

STATE OF NEW YORK

1977

2025-2026 Regular Sessions

IN ASSEMBLY

January 14, 2025

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

AN ACT to amend the social services law, in relation to payment for rapid whole genome sequencing

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

1 Section 1. The social services law is amended by adding a new section
2 367-z to read as follows:

3 § 367-z. Payment for rapid whole genome sequencing. 1. For purposes of
4 this section, "rapid whole genome sequencing" means an investigation of
5 the entire human genome, including coding and non-coding regions and
6 mitochondrial deoxyribonucleic acid, to identify disease-causing genetic
7 changes that returns the preliminary positive results within seven days
8 and final results within fifteen days from the date of receipt of the
9 sample by the lab performing the test. "Rapid whole genome sequencing"
10 includes patient-only whole genome sequencing and duo and trio whole
11 genome sequencing of the patient and biological parent or parents.

12 2. One year after the effective date of this section, and subject to
13 any required approval of the Centers for Medicare and Medicaid Services,
14 the commissioner shall authorize the payment of medical assistance funds
15 for rapid whole genome sequencing when the beneficiary:

16 (a) is under twenty-one years of age;

17 (b) has a complex or acute illness of unknown etiology, that is not
18 confirmed to be caused by an environmental exposure, toxic ingestion,
19 infection with normal response to therapy, or trauma; and

20 (c) is receiving hospital services in an intensive care unit or other
21 high acuity care unit within a hospital.

22 3. Payment provided pursuant to this section may be subject to appli-
23 cable evidence-based medical necessity criteria that shall be based on
24 all of the following:

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

LBD05345-01-5

1 (a) the patient has symptoms that suggest a broad differential diagno-
2 sis that would require an evaluation by multiple genetic tests if rapid
3 whole genome sequencing is not performed;

4 (b) the patient's treating healthcare provider has determined that
5 timely identification of a molecular diagnosis is necessary to guide
6 clinical decision-making and testing results may guide the treatment or
7 management of the patient's condition; and

8 (c) the patient has a complex or acute illness of unknown etiology
9 including at least one of the following conditions:

10 (i) congenital anomalies involving at least two organ systems or
11 complex/multiple congenital anomalies in one organ system;

12 (ii) specific organ malformations highly suggestive of a genetic
13 etiology;

14 (iii) abnormal laboratory tests or abnormal chemistry profiles
15 suggesting the presence of a genetic disease, complex metabolic disor-
16 der, or inborn error of metabolism;

17 (iv) refractory or severe hypoglycemia or hyperglycemia;

18 (v) abnormal response to therapy related to an underlying medical
19 condition affecting vital organs or bodily systems;

20 (vi) severe muscle weakness, rigidity, or spasticity;

21 (vii) refractory seizures;

22 (viii) a high-risk stratification on evaluation for a brief resolved
23 unexplained event with any of the following:

24 (A) a recurrent event without respiratory infection;

25 (B) a recurrent witnessed seizure-like event; or

26 (C) a recurrent cardiopulmonary resuscitation event;

27 (ix) abnormal cardiac diagnostic testing results suggestive of possi-
28 ble channelopathies, arrhythmias, cardiomyopathies, myocarditis, or
29 structural heart disease;

30 (x) abnormal diagnostic imaging studies suggestive of underlying
31 genetic condition;

32 (xi) abnormal physiologic function studies suggestive of an underlying
33 genetic etiology; or

34 (xii) family genetic history related to the patient's condition.

35 4. The commissioner may add conditions to those contained in paragraph
36 (c) of subdivision three of this section based upon new medical evidence
37 and may provide coverage for rapid whole genome sequencing or other next
38 generation sequencing and genetic testing in addition to the coverage
39 required under this section.

40 5. (a) Except as provided in paragraph (b) of this subdivision, genet-
41 ic data generated as a result of performing rapid whole genome sequenc-
42 ing covered pursuant to this section shall have a primary use of assist-
43 ing the ordering health care professional and treating care team to
44 diagnose and treat the patient, and as protected health information it
45 shall be subject to the requirements applicable to protected health
46 information as set forth in the Health Information Portability and
47 Accountability Act ("HIPAA"), the Health Information Technology for
48 Economic and Clinical Health Act, their attendant regulations, including
49 but not limited to the HIPAA Privacy Rule as promulgated at 45 CFR Part
50 160 and Subparts A and E of 45 CFR Part 164, and any applicable state or
51 local law.

52 (b) Genetic data generated from rapid whole genome sequencing, covered
53 pursuant to this section, can be used in scientific research if consent
54 for such use of the data has been expressly given by the patient, or the
55 patient's legal guardian in the case of a minor. The patient, the
56 patient's legal guardian in the case of a minor, or the patient's health

care provider with the patient's consent, may request access to the results of the testing covered by this section for use in other clinical settings. A health care provider may only charge a fee to the patient based on the direct costs of producing the results in a format usable in other clinical settings. A patient, or patient's legal guardian in the case of a minor, shall have the right to rescind the original consent to the use of the data in scientific research at any time, and upon receipt of a written revocation of the consent the health care provider or other entity using the data shall cease use and expunge the data from any data repository where it is held.

6. The commissioner shall take any actions necessary to implement the provisions of this section, including, but not limited to:

(a) promulgating rules and regulations to provide for payment pursuant to this section;

(b) submitting to the Centers for Medicare and Medicaid Services any new waiver application, amendment to an existing waiver, or Medicaid state plan amendment necessary to ensure federal financial participation for Medicaid coverage pursuant to this section; and

(c) any other administrative action determined to be necessary to implement the requirements of this section.

§ 2. This act shall take effect immediately.