2022 Regular Session **ENROLLED**

SENATE BILL NO. 154

BY SENATORS TALBOT, BERNARD, BOUDREAUX, BOUIE, CARTER, CONNICK, CORTEZ, FESI, HARRIS, JACKSON, MIZELL, MORRIS, PEACOCK, POPE, SMITH, STINE, WARD AND WOMACK AND REPRESENTATIVE LANDRY

AN ACT

To enact R.S. 22:1028.4 and R.S. 40:1081.12, relative to health insurance coverage of genetic testing for critically ill infants with no diagnosis; to require health insurance coverage of genetic testing for critically ill infants with no diagnosis; to provide for definitions; to provide relative to Medicaid coverage for genetic testing of critically ill infants; to provide for coverage for rapid whole genome sequencing testing of certain infants; to provide for the duties of the secretary of the Louisiana Department of Health; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 22:1028.4 is hereby enacted to read as follows:

§1028.4. Required coverage for genetic testing for critically ill infants

A. The legislature hereby finds that employing the most comprehensive diagnostic testing available using advanced molecular techniques including but not limited to traditional whole genome sequencing, rapid whole genome sequencing, and other genetic and genomic screening for critically ill infants who are receiving care in intensive care units who have an unexplained rare disease is yielding life-changing outcomes for critically ill infants.

B. If ordered by the provider, rapid whole genome sequencing testing shall be covered by all plans in this state. With rapid whole genome sequencing, physicians have been able to identify the exact cause of rare genetic diseases in

an average of three days, instead of the standard four to six weeks that genetic testing offers and allows physicians to deliver timely treatment tailored to the infant's specific condition. Rapid whole genome sequencing empowers parents to join physicians in making informed care decisions, has resulted in avoiding other costly procedures like tracheotomies or gastric tube insertions, and has led to fewer days in the hospital.

C.(1) Every health coverage plan renewed, delivered, or issued for delivery in this state shall include coverage for advanced molecular techniques including but not limited to traditional whole genome sequencing, rapid whole genome sequencing, and other genetic and genomic screening that includes individual sequencing, trio sequencing for a parent or parents of the infant, and ultra-rapid sequencing for an infant who is one year of age or younger, is receiving inpatient hospital services in an intensive care unit or in a pediatric care unit, and has a complex illness of unknown etiology.

(2) The coverage provided in this Section may be subject to annual deductibles, coinsurance, and copayment provisions as are consistent and established under the health coverage plan. 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:

(a) The infant is suspected of having a rare genetic condition that is not diagnosable by a standard clinical work-up.

(b) The infant has symptoms that suggest a broad differential diagnosis that requires an evaluation by multiple genetic tests if advanced molecular techniques including but not limited to traditional whole genome sequencing, rapid whole genome sequencing, and other genetic and genomic screening is not performed.

(c) Timely identification of a molecular diagnosis is necessary to guide clinical decision-making, and the advanced molecular techniques including but not limited to traditional whole genome sequencing, rapid whole genome sequencing, and other genetic and genomic screening results may guide the

treatment or management of the infant's condition.

(d) The infant has at least one of the following conditions:

(i) Multiple congenital anomalies.

(ii) Specific malformations highly suggestive of a genetic etiology.

(iii) Abnormal laboratory tests suggesting the presence of a genetic disease or complex metabolic phenotype like but not limited to an abnormal newborn screen, hyperarammonemia, or lactic acidosis not due to poor perfusion.

(iv) Refractory or severe hypoglycemia.

(v) Abnormal response to therapy related to an underlying medical condition affecting vital organs or bodily systems.

(vi) Severe hypotonia.

(vii) Refractory seizures.

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

(aa) A recurrent event without respiratory infection.

(bb) A recurrent event witnessed seizure-like event.

(cc) A recurrent cardiopulmonary resuscitation.

(ix) Abnormal chemistry levels including but not limited to electrolytes, bicarbonate, lactic acid, venous blood gas, and glucose suggestive of inborn error of metabolism.

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

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

D. For purposes of this Section, "health coverage plan" means any hospital, health, or medical expense insurance policy, hospital or medical service contract, employee welfare benefit plan, contract, or other agreement with a health maintenance organization or a preferred provider organization, health and accident insurance policy, or any other insurance contract of this

type in Louisiana, including group insurance plan, a self-insurance plan, and the office of group benefits programs. "Health coverage plan" does not include a plan providing coverage for excepted benefits defined in R.S. 22:1061, limited benefit health insurance plans, and short-term policies that have a term of less than twelve months.

Section 2. R.S. 40:1081.12 is hereby enacted to read as follows:

§1081.12. Medicaid coverage; genetic testing of critically ill infants

A.(1) Subject to the approval of the Centers for Medicare and Medicaid Services, the Louisiana medical assistance program shall include coverage on a fee-for-service basis for rapid whole genome sequencing testing of an infant who is enrolled in a Medicaid managed care plan and meets all of the following criteria:

(a) Is one year of age or younger.

(b) Has a complex illness of unknown etiology.

(c) Is receiving inpatient hospital services in an intensive care unit or in a pediatric care unit.

(2) Coverage provided for the infant pursuant to this Section shall include individual sequencing, trio sequencing of the parents of the infant, and ultra-rapid sequencing.

B. The secretary of the Louisiana Department of Health shall take all actions necessary to implement the provisions of this Section, including but not limited to both of the following:

(1) Promulgation of rules and regulations in accordance with the Administrative Procedure Act 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 to provide for Medicaid coverage pursuant to this Section.

Section 3. The provisions of Section 1 of this Act shall become effective on January 1, 2023.

Section 4. The provisions of this Section and Sections 2 and 3 of this Act shall become effective on August 1, 2022.

PRESIDENT OF THE SENATE

SPEAKER OF THE HOUSE OF REPRESENTATIVES

GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____