AN ACT

To enact R.S. 22:1028.4 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; 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 rapid whole genome sequencing testing 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. 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 four to six weeks standard that genetic testing offers and allows physicians to deliver timely treatment tailored to the infant’s specific condition and rapid genome sequencing empowers parents to join physicians in making...
informed care decisions. Rapid whole genome sequencing has resulted in
avoiding other costly procedures like tracheotomies or gastric tube insertions,
and has led to fewer days in the hospital.

B.(1) Every health coverage plan renewed, delivered, or issued for
delivery in this state shall include coverage for rapid whole genome sequencing
testing 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, who is receiving inpatient hospital services in an intensive
care unit or in a pediatric care unit, and the infant 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 under this
Section may be subject to applicable evidence-based medical necessity criteria
that shall be based on all of the following items:

(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 rapid whole genome
sequence testing is not performed.

(c) Timely identification of a molecular diagnosis is necessary to guide
clinical decision-making, and the rapid whole genome sequence testing 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 suggest the presence of a genetic disease
or complex metabolic phenotype like but not limited to an abnormal newborn
screen, hyperammononemia, 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 like 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.
(3) Rapid whole genome sequencing testing shall not be covered upon admission to the hospital if one of the following conditions apply:
   (a) An infection or sepsis with normal response to therapy.
   (b) A confirmed prenatal or postnatal genetic diagnosis consistent with the infant's condition.
   (c) A hypoxic-ischemic encephalopathy with a clear precipitating event.
   (d) Isolated prematurity.
   (e) Isolated transient tachypnea of the newborn.
   (f) Isolated unconjugated hyperbilirubinemia.
   (g) A nonviable neonates.
   (h) A trauma.
   (i) A meconium aspiration.
C. 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" shall 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.

D. As used in this Section, the following definitions shall apply unless the context indicates otherwise:

(1) "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention. Biomarkers include but are not limited to gene mutations or protein expression.

(2) "Biomarker testing" is the analysis of a patient's tissue, blood, or fluid biospecimen for the presences of a biomarker. Biomarker testing includes but is not limited to single-analyte tests, multi-plex panel tests, and partial or whole genome sequencing.

(3) "Rapid whole genome sequence" is a method of diagnosing genetic conditions that is done within a seventy-two hour turnaround for critically ill infants who are one year of age or younger who are receiving care in the intensive care unit or in the pediatric intensive care unit with a complex illness of unknown etiology.

Section 2. This Act shall become effective on January 1, 2023.
The original instrument and the following digest, which constitutes no part of the legislative instrument, were prepared by Beth O’Quin.

DIGEST
SB 154 Original 2022 Regular Session Talbot

Proposed law requires any health coverage plan renewed, delivered, or issued for delivery, in this state to include coverage for using rapid whole genome sequencing (rWGS) that helps a physician timely diagnosis in and guide treatment for a critically ill infant who is one year or younger and is receiving care in the intensive care unit or in the pediatric care unit and the infant has a complex illness of unknown etiology.

Proposed law provides that coverage may be subject to annual deductibles, coinsurance, copayment provisions consistent with that established under the health coverage plan and that this coverage may be subject to applicable evidence-based medical necessity criteria based on all of the following:

1. The infant is suspected of having a rare genetic condition not diagnosable by a standard clinical work-up.
2. The infant has symptoms that suggest a broad differential diagnosis that requires an evaluation by multiple genetic tests if rWGS testing is not performed.
3. Timely identification of a molecular diagnosis is necessary in order to guide clinical decision making and rWGS testing results would guide the treatment or management of the infant's condition.
4. The infant has at least one of the following conditions:
   a. Multiple congenital anomalies.
   b. Specific malformations highly suggestive of a genetic etiology.
   c. Abnormal laboratory test suggests the presence of a genetic disease or complex metabolic phenotype like but not limited to an abnormal newborn screen, hyperammonmonemia, or lactic acidosis not due to poor perfusion.
   d. Refractory or severe hypoglycemia.
   e. Abnormal response to therapy relates to an underlying medical condition that affects vital organs or bodily systems.
   f. Severe hypotonia.
   g. Refractory seizures.
   h. A high-risk stratification on evaluation for a brief resolved unexplained event with any of the following:
      i. A recurrent event without respiratory infection.
      ii. A recurrent event witnessed seizure-like event.
      iii. A recurrent cardiopulmonary resuscitation.
   i. Abnormal chemistry levels like but not limited to electrolytes, bicarbonate, lactic acid, venous blood gas, and glucose that suggest inborn error of
metabolism.

(j) Abnormal cardiac diagnostic test results suggests possible channelopathies, arrhythmias, cardiomyopathies, myocarditis, or structural heart disease.

(k) Family genetic history that relates to the infant's condition.

Proposed law provides rapid whole genome sequencing does not cover admission to the hospital if one of the following conditions apply:

1. Infection or sepsis with normal response to therapy.
2. Confirmed prenatal or postnatal genetic diagnosis is consistent with the infant's condition.
3. Hypoxic-ischemic encephalopathy with a clear precipitating event.
4. Isolated prematurity.
5. Isolated transient tachypnea of the newborn.
6. Isolated unconjugated hyperbilirubinemia.
7. Nonviable neonates.
8. Trauma.

Proposed law defines health coverage plan as 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 the state, including group insurance plans, self-insurance plans, and the office of group benefits programs. Excludes a plan providing coverage for excepted benefits in present law, limited benefit health insurance plans, and short-term policies that have a term of less than 12 months.

Proposed law defines a biomarker, biomarker testing, and rapid whole genome sequencing.

Proposed law applies to health coverage plans renewed, delivered, or issued for delivery in their state on or after January 1, 2023.

Effective January 1, 2023.

(Adds R.S. 22:1028.4)