employees to institute a certain civil action;
9 requiring a certain civil action under this Act to be brought within a certain
10 period of time; authorizing a court to award certain remedies for certain
11 violations of this Act; prohibiting the Secretary from disclosing the identity of
12 certain employees; requiring the Secretary to develop and disseminate a certain
13 document; requiring the document to include certain information; requiring a
14 medical laboratory to post the document in a conspicuous place; requiring the
15 Secretary to provide certain notice to certain entities regarding certain
16 discoveries and certain reports; requiring the Secretary to develop a certain
17 format and certain method of transmission of information; providing for certain
18 penalties for certain violations; requiring a certain annual report; and generally
19 relating to the inspection, information sharing, and whistleblower protections
20 for medical laboratories.

21 BY repealing and reenacting, without amendments,
22 Article - Health - General
23 Section 17-202(a)
24 Annotated Code of Maryland
25 (2000 Replacement Volume and 2004 Supplement)

26 BY repealing and reenacting, with amendments,
27 Article - Health - General
28 Section 17-202(b) and (c) and 17-216
29 Annotated Code of Maryland
30 (2000 Replacement Volume and 2004 Supplement)

1 BY adding to
2 Article - Health - General
3 Section 17-202.2, 17-202.3, and 17-202.4
4 Annotated Code of Maryland
5 (2000 Replacement Volume and 2004 Supplement)

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

8 **Article - Health - General**

9 17-202.

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

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

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

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

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

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

23 (i) State's inspection requirements under subsection (b)(2) of this
24 section; or

25 (ii) State's standards under this subtitle if the Secretary
26 determines the standards of the accrediting organization equivalent to the State's
27 requirements.

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

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

1 17-202.2.

2 (A) AN EMPLOYEE OF A MEDICAL LABORATORY MAY DISCLOSE INFORMATION
3 TO THE SECRETARY THAT THE EMPLOYEE REASONABLY BELIEVES EVIDENCES:

4 (1) AN ABUSE OF AUTHORITY, GROSS MISMANAGEMENT, OR GROSS
5 WASTE OF MONEY;

6 (2) A SUBSTANTIAL AND SPECIFIC DANGER TO PUBLIC HEALTH OR
7 SAFETY; OR

8 (3) A VIOLATION OF THE STANDARDS AND REQUIREMENTS FOR
9 MEDICAL LABORATORIES IN THE STATE.

10 (B) A MEDICAL LABORATORY MAY NOT TAKE AN ADVERSE EMPLOYMENT
11 ACTION INCLUDING DISCRIMINATION OR RETALIATION AGAINST AN EMPLOYEE OF A
12 MEDICAL LABORATORY BECAUSE THE EMPLOYEE DISCLOSES THE INFORMATION
13 UNDER SUBSECTION (A) OF THIS SECTION OR HAS AGREED TO COOPERATE WITH AN
14 INVESTIGATION OF THE MEDICAL LABORATORY.

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

18 (I) THE ALLEGED VIOLATION OCCURRED;

19 (II) THE EMPLOYEE RESIDES; OR

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

22 (2) THE ACTION SHALL BE BROUGHT WITHIN 2 YEARS AFTER THE
23 ALLEGED VIOLATION OF SUBSECTION (B) OF THIS SECTION OCCURRED OR WITHIN 2
24 YEARS AFTER THE EMPLOYEE FIRST BECAME AWARE OF THE ALLEGED VIOLATION.

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

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

28 (2) REINSTATE THE EMPLOYEE TO THE SAME OR AN EQUIVALENT
29 POSITION HELD BEFORE THE VIOLATION OF SUBSECTION (B) OF THIS SECTION;

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

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

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

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

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

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

7 17-202.3.

8 (A) THE SECRETARY SHALL DEVELOP AND DISSEMINATE A DOCUMENT THAT
9 INFORMS THE EMPLOYEES OF A MEDICAL LABORATORY OF THE MANNER IN WHICH
10 TO REPORT INSTANCES OF NONCOMPLIANCE OR OTHER VIOLATIONS OF THE
11 STANDARDS AND REQUIREMENTS FOR MEDICAL LABORATORIES IN THE STATE.

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

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

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

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

20 (4) A TOLL-FREE TELEPHONE NUMBER, OPERATED BY THE
21 DEPARTMENT, THROUGH WHICH AN EMPLOYEE MAY REPORT.

22 (C) A MEDICAL LABORATORY SHALL POST THE DOCUMENT DEVELOPED
23 UNDER SUBSECTION (A) OF THIS SECTION IN A CONSPICUOUS PLACE.

24 17-202.4.

25 (A) THE SECRETARY SHALL PROVIDE NOTICE TO ANY ORGANIZATION THAT
26 THE SECRETARY DETERMINES HAS OVERSIGHT AUTHORITY OVER MEDICAL
27 LABORATORIES IN THE STATE OF:

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

30 (2) A REPORT OF NONCOMPLIANCE OR OTHER VIOLATION OBTAINED
31 UNDER § 17-202.2 OF THIS SUBTITLE.

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

1 17-216.

2 (A) (1) A person who violates any provision of this subtitle is guilty of a
3 misdemeanor and on conviction is subject to a fine not exceeding \$100 for the first
4 offense and not exceeding \$500 for each subsequent conviction for a violation of the
5 same provision.

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

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

13 SECTION 2. AND BE IT FURTHER ENACTED, That, on or before December
14 15 of each year, the Secretary of Health and Mental Hygiene shall report to the
15 Governor, the Senate Education, Health, and Environmental Affairs Committee, and
16 the House Health and Government Operations Committee regarding:

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

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

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

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

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

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