

1 the purposes of diagnosis, treatment, appropriate management, or ongoing
2 monitoring of an individual's disease or condition when the test provides clinical
3 utility as demonstrated by medical and scientific evidence, including any one of the
4 following items:

5 * * *

6 (e) Consensus statements.

7 * * *

8 E. As used in this Section, the following definitions apply unless the context
9 indicates otherwise:

10 * * *

11 (6) "Consensus statements" means statements developed by an
12 independent, multidisciplinary panel of experts utilizing a transparent
13 methodology and reporting structure and with a conflict-of-interest policy. The
14 statements are aimed at specific clinical circumstances and based on the best
15 available evidence for the purpose of optimizing the outcomes of clinical care.

16 F. Whenever the commissioner has reason to believe that any health
17 insurance issuer is not in compliance with any of the provisions of this Section,
18 he shall notify the health insurance issuer. The commissioner may, in addition
19 to the penalties provided for in Subsection H of this Section, issue and cause to
20 be served upon the health insurance issuer an order requiring the health
21 insurance issuer to cease and desist from any violation.

22 G. Any health insurance issuer who violates a cease and desist order
23 issued by the commissioner pursuant to this Section while the order is in effect
24 shall be subject to one or more of the following at the commissioner's discretion:

25 (1) A monetary penalty of not more than twenty-five thousand dollars for
26 each act or violation and every day the health insurance issuer is not in
27 compliance with the cease and desist order, not to exceed an aggregate of two
28 hundred fifty thousand dollars for any six-month period.

29 (2) Suspension or revocation of the health insurance issuer's certificate

1 of authority to operate in this state.

2 (3) Injunctive relief from the district court of the district in which the
3 violation may have occurred or in the Nineteenth Judicial District Court.

4 H. As a penalty for violating this Section, the commissioner may refuse
5 to renew or may suspend or revoke the certificate of authority of any health
6 insurance issuer. In lieu of suspension or revocation of a certificate of authority,
7 the commissioner may levy a monetary penalty of not more than one thousand
8 dollars for each act or violation, not to exceed an aggregate of two hundred fifty
9 thousand dollars.

10 I. An aggrieved party affected by the commissioner's decision, act, or
11 order may demand a hearing in accordance with Chapter 12 of this Title, R.S.
12 22:2191 et seq., except as otherwise provided by this Section. If a health
13 insurance issuer has demanded a timely hearing, the penalty, fine, or order by
14 the commissioner shall not be imposed until such time as the division of
15 administrative law makes a finding that the penalty, fine, or order is warranted
16 in a hearing held in the manner provided in Chapter 12 of this Title.

17 Section 2. Section 3 of Act No. 324 of the 2023 Regular Session of the Legislature
18 is hereby amended and reenacted to read as follows:

19 * * *

20 ~~Section 3.(A) The provisions of Sections 1 and 2 of this Act shall become effective~~
21 ~~when an Act of the Louisiana Legislature containing a specific appropriation of monies for~~
22 ~~the implementation of the provisions of this Act becomes effective.~~

23 ~~(B) The provisions of this Section~~ **This Act** shall become effective upon signature
24 by the governor or, if not signed by the governor, upon expiration of the time for bills to
25 become law without signature by the governor, as provided by Article III, Section 18 of the
26 Constitution of Louisiana. If vetoed by the governor and subsequently approved by the
27 legislature, ~~the provisions of this Section~~ **this Act** shall become effective on the day
28 following such approval.

29 Section 3. The provisions of this Act apply to any new policy, contract, program, or

1 health coverage plan issued on and after January 1, 2025. Any policy, contract, or health
 2 coverage plan in effect prior to January 1, 2025, shall convert to conform to the provisions
 3 of this Act on or before the renewal date, but no later than January 1, 2026.

4 Section 4. This Act shall become effective upon signature by the governor or, if not
 5 signed by the governor, upon expiration of the time for bills to become law without signature
 6 by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If
 7 vetoed by the governor and subsequently approved by the legislature, this Act shall become
 8 effective on the day following such approval.

The original instrument and the following digest, which constitutes no part
 of the legislative instrument, were prepared by Beth O'Quin.

DIGEST

SB 48 Original 2024 Regular Session Talbot

Proposed law requires any health coverage plan renewed, delivered, or issued for delivery in this state to include coverage for biomarker testing for the purpose of the diagnosis, treatment, appropriate management, or ongoing monitoring of an individual's disease or condition when the test provides clinical utility as demonstrated by medical and scientific evidence, including any one of the following:

- (1) Labeled indications for diagnostic tests approved or cleared by the U.S. Food and Drug Administration (FDA) or indicated diagnostic tests for a drug approved by the FDA.
- (2) Warnings and precautions listed on a FDA-approved drug label.
- (3) National Coverage Determinations of the Centers for Medicare and Medicaid Services or Local Coverage Determinations of Medicare Administrative Contractors.
- (4) Nationally recognized clinical practice guidelines.

Proposed law retains present law but adds consensus states when the test provides clinical utility as demonstrated by medical and scientific evidence.

Present law defines "biomarker", "biomarker testing", "clinical utility", "health coverage plan", and "nationally recognized clinical practice guidelines".

Proposed law retains present law but adds a definition for "consensus statements" to mean statements developed by an independent, multidisciplinary panel of experts that utilize a transparent methodology and reporting structure and provides for a conflict-of-interest policy. Provides these statements are aimed at specific clinical circumstances and based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

Present law requires implementation of present law under certain circumstances.

Proposed law repeals present law.

Present law provides present law is effective upon the signature of the governor or lapse of time for gubernatorial action.

Proposed law retains present law but makes a technical change.

Proposed law provides that the commissioner of insurance (commissioner) may issue penalties or cease and desist orders if he determines that any health insurance issuer is not in compliance with proposed law.

Proposed law provides monetary penalties for violations of cease and desist orders.

Proposed law authorizes the commissioner to revoke, suspend, or nonrenew a certificate of authority of any health insurance issuer for noncompliance. Proposed law permits any aggrieved health insurance issuer the opportunity to seek judicial review of certain decisions by the commissioner.

Proposed law applies to any new policy, contract, program, or health coverage plan issued on or after Jan. 1, 2025 and requires any policy, contract, or health coverage plan in effect prior to Jan. 1, 2025, shall convert to conform to the provisions of this Act on or before the renewal date, but no later than Jan. 1, 2026.

Effective upon signature of the governor or lapse of time for gubernatorial action.

(Amends Section 3 of Act No. 324 of 2023 RS; adds R.S. 22:1028.5(B)(2)(e), (E)(6), and (F)-(I))