
By: **Delegate Donoghue**

Introduced and read first time: January 28, 2005

Assigned to: Economic Matters and Health and Government Operations

A BILL ENTITLED

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 requiring the Secretary to promptly determine whether a certain report should
13 be investigated; requiring the Secretary to conduct a prompt investigation of a
14 medical laboratory without prior notice to the medical laboratory under certain
15 circumstances; providing a civil penalty to certain individuals who notify or
16 cause to be notified certain medical laboratories of certain inspections; requiring
17 the Secretary to submit a certain report each year to the Governor and General
18 Assembly including certain information; authorizing certain employees to
19 institute a civil action in certain counties; requiring that an employee file a civil
20 action under this Act within a certain time period; establishing the remedies a
21 court may impose; providing a defense that the personnel action was based on
22 grounds other than those protected under this Act; defining certain terms; and
23 generally relating to whistleblower protection and regulation of medical
24 laboratories.

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

30 BY adding to
31 Article - Health - General
32 Section 17-701 through 17-705, inclusive, to be under the new subtitle "Subtitle

1 (II) IF THE SECRETARY DETERMINES TO INVESTIGATE A REPORT
2 RECEIVED UNDER SUBPARAGRAPH (I) OF THIS PARAGRAPH, THE SECRETARY SHALL
3 CONDUCT AN INSPECTION OF THE MEDICAL LABORATORY WITHOUT PRIOR NOTICE
4 TO THE MEDICAL LABORATORY.

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

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

12 1. THE ACTIONS TAKEN UNDER THE PROVISIONS OF THIS
13 PARAGRAPH;

14 2. THE PROMPTNESS WITH WHICH THE ACTIONS UNDER
15 THIS PARAGRAPH WERE TAKEN;

16 3. THE FINDINGS OF ANY INVESTIGATIONS CONDUCTED;
17 AND

18 4. ANY ACTIONS TAKEN BASED ON THE FINDINGS.

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

21 (i) State's inspection requirements under subsection [(b)(2)] (B)(1)
22 of this section; or

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

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

28 (3) The Secretary may inspect a medical laboratory accredited by an
29 organization for the purpose of a complaint investigation or to validate findings of the
30 accrediting organization.

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

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

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

- 1 (iii) Prohibit payment to cytotechnologists for the examination of
2 cytology specimens or slides on a piecework basis;
- 3 (iv) Require cytology laboratories to review no less than 10 percent
4 of all negative gynecological slides;
- 5 (v) Require that the cytology review be performed by an individual
6 who qualifies as a supervisory cytotechnologist or a pathologist;
- 7 (vi) Require the individual who directs the laboratory to establish
8 and administer an ongoing quality assurance program using standards acceptable to
9 the Secretary;
- 10 (vii) Require cytology laboratories to reject unsatisfactorily prepared
11 specimens, make appropriate comments regarding the quality of the specimen, and
12 maintain records on unsatisfactorily prepared specimens for 5 years subject to review
13 by the Department;
- 14 (viii) Require cytology laboratories to maintain and store for 5 years
15 from the date of examination any slide that was examined;
- 16 (ix) Require all cytology reports to be retained for at least 10 years;
- 17 (x) Prohibit any person from sending cytology specimens to a
18 laboratory, including out-of-state laboratories, not licensed by the Department;
- 19 (xi) Require all individuals who examine gynecological slides
20 acquired from persons in this State to demonstrate satisfactory performance in an
21 approved cytology proficiency testing program; and
- 22 (xii) Establish any additional standards the Secretary considers
23 necessary to assure that medical laboratories engaged in cytology provide safe and
24 reliable services.
- 25 (2) The requirements of paragraph (1) of this subsection are in addition
26 to any other relevant provision of this subtitle or relevant regulation adopted in
27 accordance with any other provision of this subtitle governing medical laboratories.
- 28 (e) (1) To assure compliance with standards adopted under subsection (d) of
29 this section, the Secretary shall adopt regulations to establish and conduct a cytology
30 proficiency testing program for all cytology personnel that examine gynecological
31 cytology specimens.
- 32 (2) All cytology proficiency tests under the State cytology proficiency
33 testing program shall be conducted by an employee of the Department of Health and
34 Mental Hygiene who shall:
- 35 (i) Hand carry all testing materials to the testing site; and
- 36 (ii) Directly supervise the on-site proficiency testing.

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

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

6 (i) Define satisfactory cytology proficiency testing performance;
7 and

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

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

13 SUBTITLE 7. MEDICAL LABORATORY WHISTLEBLOWER PROTECTION ACT.

14 17-701.

15 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
16 INDICATED.

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

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

25 17-702.

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

28 (1) DISCLOSES OR THREATENS TO DISCLOSE TO A SUPERVISOR, THE
29 DEPARTMENT, OR AN ACCREDITING ORGANIZATION ANY ACTIVITY, POLICY, OR
30 PRACTICE OF THE EMPLOYER THAT IS IN VIOLATION OF A LAW, RULE, OR
31 REGULATION REGARDING THE CLINICAL DIAGNOSTIC LABORATORY TESTS
32 PERFORMED BY THE MEDICAL LABORATORY;

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

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

5 17-703.

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

9 (1) THE ALLEGED VIOLATION OCCURRED;

10 (2) THE EMPLOYEE RESIDES; OR

11 (3) THE MEDICAL LABORATORY MAINTAINS ITS PRINCIPAL OFFICES IN
12 THE STATE.

13 (B) THE ACTION SHALL BE BROUGHT WITHIN 2 YEARS AFTER THE ALLEGED
14 VIOLATION OF § 17-702 OF THIS SUBTITLE OCCURRED, OR WITHIN 2 YEARS AFTER
15 THE EMPLOYEE FIRST BECAME AWARE OF THE ALLEGED VIOLATION OF § 17-702 OF
16 THIS SUBTITLE.

17 17-704.

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

19 (1) ISSUE AN INJUNCTION TO RESTRAIN CONTINUED VIOLATION OF
20 THIS SUBTITLE;

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

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

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

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

28 (6) ASSESS REASONABLE ATTORNEY'S FEES AND OTHER LITIGATION
29 EXPENSES AGAINST:

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

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

1 17-705.

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

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