**Unofficial Copy** **2005 Regular Session**
**SB0250/113595/1**

BY: Economic Matters Committee

AMENDMENTS TO SENATE BILL NO. 250
(Third Reading File Bill)

AMENDMENT NO. 1

On page 1, in line 2, after "Laboratories -" strike "Inspection"; and in line 2, after "Sharing" strike the comma.

AMENDMENT NO. 2

On pages 1 through 7, strike beginning with line 4 on page 1 through line 23 on page 7, inclusive, and substitute:

"FOR the purpose of prohibiting certain medical laboratories from taking or refusing to take certain personnel actions as a reprisal against certain employees who disclose or threaten to disclose unlawful behavior, refuse to participate in unlawful behavior, or provide certain information or testimony to certain public bodies conducting investigations, hearings, or inquiries into unlawful behavior; requiring the Secretary of Health and Mental Hygiene to adopt regulations that require medical laboratories to post a certain notice indicating certain information about reporting the medical laboratory's noncompliance with certain standards and requirements; requiring the Secretary to specify the form of the notice; authorizing the Secretary to grant a certain waiver to the requirement to post the notice; authorizing the Secretary to enter into certain agreements with certain accrediting organizations; requiring certain agreements to include certain information; requiring the Secretary to promptly determine whether a certain report should be investigated; requiring the Secretary to conduct a prompt investigation of a medical laboratory without prior notice to the medical laboratory under certain circumstances; providing a civil penalty to certain individuals who notify or cause to be notified certain medical laboratories of certain inspections; requiring the Secretary to submit a certain report each year to the Governor and certain committees of the General Assembly including certain information; authorizing certain employees to institute a civil action in certain counties; requiring that an employee file a civil action under this Act within a certain time period; prohibiting the Secretary from disclosing the identity of certain

(Over)

persons; establishing the remedies a court may impose; providing a defense that the personnel action was based on grounds other than those protected under this Act; altering certain criminal penalties for certain violations; defining certain terms; and generally relating to whistleblower protection and regulation of medical laboratories.

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

BY adding to
Article - Health - General
Section 17-701 through 17-705, inclusive, to be under the new subtitle "Subtitle 7. Medical Laboratory Whistleblower Protection Act"
Annotated Code of Maryland
(2000 Replacement Volume and 2004 Supplement)

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

Article - Health - General

17-202.

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

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

(3) (I) THE REGULATIONS SHALL REQUIRE EACH MEDICAL LABORATORY TO POST IN A CONSPICUOUS PLACE A NOTICE TO EMPLOYEES THAT INDICATES THE MANNER IN WHICH TO REPORT INSTANCES OF NONCOMPLIANCE

WITH MEDICAL LABORATORY STANDARDS AND REQUIREMENTS, INCLUDING DEFICIENCIES REGARDING TESTING, QUALITY, AND INADEQUATELY TRAINED PERSONNEL.

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

(III) THE NOTICE REQUIRED UNDER SUBPARAGRAPH (I) OF THIS PARAGRAPH SHALL INCLUDE:

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

2. A DESCRIPTION OF THE RIGHTS AND PROTECTIONS UNDER SUBTITLE 7 OF THIS TITLE OF INDIVIDUALS WHO REPORT INSTANCES OF NONCOMPLIANCE WITH A LAW, RULE, OR REGULATION.

(IV) THE SECRETARY SHALL SPECIFY THE FORM OF THE NOTICE.

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

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

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

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

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

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

(IV) ON OR BEFORE DECEMBER 15 OF EACH YEAR, THE SECRETARY OF HEALTH AND MENTAL HYGIENE SHALL SUBMIT A 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 OF NONCOMPLIANCE MADE AS A RESULT OF INVESTIGATIONS CONDUCTED UNDER THIS PARAGRAPH;

3. THE NUMBER OF REPORTS RECEIVED UNDER THIS PARAGRAPH;

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

5. THE NUMBER OF ACTIONS TAKEN UNDER § 17-216 OF

THIS SUBTITLE.

(V) THE SECRETARY MAY ENTER INTO AN INFORMATION SHARING AGREEMENT WITH AN APPROVED ACCREDITING ORGANIZATION TO ENSURE ONGOING COMMUNICATION THAT INCLUDES INFORMATION SHARING REGARDING A DISCOVERY OF NONCOMPLIANCE OR OTHER VIOLATIONS OBTAINED UNDER THIS SUBSECTION.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(e) (1) To assure compliance with standards adopted under subsection (d) of this section, the Secretary shall adopt regulations to establish and conduct a cytology proficiency testing

program for all cytology personnel that examine gynecological cytology specimens.

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

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

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

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

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

(i) Define satisfactory cytology proficiency testing performance; and

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

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

17-216.

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

SUBTITLE 7. MEDICAL LABORATORY WHISTLEBLOWER PROTECTION ACT.

17-701.

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

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

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

17-702.

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

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

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

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

(2) PROVIDES INFORMATION TO OR TESTIFIES BEFORE ANY PUBLIC BODY CONDUCTING AN INVESTIGATION, HEARING, OR INQUIRY INTO ANY

VIOLATION OF A LAW, RULE, OR REGULATION REGARDING THE CLINICAL DIAGNOSTIC LABORATORY TESTS PERFORMED BY THE MEDICAL LABORATORY; OR

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

17-703.

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

(1) THE ALLEGED VIOLATION OCCURRED;

(2) THE EMPLOYEE RESIDES; OR

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

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

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

17-704.

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

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

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

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

(4) REINSTATE FULL FRINGE BENEFITS AND SENIORITY RIGHTS;

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

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

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

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

17-705.

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

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