STATE OF NEW YORK

9152--A

IN ASSEMBLY

February 8, 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 requiring disclosure of information concerning non-invasive prenatal screening for chromosomal abnormalities

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 2533 to read as follows:

§ 2533. Disclosure of information concerning non-invasive prenatal screening for chromosomal abnormalities. 1. For the purposes of this section, the term "non-invasive prenatal screening" shall mean any non-invasive prenatal screening or cell free fetal DNA screening used to ascertain whether a fetus is at risk for certain chromosomal abnormalities.

2. Non-invasive prenatal screenings shall be accompanied by a written notice, provided by the entity which manufactured, supplied, or otherwise created such test or which advertised performing these prenatal screening tests, about the use of such test for screening purposes, the fact that not all high risk occurrences correspond to a positive result, the fact that not all low risk results correspond to a negative result, a clear statement indicating that non-invasive prenatal screenings are intended solely for screening purposes to assess risk of possible fetal genetic abnormalities and is not intended to be used for diagnostic purposes to determine whether such abnormalities actually exist and that any positive result should be followed by confirmatory diagnostic testing, and that additional follow up is recommended for all high risk screening. Such written notice shall be provided to a patient or a potential parent: (a) prior to any prenatal test; (b) with such test results; and (c) with any materials provided by the entity providing or facilitating the prenatal testing. Such written notice shall be reviewed and approved by the department. Such written notice shall be

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

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plainly worded and prominently displayed in any material presented to a patient or a potential parent about prenatal testing services.

c. 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. Section 266 of the public health law is amended by adding a new subdivision 7 to read as follows:

7. Non-invasive prenatal testing. In addition to the information provided pursuant to this section, the commissioner shall also develop comprehensive informational materials regarding the benefits and limitations of non-invasive prenatal testing, including the difference between non-invasive prenatal testing and prenatal diagnostic testing. Such information shall be posted on the website in a printable format, in multiple languages in accordance with section two hundred two-a of the executive law to allow all general hospitals, diagnostic and treatment centers, obstetricians, primary care providers, midwives, and other health care programs providing women's wellness services to provide the information to their patients as part of their prenatal care activities. The informational materials shall also include:

(a) the current recommendations on non-invasive prenatal testing made by the American College of Obstetricians and Gynecologists (ACOG), and the Society for Maternal Fetal Medicine, and the American College of Medical Genetics and Genomics (ACMG);

(b) a statement informing individuals that non-invasive prenatal testing is used for screening purposes to determine the potential for possible fetal genetic abnormalities and is not intended to determine whether or not such abnormalities exist;

(c) a statement informing individuals that non-invasive prenatal testing carries a risk of false-positive results and that any positive result should be followed up with prenatal diagnostic testing; and

(d) a list of the non-invasive screening tests that have been approved or cleared by the federal Food and Drug Administration (FDA), the New York State Clinical Laboratory Evaluation Program (CLEP), or both, and a summary of the known performance characteristics of these tests when available.

§ 3. This act shall take effect on the one hundred eightieth day after it shall have become a law. Effective immediately, the addition, amendment and/or repeal of any rule or regulation necessary for the implementation of this act on its effective date are authorized to be made and completed on or before such effective date.