
By: ~~Delegate Donoghue~~ Delegates Donoghue, Benson, Boteler, Boutin, Bromwell, Costa, Elliott, Frank, Goldwater, Hammen, Hubbard, Hurson, Kach, Kullen, Mandel, McDonough, Morhaim, Murray, Nathan-Pulliam, Oaks, Pendergrass, Rudolph, V. Turner, and Weldon

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Assigned to: Economic Matters and Health and Government Operations

Committee Report: Favorable with amendments

House action: Adopted

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CHAPTER _____

1 AN ACT concerning

2 **Medical Laboratories - Whistleblower Protection and Regulation**

3 FOR the purpose of prohibiting certain medical laboratories from taking or refusing
 4 to take certain personnel actions as a reprisal against certain employees who
 5 disclose or threaten to disclose unlawful behavior, refuse to participate in
 6 unlawful behavior, or provide certain information or testimony to certain public
 7 bodies investigating, hearing, or inquiring into unlawful behavior; requiring the
 8 Secretary of Health and Mental Hygiene to adopt regulations that require
 9 medical laboratories to post a certain notice indicating certain information
 10 about reporting the medical laboratory's noncompliance with certain standards
 11 and requirements; requiring the Secretary to specify the form of the notice;
 12 authorizing the Secretary to grant a certain waiver to the requirement to post
 13 the notice; authorizing the Secretary to enter certain agreements with certain
 14 accrediting organizations; requiring certain agreements to include certain
 15 information; requiring the Secretary to promptly determine whether a certain
 16 report should be investigated; requiring the Secretary to conduct a prompt
 17 investigation of a medical laboratory without prior notice to the medical
 18 laboratory under certain circumstances; providing a civil penalty to certain
 19 individuals who notify or cause to be notified certain medical laboratories of
 20 certain inspections; requiring the Secretary to submit a certain report each year
 21 to the Governor and certain committees of the General Assembly including
 22 certain information; authorizing certain employees to institute a civil action in
 23 certain counties; requiring that an employee file a civil action under this Act
 24 within a certain time period; prohibiting the Secretary from disclosing the
 25 identity of certain persons; establishing the remedies a court may impose;

1 providing a defense that the personnel action was based on grounds other than
2 those protected under this Act; altering certain criminal penalties for certain
3 violations; defining certain terms; and generally relating to whistleblower
4 protection and regulation of medical laboratories.

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

10 BY adding to
11 Article - Health - General
12 Section 17-701 through 17-705, inclusive, to be under the new subtitle "Subtitle
13 7. Medical Laboratory Whistleblower Protection Act"
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 (3) (I) THE REGULATIONS SHALL REQUIRE EACH MEDICAL
26 LABORATORY TO POST IN A CONSPICUOUS PLACE A NOTICE TO EMPLOYEES THAT
27 INDICATES THE MANNER IN WHICH TO REPORT INSTANCES OF NONCOMPLIANCE
28 WITH MEDICAL LABORATORY STANDARDS AND REQUIREMENTS, INCLUDING
29 DEFICIENCIES REGARDING TESTING, QUALITY, AND INADEQUATELY TRAINED
30 PERSONNEL.

31 (II) THE SECRETARY MAY WAIVE THE NOTICE REQUIREMENT FOR
32 A MEDICAL LABORATORY ACCREDITED BY AN ORGANIZATION APPROVED BY THE
33 SECRETARY IF THE ACCREDITING ORGANIZATION HAS AN EQUIVALENT
34 REQUIREMENT.

35 ~~(H)~~ (III) THE NOTICE REQUIRED UNDER SUBPARAGRAPH (I) OF
36 THIS PARAGRAPH SHALL INCLUDE:

1 1. THE NAME AND CONTACT INFORMATION OF THE
2 SUPERVISOR, THE DEPARTMENT, AND ACCREDITING ORGANIZATION TO REPORT
3 INSTANCES OF NONCOMPLIANCE OF A LAW, RULE, OR REGULATION; AND

4 2. A DESCRIPTION OF THE RIGHTS AND PROTECTIONS
5 UNDER THIS SECTION OF INDIVIDUALS WHO REPORT INSTANCES OF
6 NONCOMPLIANCE OF A LAW, RULE, OR REGULATION.

7 ~~(III)~~ (IV) THE SECRETARY SHALL SPECIFY THE FORM OF THE
8 NOTICE.

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

11 [(1)] (I) Conduct an inspection of each medical laboratory for which a
12 license to operate is sought; and

13 [(2)] (II) Conduct an inspection periodically of each medical laboratory
14 for which a license has been issued.

15 (2) (I) ON RECEIPT OF A REPORT OF AN INSTANCE OF A MEDICAL
16 LABORATORY'S NONCOMPLIANCE WITH A LAW, RULE, OR REGULATION, THE
17 SECRETARY SHALL PROMPTLY DETERMINE WHETHER TO INVESTIGATE THE REPORT.

18 (II) IF THE SECRETARY DETERMINES TO INVESTIGATE A REPORT
19 RECEIVED UNDER SUBPARAGRAPH (I) OF THIS PARAGRAPH, THE SECRETARY SHALL
20 CONDUCT AN INSPECTION OF THE MEDICAL LABORATORY WITHOUT PRIOR NOTICE
21 TO THE MEDICAL LABORATORY.

22 (III) ANY INDIVIDUAL WHO NOTIFIES OR CAUSES TO BE NOTIFIED A
23 MEDICAL LABORATORY OF THE TIME AND DATE OF AN INSPECTION CONDUCTED IN
24 ACCORDANCE WITH SUBPARAGRAPH (II) OF THIS PARAGRAPH IS SUBJECT TO A CIVIL
25 PENALTY NOT TO EXCEED \$2,000.

26 ~~(IV) THE SECRETARY SHALL ANNUALLY SUBMIT A REPORT TO THE
27 GOVERNOR AND, IN ACCORDANCE WITH § 2-1246 OF THE STATE GOVERNMENT
28 ARTICLE, THE GENERAL ASSEMBLY INCLUDING THE FOLLOWING INFORMATION:~~

29 ~~1. THE ACTIONS TAKEN UNDER THE PROVISIONS OF THIS
30 PARAGRAPH;~~

31 ~~2. THE PROMPTNESS WITH WHICH THE ACTIONS UNDER
32 THIS PARAGRAPH WERE TAKEN;~~

33 ~~3. THE FINDINGS OF ANY INVESTIGATIONS CONDUCTED;~~
34 ~~AND~~

35 ~~4. ANY ACTIONS TAKEN BASED ON THE FINDINGS.~~

1 (IV) ON OR BEFORE DECEMBER 15 OF EACH YEAR, THE SECRETARY
2 OF HEALTH AND MENTAL HYGIENE SHALL SUBMIT A REPORT TO THE GOVERNOR,
3 THE SENATE EDUCATION, HEALTH, AND ENVIRONMENTAL AFFAIRS COMMITTEE,
4 AND THE HOUSE HEALTH AND GOVERNMENT OPERATIONS COMMITTEE REGARDING:

5 1. THE NUMBER OF LICENSED MEDICAL LABORATORIES IN
6 THE STATE;

7 2. THE NUMBER OF DISCOVERIES MADE AS A RESULT OF
8 INVESTIGATIONS CONDUCTED UNDER THIS PARAGRAPH;

9 3. THE NUMBER OF REPORTS RECEIVED UNDER THIS
10 PARAGRAPH;

11 4. THE STEPS TAKEN TO CORRECT ANY DISCOVERIES OR
12 REPORTS IDENTIFIED UNDER THIS SECTION AND THE PROMPTNESS WITH WHICH
13 THE ACTIONS WERE TAKEN; AND

14 5. THE NUMBER OF ACTIONS TAKEN UNDER § 17-216 OF THE
15 HEALTH - GENERAL ARTICLE.

16 (V) THE SECRETARY MAY ENTER INTO AN INFORMATION SHARING
17 AGREEMENT WITH AN APPROVED ACCREDITING ORGANIZATION TO ENSURE
18 ONGOING COMMUNICATION THAT INCLUDES INFORMATION SHARING REGARDING A
19 DISCOVERY OF NONCOMPLIANCE OR OTHER VIOLATIONS OBTAINED UNDER §
20 17-202(B) OF THIS SUBTITLE.

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)] (B)(1)
24 of this 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 for the purpose of a complaint investigation or to validate findings of the
32 accrediting organization.

33 (d) (1) In addition to the regulations adopted under subsection (a) of this
34 section, the Secretary shall adopt regulations establishing specific standards for
35 medical laboratories engaged in cytology, including regulations that:

36 (i) Limit the number of slides an individual may examine;

1 (ii) Require that the examination of cytology slides be performed in
2 a medical laboratory that has a license issued by the Secretary;

3 (iii) Prohibit payment to cytotechnologists for the examination of
4 cytology specimens or slides on a piecework basis;

5 (iv) Require cytology laboratories to review no less than 10 percent
6 of all negative gynecological slides;

7 (v) Require that the cytology review be performed by an individual
8 who qualifies as a supervisory cytotechnologist or a pathologist;

9 (vi) Require the individual who directs the laboratory to establish
10 and administer an ongoing quality assurance program using standards acceptable to
11 the Secretary;

12 (vii) Require cytology laboratories to reject unsatisfactorily prepared
13 specimens, make appropriate comments regarding the quality of the specimen, and
14 maintain records on unsatisfactorily prepared specimens for 5 years subject to review
15 by the Department;

16 (viii) Require cytology laboratories to maintain and store for 5 years
17 from the date of examination any slide that was examined;

18 (ix) Require all cytology reports to be retained for at least 10 years;

19 (x) Prohibit any person from sending cytology specimens to a
20 laboratory, including out-of-state laboratories, not licensed by the Department;

21 (xi) Require all individuals who examine gynecological slides
22 acquired from persons in this State to demonstrate satisfactory performance in an
23 approved cytology proficiency testing program; and

24 (xii) Establish any additional standards the Secretary considers
25 necessary to assure that medical laboratories engaged in cytology provide safe and
26 reliable services.

27 (2) The requirements of paragraph (1) of this subsection are in addition
28 to any other relevant provision of this subtitle or relevant regulation adopted in
29 accordance with any other provision of this subtitle governing medical laboratories.

30 (e) (1) To assure compliance with standards adopted under subsection (d) of
31 this section, the Secretary shall adopt regulations to establish and conduct a cytology
32 proficiency testing program for all cytology personnel that examine gynecological
33 cytology specimens.

34 (2) All cytology proficiency tests under the State cytology proficiency
35 testing program shall be conducted by an employee of the Department of Health and
36 Mental Hygiene who shall:

1 (i) Hand carry all testing materials to the testing site; and

2 (ii) Directly supervise the on-site proficiency testing.

3 (3) A medical laboratory shall pay the Department a fee established by
4 the Secretary to cover the cost of the laboratory's State cytology proficiency testing
5 program under this section.

6 (4) The Secretary shall adopt regulations for the cytology proficiency
7 testing program that:

8 (i) Define satisfactory cytology proficiency testing performance;
9 and

10 (ii) Set standards and requirements that a cytology proficiency
11 testing program must meet before it can be designated an approved program.

12 (5) The Secretary may accept the testing results of an approved cytology
13 proficiency testing program as meeting the cytology proficiency testing requirement
14 of this subtitle.

15 17-216.

16 A person who violates any provision of this subtitle is guilty of a misdemeanor
17 and on conviction is subject to a fine not exceeding [\$100] \$5,000 for the first offense
18 and not exceeding [\$500] \$10,000 for each subsequent conviction for a violation of the
19 same provision. Each day a violation is continued after the first conviction is a
20 subsequent offense.

21 SUBTITLE 7. MEDICAL LABORATORY WHISTLEBLOWER PROTECTION ACT.

22 17-701.

23 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
24 INDICATED.

25 (B) "EMPLOYEE" MEANS ANY INDIVIDUAL LICENSED, CERTIFIED, OR HIRED
26 TO PERFORM SERVICES FOR AND UNDER THE CONTROL AND DIRECTION OF A
27 MEDICAL LABORATORY FOR WAGES AND OTHER REMUNERATION.

28 (C) "SUPERVISOR" MEANS ANY INDIVIDUAL WITHIN A MEDICAL LABORATORY
29 ORGANIZATION WHO HAS THE AUTHORITY TO DIRECT AND CONTROL THE WORK
30 PERFORMANCE OF AN EMPLOYEE, OR WHO HAS MANAGERIAL AUTHORITY TO TAKE
31 CORRECTIVE ACTION REGARDING THE VIOLATION OF A LAW, RULE, OR REGULATION
32 OF WHICH THE EMPLOYEE COMPLAINS.

33 17-702.

34 A MEDICAL LABORATORY MAY NOT TAKE OR REFUSE TO TAKE ANY PERSONNEL
35 ACTION AS A REPRISAL AGAINST AN EMPLOYEE BECAUSE THE EMPLOYEE:

1 (1) DISCLOSES OR THREATENS TO DISCLOSE TO A SUPERVISOR, THE
2 DEPARTMENT, OR AN ACCREDITING ORGANIZATION ANY ACTIVITY, POLICY, OR
3 PRACTICE OF THE EMPLOYER THAT IS IN VIOLATION OF A LAW, RULE, OR
4 REGULATION REGARDING THE CLINICAL DIAGNOSTIC LABORATORY TESTS
5 PERFORMED BY THE MEDICAL LABORATORY THAT THE EMPLOYEE REASONABLY
6 AND IN GOOD FAITH BELIEVES EVIDENCES:

7 (I) A SUBSTANTIAL AND SPECIFIC DANGER TO PUBLIC HEALTH OR
8 SAFETY; OR

9 (II) A VIOLATION OF THE STANDARDS AND REQUIREMENTS FOR
10 MEDICAL LABORATORIES IN THE STATE;

11 (2) PROVIDES INFORMATION TO OR TESTIFIES BEFORE ANY PUBLIC
12 BODY CONDUCTING AN INVESTIGATION, HEARING, OR INQUIRY INTO ANY
13 VIOLATION OF A LAW, RULE, OR REGULATION REGARDING THE CLINICAL
14 DIAGNOSTIC LABORATORY TESTS PERFORMED BY THE MEDICAL LABORATORY; OR

15 (3) OBJECTS TO OR REFUSES TO PARTICIPATE IN ANY ACTIVITY, POLICY,
16 OR PRACTICE IN VIOLATION OF A LAW, RULE, OR REGULATION REGARDING THE
17 CLINICAL DIAGNOSTIC LABORATORY TESTS PERFORMED BY THE MEDICAL
18 LABORATORY.

19 17-703.

20 (A) AN EMPLOYEE WHO IS SUBJECT TO A PERSONNEL ACTION IN VIOLATION
21 OF § 17-702 OF THIS SUBTITLE MAY INSTITUTE A CIVIL ACTION IN THE COUNTY
22 WHERE:

23 (1) THE ALLEGED VIOLATION OCCURRED;

24 (2) THE EMPLOYEE RESIDES; OR

25 (3) THE MEDICAL LABORATORY MAINTAINS ITS PRINCIPAL OFFICES IN
26 THE STATE.

27 (B) THE ACTION SHALL BE BROUGHT WITHIN ~~2-YEARS~~ 1 YEAR AFTER THE
28 ALLEGED VIOLATION OF § 17-702 OF THIS SUBTITLE OCCURRED, OR WITHIN ~~2-YEARS~~
29 1 YEAR AFTER THE EMPLOYEE FIRST BECAME AWARE OF THE ALLEGED VIOLATION
30 OF § 17-702 OF THIS SUBTITLE.

31 (C) IF A REPORT MADE UNDER THIS SECTION IS MADE ANONYMOUSLY, THE
32 SECRETARY MAY NOT DISCLOSE THE IDENTITY OF THE EMPLOYEE MAKING THE
33 REPORT TO A MEDICAL LABORATORY.

1 17-704.

2 IN AN ACTION BROUGHT UNDER THIS SUBTITLE, A COURT MAY:

3 (1) ISSUE AN INJUNCTION TO RESTRAIN CONTINUED VIOLATION OF
4 THIS SUBTITLE;

5 (2) REINSTATE THE EMPLOYEE TO THE SAME OR AN EQUIVALENT
6 POSITION HELD BEFORE THE VIOLATION OF § 17-702 OF THIS SUBTITLE;

7 (3) REMOVE ANY ADVERSE PERSONNEL RECORD ENTRIES BASED ON OR
8 RELATED TO THE VIOLATION OF § 17-702 OF THIS SUBTITLE;

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

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

12 (6) ASSESS REASONABLE ATTORNEY'S FEES AND OTHER LITIGATION
13 EXPENSES AGAINST:

14 (I) THE MEDICAL LABORATORY, IF THE EMPLOYEE PREVAILS; OR

15 (II) THE EMPLOYEE, IF THE COURT DETERMINES THAT THE
16 ACTION WAS BROUGHT BY THE EMPLOYEE IN BAD FAITH AND WITHOUT BASIS IN
17 LAW OR FACT.

18 17-705.

19 IN AN ACTION BROUGHT UNDER THIS SUBTITLE, IT IS A DEFENSE THAT THE
20 PERSONNEL ACTION WAS BASED ON GROUNDS OTHER THAN THE EMPLOYEE'S
21 EXERCISE OF ANY RIGHTS PROTECTED UNDER THIS SUBTITLE.

22 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take
23 effect October 1, 2005.