

STATE OF NEW YORK

9235--A

IN ASSEMBLY

February 22, 2024

Introduced by M. of A. PAULIN -- read once and referred to the Committee on Health -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the public health law, in relation to certificates of qualification for clinical laboratories and blood banks

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

1 Section 1. Section 572 of the public health law, as amended by chapter
2 436 of the laws of 1993, is amended to read as follows:

3 § 572. Certificates of qualification. No person shall act as a direc-
4 tor in a clinical laboratory located in or accepting specimens from New
5 York state or in a blood bank located in or collecting, processing,
6 storing or distributing blood products in New York state unless a valid
7 certificate of qualification has been issued as provided in section five
8 hundred seventy-three of this title. [~~A certificate shall be issued~~
9 ~~authorizing the holder to perform or direct one or more procedures or~~
10 ~~one or more categories of such procedures.~~]

11 § 2. Section 573 of the public health law, as amended by chapter 436
12 of the laws of 1993, is amended to read as follows:

13 § 573. Issuance of certificates of qualification. 1. [~~The public~~
14 ~~health council shall prescribe minimum qualifications for directors in~~
15 ~~areas of testing, including, but not limited to, microbiology, immunolo-~~
16 ~~gy, chemistry, hematology, biophysics, cytology, pathology, genetics and~~
17 ~~blood banking.~~

18 ~~2.~~] The department shall issue a certificate of qualification to any
19 person who meets [~~such~~] prescribed minimum qualifications under federal
20 regulations, including board certification as required and who otherwise
21 demonstrates to the department that such person possesses the character,
22 competence, training and ability to administer properly the technical
23 and scientific operation of a clinical laboratory or blood bank, includ-
24 ing supervision of procedures and reporting of findings of tests.

25 [~~3.~~] 2. Application for a certificate of qualification shall be made
26 on forms provided by the department [~~and shall contain the procedures or~~

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

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1 ~~categories of procedures for which the certificate is sought~~] and such
2 other information as the department may require.

3 [4.] 3. The certificate shall be valid for a period of two years from
4 the date of issuance and may be renewed for successive [~~two-year~~] two-
5 year periods thereafter. The original application and each renewal
6 application shall be accompanied by a registration fee of [~~forty~~] one
7 hundred fifty dollars.

8 [5.] 4. Notwithstanding the provisions of this section, the commis-
9 sioner may issue a temporary certificate of qualification to any person
10 pending the issuance of a certificate as provided in this section. A
11 temporary certificate shall be valid for a period of thirty days from
12 the date of its issuance and may be renewed for a maximum of four
13 successive periods of thirty days.

14 § 3. Subdivision 2 of section 575 of the public health law, as amended
15 by section 19 of part A of chapter 59 of the laws of 2011, is amended to
16 read as follows:

17 2. A permit [~~or permit category~~] shall not be issued unless a valid
18 certificate of qualification [~~in the category of procedures for which~~
19 ~~the permit is sought~~] has been issued [~~to the director~~] pursuant to the
20 provisions of section five hundred seventy-three of this title, unless
21 all fees and outstanding penalties, if any, have been paid, and the
22 department finds that the clinical laboratory or blood bank is compe-
23 tently staffed and properly equipped, and will be operated in the manner
24 required by this title.

25 § 4. Section 576-a of the public health law, as amended by chapter 436
26 of the laws of 1993, is amended to read as follows:

27 § 576-a. Clinical laboratories and cytotechnologists examining Pap
28 smears. 1. Definitions. As used in this section, unless the context
29 clearly requires otherwise, the following terms shall have the following
30 meanings:

31 (a) "Cytotechnologist". A clinical laboratory professional specializ-
32 ing in the analysis of cytopathology samples, including Pap smears, for
33 cervical cancer and related diseases who meets the qualifications speci-
34 fied by the department.

35 (b) "Cytotechnologist work standard". (i) A limitation on the number
36 of Pap smears (also known as gynecologic slides) and non-gynecologic
37 slides a cytotechnologist may examine during a particular time period,
38 or other limitation on the quantity, speed or manner of examination of
39 slides by a cytotechnologist, under regulations of the department.

40 (ii) [~~Unless otherwise provided by the department, the cytotechnolo-~~
41 ~~gist work standard shall be: No cytotechnologist may examine more than~~
42 ~~eighty one slide gynecologic cases or fifty two slide gynecologic cases~~
43 ~~per work day. If a cytotechnologist also examines non-gynecologic~~
44 ~~slides in a given work day the cytotechnologist's workload for gynecolo-~~
45 ~~gic slides shall be correspondingly reduced, in accordance with writ-~~
46 ~~ten guidelines prepared by the clinical laboratory and filed with the~~
47 ~~department, so that a cytotechnologist examines no more than a total of~~
48 ~~one hundred gynecologic and non-gynecologic slides per work day.] The
49 department may establish regulations for cytotechnologist workload stan-
50 dards that shall be at least as stringent as federal regulations.~~

51 (c) "Employ". To employ or contract with a cytotechnologist to examine
52 gynecologic slides.

53 (d) "Clinical laboratory". A clinical laboratory issued a permit
54 pursuant to this title.

55 (e) "Work day". A twenty-four hour period during which a cytotechnolo-
56 gist examines gynecologic slides for a clinical laboratory.

1 2. Compliance with cytotechnologist work standard. No cytotechnologist
2 shall exceed the applicable cytotechnologist work standard. No clinical
3 laboratory shall require, authorize, encourage or permit any cytotech-
4 nologist to exceed the applicable cytotechnologist work standard. In
5 determining whether a cytotechnologist exceeds the applicable cytotech-
6 nologist work standard, all work done by the cytotechnologist during a
7 given work day shall be considered, without regard to which clinical
8 laboratory or other person for which or whom it was performed.

9 ~~3. [Registration of cytotechnologist. All cytotechnologists who are
10 employed by a clinical laboratory must register with the department. The
11 department shall, by regulation, prescribe a form and procedure for the
12 registration of cytotechnologists. The registration form shall include
13 at least the name, address, and an individual identification number
14 determined by the department. The department shall notify each regis-
15 trant of his or her identification number.~~

16 ~~4. Employment of registered cytotechnologists. No clinical laboratory
17 shall employ a cytotechnologist unless the cytotechnologist is regis-
18 tered under this section.~~

19 ~~5.]~~ Record-keeping. (a) Each clinical laboratory shall maintain
20 records, in a form prescribed by the department, which set forth, for
21 each cytotechnologist employed by the clinical laboratory:

22 (i) the name [~~and identification number~~] of the cytotechnologist;
23 (ii) the number of hours worked by the cytotechnologist in each work
24 day;

25 (iii) the number of gynecologic slides and non-gynecologic slides
26 examined by the cytotechnologist [~~, and how many were one slide and two
27 slide cases,~~] during each work day; and

28 (iv) such other information as the department may require by regu-
29 lation.

30 (b) [~~Each cytotechnologist shall maintain records, in a form
31 prescribed by the department, which set forth:~~

32 ~~(i) the number of hours worked by the cytotechnologist in each work
33 day,~~

34 ~~(ii) the number of gynecologic slides and non-gynecologic slides exam-
35 ined and how many were one slide and two slide cases, during each work
36 day,~~

37 ~~(iii) the name and address of the clinical laboratory or other person
38 for which or whom the slides were examined, and~~

39 ~~(iv) such other information as the department may require by regu-
40 lation.~~

41 ~~(e)]~~ Such records of clinical laboratories and cytotechnologists shall
42 be made available for inspection and copying by the department upon
43 request.

44 [~~6.]~~ 4. Multiple employers. Whenever a cytotechnologist is employed by
45 more than one clinical laboratory or other person during a work day, the
46 cytotechnologist shall advise each clinical laboratory of any previous
47 employment during the work day and the amount of work performed, to
48 insure that the applicable cytotechnologist work standard is not
49 exceeded.

50 [~~7.]~~ 5. Standards for gynecologic slides. (a) A gynecologic slide of a
51 Pap smear shall not be tested or reported on if:

52 (i) the apparent condition of the specimen indicates that it is unsat-
53 isfactory for testing or that it is inappropriate for the test
54 requested;

1 (ii) it has been collected, labeled, preserved or otherwise handled in
2 such a manner that it has become unsatisfactory or unreliable as a test
3 specimen;

4 (iii) the slide is broken;

5 (iv) it contains insufficient cells or the cells are obscured by
6 inflammation, blood or lubricating ointment, so that an adequate diagno-
7 sis cannot be made; or

8 (v) the slide is otherwise unsatisfactory, as defined by department
9 regulations.

10 (b) If the slide is unsatisfactory as set forth in this subdivision,
11 the clinical laboratory shall have an affirmative duty to advise the
12 collecting physician or other practitioner that the slide is unsatisfac-
13 tory and request the submission of a new slide.

14 ~~[8.]~~ **6.** Re-examination of slides. The department shall prescribe, by
15 regulation, a system of targeted re-examination of gynecologic slides
16 examined and found to be not abnormal or questionable. The factors to be
17 considered in the targeted re-examination may include, but are not
18 limited to, the prior cancer and other history of the patient, the
19 results of previous slide examinations, and the experience and ability
20 of the cytotechnologist. Each clinical laboratory shall follow the
21 prescribed re-examination system.

22 ~~[9. Regulations. The department may, by regulation, establish cyto-~~
23 ~~technologist work standards. Those standards may include, but shall not~~
24 ~~be limited to, standards which take into account the experience and~~
25 ~~qualifications of the cytotechnologists and the performance of the clin-~~
26 ~~ical laboratory in proficiency testing programs conducted by the depart-~~
27 ~~ment. However, those standards shall not exceed by more than twenty~~
28 ~~percent the maximum numbers of slides which may be examined in a work~~
29 ~~day under clause (ii) of paragraph (b) of subdivision one of this~~
30 ~~section. Such standards shall be at least as stringent as federal stand-~~
31 ~~ards promulgated under the federal clinical laboratory improvement~~
32 ~~amendments of nineteen hundred eighty-eight.~~

33 ~~10.]~~ **7.** Notwithstanding any provisions of [~~subdivisions~~] **subdivision**
34 one [~~and nine~~] of this section to the contrary, the department may,
35 pursuant to regulation, increase the maximum number of slides which may
36 be examined in a work day for clinical laboratories using slide examina-
37 tion or preparation technology approved by the federal food and drug
38 administration, provided that such standards shall be at least as strin-
39 gent as federal standards promulgated under the federal clinical labora-
40 tory improvement amendments of nineteen hundred eighty-eight or other
41 applicable federal law.

42 ~~[11.]~~ **8.** Violations. (a) Sections twelve, twelve-a, and twelve-b of
43 this chapter shall apply to violations of this section, except that the
44 civil penalty for a violation of this section by a cytotechnologist
45 shall not exceed five hundred dollars.

46 (b) [~~If a cytotechnologist violates this section, the department may~~
47 ~~suspend or revoke the cytotechnologist's registration under this~~
48 ~~section, pursuant to department regulations including appropriate due~~
49 ~~process protections for the cytotechnologist.~~

50 ~~(c)]~~ If any clinical laboratory or other person violating this section
51 is licensed, certified or registered by the department under other
52 provisions of law, the violation of this section may be grounds for
53 disciplining the person under such law.

54 § 5. This act shall take effect immediately.