By: A. Johnson of Harris H.B. No. 2641

A BILL TO BE ENTITLED

AN ACT

relating to Medicaid coverage and reimbursement for the provision of rapid whole genome sequencing to certain infants with acute or complex illnesses.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subchapter B, Chapter 32, Human Resources Code, is amended by adding Section 32.03125 to read as follows:

Sec. 32.03125. REIMBURSEMENT FOR RAPID WHOLE GENOME SEQUENCING. (a) In this section:

(1) "Rapid whole genome sequencing" means an investigation of the entire human genome, including coding and noncoding regions and mitochondrial deoxyribonucleic acid, to identify disease-causing genetic changes that returns preliminary positive results not later than the fifth day after the date the sequencing is ordered and final results not later than the 14th day after the date the sequencing is ordered. The term includes patient-only whole genome sequencing and duo and trio whole genome sequencing of the patient and a biological parent or parents of the patient.

(2) "Recipient" means a medical assistance recipient.

(b) The commission shall ensure medical assistance reimbursement is provided for the provision of rapid whole genome sequencing in accordance with this section to a recipient who:

(1) is younger than one year of age;

(2) has a complex or acute illness of unknown origin that is not confirmed to be caused by:

(A) an environmental exposure;

(B) a toxic ingestion;

(C) an infection with a normal response to therapy; or

(D) trauma; and

(3) is receiving inpatient hospital treatment in an intensive care unit or high acuity pediatric care unit.

(c) The executive commissioner by rule shall establish a medical assistance program reimbursement rate for the provision of rapid whole genome sequencing to a recipient by a genome sequencing provider.

(d) The provision of rapid whole genome sequencing may be subject to applicable evidence-based utilization review required by the commission that is based on whether:

(1) the recipient's symptoms suggest a broad differential diagnosis that would require an evaluation by multiple genetic tests if comprehensive genetic testing is not performed;

(2) the recipient's treating genome sequencing provider determines that a timely identification of a molecular diagnosis is necessary to guide clinical decision-making and testing results may guide the treatment or management of the recipient's condition; and

(3) the recipient has a complex or acute illness of unknown origin that includes at least one of the following:

(A) congenital anomalies involving at least two

organ systems or complex or multiple congenital anomalies in one organ system;

(B) specific organ malformations highly suggestive of a genetic origin;

(C) abnormal laboratory tests or abnormal chemistry profiles suggesting the presence of a genetic disease, complex metabolic disorder, or inborn error of metabolism, including an abnormal newborn screen, hyperammonemia, or severe lactic acidosis not due to poor perfusion;

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

(i) a lack of coordination;

(ii) a recurrent event without respiratory infection;

(iii) a recurrent witnessed seizure-like event; or

(iv) 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 such as a storage disorder or brain white matter disease;

(K) abnormal physiologic function studies suggestive of an underlying genetic origin such as a bleeding disorder or immune deficiency disorder; or

(L) family genetic history related to the recipient's condition.

(e) Except as provided by Subsection (g), genetic data created as a result of rapid whole genome sequencing provided in accordance with this section must primarily be used to assist the genome sequencing provider who ordered the test and other health care providers treating the recipient who is the subject of the sequencing in the diagnosis and treatment of the recipient.

(f) Genetic data described by Subsection (e) is subject to the requirements applicable to protected health information under the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191), the American Recovery and Reinvestment Act of 2009 (Pub. L. No. 111-5), and the rules adopted under those laws, including 45 C.F.R. Part 160 and 45 C.F.R. Part 164, Subparts A and E.

(g) A person may use genetic data described by Subsection (e) in scientific research if the person receives express consent for that use by the recipient or the recipient's parent, legal guardian, or managing conservator if the recipient is a minor. The

recipient or recipient's parent, legal guardian, or managing conservator may provide a written revocation of that consent to the person at any time, and the person shall cease using the data and expunge the data from the person's data repository immediately on receipt of the revocation.

(h) A recipient or the recipient's parent, legal guardian, or managing conservator if the recipient is a minor may request access to the results of rapid whole genome sequencing authorized under this section for use in other clinical settings.

SECTION 2. If before implementing any provision of this Act a state agency determines that a waiver or authorization from a federal agency is necessary for implementation of that provision, the agency affected by the provision shall request the waiver or authorization and may delay implementing that provision until the waiver or authorization is granted.

SECTION 3. This Act takes effect September 1, 2023.