
By: Delegate Morhaim

Introduced and read first time: January 24, 1996

Assigned to: Environmental Matters

Committee Report: Favorable

House action: Adopted

Read second time: February 20, 1996

CHAPTER ____

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:

2

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

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

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

7 17-208.

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

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

11 (1) Medical laboratory;

12 (2) Laboratory director; and

13 (3) Owner of the laboratory.

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

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

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

17 (3) Tests or examinations that may be offered or performed by the
18 laboratory; or

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

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

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

24 17-502.

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

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

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

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

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

3

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

3 17-506.

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

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

7 (1) How the blood collection and testing is conducted;

8 (2) The type of training provided to the individual who takes the blood
9 specimen;

10 (3) The infection control procedures utilized by the applicant;

11 (4) The training in the function and use of the measuring instrument
12 provided to the person performing the measurements;

13 (5) The quality control procedures utilized by the applicant for the
14 measuring instrument and how these procedures conform to the specifications of the
15 instrument's manufacturer; and

16 (6) The counseling and referral procedures utilized by the applicant and
17 how these procedures conform to standards adopted by the Secretary after taking into
18 consideration the standards set by the National Institutes of Health.]

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

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

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

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

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