STATE OF NEW YORK

9413

IN ASSEMBLY

March 3, 2022

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

AN ACT to amend the public health law, in relation to requiring a written notice on the occurrence of a false-positive result for any condition tested during a prenatal test

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

Section 1. The public health law is amended by adding a new section 2 2533 to read as follows:

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- § 2533. Disclosure of information concerning prenatal testing. a. The following terms as used in this section shall mean the following:
- 5 1. "Laboratory" shall have the same meaning as is set forth in section five hundred seventy-one of this chapter.
- 7 2. "Prenatal testing services" means any service provided by a hospital to identify potential problems with a pregnancy or the relative 9 likelihood of abnormalities in a fetus. Such services shall include but 10 not be limited to services that test placental tissue or the blood of a 11 pregnant patient.
- 12 3. "Material" means any advertisement, promotional brochure, website or documentation that may be presented to a patient or a potential 13 parent to recommend prenatal testing services offered by a hospital. 14
- 15 4. "Percentage of positives being a false-positive" means the ratio of 16 the number of false-positive results divided by the sum of the number of false-positive results and the number of true positives. 17
- b. Every prenatal test shall include a written notice, provided by the entity which manufactured, supplied, or otherwise created such test or 19 20 which advertised performing prenatal tests, about the occurrence of a 21 false-positive result, including but not limited to the percentage of positives being a false-positive, for any condition tested during such 23 prenatal test. Such written notice shall be provided to a patient or a potential parent: (i) prior to any prenatal test; (ii) with such test 24 results; and (iii) with any materials provided by the entity providing 26 or facilitating the prenatal testing. Such written notice shall be developed by the department and shall include all data used by a labora-27

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

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tory to determine such false-positive results. If such data cannot be obtained for a condition tested during a prenatal test from the laboratory, such condition shall not be offered to a patient or a potential 4 parent to be included in the prenatal testing services. Such written notice shall be plainly worded and prominently displayed in any material presented to a patient or a potential parent about prenatal testing services.

- c. Every hospital or health care provider offering prenatal testing services shall provide a written notice about the occurrence of a falsepositive result, which may include the percentage of positives being a false-positive as required under subdivision b of this section, for any condition tested during such prenatal test; provided, however, such notice shall not be required if such notice is provided to the patient or potential parent by the entity which manufactured, supplied, or otherwise created such test or which advertised performing prenatal tests under subdivision b of this section. Such written notice shall be provided to a patient or a potential parent prior to any prenatal test and when a patient or a potential parent receives such test results. Such written notice shall be developed by the department and shall include all data used by a laboratory to determine such false-positive results. If such data cannot be obtained for a condition tested during a prenatal test from the laboratory, such condition shall not be offered to a patient or a potential parent to be included in the prenatal testing services. Such written notice shall be plainly worded and prominently displayed in any material presented to a patient or a potential parent about prenatal testing services.
- 27 d. Notwithstanding the provision of subdivision b or c of this 28 section, if prior to receiving material from an entity or hospital on the prenatal testing services offered by such entity or hospital a 29 30 patient requests a certain condition to be tested during the prenatal 31 test, such condition shall be tested for if such test is available. 32 When a patient receives the results of such prenatal test, if there is data on any condition tested such data shall be provided to the patient 33 34 pursuant to subdivision b or c of this section.
 - e. Nothing contained in this section shall be construed to limit a health care practitioner licensed, certified, or authorized under title eight of the education law from recommending certain prenatal testing services according to the practitioner's reasonable and good faith professional judgment based on the facts of a patient's case.
- § 2. This act shall take effect on the thirtieth day after 40 have become a law. Effective immediately, the addition, amendment and/or 41 42 repeal of any rule or regulation necessary for the implementation of 43 this act on its effective date are authorized to be made and completed 44 on or before such effective date.