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

Coding: Words which are struck through are deletions from existing law; words in **boldface type and underscored** are additions.
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, hyperammonia, 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.

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PRESIDENT OF THE SENATE

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SPEAKER OF THE HOUSE OF REPRESENTATIVES

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GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: ____________