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

Introduced and read first time: February 4, 2005

Assigned to: Education, Health, and Environmental Affairs

A BILL ENTITLED

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;
7 establishing a civil penalty for noncompliance; and generally relating to the
8 regulation of medical laboratories.

9 BY repealing and reenacting, with amendments,
10 Article - Health - General
11 Section 17-210
12 Annotated Code of Maryland
13 (2000 Replacement Volume and 2004 Supplement)

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

16 **Article - Health - General**

17 17-210.

18 (a) The Secretary may deny a license to any applicant or suspend, revoke, or
19 limit a license or the authority to offer or perform any class of service, complexity of
20 testing, or tests that the license sets forth, if the medical laboratory or its director or
21 other personnel fail to meet the standards and requirements under this subtitle and
22 in regulations adopted pursuant to this subtitle.

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

1 (2) (I) IF THE SECRETARY FINDS THAT A MEDICAL LABORATORY
2 PROVIDED ERRONEOUS, INVALID, OR UNRELIABLE TEST RESULTS TO PHYSICIANS,
3 PATIENTS, OR OTHER PERSONS, THE SECRETARY MAY ORDER THE MEDICAL
4 LABORATORY TO RETEST PATIENTS OR TO NOTIFY PHYSICIANS, PATIENTS, ALL
5 LOCAL HEALTH DEPARTMENTS, OR THE GENERAL PUBLIC OF THE NEED TO BE
6 RETESTED INSTEAD OF OR IN ADDITION TO TAKING THE OTHER ACTIONS
7 AUTHORIZED UNDER THIS SECTION.

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

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

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