

HOUSE No. 1197

The Commonwealth of Massachusetts

PRESENTED BY:

Danielle W. Gregoire

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act to provide rapid whole genome sequencing.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
<i>Danielle W. Gregoire</i>	<i>4th Middlesex</i>	<i>1/17/2023</i>

HOUSE No. 1197

By Representative Gregoire of Marlborough, a petition (accompanied by bill, House, No. 1197) of Danielle W. Gregoire for legislation to provide rapid whole genome sequencing. Health Care Financing.

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Third General Court
(2023-2024)

An Act to provide rapid whole genome sequencing.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 SECTION 1. Notwithstanding any general or special law to the contrary, the Executive
2 Office of Health and Human Service in conjunction with the Office of MassHealth shall ensure
3 the provision of rapid whole genome sequencing when the following clinical criteria are met.

4 For purposes of this section, “rapid whole genome sequencing” is defined as an
5 investigation of the entire human genome, including coding and non-coding regions and
6 mitochondrial deoxyribonucleic acid, to identify disease-causing genetic changes that returns the
7 preliminary positive results within 5 days and final results within 14 days. When used in this
8 section “rapid whole genome sequencing” includes patient-only whole genome sequencing and
9 duo and trio whole genome sequencing of the patient and biological parent or parents.

10 Subject to any required approval of the Centers for Medicare and Medicaid Services, the
11 Commonwealth shall include coverage of rapid whole genome sequencing as a separately
12 payable service for Medicaid beneficiaries when all of the following criteria are met: (i) the

13 beneficiary is twenty-one years of age or younger (ii) the beneficiary has a complex or acute
14 illness of unknown etiology, that is not confirmed to be caused by an environmental exposure,
15 toxic ingestion, infection with normal response to therapy, or trauma, and (iii) the beneficiary is
16 receiving inpatient hospital services in an intensive care unit or high acuity pediatric care unit.

17 The coverage provided pursuant to this Section may be subject to applicable evidence-
18 based medical necessity criteria that shall be based on all of the following: (i) the patient has
19 symptoms that suggest a broad differential diagnosis that would require an evaluation by
20 multiple genetic tests if rapid whole genome sequencing is not performed, (ii) the patient's
21 treating healthcare provider has determined that timely identification of a molecular diagnosis is
22 necessary to guide clinical decision-making and testing results may guide the treatment or
23 management of the patient's condition, (iii) complex or acute illness of unknown etiology
24 including at least one of the following conditions:

25 i) Congenital anomalies involving at least 2 organ systems or complex/multiple
26 congenital anomalies in one organ system.

27 ii) Specific organ malformations highly suggestive of a genetic etiology.

28 iii) Abnormal laboratory tests or abnormal chemistry profiles suggesting the presence
29 of a genetic disease, complex metabolic disorder, or inborn error of metabolism like but not
30 limited to an abnormal newborn screen, hyperammonemia, or severe lactic acidosis not due to
31 poor perfusion.

32 iv) Refractory or severe hypoglycemia or hyperglycemia.

- 33 v) Abnormal response to therapy related to an underlying medical condition
34 affecting vital organs or bodily systems.
- 35 vi) Severe muscle weakness, rigidity, or spasticity.
- 36 vii) Refractory seizures.
- 37 viii) A high-risk stratification on evaluation for a brief resolved unexplained event
38 with any of the following:
- 39 (1) A recurrent event without respiratory infection.
- 40 (2) A recurrent event witnessed seizure-like event.
- 41 (3) A recurrent cardiopulmonary resuscitation.
- 42 ix) Abnormal cardiac diagnostic testing results suggestive of possible
43 channelopathies, arrhythmias, cardiomyopathies, myocarditis, or structural heart disease.
- 44 x) Abnormal diagnostic imaging studies suggestive of underlying genetic condition.
- 45 xi) Abnormal physiologic function studies suggestive of an underlying genetic
46 etiology.
- 47 xii) Family genetic history related to the patient's condition.
- 48 Genetic data generated as a result of performing rapid whole genome sequencing,
49 covered pursuant to this Section, shall have a primary use of assisting the ordering health care
50 professional and treating care team to diagnose and treat the patient, and as protected health
51 information it shall be subject to the to the requirements applicable to protected health

52 information as set forth in the Health Information Portability and Accountability Act (“HIPAA”),
53 the Health Information Technology for Economic and Clinical Health Act, and their attendant
54 regulations, including but not limited to the HIPAA Privacy Rule as promulgated at 45 CFR Part
55 160 and Subparts A and E of 45 CFR Part 164.

56 The Executive Office of Health and Human Services shall take any actions necessary to
57 implement the provisions of this Section, which can include, if deemed necessary, the following:
58 (i) promulgation of rules and regulations to provide for Medicaid coverage pursuant to this
59 Section, (ii) submission to the Centers for Medicare and Medicaid Services of any new waiver
60 application, amendment to an existing waiver, or Medicaid state plan amendment necessary to
61 ensure federal financial participation for Medicaid coverage pursuant to this Section, or (iii) any
62 other administrative action determined by the Secretary as necessary to implement the
63 requirements of this Section.

64 SECTION 2. This act shall take effect upon passage.