1 HOUSE OF REPRESENTATIVES - FLOOR VERSION 2 STATE OF OKLAHOMA 3 1st Session of the 60th Legislature (2025) HOUSE BILL 1576 4 By: Lawson of the House 5 and Hicks of the Senate 6 7 8 AS INTRODUCED 9 An Act relating to Medicaid; defining terms; requiring the Oklahoma Health Care Authority to 10 provide coverage through Medicaid for certain services; providing certain criteria; providing for certain medical necessity criteria; authorizing 11 discretion to the Chief Operating Officer of the Oklahoma Health Care Authority; providing for Health 12 Information Portability and Accountability Act 1.3 requirements; providing for scientific research; providing for consent to provide data for research; 14 providing for opting-out; providing for minors; providing for the promulgation of rules and regulations; providing for waiver application; 15 providing for codification; providing for an 16 effective date; and declaring an emergency. 17 18 19 BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA: 20 SECTION 1. NEW LAW A new section of law to be codified 21 in the Oklahoma Statutes as Section 4005 of Title 56, unless there 22 is created a duplication in numbering, reads as follows: 23 For purposes of this section, "rapid whole genome sequencing Α. 24 (RWGS)" 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:

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- 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 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; 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,
 - 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,

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- 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,
 - (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 underlying genetic condition,
- k. abnormal physiologic function studies suggestive of an underlying genetic etiology, or
- 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 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.

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- 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 will take any actions necessary to implement the

 provisions of this section, which can include, if deemed necessary,

 the following:
 - 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.

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COMMITTEE REPORT BY: COMMITTEE ON HEALTH AND HUMAN SERVICES OVERSIGHT, dated 02/26/2025 - DO PASS.