AN ACT relating to rapid whole genome sequencing.

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

➔SECTION 1. A NEW SECTION OF KRS CHAPTER 205 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) The Department for Medicaid Services and any managed care organization with whom the department contracts for the delivery of Medicaid services shall provide coverage and reimbursement for rapid whole genome sequencing when the beneficiary:***

***(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.***

***(5) The Department for Medicaid Services:***

***(a) Shall promulgate administrative regulations in accordance with KRS Chapter 13A to implement this section; and***

***(b) May provide additional coverage for rapid whole genome sequencing or other next-generation sequencing and genetic testing for Medicaid beneficiaries.***

➔Section 2. KRS 205.6485 is amended to read as follows:

(1) As used in this section, "KCHIP" means the Kentucky Children's Health Insurance Program.

(2) The Cabinet for Health and Family Services shall:

(a) Prepare a state child health plan, known as KCHIP, meeting the requirements of Title XXI of the Federal Social Security Act, for submission to the Secretary of the United States Department of Health and Human Services within such time as will permit the state to receive the maximum amounts of federal matching funds available under Title XXI; and

(b) By administrative regulation promulgated in accordance with KRS Chapter 13A, establish the following:

1. The eligibility criteria for children covered by KCHIP, which shall include a provision that no person eligible for services under Title XIX of the Social Security Act, 42 U.S.C. secs. 1396 to 1396v, as amended, shall be eligible for services under KCHIP, except to the extent that Title XIX coverage is expanded by KRS 205.6481 to 205.6495 and KRS 304.17A-340;

2. The schedule of benefits to be covered by KCHIP, which shall:

a. Be at least equivalent to one (1) of the following:

i. The standard Blue Cross/Blue Shield preferred provider option under the Federal Employees Health Benefit Plan established by 5 U.S.C. sec. 8903(1);

ii. A mid-range health benefit coverage plan that is offered and generally available to state employees; or

iii. Health insurance coverage offered by a health maintenance organization that has the largest insured commercial, non-Medicaid enrollment of covered lives in the state; and

b. Comply with subsection (6) of this section;

3. The premium contribution per family for health insurance coverage available under KCHIP, which shall be based:

a. On a six (6) month period; and

b. Upon a sliding scale relating to family income not to exceed:

i. Ten dollars ($10), to be paid by a family with income between one hundred percent (100%) to one hundred thirty-three percent (133%) of the federal poverty level;

ii. Twenty dollars ($20), to be paid by a family with income between one hundred thirty-four percent (134%) to one hundred forty-nine percent (149%) of the federal poverty level; and

iii. One hundred twenty dollars ($120), to be paid by a family with income between one hundred fifty percent (150%) to two hundred percent (200%) of the federal poverty level, and which may be made on a partial payment plan of twenty dollars ($20) per month or sixty dollars ($60) per quarter;

4. There shall be no copayments for services provided under KCHIP; and

5. a. The criteria for health services providers and insurers wishing to contract with the Commonwealth to provide coverage under KCHIP.

b. The cabinet shall provide, in any contracting process for coverage of preventive services, the opportunity for a public health department to bid on preventive health services to eligible children within the public health department's service area. A public health department shall not be disqualified from bidding because the department does not currently offer all the services required by this section. The criteria shall be set forth in administrative regulations under KRS Chapter 13A and shall maximize competition among the providers and insurers. The Finance and Administration Cabinet shall provide oversight over contracting policies and procedures to assure that the number of applicants for contracts is maximized.

(3) Within twelve (12) months of federal approval of the state's Title XXI child health plan, the Cabinet for Health and Family Services shall assure that a KCHIP program is available to all eligible children in all regions of the state. If necessary, in order to meet this assurance, the cabinet shall institute its own program.

(4) KCHIP recipients shall have direct access without a referral from any gatekeeper primary care provider to dentists for covered primary dental services and to optometrists and ophthalmologists for covered primary eye and vision services.

(5) KCHIP shall comply with**:**

***(a)*** KRS 304.17A-163**;** ~~[ and ]~~

***(b) KRS*** 304.17A-1631***; and***

***(c) Section 1 of this Act***.

(6) The schedule of benefits required under subsection (2)(b)2. of this section shall

include:

(a) Preventive services;

(b) Vision services, including glasses;

(c) Dental services, including sealants, extractions, and fillings; and

(d) The coverage required under KRS 304.17A-129 and 304.17A-145.

➔Section 3. If the Department for Medicaid Services or the Cabinet for Health and Family Services determines that a state plan amendment, waiver, or any other form of authorization or approval from any federal agency is necessary prior to implementation of Section 1 or 2 of this Act for any reason, including the loss of federal funds, the department or cabinet shall, within 90 days after the effective date of this Act, request any necessary state plan amendment, waiver, authorization, or approval, and may only delay full implementation of those provisions for which a state plan amendment, waiver, authorization, or approval was deemed necessary until the state plan amendment, waiver, authorization, or approval is granted or approved.

➔Section 4. The Department for Medicaid Services or the Cabinet for Health and Family Services, shall, in accordance with KRS 205.525, provide a copy of any state plan amendment, waiver application, or other request for authorization or approval submitted pursuant to Section 3 of this Act to the Legislative Research Commission for referral to the Interim Joint Committee on Health Services and the Interim Joint Committee on Appropriations and Revenue and shall provide an update on the status of any application or request submitted pursuant to Section 3 of this Act at the request of the Legislative Research Commission or any committee thereof.