

SENATE BILL NO. 394

BY SENATOR BERNARD

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AN ACT

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

Be it enacted by the Legislature of Louisiana:

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

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

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

(1) The drug has been approved by the United States Food and Drug Administration.

(2) The drug is prescribed by a licensed healthcare provider for the treatment of a life threatening, chronic, or seriously debilitating disease or condition in a minor and the drug has been approved by the United States Food and Drug Administration for the same condition or disease in an adult and the

1 drug is medically necessary to treat the disease or condition.

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

4 (a) The American Medical Association Drug Evaluations.

5 (b) The American Hospital Formulary Service Drug Information.

6 (c) The United States Pharmacopeia Dispensing Information, Volume 1,
7 "Drug Information for the Health Care Professional".

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

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

13 B. If requested by the health insurance insurer, the prescriber shall be
14 responsible for submitting to the health insurance insurer documentation
15 supporting compliance with the provision of this Section.

16 C. Any coverage required by this Section shall include medically
17 necessary services associated with the administration of a drug that is subject
18 to the conditions of the health coverage plan.

19 D. The provisions of this Section shall not require coverage for any of the
20 following:

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

23 (2) An experimental drug not approved by the United States Food and
24 Drug Administration.

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

27 E. The coverage provided in this Section may be subject to annual
28 deductibles, coinsurance, and copayment provisions as are consistent with those
29 established under the health coverage plan and may be subject to prior
30 authorization.

1 F. For purposes of this Section, "health coverage plan" means any
2 hospital or medical expense insurance policy, hospital or medical service
3 contract, employee welfare benefit plan, contract, or other agreement with a
4 health maintenance organization or a preferred provider organization, health
5 and accident insurance policy, or any other insurance contract of this insurance
6 plan, and the office of group benefits programs. "Health coverage plan" does
7 not include a plan providing coverage for excepted benefits defined in R.S.
8 22:1061, limited benefit health insurance plans, and short-term policies that
9 have a term of less than twelve months.

10 Section 2. This Act shall become effective on January 1, 2023; if vetoed by the
11 governor and subsequently approved by the legislature, this Act shall become effective on
12 the day following the approval by the legislature.

PRESIDENT OF THE SENATE

SPEAKER OF THE HOUSE OF REPRESENTATIVES

GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____