HLS 24RS-1030 ENGROSSED

2024 Regular Session

HOUSE BILL NO. 815

1

BY REPRESENTATIVE BILLINGS

HEALTH/LDH: Provides relative to certain federally-regulated information

AN ACT

2 To enact Subpart E of Part IV of Chapter 5-D of Title 40 of the Louisiana Revised Statutes 3 of 1950, to be comprised of R.S. 40:1176.1, relative to certain federally-regulated 4 information; to require compliance with federal rules and regulations; to assign 5 certain duties to the Louisiana Department of Health; to impose penalties; to require 6 compliance from the Louisiana Department of Health; to provide for applicability; 7 and to provide for related matters. 8 Be it enacted by the Legislature of Louisiana: 9 Section 1. Subpart E of Part IV of Chapter 5-D of Title 40 of the Louisiana Revised 10 Statutes of 1950, comprised of R.S. 40:1176.1, is hereby enacted to read as follows: 11 SUBPART E. RIGHT TO FEDERALLY-REGULATED AND APPROVED MEDICAL 12 AND PHARMACEUTICAL INFORMATION 13 §1176.1. Right to federally-regulated drug and treatment information; prohibition 14 of noncompliant materials; penalties 15 A. The Louisiana Department of Health shall ensure that all descriptive 16 advertising and promotional materials relating to drugs, pharmaceuticals, medical 17 devices, or vaccines created or displayed by the department follow the respective 18 federal laws and adhere to the United States Food and Drug Administration rules 19 regarding commercial advertising.

1	B.(1) The manufacturer of any drug, pharmaceutical, medical device, or
2	vaccine whose advertisements or related promotional materials are displayed or
3	distributed by the Louisiana Department of Health but are determined by the
4	department to be noncompliant with the provisions set forth in Subsection A of this
5	Section shall receive notice from the Louisiana Department of Health within thirty
6	days of the publication or broadcast of the noncompliant advertisement or material
7	or within thirty days of the determination of noncompliance.
8	(2) The manufacturer shall remedy its noncompliance within thirty days of
9	receiving notice.
10	(3) If, after notice has been received, the thirty-day-period has lapsed, and
11	the drug, pharmaceutical, medical device, or vaccine-related advertisement or
12	promotional material still does not comply with the provisions of this Section, it shall
13	be subject to immediate removal from display or distribution by the Louisiana
14	Department of Health.
15	C.(1) The Louisiana Department of Health shall produce only drug,
16	pharmaceutical, medical device, or vaccine-related advertisements and promotional
17	materials that comply with the provisions of this Section and the regulations set forth
18	by the United States Food and Drug Administration.
19	(2) The Louisiana Department of Health shall promulgate rules as necessary
20	to implement the provisions of this Section.
21	D. This Section shall not apply to entities regulated in accordance with the
22	Federal Food, Drug, and Cosmetic Act, 21 U.S.C.

## **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)]

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Billings

**Abstract:** Requires the La. Dept. of Health (LDH) to ensure that all descriptive advertising and promotional material relating to drugs, pharmaceuticals, medical devices, or vaccinations follow certain federal laws and rules.

CODING: Words in struck through type are deletions from existing law; words <u>underscored</u> are additions.

<u>Proposed law</u> requires LDH to ensure that all descriptive advertising and promotional material relating to drugs, pharmaceuticals, medical devices, or vaccinations follow certain federal laws and rules.

<u>Proposed law</u> provides that the federal rules and regulations relative to commercial advertisement shall apply.

<u>Proposed law</u> provides that notice of noncompliance shall be given to the manufacturer of the drug, pharmaceutical, medical device, or vaccine-related advertisement or promotional material within 30 days of such noncompliant advertisements or promotional material or within thirty days of the determination of noncompliance.

<u>Proposed law</u> requires the manufacturer to remedy its noncompliance within 30 days of receiving notice.

<u>Proposed law</u> provides that if, after notice has been received and the 30-day period has lapsed, the drug, pharmaceutical, medical device, or vaccine-related advertisement or promotional material shall be subject to immediate removal from display or distribution by LDH if it continues to be noncompliant.

<u>Proposed law</u> requires LDH to produce only advertisements and promotional materials that comply with the provisions of <u>proposed law</u> and federal regulations.

(Adds R.S. 40:1176.1)

## Summary of Amendments Adopted by House

The Committee Amendments Proposed by <u>House Committee on Health and Welfare</u> to the original bill:

- 1. Change references <u>from</u> "medical treatment" <u>to</u> "medical device".
- 2. Change references <u>from</u> "publication or broadcast" <u>to</u> "display or distribution by LDH".
- 3. Remove <u>proposed law</u> provision that requires LDH to utilize existing staff to implement <u>proposed law</u>.
- 4. Require all descriptive advertising and promotional material relating to drugs, pharmaceuticals, medical devices, or vaccinations to comply with the Federal Food, Drug, and Cosmetic Act.
- 5. Provide that notice of noncompliance shall be given to the manufacturer of the drug, pharmaceutical, medical device, or vaccine-related advertisement or promotional material within 30 days of the noncompliant advertisements or promotional material or within 30 days of the determination of noncompliance.
- 6. Make technical corrections.