SENATE DOCKET, NO. 1247 FILED ON: 1/16/2025

SENATE . . . . . No. 847

The Commonwealth of Massachusetts

PRESENTED BY:

John J. Cronin

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 relative to rapid whole genome sequencing.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
John J. Cronin	*Worcester and Middlesex*

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By Mr. Cronin, a petition (accompanied by bill, Senate, No. 847) of John J. Cronin for legislation relative to converge for rapid whole genome sequencing. Health Care Financing.

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Fourth General Court
(2025-2026)

An Act relative to 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:

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

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

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

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

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

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

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

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

iv) Refractory or severe hypoglycemia or hyperglycemia.

v) Abnormal response to therapy related to an underlying medical condition affecting vital organs or bodily systems.

vi) Severe muscle weakness, rigidity, or spasticity.

vii) Refractory seizures.

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

(1) A recurrent event without respiratory infection.

(2) A recurrent event witnessed seizure-like event.

(3) A recurrent cardiopulmonary resuscitation.

ix) Abnormal cardiac diagnostic testing results suggestive of possible channelopathies, arrhythmias, cardiomyopathies, myocarditis, or structural heart disease.

x) Abnormal diagnostic imaging studies suggestive of underlying genetic condition.

xi) Abnormal physiologic function studies suggestive of an underlying genetic etiology.

xii) Family genetic history related to the patient's condition.

Genetic data generated as a result of performing rapid whole genome sequencing, covered pursuant to this Section, shall have a primary use of assisting the ordering health care professional and treating care team to diagnose and treat the patient, and as protected health information it shall be subject to the to the requirements applicable to protected health information as set forth in the Health Information Portability and Accountability Act ("HIPAA"),

the Health Information Technology for Economic and Clinical Health Act, and their attendant regulations, including but not limited to the HIPAA Privacy Rule as promulgated at 45 CFR Part 160 and Subparts A and E of 45 CFR Part 164.

The Executive Office of Health and Human Services shall take any actions necessary to implement the provisions of this Section, which can include, if deemed necessary, the following: (i) promulgation of rules and regulations to provide for Medicaid coverage pursuant to this Section, (ii) submission to the Centers for Medicare and Medicaid Services of 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, or (iii) any other administrative action determined by the Secretary as necessary to implement the requirements of this Section.

SECTION 2. This act shall take effect upon passage.