

By: **Chairman, Education, Health, and Environmental Affairs Committee**
(By Request - Departmental - Health and Mental Hygiene)

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Assigned to: Education, Health, and Environmental Affairs

Committee Report: Favorable with amendments
Senate action: Adopted
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CHAPTER _____

1 AN ACT concerning

2 **Department of Health and Mental Hygiene - Medical Laboratories - Retests**
3 **and Public Notification**

4 FOR the purpose of authorizing the Secretary of Health and Mental Hygiene to order
5 certain laboratories to ~~retest patients and provide public notification to~~
6 physicians, patients, and the general public in the event of testing errors notify
7 certain physicians or other individuals of certain test results and take certain
8 measures to reduce or eliminate certain threats under certain circumstances;
9 establishing a civil penalty for noncompliance; and generally relating to the
10 regulation of medical laboratories.

11 BY repealing and reenacting, with amendments,
12 Article - Health - General
13 Section 17-210
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 17-210.

20 (a) The Secretary may deny a license to any applicant or suspend, revoke, or
21 limit a license or the authority to offer or perform any class of service, complexity of
22 testing, or tests that the license sets forth, if the medical laboratory or its director or

1 other personnel fail to meet the standards and requirements under this subtitle and
 2 in regulations adopted pursuant to this subtitle.

3 (b) (1) If the Secretary finds that a laboratory issued a license under this
 4 subtitle no longer meets the standards and requirements under this subtitle and in
 5 regulations adopted pursuant to this subtitle, the Secretary may impose a directed
 6 plan of correction or limit the testing authorized by the license instead of suspending
 7 or revoking a license.

8 ~~(2) (4) IF THE SECRETARY FINDS THAT A MEDICAL LABORATORY~~
 9 ~~PROVIDED ERRONEOUS, INVALID, OR UNRELIABLE TEST RESULTS TO PHYSICIANS,~~
 10 ~~PATIENTS, OR OTHER PERSONS, THE SECRETARY MAY ORDER THE MEDICAL~~
 11 ~~LABORATORY TO RETEST PATIENTS OR TO NOTIFY PHYSICIANS, PATIENTS, ALL~~
 12 ~~LOCAL HEALTH DEPARTMENTS, OR THE GENERAL PUBLIC OF THE NEED TO BE~~
 13 ~~RETESTED INSTEAD OF OR IN ADDITION TO TAKING THE OTHER ACTIONS~~
 14 ~~AUTHORIZED UNDER THIS SECTION.~~

15 (2) (I) IF THE SECRETARY FINDS THAT A MEDICAL LABORATORY
 16 PROVIDED ERRONEOUS OR QUESTIONABLE TEST RESULTS THAT POSE A THREAT TO
 17 THE HEALTH AND SAFETY OF PATIENTS, THE SECRETARY MAY ORDER THE
 18 LABORATORY TO:

19 1. NOTIFY THE PHYSICIANS OR OTHER INDIVIDUALS WHO
 20 ORDERED THE TESTS OF THE ERRONEOUS OR QUESTIONABLE TEST RESULTS; AND

21 2. TAKE ANY ADDITIONAL MEASURES NECESSARY TO
 22 REDUCE OR ELIMINATE THE THREAT TO THE HEALTH AND SAFETY OF PATIENTS,
 23 INCLUDING THE NOTIFICATION OF PATIENTS AND THE OFFERING OF RETESTS.

24 (II) A MEDICAL LABORATORY THAT FAILS TO COMPLY WITH AN
 25 ORDER ISSUED BY THE SECRETARY UNDER SUBPARAGRAPH (I) OF THIS PARAGRAPH
 26 IS SUBJECT TO A CIVIL PENALTY OF UP TO \$1,000 FOR EACH DAY OF
 27 NONCOMPLIANCE AFTER THE DEADLINE FOR COMPLIANCE STATED IN THE
 28 SECRETARY'S ORDER, NOT TO EXCEED A MAXIMUM PENALTY OF \$50,000, INSTEAD OF
 29 OR IN ADDITION TO ANY OTHER SANCTION IMPOSED UNDER THIS SECTION.

30 (c) Except as otherwise provided in the Administrative Procedure Act, before
 31 the Secretary denies, suspends or revokes a license, OR IMPOSES A CIVIL PENALTY
 32 under this section, the Secretary shall give the applicant or licensee notice and an
 33 opportunity for a hearing.

34 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take
 35 effect July 1, 2005.

