

2022 Regular Session

SENATE BILL NO. 154

BY SENATOR TALBOT

HEALTH/ACC INSURANCE. Provides for health insurance coverage of genetic testing for critically ill infants with no diagnosis. (1/1/23)

1 AN ACT

2 To enact R.S. 22:1028.4 relative to health insurance coverage of genetic testing for critically
3 ill infants with no diagnosis; to require health insurance coverage of genetic testing
4 for critically ill infants with no diagnosis; to provide for definitions; and to provide
5 for related matters.

6 Be it enacted by the Legislature of Louisiana:

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

8 **§1028.4. Required coverage for genetic testing for critically ill infants**

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

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

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

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

15 (2) The coverage provided in this Section may be subject to annual
16 deductibles, coinsurance, and copayment provisions as are consistent and
17 established under the health coverage plan. The coverage provided under this
18 Section may be subject to applicable evidence-based medical necessity criteria
19 that shall be based on all of the following items:

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

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

27 (c) Timely identification of a molecular diagnosis is necessary to guide
28 clinical decision-making, and the advanced molecular techniques including but
29 not limited to traditional whole genome sequencing, rapid whole genome

1 sequencing, and other genetic and genomic screening results may guide the
2 treatment or management of the infant's condition.

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

4 (i) Multiple congenital anomalies.

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

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

9 (iv) Refractory or severe hypoglycemia.

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

12 (vi) Severe hypotonia.

13 (vii) Refractory seizures.

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

16 (aa) A recurrent event without respiratory infection.

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

18 (cc) A recurrent cardiopulmonary resuscitation.

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

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

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

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

1 health and accident insurance policy, or any other insurance contract of this
 2 type in Louisiana, including group insurance plan, a self-insurance plan, and
 3 the office of group benefits programs. "Health coverage plan" shall not include
 4 a plan providing coverage for excepted benefits defined in R.S. 22:1061, limited
 5 benefit health insurance plans, and short-term policies that have a term of less
 6 than twelve months.

7 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 Engrossed

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 advanced molecular techniques including but not limited to traditional whole genome sequencing, rapid whole genome sequencing, and other genetic and genomic screening 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, hyperammonemia, 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 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 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)

Summary of Amendments Adopted by Senate

Committee Amendments Proposed by Senate Committee on Insurance to the original bill

1. Makes technical changes.
2. Removes rapid whole genome sequencing testing, and adds advanced molecular techniques including but not limited to traditional whole genome sequencing, rapid whole genome sequencing, and other genetic and genomic screening.
3. Adds that all plans in this state are required to cover rapid genome sequencing testing if a provider orders the test.
4. Removes the provision that lists what is not covered by rapid whole genome sequencing.
5. Removes the definitions for biomarker, biomarker testing, and rapid whole genome sequencing.