HOUSE BILL 1826
By Martin B

SENATE BILL 1762

By Briggs

AN ACT to amend Tennessee Code Annotated, Title 8; Title 56 and Title 71, relative to coverage of rapid whole genome sequencing.

WHEREAS, the provision of rapid whole genome sequencing is a powerful diagnostic tool for individuals with rare genetic conditions in which the specific etiology of the condition is unclear; and

WHEREAS, rapid whole genome sequencing for critically ill children with an undiagnosed condition who are receiving treatment in an intensive care unit demonstrates significant clinical utility, is cost-effective, and yields life-changing outcomes when ordered as a first-line test; and

WHEREAS, studies have shown that, by using rapid whole genome sequencing, providers have been able to identify the exact cause of rare genetic diseases in a matter of days, instead of the standard four to six weeks that other genetic testing currently offers; and

WHEREAS, the comprehensive nature of the test, along with the speed of results, allows providers to deliver timely treatment tailored to a child's specific condition; and

WHEREAS, access to the results of rapid whole genome sequencing empowers parents to join providers in making the most informed care decisions that can avoid other costly tests and invasive procedures, resulting in fewer days in the hospital; now, therefore,

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 71, Chapter 5, Part 1, is amended by adding the following as a new section:

(a) As used in this section, "rapid whole genome sequencing" means 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 seven (7) days and final results within fifteen (15) days from the date of receipt of the sample by the lab performing the test. "Rapid whole genome sequencing" includes patient-only whole genome sequencing, duo whole genome sequencing of the patient and one (1) biological parent, and trio whole genome sequencing of the patient and both biological parents.

(b) Subject to any required approval of the federal centers for medicare and medicaid services (CMS), TennCare shall cover rapid whole genome sequencing as a separately payable service for beneficiaries when:

(1) The beneficiary is under twenty-one (21) years of age;

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

(3) The beneficiary is receiving hospital services in an intensive care unit or other high-acuity care unit within a hospital.

(c) Coverage provided pursuant to this section is subject to applicable evidence-based medical necessity criteria that must include, but is not limited to:

(1) 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;

(2) The patient has a determination from the patient's treating healthcare provider that:

(A) Timely identification of a molecular diagnosis is necessary to guide clinical decision-making; and

(B) Testing results may guide the treatment or management of the patient's condition; and

(3) Except as otherwise provided in subsection (d), the patient has a complex or acute illness of unknown etiology, including at least one (1) of the following:

(A) Congenital anomalies involving at least two (2) organ systems or complex or multiple congenital anomalies in one (1) organ system;

(B) Specific organ malformations highly suggestive of a genetic etiology;

(C) Abnormal laboratory tests or abnormal chemistry profiles suggesting the presence of a genetic disease, complex metabolic disorder, or inborn error of metabolism;

(D) Refractory or severe hypoglycemia or hyperglycemia;

(E) Abnormal response to therapy related to an underlying medical condition affecting vital organs or bodily systems;

(F) Severe muscle weakness, rigidity, or spasticity;

(G) Refractory seizures;

(H) A high-risk stratification on evaluation for a brief resolved unexplained event with:

(i) A recurrent event without respiratory infection;

(ii) A recurrent witnessed seizure-like event; or

(iii) A recurrent cardiopulmonary resuscitation;

(I) Abnormal cardiac diagnostic testing results suggestive of possible channelopathies, arrhythmias, cardiomyopathies, myocarditis, or structural heart disease;

(J) Abnormal diagnostic imaging studies suggestive of an underlying genetic condition;

(K) Abnormal physiologic function studies suggestive of an underlying genetic etiology; or

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

(d) This section does not prohibit the bureau of TennCare from adding additional conditions to those contained in subdivision (c)(3) based upon new medical evidence or from providing additional coverage for rapid whole genome sequencing or other next-generation sequencing and genetic testing for medicaid beneficiaries.

(e) Genetic data generated from rapid whole genome sequencing covered pursuant to this section has a primary use of assisting the ordering healthcare provider and treating care team to diagnose and treat the patient, and as protected health information, is subject to the requirements set forth in the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C. § 1320d et seq.) and the federal Health Information Technology for Economic and Clinical Health Act (HITECH) (42 U.S.C. § 300jj et seq. and 42 U.S.C. § 17901 et seq.).

(f) Notwithstanding subsection (e), genetic data generated from rapid whole genome sequencing covered pursuant to this section may be used in scientific research if consent for use of the data has been expressly given by the patient, or the patient's legal guardian in the case of a minor. The patient, the patient's legal guardian, or the patient's healthcare 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 healthcare provider may charge a fee based on the costs of producing the results to the extent allowed under § 63-2-102 and § 68-11-304. A patient or patient's legal guardian has the right to rescind consent given pursuant to this subsection (f) for use of the data in

scientific research at any time, and upon receipt of a written revocation of the consent, the healthcare provider or other entity using the data shall cease use and expunge the data from each data repository where the data is held.

(g) The bureau of TennCare is authorized to promulgate rules and take necessary administrative action to effectuate this section. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5. The bureau of TennCare is authorized to submit to CMS new waiver applications and amendments to existing waivers necessary to ensure federal financial participation for medicaid coverage pursuant to this section.

SECTION 2. For purposes of rulemaking and other administrative actions, this act takes effect upon becoming a law, the public welfare requiring it. For all other purposes, this act takes effect July 1, 2024, the public welfare requiring it.