

2022 Regular Session

HOUSE BILL NO. 117

BY REPRESENTATIVE ECHOLS

DRUGS/PRESCRIPTION: Provides relative to prescribing, administering, and dispensing of drugs for off-label use

1 AN ACT

2 To enact R.S. 37:1704 and R.S. 40:2109.4, relative to prescribing, administering, and
3 dispensing of drugs by certain licensed healthcare professionals; to authorize the
4 prescription, administration, and dispensing of certain drugs for off-label use by
5 healthcare professionals with prescriptive authority; to prohibit certain actions
6 against such healthcare professionals by licensing boards and commissions and by
7 hospitals in connection with the prescription, administration, and dispensing of drugs
8 for off-label use; and to provide for related matters.

9 Be it enacted by the Legislature of Louisiana:

10 Section 1. R.S. 37:1704 is hereby enacted to read as follows:

11 §1704. Prescription, administration, and dispensing of FDA-approved drugs for
12 off-label use

13 A. As used in this Section, the following terms have the meaning ascribed
14 in this Subsection:

15 (1) "FDA" means the United States Food and Drug Administration.

16 (2) "Off-label use" means the use of a prescription drug for an indication for
17 which it has not been approved by the FDA or the use of such drug in an age group,
18 dosage, or route of administration that has not been approved by the FDA.

19 B. Any person who is licensed pursuant to the provisions of this Title to
20 practice a healthcare profession and has prescriptive authority may prescribe,

1 administer, or dispense for an off-label use a drug that has been approved for a
2 specific use by the FDA when he determines, in his professional judgment, that such
3 off-label use is appropriate for the care and treatment of a patient.

4 C.(1) No licensing board or commission created by the provisions of this
5 Title shall initiate any disciplinary proceeding against a licensed healthcare
6 professional with prescriptive authority for prescribing, administering, or dispensing
7 for an off-label use, as authorized by Subsection B of this Section, a drug that has
8 been approved for a specific use by the FDA.

9 (2) No licensed healthcare professional with prescriptive authority who, as
10 authorized by Subsection B of this Section, prescribes, administers, or dispenses for
11 an off-label use a drug that has been approved for a specific use by the FDA shall be
12 subject to disciplinary action solely because of such prescribing, administering, or
13 dispensing.

14 D. No pharmacist shall refuse to dispense a drug for which a prescriber has
15 issued a valid prescription in accordance with Subsection B of this Section.

16 E. Nothing in this Section shall be construed to grant any person immunity
17 from investigation or disciplinary action for violating any other provision of this
18 Title.

19 Section 2. R.S. 40:2109.4 is hereby enacted to read as follows:

20 §2109.4. Off-label prescribing; action against professional or clinical privileges by
21 hospitals prohibited

22 A. As used in this Section, the following terms have the meaning ascribed
23 in this Subsection:

24 (1) "FDA" means the United States Food and Drug Administration.

25 (2) "Off-label use" means the use of a prescription drug for an indication for
26 which it has not been approved by the FDA or the use of such drug in an age group,
27 dosage, or route of administration that has not been approved by the FDA.

28 B. No hospital shall deny, revoke, terminate, diminish, or curtail in any way
29 any professional or clinical privilege of any person who is licensed pursuant to the

1 provisions of Title 37 of the Louisiana Revised Statutes of 1950 to practice a
 2 healthcare profession and has prescriptive authority solely on the grounds that the
 3 person has prescribed, administered, or dispensed for off-label use a drug that has
 4 been approved for a specific use by the FDA if such prescribing, administering, or
 5 dispensing was done in accordance with the provisions of R.S. 37:1704(B).

DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

HB 117 Original

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Echols

Abstract: Authorizes the prescription, administration, and dispensing of certain drugs for off-label use by healthcare professionals with prescriptive authority.

Present law provides for licensure and regulation by the state of various types of healthcare professionals.

Proposed law retains present law and authorizes any person who is licensed to practice a healthcare profession pursuant to present law, and who has prescriptive authority, to prescribe, administer, or dispense for an off-label use a drug that has been approved for a specific use by the United States Food and Drug Administration (FDA) when he determines, in his professional judgment, that such off-label use is appropriate for the care and treatment of a patient.

Proposed law prohibits healthcare professional licensing boards and commission created by present law from initiating any disciplinary proceeding against a licensed healthcare professional with prescriptive authority for prescribing, administering, or dispensing for an off-label use a drug that has been approved for a specific use by the FDA.

Proposed law stipulates that no licensed healthcare professional with prescriptive authority who prescribes, administers, or dispenses for an off-label use a drug that has been approved for a specific use by the FDA shall be subject to disciplinary action solely because of such prescribing, administering, or dispensing.

Proposed law prohibits pharmacists from refusing to dispense a drug for which a prescriber has issued a valid prescription in accordance with proposed law.

Proposed law provides that nothing therein shall be construed to grant any person immunity from investigation or disciplinary action for violating any provision of present law relative to healthcare professions and occupations.

Proposed law prohibits hospitals from denying, revoking, terminating, diminishing, or curtailing in any way any professional or clinical privilege of any person who is licensed to practice a healthcare profession pursuant to present law and has prescriptive authority solely on the grounds that the person has prescribed, administered, or dispensed for off-label use a drug that has been approved for a specific use by the FDA if such prescribing, administering, or dispensing was done in accordance with proposed law.

Proposed law defines "off-label use", for purposes of proposed law, as the use of a prescription drug for an indication for which it has not been approved by the FDA or the use

of such drug in an age group, dosage, or route of administration that has not been approved by the FDA.

(Adds R.S. 37:1704 and R.S. 40:2109.4)