

# STATE OF NEW YORK

1159--B

Cal. No. 381

2023-2024 Regular Sessions

## IN SENATE

January 10, 2023

Introduced by Sens. SKOUFIS, THOMAS, WEBB -- read twice and ordered printed, and when printed to be committed to the Committee on Health -- recommitted to the Committee on Health in accordance with Senate Rule 6, sec. 8 -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee -- reported favorably from said committee, ordered to first and second report, ordered to a third reading, amended and ordered reprinted, retaining its place in the order of third reading

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

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

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1 any positive result should be followed by confirmatory diagnostic test-  
2 ing, and that additional follow up is recommended for all high risk  
3 screening. Such written notice shall be provided to a patient or a  
4 potential parent: (a) prior to any prenatal test; (b) with such test  
5 results; and (c) with any materials provided by the entity providing  
6 or facilitating the prenatal testing. Such written notice shall be  
7 reviewed and approved by the department. Such written notice shall be  
8 plainly worded and prominently displayed in any material presented to a  
9 patient or a potential parent about prenatal testing services.

10 c. Nothing contained in this section shall be construed to limit a  
11 health care practitioner licensed, certified, or authorized under title  
12 eight of the education law from recommending certain prenatal testing  
13 services according to the practitioner's reasonable and good faith  
14 professional judgment based on the facts of a patient's case.

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

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

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

33 (b) a statement informing individuals that non-invasive prenatal test-  
34 ing is used for screening purposes to determine the potential for possi-  
35 ble fetal genetic abnormalities and is not intended to determine whether  
36 or not such abnormalities exist;

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

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

45 § 3. This act shall take effect on the one hundred eightieth day after  
46 it shall have become a law. Effective immediately, the addition, amend-  
47 ment and/or repeal of any rule or regulation necessary for the implemen-  
48 tation of this act on its effective date are authorized to be made and  
49 completed on or before such effective date.