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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 965 Session of 2023

INTRODUCED BY CULVER, LAUGHLIN, COLLETT, DILLON, CAPPELLETTI, J. WARD, PHILLIPS-HILL, COMITTA, SCHWANK AND HUTCHINSON, NOVEMBER 9, 2023

REFERRED TO HEALTH AND HUMAN SERVICES, NOVEMBER 9, 2023

AN ACT

Amending the act of June 13, 1967 (P.L.31, No.21), entitled "An act to consolidate, editorially revise, and codify the public welfare laws of the Commonwealth," in public assistance, providing for coverage of rapid whole genome sequencing.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. The act of June 13, 1967 (P.L.31, No.21), known as the Human Services Code, is amended by adding a section to read:

Section 449.3. Coverage of Rapid Whole Genome Sequencing.--

(a) Subject to any required approval of the Centers for Medicare and Medicaid Services, the department shall include coverage of rapid whole genome sequencing for medical assistance beneficiaries enrolled in HealthChoices managed care program and fee-for-service program, if:

(1) the beneficiary is under one year 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, toxic ingestion, 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.

(b) The coverage provided under this section may be subject to applicable evidence-based medical necessity criteria that shall be based on all of the following:

(1) The beneficiary 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 beneficiary'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 beneficiary's condition.

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

(i) Congenital anomalies involving at least two organ systems or complex or 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.

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

(A) A recurrent event without respiratory infection.

(B) A recurrent seizure-like event.

(C) A recurrent cardiopulmonary resuscitation.

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

(ix) Abnormal diagnostic imaging studies suggestive of underlying genetic condition.

(x) Abnormal physiologic function studies suggestive on an underlying genetic etiology.

(xi) Family genetic history related to the beneficiaries' condition.

(c) The department shall make payment for the testing required under this section as a fee-for-service reimbursement for medical assistance beneficiaries enrolled in HealthChoices managed care program and fee-for-service program, if the beneficiaries meet the eligibility criteria of this section.

(d) Nothing in this section shall prohibit the secretary from adding additional conditions to those contained in subsection (b)(3) based upon new medical evidence or from providing coverage for rapid whole genome sequencing or other next generation sequencing and genetic testing for medical assistance 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 under this section shall have a

primary use of assisting the ordering health care professional and treating care team to diagnose and treat the beneficiary and shall be subject to the requirements applicable to protected health information as specified in the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191, 110 Stat. 1936) and the Health Information Technology for Economic and Clinical Health Act (Public Law 111-5, 123 Stat. 226-279 and 467-496) and the attendant regulations including, but not limited to, the Health Information Portability Act Privacy Rule as promulgated at 45 CFR Pt. 160 (relating to general administrative requirements) and 45 CFR Pt. 164 Subpts. A (relating to general provisions) and E (relating to privacy of individually identifiable health information).

(f) Genetic data generated from rapid whole genome sequencing covered under this section may be used in scientific research if consent for such use of the data is expressly given by the beneficiary or the beneficiary's legal guardian, in the case of a minor. The beneficiary, or the beneficiary's health care provider with the beneficiary's consent or consent of beneficiary's legal guardian, may request access to the results of the testing covered under this section for use in other clinical settings. A health care provider may only charge a de minimis fee to the beneficiary based on the direct costs of producing the results in a format usable in other clinical settings. A beneficiary or beneficiary'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 secretary may take any actions necessary to implement the provisions of this section, which may include the following:

(1) submission to the Centers for Medicare and Medicaid Services of a Medicaid State plan amendment necessary to ensure Federal financial participation for medial assistance coverage under this section; or

(2) any other administrative action determined by the secretary as necessary to implement the requirement of this section.

(h) As used in this section, the following words and phrases shall have the following meanings:

"Rapid whole genome sequencing" means the investigation of the entire human genome, including coding and noncoding regions and mitochondrial deoxyribonucleic acid, to identify disease-causing genetic changes that returns the preliminary positive results within seven days and final results within fifteen days from the date of receipt of the sample by the lab performing the test. The term includes beneficiary-only whole genome sequencing and duo and trio whole genome sequencing of the beneficiary and biological parent or parents.

Section 2. This act shall take effect immediately.