

STATE OF NEW YORK

10125

IN ASSEMBLY

February 2, 2026

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

AN ACT to amend the public health law, in relation to exempting waived tests from clinical laboratory requirements

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

1 Section 1. Paragraphs (a), (b), (e) and (h) of subdivision 3 of
2 section 579 of the public health law, paragraphs (a), (e) and (h) as
3 added by chapter 204 of the laws of 2008, paragraph (b) as amended by
4 chapter 479 of the laws of 2013, are amended and a new paragraph (j) is
5 added to read as follows:

6 (a) This title shall not be applicable to any person, partnership,
7 corporation or other entity performing any [~~waived test or~~] provider-
8 performed microscopy procedure, provided such person, partnership,
9 corporation or other legal entity: (i) holds a valid certificate of
10 registration issued by the department authorizing the performance of one
11 or more [~~waived tests or~~] provider-performed microscopy procedures; and
12 (ii) only performs tests authorized by the certificate of registration;
13 and (iii) otherwise complies with all applicable requirements of this
14 subdivision.

15 (b) The department may issue a certificate of registration authorizing
16 the performance of one or more [~~waived tests or~~] provider-performed
17 microscopy procedures for a period of up to two years if the applicant:
18 (i) files a completed application with the department on such forms as
19 the commissioner may prescribe; (ii) provides documentation acceptable
20 to the department demonstrating the ability to comply with the require-
21 ments of this subdivision; and (iii) pays a two hundred dollar biennial
22 registration fee for each location where services are rendered; except
23 that a voluntary ambulance service as defined in article thirty of [~~the~~
24 ~~public health law~~] this chapter and operated under section two hundred
25 nine-b of the general municipal law shall be exempt from the requirement
26 to pay a fee to obtain this certificate of registration; and except that
27 the following may operate multiple locations under a single registration
28 and pay a single registration fee: (A) not-for-profit, state or local

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

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1 government laboratories or programs engaged in limited public health
2 testing not exceeding fifteen types of tests per registration; or (B)
3 applicants that maintain a fixed location in the state and are approved
4 by the department to move from testing site to testing site.

5 (e) Notwithstanding the foregoing, if the commissioner determines that
6 the performance of a particular [~~waived test or~~] provider-performed
7 microscopy procedure in a facility or location which does not possess a
8 New York state clinical laboratory permit creates a risk of harm to the
9 subjects of such test, the commissioner may issue an order prohibiting
10 such test from being performed in any location other than a permitted
11 clinical laboratory, physician's office or other location exempted by
12 subdivision one or two of this section.

13 (h) Any person, partnership, corporation or other entity performing
14 [~~waived tests or~~] provider-performed microscopy procedures without being
15 authorized to do so pursuant to this title shall be subject to a civil
16 penalty of up to five hundred dollars for each test performed, not to
17 exceed two thousand dollars per day for each day tests are performed, in
18 violation of this subdivision.

19 (j) Notwithstanding any other provision of law to the contrary, this
20 title shall not apply to any waived test.

21 § 2. This act shall take effect on the one hundred twentieth day after
22 it shall have become a law.