

2022 Regular Session

SENATE BILL NO. 394

BY SENATOR BERNARD

INSURANCE POLICIES. Requires coverage for drugs under certain conditions and the drug is approved by the United States Food and Drug Administration. (8/1/22)

1 AN ACT

2 To enact R.S. 22:1060.8, relative to coverage of drugs under certain conditions when the
3 drug is approved by the United States Food and Drug Administration; to require a
4 health benefit plan to cover drugs for off-label use with certain terms and conditions;
5 to require a health benefit plan to cover drugs for children under certain terms and
6 conditions; to provide exclusions and limitations; to provide definitions; and to
7 provide for related matters.

8 Be it enacted by the Legislature of Louisiana:

9 Section 1. R.S. 22:1060.8 is hereby enacted to read as follows:

10 **§1060.8. Coverage of drugs approved by the United States Food and Drug**
11 **Administration; exclusions; definitions**

12 **A. No health coverage plan delivered or issued for delivery in this state**
13 **shall limit or exclude coverage for a drug on the basis that the drug is**
14 **prescribed for a use that is different from the use for which that drug has been**
15 **approved by the United States Food and Drug Administration and all of the**
16 **following items apply:**

17 **(1) The drug has been approved by the United States Food and Drug**

1 **Administration.**

2 **(2) The drug is prescribed by a licensed health care provider for the**
3 **treatment of one of the following items:**

4 **(a) A life-threatening disease or condition.**

5 **(b) A chronic or seriously debilitating disease or condition, the drug is**
6 **medically necessary to treat that disease or condition.**

7 **(c) For treatment of a disease or condition in a child and the drug has**
8 **been approved by the United States Food and Drug Administration for a similar**
9 **condition or disease in an adult and the drug is medically necessary to treat the**
10 **disease or condition.**

11 **(3) The drug has been recognized for the treatment of the disease or**
12 **condition or pediatric application by one of the following:**

13 **(a) The American Medical Association Drug Evaluations.**

14 **(b) The American Hospital Formulary Service Drug Information.**

15 **(c) The United States Pharmacopoeia Dispensing Information, Volume 1,**
16 **"Drug Information for the Health Care Professional".**

17 **(d) Recognized in two articles from major peer reviewed medical**
18 **journals that present data supporting the proposed off-label use or uses as**
19 **generally safe and effective unless there is clear and convincing contradictory**
20 **evidence presented in a major peer reviewed journal.**

21 **(4) The drug is on the insurer's formulary or preferred drug list, if any.**

22 **B. If requested by the health insurance insurer, the prescriber shall be**
23 **responsible for submitting to the health insurance insurer documentation**
24 **supporting compliance with the provision of this Section.**

25 **C. Any coverage required by this Section shall include medically**
26 **necessary services associated with the administration of a drug that is subject**
27 **to the conditions of the health coverage plan.**

28 **D. The provisions of this Section shall not require coverage for any of the**
29 **following:**

1 **(1) The treatment of a condition or disease that is excluded under the**
2 **terms of the health coverage plan.**

3 **(2) An experimental drug not approved by the United States Food and**
4 **Drug Administration.**

5 **(3) A drug not listed on the health coverage plan formulary or preferred**
6 **drug list, if any.**

7 **E. The coverage provided in this Section may be subject to annual**
8 **deductibles, coinsurance, and copayment provisions as are consistent with those**
9 **established under the health coverage plan and may be subject to prior**
10 **authorization.**

11 **F. For purposes of this Section, "health coverage plan" means any**
12 **hospital or medical expense insurance policy, hospital or medical service**
13 **contract, employee welfare benefit plan, contract, or other agreement with a**
14 **health maintenance organization or a preferred provider organization, health**
15 **and accident insurance policy, or any other insurance contract of this insurance**
16 **plan, and the office of group benefits programs. "Health coverage plan" shall**
17 **not include a plan providing coverage for excepted benefits defined in R.S.**
18 **22:1061, limited benefit health insurance plans, and short-term policies that**
19 **have a term of less than twelve months.**

20 **G. As used in this Section, the following terms shall apply unless the**
21 **context indicates otherwise:**

22 **(1) "Chronic and seriously debilitating" means a disease or condition**
23 **that causes significant long-term morbidity and requires ongoing treatment to**
24 **maintain remission or prevent deterioration.**

25 **(2) "Life-threatening" means all of the following:**

26 **(a) The likelihood of death is high unless the course of the disease or**
27 **condition is interrupted.**

28 **(b) Potentially fatal outcomes, when the end point of clinical intervention**
29 **is survival.**

1 **(c) The natural process of aging shall not be considered a disease or**
2 **condition for the purposes of this Section.**

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

DIGEST

SB 394 Original 2022 Regular Session Bernard

Proposed law prohibits a health benefit plan delivered or issued for delivery in this state to limit or exclude coverage for a drug approved by the United States Food and Drug Administration (FDA) based on the drug if prescribed for a use different from what the drug was approved for and all of the following applies:

- (1) The drug is approved by the FDA.
- (2) The drug is prescribed by a contracting licensed health care professional and it is medically necessary for the treatment of one of the following:
 - (a) A life-threatening disease or condition.
 - (b) A chronic or seriously debilitating disease or condition, the drug is medically necessary to treat that disease or condition.
 - (c) To treat a disease or condition in a child and the drug is approved by the FDA for a similar condition or disease in an adult and the drug is medically necessary to treat that disease or condition.
- (3) The drug is recognized for treatment of that disease or condition or pediatric application by one of the following:
 - (a) The American Medical Association Drug Evaluations.
 - (b) The American Hospital Formulary Service Drug Information.
 - (c) The United States Pharmacopoeia Dispensing Information, Volume 1, "Drug Information for the Health Care Professional".
 - (d) Two articles from major peer reviewed medical journals presented data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed journal.
- (4) The drug is on the insurer's formulary or preferred drug list, if any.

Proposed law requires the prescriber is responsible for submitting documentation to support compliance with the proposed law if requested by the health insurance insurer.

Proposed law provides the health coverage plan is not required to provide coverage for all of the following:

- (1) A treatment for a condition or disease that is excluded under the terms of the health coverage plan.
- (2) Experimental drugs not approved by the FDA.

- (3) A drug not listed on the health coverage plan formulary or preferred drug list, if any.

Proposed law provides coverage can be subject to annual deductibles, coinsurance, and copayment provisions established under the health coverage plan and coverage can be subject to prior authorization.

Proposed law defines "health coverage plan", "chronic and seriously debilitating", and "life-threatening".

Effective August 1, 2022.

(Adds R.S. 22:1060.8)