

STATE OF NEW YORK

10781

IN ASSEMBLY

May 18, 2018

Introduced by M. of A. GOTTFRIED -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to clinical laboratory supervision

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

1 Section 1. The public health law is amended by adding a new section
2 576-d to read as follows:

3 § 576-d. Clinical laboratory supervision. 1. (a) Each clinical labora-
4 tory shall have one or more supervisors who shall, under the general
5 direction of the director, supervise the technical personnel and report-
6 ing of findings, perform tests requiring special scientific skills, and,
7 in the absence of the director, be responsible for the proper perform-
8 ance of all laboratory procedures.

9 (b) A director who qualifies as provided in regulations promulgated
10 pursuant to section five hundred seventy-three of this title shall also
11 be deemed qualified as a supervisor.

12 (c) Depending upon the size and functions of the clinical laboratory,
13 the department may authorize the director to also serve as the supervi-
14 sor of such laboratory.

15 (d) The supervisor shall be on the clinical laboratory premises or
16 available by phone or synchronous two-way electronic audio visual commu-
17 nications within thirty minutes during all hours in which tests are
18 performed; provided, that if the supervisor is not on the laboratory
19 premises and the person performing the test qualifies as a medical tech-
20 nologist as provided in regulations promulgated pursuant to sections
21 five hundred seventy-four and five hundred seventy-six of this title,
22 and thirty-one hundred twenty-one of this chapter, the results of his or
23 her work are reviewed by the supervisor or director during his or her
24 next duty period, and a record is maintained to reflect the actual
25 review.

26 (e) An individual who qualifies as a supervisor as provided in regu-
27 lations promulgated pursuant to sections five hundred seventy-four and
28 five hundred seventy-six of this title, and thirty-one hundred twenty-

EXPLANATION--Matter in italics (underscored) is new; matter in brackets
[-] is old law to be omitted.

LBD13946-02-8

1 one of this chapter shall supervise technical personnel in the specialty
2 of cytology only.

3 2. (a) For the purposes of this subdivision, "clinical laboratory
4 improvement amendments" means the federal Clinical Laboratory Improve-
5 ment Amendment of 1988, Public Law 100-578, as amended and any regu-
6 lations or guidance issued thereunder.

7 (b) Every clinical supervisor shall meet one of the following require-
8 ments:

9 (i) the supervisor is a physician licensed to practice medicine or
10 osteopathy in the state, or who has earned a doctoral degree in a chemi-
11 cal, physical or biological science from an accredited institution.
12 "Accredited", as used in this paragraph, refers to accreditation by a
13 nationally recognized accrediting agency or association, as determined
14 by the United States commissioner of education. Such supervisor shall,
15 subsequent to graduation, have had at least the required number of
16 years' experience in one of the laboratory specialties in a clinical
17 laboratory or blood bank having a director at the doctoral level, as
18 provided for and consistent with the clinical laboratory improvement
19 amendments. The clinical laboratory or blood bank shall be part of a
20 hospital, health department, university, medical research institution,
21 or other institution which provides equivalent training;

22 (ii) the supervisor holds a degree of master of arts or master of
23 science in a chemical, physical or biological science from an accredited
24 institution and, subsequent to graduation, has had at least the required
25 number of years spent working in the designated laboratory specialty in
26 a clinical laboratory having a director at the doctoral level, as
27 provided for and consistent with the clinical laboratory improvement
28 amendments. The clinical laboratory or blood bank shall be part of a
29 hospital, health department, university, medical research institution or
30 other institution which provides equivalent training;

31 (iii) the supervisor is qualified as a medical technologist as
32 provided in regulations promulgated pursuant to sections five hundred
33 seventy-four and five hundred seventy-six of this title, and thirty-one
34 hundred twenty-one of this chapter and has had at least the required
35 number of years of pertinent clinical laboratory experience, including
36 training, subsequent to qualifying, spent working in a clinical labora-
37 tory having a director at the doctoral level, as provided for and
38 consistent with the clinical laboratory improvement amendments. The
39 clinical laboratory or blood bank shall be part of a hospital, universi-
40 ty, health department, medical research institution or other institution
41 which provides equivalent training; or

42 (iv) the supervisor is qualified as a cytotechnologist as provided in
43 regulations promulgated pursuant to sections five hundred seventy-four
44 and five hundred seventy-six of this title, and thirty-one hundred twen-
45 ty-one of this chapter and subsequent to qualifying, has had at least
46 the required number of years of pertinent clinical laboratory experi-
47 ence, including training, in cytotechnology in a laboratory having a
48 doctoral level director qualified in cytopathology, as provided for and
49 consistent with the clinical laboratory improvement amendments. The
50 clinical laboratory shall be part of a hospital, health department,
51 university, medical research institution, or other institution which
52 provides equivalent training.

53 (c) With respect to individuals first qualifying prior to April first,
54 nineteen hundred seventy-two, an exception to the requirements of
55 subparagraph (i), (ii) or (iii) of paragraph (b) of this subdivision may
56 be made if:

1 (i) the supervisor was performing the duties of a clinical laboratory
2 supervisor at any time between July first, nineteen hundred sixty-one
3 and September first, nineteen hundred seventy-one;

4 (ii) the supervisor has had at least fifteen years of pertinent clin-
5 ical laboratory experience prior to September first, nineteen hundred
6 seventy-one; provided, that, a minimum of thirty semester hours of cred-
7 it toward a bachelor's degree in a chemical, physical or biological
8 science, or thirty semester hours in an approved school of medical tech-
9 nology shall reduce the required years of experience by two years, with
10 any additional hours further reducing the required years of experience
11 at the rate of fifteen hours for one year; and

12 (iii) he or she has performed the duties of a supervisor for at least
13 two years during the qualifying fifteen years in:

14 (A) a clinical laboratory having a director at the doctoral level of a
15 hospital, university, health department or medical research institution;
16 or

17 (B) in a laboratory approved under the Medicare supplementary medical
18 insurance program, provided also, that where qualifying years in a clin-
19 ical laboratory described in clause (A) of this subparagraph are
20 obtained after January thirtieth, nineteen hundred sixty-nine, such
21 laboratory meets applicable conditions under the Medicare health insur-
22 ance program, or under the regulations issued pursuant to the federal
23 Clinical Laboratories Improvement Act of 1967.

24 § 2. This act shall take effect immediately.