

ASSEMBLY, No. 523

STATE OF NEW JERSEY

219th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2020 SESSION

Sponsored by:

Assemblywoman ANGELICA M. JIMENEZ

District 32 (Bergen and Hudson)

SYNOPSIS

Requires clinical laboratory that provides services for accountable care organization to establish clinical laboratory testing advisory board.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel.



1 AN ACT concerning clinical laboratories and amending and
2 supplementing P.L.1975, c.166.

3

4 BE IT ENACTED by the Senate and General Assembly of the State
5 of New Jersey:

6

7 1. Section 2 of P.L.1975, c.166 (C.45:9-42.27) is amended to
8 read as follows:

9 2. As used in **[this act]** P.L.1975, c.166 (C.45:9-42.26 et seq.)
10 and (P.L. , c.) (C.) (pending before the Legislature as this
11 bill):

12 **[a.]** "Clinical laboratory" means any facility used for the
13 performance of chemical, bacteriologic, virologic, parasitologic,
14 serologic, hematologic, immunohematologic, biophysical,
15 cytologic, or other examinations of materials derived from the
16 human body for the purpose of yielding information for the
17 diagnosis, prevention, or treatment of disease or the assessment of
18 medical condition. Anatomic pathology is not considered to be
19 within the scope of this definition. Any facility used for the
20 collection, processing, and transmission of specimens to another
21 facility for the performance of clinical tests falls within the purview
22 of **[this act]** P.L.1975, c.166 (C.45:9-42.26 et seq.).

23 **[b.]** "Department" means the **[State]** Department of Health.

24 **[c.]** "Commissioner" means the **[State]** Commissioner of
25 Health or **[his]** the commissioner's duly authorized agent.

26 **[d.]** "Clinical laboratory owner" means a person or agency in
27 whom is vested the rights of control, possession, and dominion of a
28 clinical laboratory and for the purposes of **[this act]** P.L.1975,
29 c.166 (C.45:9-42.26 et seq.) shall include a county, municipality, or
30 any other owner of an institution operating a clinical laboratory.

31 **[e.]** "Clinical laboratory director" means a person who is
32 responsible for the administration of the technical and scientific
33 operation of a clinical laboratory, including, but not limited to,
34 supervision of procedures for testing and reporting of results.
35 Nothing in **[this act]** P.L.1975, c.166 (C.45:9-42.26 et seq.) shall
36 be deemed to exempt the director of a clinical laboratory from the
37 licensure requirements of P.L.1953, c. 420 (C. 45:9-42.1 et seq.),
38 where **[such]** those requirements would otherwise be applicable.

39 **[f.]** "Clinical laboratory evaluation program" means a program
40 of evaluating the proficiency of clinical laboratories by the
41 department.

42 "Clinical laboratory testing" means testing performed by a
43 clinical laboratory pursuant to P.L.1975, c.166 (C.45:9-42.26 et
44 seq.) or otherwise subject to 42 U.S.C. s.263a.

45 **[g.]** "Anatomic pathology" means the gross or microscopic

EXPLANATION – Matter enclosed in bold-faced brackets **[thus]** in the above bill is
not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.

1 examination of tissues by a physician specifically trained to
2 interpret and diagnose disease by **【such】** means of that
3 examination.

4 **【h.】** "Person" means any individual, partnership, limited
5 partnership, corporation, or other legal entity.
6 (cf: P.L.1975, c.166, s.2)
7

8 2. (New section) a. A clinical laboratory licensed pursuant to
9 P.L.1975, c.166 (C.45:9-42.26 et seq.), which is providing services
10 for an entity that is operating as an accountable care organization in
11 accordance with any applicable requirements of State and federal
12 law, shall be required to establish a clinical laboratory testing
13 advisory board for the purposes of subsection b. of this section.

14 b. The clinical laboratory testing advisory board shall be
15 authorized to consider and make recommendations to the governing
16 board of the accountable care organization for the adoption of
17 guidelines or protocols concerning:

18 (1) clinical laboratory testing that is utilized for diagnostic
19 purposes or disease management, including guidelines or protocols
20 designed to ensure the appropriateness of testing; and

21 (2) pathologist consultation on episodes of care.

22 c. The composition of the clinical laboratory testing advisory
23 board shall be determined by the accountable care organization,
24 except that the clinical laboratory testing advisory board shall
25 include among its members at least one physician who is legally
26 affiliated with the accountable care organization and is a clinical
27 laboratory director of a clinical laboratory that is providing services
28 for the accountable care organization.

29 d. The provisions of this act shall not be construed to require
30 that the governing board of an accountable care organization adopt
31 a clinical laboratory testing guideline or protocol recommended by
32 a clinical laboratory testing advisory board pursuant to subsection b.
33 of this section.
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35 3. This act shall take effect on the first day of the fourth month
36 next following the date of enactment.
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38 STATEMENT

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40 This bill requires a licensed clinical laboratory that is providing
41 services for an accountable care organization (ACO) to establish a
42 clinical laboratory testing advisory board.

43 The clinical laboratory testing advisory board is authorized to
44 consider and make recommendations to the governing board of the
45 ACO for the adoption of guidelines or protocols concerning: (1)
46 clinical laboratory testing that is utilized for diagnostic purposes or
47 disease management, including guidelines or protocols designed to
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1 ensure the appropriateness of testing; and (2) pathologist
2 consultation on episodes of care.

3 The composition of the clinical laboratory testing advisory board
4 is to be determined by the ACO, except that the clinical laboratory
5 testing advisory board must include among its members at least one
6 physician who is legally affiliated with the ACO and is a clinical
7 laboratory director of a clinical laboratory that is providing services
8 for the ACO.

9 The provisions of this bill are not to be construed to require that
10 the governing board of an ACO adopt a clinical laboratory testing
11 guideline or protocol recommended by a clinical laboratory testing
12 advisory board.