AN ACT relating to coverage for rapid whole genome sequencing.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

➔SECTION 1. A NEW SECTION OF KRS CHAPTER 18A IS CREATED TO READ AS FOLLOWS:

(1) As used in this section, "rapid whole genome sequencing":

(a) 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 laboratory preforming the test; and

(b) Includes:

1. Patient-only whole genome sequencing;

2. Duo sequencing of the patient and one (1) biological parent; and

3. Trio sequencing of the patient and both biological parents.

(2) Notwithstanding any provision of law to the contrary, any fully insured or self-insured health benefit plan, as defined in KRS 304.17A-005, offered, issued, or renewed to public employees under KRS 18A.225, 18A.2254, or any other provision of this chapter shall provide coverage and reimbursement for rapid whole genome sequencing when the insured:

(a) Is under twenty-one (21) years of age;

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

(c) Is receiving hospital services in an intensive care unit or other high-acuity care unit within a hospital.

(3) Coverage required under this section shall be subject to applicable evidence-based medical necessity criteria that shall include but may not be limited to:

(a) The patient has symptoms that suggest a broad differential diagnosis that would require evaluation by multiple genetic tests if rapid whole genome sequencing is not performed;

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

1. Timely identification of a molecular diagnosis is necessary to guide the clinical decision-making process; and

2. Testing results may guide treatment or management of the patient's clinical condition; and

(c) The patient has a complex or acute illness of unknown etiology, including at least one (1) of the following:

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

2. Specific organ malformations which are highly suggestive of a genetic etiology;

3. Abnormal laboratory test results or abnormal chemistry profiles that suggest the presence of a genetic disease, complex metabolic disorder, or inborn error of metabolism;

4. Refractory or severe hypoglycemia or hyperglycemia;

5. Abnormal response to therapy related to an underlying medical condition affecting vital organs or bodily systems;

6. Severe muscle weakness, rigidity, or spasticity;

7. Refractory seizures;

8. A high-risk stratification on evaluation for a brief resolved unexplained event with:

a. A recurrent event without respiratory infection;

b. A recurrent witnessed seizure-like event; or

c. A recurrent cardiopulmonary resuscitation;

9. Abnormal cardiac diagnostic test results that suggest possible channelopathies, arrhythmias, cardiomyopathies, myocarditis, or structural heart disease;

10. Abnormal diagnostic imaging studies that suggest an underlying genetic condition;

11. Abnormal physiologic function studies that suggest an underlying genetic etiology;

12. A family history related to the patient's condition; or

13. Any other condition approved by the Department for Medicaid Services based upon new medical evidence.

(4) (a) Genetic data generated from rapid whole genome sequencing covered under this section has a primary use of assisting the ordering healthcare provider and the treating care team to diagnose and treat the patient, is protected health information, and is subject to the requirements of the federal Health Insurance Portability and Accountability Act of 1996 and the federal Health Information Technology for Economic and Clinical Health Act.

(b) Notwithstanding paragraph (a) of this subsection, genetic data generated from rapid whole genome sequencing covered under this section may be used in scientific research if informed consent for that use has been expressly given by the patient, or the patient's legal guardian if the patient is a minor. The patient, the patient's legal guardian, or the patient's healthcare provider with the patient's informed consent may request access to the results of the testing covered under this section for use in other clinical settings.

(c) A patient, or a patient's legal guardian if the patient is a minor, may rescind informed consent given under paragraph (b) of this subsection for the use

of genetic data in scientific research at any time. Upon receipt of a written revocation of consent, the patient's healthcare provider and any other individual or entity using the genetic data shall cease use and expunge all of the patient's genetic data from any data repository where the data is held.