

2017 Regular Session

HOUSE BILL NO. 436

BY REPRESENTATIVES TALBOT, HOLLIS, LEBAS, DUSTIN MILLER, MORENO,
AND THIBAUT

Prefiled pursuant to Article III, Section 2(A)(4)(b)(i) of the Constitution of Louisiana.

DRUGS/PRESCRIPTION: Requires drug manufacturers to provide information regarding
prescription drug prices

1 AN ACT

2 To enact amend and reenact R.S. 44:4.1(B)(26) and to enact Part VIII of Chapter 12 of Title

3 40 of the Louisiana Revised Statutes of 1950, to be comprised of R.S. 40:2255.1

4 through 2255.21, relative to prescription drug prices; to provide legislative findings

5 and purpose; to provide for definitions; to establish the Prescription Drug Review

6 Committee; to provide for the membership, powers, and duties of the committee; to

7 require drug manufacturers to provide drug pricing information to the committee; to

8 require educational or marketing materials for prescription drugs directed to

9 healthcare providers to include price information; to establish the minimum price

10 information content; to authorize enforcement pursuant to the Unfair Trade Practices

11 and Consumer Protection Law; to provide for a public records exception; and to

12 provide for related matters.

13 Be it enacted by the Legislature of Louisiana:

14 Section 1. Part VIII of Chapter 12 of Title 40 of the Louisiana Revised Statutes of

15 1950, comprised of R.S. 40:2255.1 through 2255.21, is hereby enacted to read as follows:

1 PART VIII. PHARMACEUTICAL COST TRANSPARENCY

2 SUBPART A. GENERAL PROVISIONS

3 §2255.1. Legislative findings; purpose

4 A.(1) The Legislature of Louisiana hereby finds that the costs of prescription
5 drugs have been increasing dramatically without any attributed reason.

6 (2) The legislature further finds that containing healthcare costs requires
7 containing prescription drug costs.

8 B. Therefore, the legislature hereby declares, in order to contain prescription
9 drug costs, it is essential to understand the drivers of those costs, as transparency is
10 typically the first step toward cost containment.

11 §2255.2. Definitions

12 As used in this Part, the following words have the following meanings unless
13 the context indicates otherwise:

14 (1) "Average wholesale price" means the wholesale price charged on a
15 specific prescription drug that is assigned by the drug manufacturer and listed in a
16 nationally recognized drug pricing file.

17 (2) "Committee" means the Prescription Drug Review Committee
18 established pursuant to this Part.

19 (3) "Department" means the Department of Insurance.

20 (4) "Manufacturer" means any entity which is engaged in the production,
21 preparation, propagation, compounding, conversion, or processing of prescription
22 drugs, whether directly or indirectly by extraction from substances of natural origin,
23 independently by means of chemical synthesis, or by a combination of extraction and
24 chemical synthesis, or any entity engaged in the packaging, repackaging, labeling,
25 relabeling, or distribution of prescription drugs. The term shall not include a
26 wholesale distributor of prescription drugs licensed pursuant to the Louisiana Drug
27 and Device Distributors Act, R.S. 37:3461 et seq., a retailer, or a pharmacist licensed
28 pursuant to the Louisiana Pharmacy Practice Act, R.S. 37:1161 et seq.

29 (5) "Prescription drug" means a drug as defined in 21 U.S.C. 321.

1 (6) "Prescription drug marketing" means to provide educational or marketing
2 information or materials regarding a prescription drug in any form including but not
3 limited to all of the following:

4 (1) Face-to-face meetings.

5 (2) Physical mailings.

6 (3) Telephone conversations.

7 (4) Electronic mail or facsimile.

8 SUBPART B. PRESCRIPTION DRUG REVIEW COMMITTEE

9 §2255.11. Prescription Drug Review Committee

10 A. The Prescription Drug Review Committee is hereby established within
11 the Department of Insurance.

12 B. The committee shall consist of the following members:

13 (1) The commissioner of insurance or his designee.

14 (2) The secretary of the Louisiana Department of Health or his designee.

15 (3) The president of the Louisiana Board of Pharmacy or his designee.

16 (4) Two public members appointed by the governor.

17 (5) Two public members appointed by the president of the Senate.

18 (6) Two public members appointed by the speaker of the House of
19 Representatives.

20 C. The public members shall have a significant healthcare or pharmacy
21 background.

22 D.(1) Each public member shall serve for a term of five years.

23 (2) Each public member shall hold office for the term of appointment and
24 until their successor is appointed and qualified.

25 E. Any vacancy in the membership of the committee shall be filled for the
26 unexpired term in the manner provided for the original appointment. Members shall
27 be eligible for reappointment to the committee.

1 F.(1) The committee shall organize as soon as possible after the appointment
2 of its members and shall annually elect a chairperson and vice-chairperson from
3 among its members, and a secretary who need not be a member of the committee.

4 (2) The committee shall meet at least four times a year and may hold
5 additional meetings as necessary to discharge its duties. The committee shall also
6 meet at the call of the chairperson or the commissioner of insurance.

7 G. A majority of the membership of the committee shall constitute a quorum
8 for the transaction of committee business.

9 H. Members of the committee shall serve without compensation.

10 I. The department shall provide the committee with staff support from
11 existing personnel within the department and meeting facilities as is necessary for
12 the committee to carry out its duties.

13 §2255.12. Critical prescription drug list

14 A. The committee shall develop a list of critical prescription drugs made
15 available in Louisiana for which there is a substantial public interest in
16 understanding the development of pricing for the drugs.

17 B. In developing the list required by Subsection A of this Section, the
18 committee shall consider, at a minimum, all of the following factors:

19 (1) The cost of the drug to public healthcare programs including but not
20 limited to Medicaid.

21 (2) The current cost of the drug in the state.

22 (3) The extent of use of the drug within the state.

23 (4) The availability and cost of comparable or therapeutically equivalent
24 courses of treatment.

25 (5) The rate at which the drug is deemed to produce successful outcomes
26 when used to treat the conditions for which it is most commonly prescribed.

27 (6) Any other objectively quantifiable factors as the committee determines
28 to be relevant to evaluating the significance of the availability of the drug in
29 Louisiana.

1 C. The committee may also consider recommendations for drugs to be
2 included in the list submitted by government agencies, members of the public, and
3 professional organizations representing the pharmaceutical industry, healthcare
4 practitioners, pharmaceutical manufacturers, managed care plans, prescription drug
5 benefit managers, and other insurers.

6 D. The list developed pursuant to this Section shall be reviewed and updated
7 by the committee at least once every three years.

8 §2255.13. Manufacturer reporting

9 A. For each prescription drug that the committee places on the critical
10 prescription drug list pursuant to R.S. 40:2255.12, the committee shall require the
11 manufacturer of the drug to report the following information to the committee:

12 (1) Total cost of production and approximate cost of production per dose.
13 (2) Research and development costs of the drug including but not limited to
14 all of the following:

15 (a) Research and development costs that are paid with public funds.

16 (b) After-tax research and development costs paid by the manufacturer.

17 (c) Research and development costs paid by third parties.

18 (3) Marketing and advertising costs for the drug, apportioned by marketing
19 activities that are directed to consumers, marketing activities that are directed to
20 prescribers, and the total cost of all marketing and advertising that is directed
21 primarily to Louisiana consumers and prescribers.

22 (4) The prices for the drug that are charged to purchasers outside the United
23 States, by country, for a representative set of countries determined by the committee.

24 (5)(a) Prices charged to typical Louisiana purchasers including but not
25 limited to all of the following:

26 (i) Pharmacies.

27 (ii) Pharmacy chains.

28 (iii) Pharmacy wholesalers.

29 (iv) Other direct purchasers.

1 (b) True net typical prices charged to prescription drug benefit managers for
2 distribution in Louisiana, net of any rebates or other payments from the manufacturer
3 to the pharmacy benefit manager and the pharmacy benefit manager to the
4 manufacturer.

5 §2255.14. Rulemaking; enforcement

6 A. The commissioner of insurance, on behalf of the committee, shall adopt,
7 pursuant to the Administrative Procedure Act, R.S. 49:950 et seq., any rules and
8 regulations necessary to implement the provisions of this Subpart.

9 B. The failure of a manufacturer to provide the information required by this
10 Subpart shall constitute a prohibited practice under the Unfair Trade Practices and
11 Consumer Protection Law, R.S. 51:1401 et seq., and shall be subject to the
12 enforcement provisions of that Chapter.

13 §2255.15. Confidentiality

14 A. Information reported to the committee pursuant to R.S. 40:2255.13 shall
15 not be deemed to be a public or government record. The information shall be kept
16 confidential and shall be exempt from disclosure.

17 B. Any public reporting of information submitted pursuant to R.S.
18 40:2255.13 shall be aggregated to protect the financial, competitive, or proprietary
19 nature of the information.

20 §2255.16. Report to the legislature

21 A.(1) The committee shall prepare an annual report on prescription drug
22 prices and their role in overall healthcare spending in the state based on the data
23 submitted to the committee pursuant to R.S. 40:2255.13 and in accordance with R.S.
24 40:2255.15.

25 (2) The committee shall identify and include in the report a list of those
26 prescription drugs that have a cost in Louisiana that is excessively high when
27 compared with the cost of the drug in other states and countries and when compared
28 with the overall cost of researching, developing, and producing the drug in light of
29 the number of years the drug has been made available for distribution.

1 (3) The committee may include in the report recommendations for actions
2 to lower prescription drug costs and spending across the state while maintaining
3 access to and the quality of health care.

4 B. The committee shall submit the report to the House and Senate
5 committees on health and welfare no later than sixty days prior to the start of the
6 regular legislative session. The committee shall also make the report publicly
7 available on the website of the Department of Insurance and the Louisiana
8 Department of Health.

9 SUBPART C. DISCLOSURE OF PRESCRIPTION DRUG PRICE INFORMATION

10 §2255.21. Disclosure of prescription drug price information; educational or
11 marketing materials; minimum content; violations

12 A. Any person engaging in any form of prescription drug marketing directly
13 to a healthcare provider with the intent that the provider may prescribe the drug for
14 use by his patients shall include price information in the materials.

15 B. The price information required by Subsection A of this Section shall
16 include, at a minimum, all of the following:

17 (1) The date that the educational or marketing materials were prepared.

18 (2) The name of the drug and of the current manufacturer.

19 (3)(a) The average wholesale price of a thirty-day supply of the drug
20 described in the materials as of the date the educational or marketing materials were
21 prepared.

22 (b) If the described drug is designed to be administered for a duration of
23 therapy of less than thirty days, the proposed duration and average wholesale price
24 for that period of time as of the date the educational or marketing materials were
25 prepared.

26 (c) The disclosure of the average wholesale price shall account for each
27 labeled indication and reflect any differences as a result of different strengths and
28 dosage forms approved for sale.

Proposed law provides that failure of a manufacturer to provide the required information is a prohibited practice under the Unfair Trade Practices and Consumer Protection Law.

Proposed law requires information reported to the committee to be kept confidential and prohibits the disclosure of the information as a public record. Further requires any public reporting of information to be aggregated to protect the financial, competitive, or proprietary nature of the information.

Proposed law requires the committee to prepare an annual report on prescription drug prices and their role in overall healthcare spending in the state based on the data submitted to the committee. Further requires the committee to include in the report a list of those prescription drugs that have a cost in La. that is excessively high when compared with the cost of the drug in other states and countries and when compared with the overall cost of researching, developing, and producing the drug in light of the number of years the drug has been made available for distribution.

Proposed law requires any person engaging in any form of prescription drug marketing directly to a healthcare provider with the intent that the provider may prescribe the drug for use by his patients to include, at a minimum, the following price information in the materials:

- (1) The date that the educational or marketing materials were prepared.
- (2) The name of the drug and of the current manufacturer.
- (3) The average wholesale price of a 30-day supply of the drug described in the materials, or if the described drug is designed to be administered for a duration of therapy of less than 30 days, the proposed duration and average wholesale price for that period of time.
- (4) The date that the drug was first marketed in the U.S. and the average wholesale price as of that date.
- (5) The average wholesale price on each date that the price of the drug has changed since the drug was first marketed in the U.S.

Proposed law requires the completed form to be provided to the healthcare provider at the same time and in the same manner as any other marketing materials provided to the provider. Further provides, if the marketing activities are performed telephonically, the form to be sent to the healthcare provider by mail or electronically within one business day of the marketing activity.

A violation of proposed law constitutes a prohibited practice under the Unfair Trade Practices and Consumer Protection Law.

(Amends R.S. 44:4.1(B)(26); Adds R.S. 40:2255.1, 2251.2, R.S. 40:2255.11-2251.16, and R.S. 40:2255.21)