2020 Regular Session

HOUSE BILL NO. 616

BY REPRESENTATIVES STAGNI, HUGHES, AND TRAVIS JOHNSON

DRUGS/PRESCRIPTION: Provides for disclosure of prescription drug cost information

AN ACT

To amend and reenact R.S. 22:1657.1(B) and Part VIII of Chapter 12 of Title 40 of the Louisiana Revised Statutes of 1950, comprised of R.S. 40:2255.1 and 2255.11, relative to information concerning costs of prescription drugs; to provide for definitions; to provide relative to the pharmacy benefit manager rebate transparency report; to require reporting of certain pharmaceutical cost information by drug manufacturers; to require disclosure of pharmaceutical cost information to prescribers; to require the Louisiana Department of Health to publish on its website drug cost information reported by drug manufacturers; to provide special reporting requirements relative to drugs that meet or exceed a certain cost threshold; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 22:1657.1(B) is hereby amended and reenacted to read as follows:

§1657.1. Pharmacy benefit manager rebate transparency report

* * *

B. As used in this Section, the following definitions shall apply:

(1) "Aggregate retained rebate percentage" means the percentage calculated for each prescription drug for which a pharmacy benefit manager receives rebates under a particular health benefit plan expressed without disclosing any identifying information regarding the health benefit plan, prescription drug, or therapeutic class.

The percentage shall be calculated by dividing the aggregate rebates that the pharmacy benefit manager received during the prior calendar year from a pharmaceutical manufacturer related to utilization of the manufacturer's prescription drug by health benefit plan enrollees that did not pass through to the health benefit plan or health insurance issuer by the aggregate rebates that the pharmacy benefit manager received during the prior calendar year from a pharmaceutical manufacturer related to utilization of the manufacturer's prescription drug by health benefit plan enrollees.

(2) "Health benefit plan", "plan", "benefit", or "health insurance coverage" means services consisting of medical care provided directly through insurance, reimbursement, or other means, and including items and services paid for as medical care under any hospital or medical service policy or certificate, hospital or medical service plan contract, preferred provider organization contract, or health maintenance organization contract offered by a health insurance issuer. However, excepted benefits are not included as a "health benefit plan".

(3) "Health insurance issuer" means any entity that offers health insurance coverage through a plan, policy, or certificate of insurance subject to state law that regulates the business of insurance. "Health insurance issuer" shall also include a health maintenance organization, as defined and licensed pursuant to Subpart I of Part I of Chapter 2 of this Code.

(4) "Pharmaceutical drug manufacturer" means a person engaged in the business of producing, preparing, propagating, compounding, converting, processing, packaging, labeling, or distributing a prescription drug. The term does not include a wholesale distributor or retailer of prescription drugs or a pharmacist licensed in accordance with the provisions of Chapter 14 of Title 37 of the Louisiana Revised Statutes of 1950.

(5) "Prescription drug" means a drug as defined in 21 U.S.C. 321, except "prescription drug" shall not include any animal health product.

~~(4)~~ (6) "Rebates" means all rebates, discounts, and other price concessions, based on utilization of a prescription drug and paid by the manufacturer or other party other than an enrollee, directly or indirectly, to the pharmacy benefit manager after the claim has been adjudicated at the pharmacy. Rebates shall include a reasonable estimate of any volume-based discount or other discounts.

(7) "Specialty drug" means a prescription drug covered under Medicare Part D that exceeds the specialty tier cost threshold established by the Centers for Medicare and Medicaid Services.

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Section 2. Part VIII of Chapter 12 of Title 40 of the Louisiana Revised Statutes of 1950, comprised of R.S. 40:2255.1 and 2255.11, is hereby amended and reenacted to read as follows:

PART VIII. PHARMACEUTICAL COST TRANSPARENCY

SUBPART A. GENERAL PROVISIONS

§2255.1. Definitions

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

(1) "Animal health product" means a medical product approved and licensed for use in animal or veterinary medicine, including a pharmaceutical, a biologic, an insecticide, and a parasiticide.

(2) "Department" means the Louisiana Department of Health.

(3) "Pharmaceutical drug manufacturer" means a person engaged in the business of producing, preparing, propagating, compounding, converting, processing, packaging, labeling, or distributing a drug. The term does not include a wholesale distributor or retailer of prescription drugs or a pharmacist licensed in accordance with the provisions of Chapter 14 of Title 37 of the Louisiana Revised Statutes of 1950.

(4) "Prescriber" means a licensed healthcare professional with prescriptive authority.

(5) "Prescription drug" ~~means~~ and "drug" mean a drug as defined in 21 U.S.C. 321, except "prescription drug" shall not include any animal health product.

~~(2)~~ (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.

(7) "Therapeutic class" means a group of similar drugs that have the same or similar mechanisms of action and are used to treat a specific condition.

(8) "Wholesale acquisition cost" means, with respect to a drug, the list price of the pharmaceutical drug manufacturer for the drug charged to wholesalers or direct purchasers in the United States, as reported in wholesale price guides or other publications of drug pricing data. The term shall not include any rebates, prompt pay or other discounts, or other reductions in price.

SUBPART B. DISCLOSURE OF PRESCRIPTION DRUG PRICE INFORMATION

§2255.11. Disclosure of prescription drug price information

A. Each drug manufacturer or pharmaceutical marketer who engages in any form of prescription drug marketing to a prescriber, his designee, or any member of his staff in Louisiana shall provide to the Louisiana Board of Pharmacy no later than January first, April first, July first, and October first of each calendar year the current wholesale acquisition cost information for the United States Food and Drug Administration approved drugs marketed in the state by that manufacturer.

B.(1) Each drug manufacturer and representative, agent, and employee of a drug manufacturer who, while employed by or under contract to represent a drug manufacturer, engages in any form of prescription drug marketing shall provide to a prescriber, in writing, the wholesale acquisition cost of a prescription drug when,

in the course of conducting business, the manufacturer, representative, agent, or employee provides information concerning the drug to the prescriber.

(2) When providing the information required by Paragraph (1) of this Subsection, a manufacturer or representative, agent, or employee of a manufacturer shall also disseminate the names of at least three generic prescription drugs from the same therapeutic class; or if three are not available, as many as are available for prescriptive use.

C.(1) No later than January 15 of each calendar year, a pharmaceutical drug manufacturer shall submit a report to the department stating the current wholesale acquisition cost information for the United States Food and Drug Administration-approved drugs sold in or into this state by that manufacturer.

(2) The department shall develop an Internet webpage to provide to the general public drug price information submitted pursuant to Paragraph (1) of this Subsection. The department shall make the webpage available on its internet website with a dedicated link that is prominently displayed on the home page or by a separate easily identifiable internet address.

(3)(a) The requirements of this Paragraph shall apply only to drugs with a wholesale acquisition cost of at least one hundred dollars for a thirty-day supply before the effective date of an increase described by Subparagraph (b) of this Paragraph.

(b) Not later than the thirtieth day after the effective date of an increase of forty percent or more over the preceding three calendar years or fifteen percent or more in the preceding calendar year in the wholesale acquisition cost of a drug to which this Paragraph applies, a pharmaceutical drug manufacturer shall submit a report to the department which includes all of the following information:

(i) The name of the drug.

(ii) Whether the drug is a brand name or generic.

(iii) The effective date of any change or any reportable change in the wholesale acquisition cost price.

(iv) Aggregate, company-level research and development costs for the most recent year for which final audit data is available.

(v) The name of each of the manufacturer's prescription drugs approved by the United States Food and Drug Administration in the previous three calendar years.

(vi) The name and annual revenues derived from United States sales of each drug manufacturer's prescription drugs that lost patent exclusivity in the United States in the previous three calendar years.

(vii) A statement regarding the factor or factors that caused the increase in the wholesale acquisition cost and an explanation of the role of each factor's impact on the cost.

(4) The quality and types of information and data that a pharmaceutical drug manufacturer submits to the department as required by Paragraph (3) of this Subsection shall be consistent with the quality and types of information and data that the manufacturer includes in its annual consolidated report on Securities and Exchange Commission Form 10-K or any other public disclosure.

(5) Not later than the sixtieth day after receiving a report submitted as required by Paragraph (3) of this Subsection, the secretary of the department shall publish the report on the webpage provided for in Paragraph (2) of this Subsection.

(6) The reporting entity shall certify, under penalty of perjury, the accuracy of all information that it reports pursuant to the requirements of this Subsection.

(7) The secretary of the department may promulgate rules in accordance with the Administrative Procedure Act to implement the provisions of this Subsection.

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 616 Original 2020 Regular Session Stagni

Abstract: Requires disclosure of prescription drug cost information to the La. Department of Health by drug manufacturers and publication by the department of that information.

Present law, R.S. 22:1657.1, requires and provides specifications for a pharmacy benefit manager rebate transparency report. Proposed law retains present law and adds thereto five defined terms and corresponding definitions.

Present law, R.S. 40:2255.1 et seq., provides for disclosure of prescription drug cost information to the La. Board of Pharmacy by drug manufacturers and pharmaceutical marketers. Proposed law retains present law and adds thereto requirements for reporting of prescription drug cost information directly to prescribers and to the La. Department of Health (LDH).

Proposed law requires each drug manufacturer and representative, agent, and employee of a drug manufacturer who engages in any form of prescription drug marketing to provide to a prescriber, in writing, the wholesale acquisition cost of a prescription drug when, in the course of conducting business, the manufacturer, representative, agent, or employee provides information concerning the drug to the prescriber. Stipulates that when providing the required cost information, a manufacturer or representative, agent, or employee of a manufacturer shall also disseminate to the prescriber the names of at least three generic prescription drugs from the same therapeutic class; or if three are not available, as many as are available for prescriptive use.

Proposed law requires that no later than January 15 of each calendar year, a pharmaceutical drug manufacturer shall submit a report to LDH stating the current wholesale acquisition cost information for drugs sold in or into this state by that manufacturer. Requires LDH to develop a webpage to provide to the general public drug price information submitted pursuant to proposed law.

Proposed law provides special reporting requirements relative to drugs with a wholesale acquisition cost of at least $100 for a 30-day supply before the effective date of a price increase described by proposed law. Requires that not later than the 30th day after the effective date of an increase of 40% or more over the preceding three calendar years, or 15% or more in the preceding calendar year, in the wholesale acquisition cost of a drug at or above the cost threshold provided in proposed law, a drug manufacturer shall submit a report to LDH which includes all of the following information:

(1) The name of the drug.

(2) Whether the drug is a brand name or generic.

(3) The effective date of any change or any reportable change in the wholesale acquisition cost price.

(4) Aggregate, company-level research and development costs for the most recent year for which final audit data is available.

(5) The name of each of the manufacturer's prescription drugs approved by the United States Food and Drug Administration in the previous three calendar years.

(6) The name and annual revenues derived from United States sales of each drug manufacturer's prescription drugs that lost patent exclusivity in the United States in the previous three calendar years.

(7) A statement regarding the factor or factors that caused the increase in the wholesale acquisition cost and an explanation of the role of each factor's impact on the cost.

Proposed law requires that the quality and types of information and data that a drug manufacturer submits to LDH, as required by proposed law, be consistent with the quality and types of information and data that it includes in its annual consolidated report on Securities and Exchange Commission Form 10-K or any other public disclosure.

Proposed law requires that no later than the 60th day after receiving a report containing the information listed above, LDH shall publish the report on the webpage provided for in proposed law.

Proposed law requires that the reporting entity certify, under penalty of perjury, the accuracy of all information that it reports pursuant to the requirements of proposed law.

(Amends R.S. 22:1657.1(B) and R.S. 40:2255.1 and 2255.11)