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:

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

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

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

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

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

[~~3.~~] **2.** Application for a certificate of qualification shall be made 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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~~categories of procedures for which the certificate is sought~~] and such other information as the department may require.

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

[~~5.~~] **4.** Notwithstanding the provisions of this section, the commissioner may issue a temporary certificate of qualification to any person pending the issuance of a certificate as provided in this section. A temporary certificate shall be valid for a period of thirty days from the date of its issuance and may be renewed for a maximum of four successive periods of thirty days.

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

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

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

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

(a) "Cytotechnologist". A clinical laboratory professional specializing in the analysis of cytopathology samples, including Pap smears, for cervical cancer and related diseases who meets the qualifications specified by the department.

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

(ii) [~~Unless otherwise provided by the department, the cytotechnologist work standard shall be: No cytotechnologist may examine more than eighty one-slide gynecologic cases or fifty two-slide gynecologic cases per work day. If a cytotechnologist also examines non-gynecologic slides in a given work day the cytotechnologist's workload for gynecologic slides shall be correspondingly reduced, in accordance with written guidelines prepared by the clinical laboratory and filed with the department, so that a cytotechnologist examines no more than a total of one hundred gynecologic and non-gynecologic slides per work day.~~] **The department may establish regulations for cytotechnologist workload standards that shall be at least as stringent as federal regulations.**

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

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

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

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

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

~~4. Employment of registered cytotechnologists. No clinical laboratory shall employ a cytotechnologist unless the cytotechnologist is registered under this section.~~

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

(i) the name [~~and identification number~~] of the cytotechnologist;

(ii) the number of hours worked by the cytotechnologist in each work day;

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

(iv) such other information as the department may require by regulation.

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

~~(i) the number of hours worked by the cytotechnologist in each work day;~~

~~(ii) the number of gynecologic slides and non-gynecologic slides examined and how many were one-slide and two-slide cases, during each work day;~~

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

~~(iv) such other information as the department may require by regulation.~~

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

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

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

(i) the apparent condition of the specimen indicates that it is unsatisfactory for testing or that it is inappropriate for the test requested;

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

(iii) the slide is broken;

(iv) it contains insufficient cells or the cells are obscured by inflammation, blood or lubricating ointment, so that an adequate diagnosis cannot be made; or

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

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

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

[~~9. Regulations. The department may, by regulation, establish cytotechnologist work standards. Those standards may include, but shall not be limited to, standards which take into account the experience and qualifications of the cytotechnologists and the performance of the clinical laboratory in proficiency testing programs conducted by the department. However, those standards shall not exceed by more than twenty percent the maximum numbers of slides which may be examined in a work day under clause (ii) of paragraph (b) of subdivision one of this section. Such standards shall be at least as stringent as federal standards promulgated under the federal clinical laboratory improvement amendments of nineteen hundred eighty-eight.~~

~~10.~~] 7. Notwithstanding any provisions of [~~subdivisions~~] subdivision one [~~and nine~~] of this section to the contrary, the department may, pursuant to regulation, increase the maximum number of slides which may be examined in a work day for clinical laboratories using slide examination or preparation technology approved by the federal food and drug administration, provided that such standards shall be at least as stringent as federal standards promulgated under the federal clinical laboratory improvement amendments of nineteen hundred eighty-eight or other applicable federal law.

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

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

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

§ 5. This act shall take effect immediately.