

STATE OF NEW YORK

9152

IN ASSEMBLY

February 8, 2024

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

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:

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

3 § 2533. Disclosure of information concerning non-invasive prenatal
4 screening for chromosomal abnormalities. 1. For the purposes of this
5 section, the following terms shall mean the following:

6 (a) "Laboratory" shall have the same meaning as is set forth in
7 section five hundred seventy-one of this chapter.

8 (b) "Non-invasive prenatal screening" shall mean any non-invasive
9 prenatal screening or cell free fetal DNA screening used to ascertain
10 whether a fetus is at risk for certain chromosomal abnormalities.

11 2. Non-invasive prenatal screenings shall be accompanied by a written
12 notice, provided by the entity which manufactured, supplied, or other-
13 wise created such test or which advertised performing these prenatal
14 screening tests, about the use of such test for screening purposes, the
15 fact that not all high risk occurrences correspond to a positive result,
16 the fact that not all low risk results correspond to a negative result,
17 a clear statement indicating that non-invasive prenatal screenings are
18 intended solely for screening purposes to assess risk of possible fetal
19 genetic abnormalities and is not intended to be used for diagnostic
20 purposes to determine whether such abnormalities actually exist and that
21 any positive result should be followed by confirmatory diagnostic test-
22 ing, and that additional follow up is recommended for all high risk
23 screening. Such written notice shall be provided to a patient or a
24 potential parent: (a) prior to any prenatal test; (b) with such test
25 results; and (c) with any materials provided by the entity providing
26 or facilitating the prenatal testing. Such written notice shall be
27 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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1 plainly worded and prominently displayed in any material presented to a
2 patient or a potential parent about prenatal testing services.

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

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

10 7. Non-invasive prenatal testing. In addition to the information
11 provided pursuant to this section, the commissioner shall also develop
12 comprehensive informational materials regarding the benefits and limita-
13 tions of non-invasive prenatal testing, including the difference between
14 non-invasive prenatal testing and prenatal diagnostic testing. Such
15 information shall be posted on the website in a printable format, in
16 each of the top six languages spoken in the state, other than English,
17 according to the latest available data from the United States Census
18 Bureau, to allow all general hospitals, diagnostic and treatment
19 centers, obstetricians, primary care providers, midwives, and other
20 health care programs providing women's wellness services to provide the
21 information to their patients as part of their prenatal care activities.
22 The informational materials shall also include:

23 (a) the current recommendations on non-invasive prenatal testing made
24 by the American College of Obstetricians and Gynecologists (ACOG) and
25 the Society for Maternal Fetal Medicine;

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

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

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

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