ENGROSSED HOUSE
BILL NO. 1576 By: Lawson of the House

and

Hicks of the Senate

[Medicaid - Oklahoma Health Care Authority - coverage – criteria – Health Information Portability and Accountability Act requirements - scientific research - waiver application – codification - effective date – emergency]

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 4005 of Title 56, unless there is created a duplication in numbering, reads as follows:

A. 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 seven (7) days

and final results within fifteen (15) to twenty-one (21) days from the date of receipt of the sample by the lab performing the test, and includes patient-only whole genome sequencing (WGS) and duo and trio whole genome sequencing of the patient and biological parent or parents.

B. Subject to any required approval of the Centers for Medicare and Medicaid Services, the Oklahoma Health Care Authority shall include coverage of rapid whole genome sequencing as a separately payable service for Medicaid beneficiaries when all of the following criteria are met:

1. Beneficiary is under twenty-one (21) years of age;

2. 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

3. Beneficiary is receiving hospital services in an intensive care unit or other high acuity care unit within a hospital.

C. 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:

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's treating health care 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; and

3. The patient has a complex or acute illness of unknown etiology, including at least one of the following conditions:

a. congenital anomalies involving at least two organ systems or complex and multiple congenital anomalies in one 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 any of the following:

(1) a recurrent event without respiratory infection,

(2) a recurrent event witnessed seizure-like event, or

(3) 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. Nothing in this section prohibits the Chief Operating Officer of the Oklahoma Health Care Authority from adding additional conditions to those contained in paragraph 3 of subsection C of this section based upon new medical evidence or from providing coverage for rapid whole genome sequencing or other next generation sequencing (NGS) and genetic testing for Medicaid beneficiaries that is in addition to the coverage required under this section.

E. 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 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.

F. Genetic data generated from rapid whole genome sequencing, covered pursuant to this section, can be used in scientific research if consent for such 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 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 small 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.

G. The Chief Operating Officer of the Oklahoma Health Care Authority shall take any actions necessary to implement the provisions of this section, which may include, if deemed necessary, the following:

1. Promulgation of rules and regulations to provide for Medicaid coverage pursuant to this section;

2. 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

3. Any other administrative action determined by the Chief Operating Officer as necessary to implement the requirements of this section.

SECTION 2. This act shall become effective July 1, 2025.

SECTION 3. It being immediately necessary for the preservation of the public peace, health or safety, an emergency is hereby declared to exist, by reason whereof this act shall take effect and be in full force from and after its passage and approval.

Passed the House of Representatives the 3rd day of March, 2025.

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Presiding Officer of the House
of Representatives

Passed the Senate the ____ day of _____, 2025.

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Presiding Officer of the Senate