

---

**By: Delegate Morhaim**

Introduced and read first time: January 24, 1996

Assigned to: Environmental Matters

---

A BILL ENTITLED

1 AN ACT concerning

2 **Cholesterol Testing**

3 FOR the purpose of exempting certain licensed medical laboratories from a requirement  
4 to obtain a permit to conduct cholesterol testing; repealing certain informational  
5 requirements that an applicant must submit to the Secretary of Health and Mental  
6 Hygiene when applying for a permit to conduct cholesterol testing; and generally  
7 relating to cholesterol testing.

8 BY repealing and reenacting, without amendments,  
9 Article - Health - General  
10 Section 17-205(a) and 17-208  
11 Annotated Code of Maryland  
12 (1994 Replacement Volume and 1995 Supplement)

13 BY repealing and reenacting, with amendments,  
14 Article - Health - General  
15 Section 17-502 and 17-506  
16 Annotated Code of Maryland  
17 (1994 Replacement Volume and 1995 Supplement)

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

20 **Article - Health - General**

21 17-205.

22 (a) A person shall hold a license issued by the Secretary before the person may:

23 (1) Offer or perform medical laboratory tests or examinations in this State;

24 (2) Offer or perform medical laboratory tests or examinations on specimens  
25 acquired from health care providers in this State at a medical laboratory located outside  
26 this State; or

27 (3) Represent or service in this State a medical laboratory regardless of the  
28 laboratory's location.

2

1 17-208.

2 (a) The Secretary shall issue a license to any applicant who meets the standards  
3 and requirements of this subtitle and in regulations adopted pursuant to this subtitle.

4 (b) A medical laboratory license shall include the name of the:

5 (1) Medical laboratory;

6 (2) Laboratory director; and

7 (3) Owner of the laboratory.

8 (c) A medical laboratory license shall designate the:

9 (1) Complexity of testing that the laboratory may offer or perform;

10 (2) Classes of services that may be offered;

11 (3) Tests or examinations that may be offered or performed by the  
12 laboratory; or

13 (4) Any combination of (1), (2), and (3).

14 (d) A medical laboratory may not operate in any manner beyond what is  
15 designated by its license.

16 (e) A medical laboratory license issued by the Secretary under this subtitle is not  
17 transferrable.

18 17-502.

19 (A) Except as provided under SUBSECTION (B) OF THIS SECTION AND § 17-503  
20 of this subtitle, [any person, including any medical laboratory issued a permit under  
21 Subtitle 2 of this title,] A PERSON shall obtain a permit from the Department before:

22 (1) Offering to provide a test to detect the amount of cholesterol in an  
23 individual's blood; and

24 (2) Conducting the cholesterol test outside a permanently located medical  
25 laboratory issued a permit or excepted from a permit under Subtitle 2 of this title.

26 (B) A CHOLESTEROL TESTING PERMIT IS NOT REQUIRED UNDER THIS  
27 SUBTITLE FOR A MEDICAL LABORATORY THAT:

28 (1) IS LICENSED UNDER SUBTITLE 2 OF THIS TITLE; AND

29 (2) AS SET FORTH IN THE LICENSE, PROVIDES TESTS OR SERVICES IN  
30 THE DISCIPLINE OF CHEMISTRY OR HEALTH AWARENESS.

31 17-506.

32 (a) An applicant for a permit shall submit an application to the Secretary on the  
33 form that the Secretary requires.

34 [(b) An application shall require the following information from the applicant:

3

- 1           (1) How the blood collection and testing is conducted;
- 2           (2) The type of training provided to the individual who takes the blood  
3 specimen;
- 4           (3) The infection control procedures utilized by the applicant;
- 5           (4) The training in the function and use of the measuring instrument  
6 provided to the person performing the measurements;
- 7           (5) The quality control procedures utilized by the applicant for the  
8 measuring instrument and how these procedures conform to the specifications of the  
9 instrument's manufacturer; and
- 10           (6) The counseling and referral procedures utilized by the applicant and  
11 how these procedures conform to standards adopted by the Secretary after taking into  
12 consideration the standards set by the National Institutes of Health.]

13           [(c)] (B) (1) The applicant shall pay to the Department the application fee set  
14 by the Secretary.

15           (2) The fees charged shall be set so as to produce funds sufficient to cover  
16 the actual documented direct and indirect cost of administering the permit program.

17           (3) The Secretary shall waive all permit fees for local and county health  
18 departments.

19           [(d)] (C) The Secretary shall waive all renewal fees for local and county health  
20 departments.

21           SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect  
22 October 1, 1996.