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

AN ACT

To amend and reenact R.S. 44:4.1(B)(26) and to enact R.S. 22:1060.7 and Part VIII of Chapter 12 of Title 40 of the Louisiana Revised Statutes of 1950, to be comprised of R.S. 40:2255.1 through 2255.21, relative to prescription drug prices; to require an annual report of certain prescription drug claims data by health insurance issuers and pharmacy benefit managers; to provide legislative findings and purpose; to provide for definitions; to establish the Prescription Drug Review Committee; to provide for the membership, powers, and duties of the committee; to require educational or marketing materials for prescription drugs directed to healthcare providers to include price information; to establish the minimum price information content; to provide for a public records exception; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 22:1060.7 is hereby enacted to read as follows:

§1060.7. Patient access to prescription drugs; annual report

Each health insurance issuer that offers a health benefit plan in this state and each pharmacy benefit manager that contracts with an issuer that offers a health benefit plan in this state shall submit to the Department of Insurance, on an annual basis and with respect to each health benefit plan offered, all of the following

information for certain therapeutic classes of prescription drugs identified by the Department of Insurance:

(1) The number of requests for exceptions to the health benefit plan's formulary and the number of claims approved and the number of claims denied.

(2) A list of all services subject to prior authorization or other utilization management, the type of utilization management applied, and the clinical or other rationale for the utilization management.

(3) The methodology used for any study done to inform coverage, formulary placement, or utilization management for any medical item or service.

(4) The number of pharmacy claims transactions approved and the number of pharmacy claims rejected due to a prior authorization or other utilization management requirement including but not limited to step therapy.

(5) The proportion of insureds who do not fill a prescription for an alternative therapy within sixty days of a denial of a request for an exception and the proportion of insureds who do not fill a prescription for an alternative therapy within sixty days.

(6) The total number of dollars spent on research to support and develop the clinical criteria used in making coverage determinations for items and services not specifically listed in the benefits contract as excluded from coverage under the health benefit plan.

Section 2. Part VIII of Chapter 12 of Title 40 of the Louisiana Revised Statutes of 1950, comprised of R.S. 40:2255.1 through 2255.21, is hereby enacted to read as follows:

PART VIII. PHARMACEUTICAL COST TRANSPARENCY

SUBPART A. GENERAL PROVISIONS

§2255.1. Legislative findings; purpose

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

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

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

§2255.2. Definitions

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

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

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

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

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

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

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

(a) Face-to-face meetings.

(b) Physical mailings.

(c) Telephone conversations.

(d) Electronic mail or facsimile.

SUBPART B. PRESCRIPTION DRUG REVIEW COMMITTEE

§2255.11. Prescription Drug Review Committee

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

B. The committee shall consist of the following members:

(1) The commissioner of insurance or his designee.

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

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

(4) Two public members appointed by the governor.

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

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

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

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

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

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

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

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

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

H. Members of the committee shall serve without compensation.

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

§2255.12. Critical prescription drug list

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

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

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

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

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

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

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

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

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

§2255.13. Manufacturer reporting

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

(1) Total cost of production and approximate cost of production per dose.

(2) Research and development costs of the drug including but not limited to all of the following:

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

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

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

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

§2255.14. Rulemaking

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

§2255.15. Confidentiality

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

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

§2255.16. Report to the legislature

A.(1) The committee shall 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 pursuant to R.S. 40:2255.13 and in accordance with R.S. 40:2255.15.

(2) The committee shall identify and include in the report a list of those prescription drugs that have a cost in Louisiana 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.

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

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

SUBPART C. DISCLOSURE OF PRESCRIPTION DRUG PRICE INFORMATION

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

A. 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 shall include price information in the materials.

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

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

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

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

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

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

(4) The date that the drug was first marketed in the United States 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 United States.

C.(1) The disclosures required by this Section shall be made on a form and in a manner prescribed by the Louisiana Department of Health.

(2) The completed form shall be provided to the healthcare provider at the same time and in the same manner as any other marketing materials provided to the provider. If the marketing activities are performed telephonically, then the form shall be sent to the healthcare provider by mail or electronically within one business day of the marketing activity.

D. The Louisiana Department of Health shall adopt, pursuant to the Administrative Procedure Act, R.S. 49:950 et seq., any rules and regulations necessary to implement and enforce the provisions of this Section.

Section 3. R.S. 44:4.1(B)(26) is hereby amended and reenacted to read as follows:

§4.1. Exceptions

* * *

B. The legislature further recognizes that there exist exceptions, exemptions, and limitations to the laws pertaining to public records throughout the revised statutes and codes of this state. Therefore, the following exceptions, exemptions, and limitations are hereby continued in effect by incorporation into this Chapter by citation:

* * *

(26) R.S. 40:3.1, 31.14, 31.27, 39.1, 41, 73, 95, 96, 526, 528, 1007, 1061.21, 1079.18, 1081.10, 1105.6, 1105.8, 1133.8, 1171.4, 1203.4, 1231.4, 1379.1.1(D), 1379.3, 2009.8, 2009.14, 2010.5, 2017.9, 2018, 2019, 2020, 2106, 2138, 2255.15, 2532, 2845.1

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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 436 Engrossed 2017 Regular Session Talbot

Abstract: Requires the disclosure of certain pharmacy claims data and prescription drug price information.

Proposed law requires each health insurance issuer that offers a health benefit plan in this state and each pharmacy benefit manager that contracts with an issuer that offers a health benefit plan in this state to submit to the Dept. of Insurance (DOI), on an annual basis and with respect to each health benefit plan offered, all of the following information for certain therapeutic classes of prescription drugs identified by DOI:

(1) The number of requests for exceptions to the health benefit plan's formulary and the number of claims approved and the number of claims denied.

(2) A list of all services subject to prior authorization or other utilization management, the type of utilization management applied, and the clinical or other rationale for the utilization management.

(3) The methodology used for any study done to inform coverage, formulary placement, or utilization management for any medical item or service.

(4) The number of pharmacy claims transactions approved and the number of pharmacy claims rejected due to a prior authorization or other utilization management requirement including but not limited to step therapy.

(5) The proportion of insureds who do not fill a prescription for an alternative therapy within 60 days of a denial of a request for an exception and the proportion of insureds who do not fill a prescription for an alternative therapy within 60 days.

(6) The total number of dollars spent on research to support and develop the clinical criteria used in making coverage determinations for items and services not specifically listed in the benefits contract as excluded from coverage under the health benefit plan.

Proposed law defines "average wholesale price", "committee", "department", "manufacturer" "prescription drug", and "prescription drug marketing".

Proposed law establishes the Prescription Drug Review Committee (committee) within DOI consisting of the following members:

(1) The commissioner of insurance or his designee.

(2) The secretary of the La. Dept. of Health or his designee.

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

(4) Two public members appointed by the governor.

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

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

Proposed law requires the public members to have a significant healthcare or pharmacy background and provides that each shall serve for a term of five years.

Proposed law requires the committee to develop a list of critical prescription drugs made available in La., for which there is a substantial public interest in understanding the development of pricing for the drugs.

Proposed law requires the manufacturer of each prescription drug that the committee places on the critical prescription drug list to report the following information to the committee:

(1) Total cost of production and approximate cost of production per dose.

(2) Research and development costs of the drug.

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

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.

(Amends R.S. 44:4.1(B)(26); Adds R.S. 22:1060.7 and R.S. 40:2255.1-2255.21)

Summary of Amendments Adopted by House

The Committee Amendments Proposed by House Committee on Health and Welfare to the original bill:

1. Require an annual report of certain prescription drug claims data by health insurance issuers and pharmacy benefit managers.

2. Delete provisions allowing recommendations for additional drugs to be included on the critical prescription drug list.

3. Delete the requirement that drug manufacturers disclose pricing information to the committee.

4. Delete provisions authorizing enforcement under the Unfair Trade Practices and Consumer Protection Law.

5. Make technical changes.