HOUSE BILL No. 1116

DIGEST OF INTRODUCED BILL

Citations Affected: IC 27-1-24.6.

Synopsis: Drug information reporting. Requires prescription drug manufacturers, health insurance issuers, pharmacy benefits managers, and wholesale drug distributors (reporting entities) to report certain information to the department of insurance (department), including increases in the wholesale acquisition cost of brand name drugs and generic drugs, the introduction into the United States of a new drug, and spending on prescription drugs before enrollee cost sharing for each of the top 25 prescription drugs and drug groups. Requires reporting entities to pay an annual assessment to support the operational costs incurred by the department in connection with the reporting. Requires a reporting entity to certify under the penalty of perjury that a required report is accurate. Authorizes the insurance commissioner to impose a civil penalty on a reporting entity that fails to comply with a reporting requirement. Requires the department to annually prepare and make available on its web site a report on emerging trends in prescription drug prices. Requires the department to keep confidential and protect from public disclosure all information submitted by reporting entities.

Effective: July 1, 2020.

Shackleford

January 8, 2020, read first time and referred to Committee on Insurance.

Introduced

Second Regular Session of the 121st General Assembly (2020)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2019 Regular Session of the General Assembly.

HOUSE BILL No. 1116

A BILL FOR AN ACT to amend the Indiana Code concerning insurance.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 27-1-24.6 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2020]:

Chapter 24.6. Prescription Drug Price Transparency and Cost Control

Sec. 1. As used in this chapter, "brand name drug" means a prescription drug approved under 21 U.S.C. 355(b) or 42 U.S.C. 262.

Sec. 2. As used in this chapter, "department" refers to the department of insurance.

Sec. 3. As used in this chapter, "drug group" means a group of drugs defined by the department for the purposes of this chapter to facilitate revenue and cost reporting by manufacturers under this chapter.

Sec. 4. As used in this chapter, "insurance issuer" means a company or organization that is licensed by the department to issue coverage entitling a beneficiary to receive a defined set of

health care benefits in exchange for a defined consideration such as a premium.

Sec. 5. As used in this chapter, "manufacturer" means any entity that:

(1) holds the NDC for a prescription drug;

(2) is engaged in the:

(A) production, preparation, propagation, compounding, conversion, or processing of drug products; or

(B) packaging, repackaging, labeling, relabeling, or distribution of drug products; and

(3) is not a wholesale distributor of drugs or a retail pharmacy licensed under state law.

Sec. 6. As used in this chapter, "market introduction" means the month and year in which the manufacturer acquired or first marketed the drug for sale in the United States.

Sec. 7. As used in this chapter, "national drug code" (or "NDC") means the numerical code maintained by the federal Food and Drug Administration that includes the labeler code, product code, and package code.

Sec. 8. (a) As used in this chapter, "pharmacy benefits manager" means any entity that administers the prescription drug, prescription device, and pharmacist services portion of a health care plan on behalf of an insurance issuer.

(b) The term includes insurance issuers that do not use a separate pharmacy benefits manager to administer their prescription drug programs.

Sec. 9. As used in this chapter, "reporting entity" means any manufacturer, insurance issuer, pharmacy benefits manager, wholesale drug distributor, or other entity required to report to the department under this chapter.

Sec. 10. (a) As used in this chapter, "wholesale acquisition cost" (or "WAC") means the manufacturer's list price to wholesalers or direct purchasers in the United States on December 31 of the reference year, as reported in wholesale price guides or other publications of drug or biological pricing data.

(b) The term does not include prompt pay discounts or other discounts, rebates, or reductions in price.

Sec. 11. As used in this chapter, "wholesale acquisition cost unit" (or "WAC unit") is the lowest identifiable quantity of the drug or biological that is dispensed, exclusive of any diluent, without reference to volume measures pertaining to liquids. If reporting by drug group as indicated by the department, it is the

total number of WAC units in the drug group.

Sec. 12. As used in this chapter, "wholesale drug distributor" means an entity that is:

(1) engaged in the sale of prescription drugs to persons other than a consumer or patient; and

(2) licensed by the Indiana board of pharmacy.

Sec. 13. (a) A manufacturer shall notify the department if:

(1) it is increasing the WAC of a brand name drug by more than twenty percent (20%) per WAC unit during any twelve (12) month period; or

(2) it is increasing the WAC of a generic drug priced at ten dollars ($10) or more per WAC unit by more than twenty percent (20%) during any twelve (12) month period.

(b) A notice required by subsection (a) shall be provided in writing at least sixty (60) days before the planned effective date of the increase.

(c) A manufacturer that is required to notify the department under subsection (a) shall report to the department all data elements specified in the National Academy for State Health Policy Model Act report template at least thirty (30) days before the price increase.

Sec. 14. (a) A manufacturer shall notify the department if it intends to introduce into the United States a new drug that has a WAC of at least six hundred seventy dollars ($670) per WAC unit.

(b) The notice required by subsection (a) shall be provided in writing at least sixty (60) days before the market introduction of the new drug.

(c) A manufacturer that is required to notify the department under subsection (a) shall report to the department all data elements specified in the National Academy for State Health Policy Model Act report template at least sixty (60) days before the date of market introduction.

Sec. 15. For the purposes of sections 13 and 14 of this chapter:

(1) the WAC amount that prompts reporting is the current or proposed WAC; and

(2) the current or proposed WAC, if reported by a drug group, is the average WAC weighted by the relevant number of WAC units.

Sec. 16. All information reported under sections 13 and 14 of this chapter is subject to the confidentiality and protection from public disclosure required by section 23 of this chapter.

Sec. 17. (a) A pharmacy benefit manager shall, to the extent

allowed by law, report annually to the department all data elements specified in the National Academy for State Health Policy Model Act report template within sixty (60) days after receiving notification by the department indicating the specific drugs or drug groups for which reporting is required.

(b) All information reported under this section is subject to the confidentiality and protection from public disclosure required by section 23 of this chapter.

Sec. 18. (a) A wholesale drug distributor shall report annually to the department all data elements specified in the National Academy for State Health Policy Model Act report template within sixty (60) days after receiving notification by the department indicating the specific drugs or drug groups for which reporting is required.

(b) All information reported under this section is subject to the confidentiality and protection from public disclosure required by section 23 of this chapter.

Sec. 19. (a) An insurance issuer designated by the department as a reporting entity shall report annually to the department, to the extent allowed by law, spending on prescription drugs before enrollee cost sharing, in total and per prescription drug user, for each of the top twenty-five (25) prescription drugs and drug groups as defined by the department, in the following categories:

(1) The greatest total spending before enrollee cost sharing in the last calendar year.

(2) The greatest total spending per user of any drug in the drug group before enrollee cost sharing in the last calendar year.

(3) The highest year-over-year increase in total spending before enrollee cost sharing.

(4) The highest year-over-year increase in total spending per user of any drug in the drug group before enrollee cost sharing.

(b) For each drug and drug group as defined by the department, the insurance issuer shall report to the department all data elements specified in the National Academy for State Health Policy Model Act report template within sixty (60) days after the end of each calendar year.

Sec. 20. A reporting entity shall register with the department:

(1) on a form; and

(2) in the manner;

specified by the department not later than January 31 of each

calendar year.

Sec. 21. (a) A reporting entity shall pay an annual assessment to support the operational costs of the activities of the department required by this chapter, including the:

(1) staff salaries;

(2) administrative expenses;

(3) data system expenses; and

(4) consulting fees;

incurred by the department under this chapter.

(b) The total annual assessments imposed on reporting entities under this section shall be based on the total annual allocation authorized by the general assembly for the operational costs of the activities of the department under this chapter, as indicated in the state fiscal year budget of the department. The amount to be assessed shall be reduced by the difference between the total annual authorized allocation for the next state fiscal year and any amounts that remain available to the department for purposes of this chapter from the prior state fiscal year.

(c) Any assessment reduction under subsection (b) shall be applied proportionately to the categorical groups assessed. Annual assessments shall be at least one hundred dollars ($100) for each individual reporting entity required to pay an assessment under this section.

(d) The department shall send requests for payment of the final assessments imposed under this section to all reporting entities.

(e) All assessments shall be due and payable to the department not more than thirty (30) days after receipt of the request for payment sent under subsection (d).

Sec. 22. (a) A reporting entity shall certify under the penalty of perjury that a report required under this chapter is accurate.

(b) The insurance commissioner may under IC 4-21.5 impose a civil penalty on a reporting entity that fails to comply with any section of this chapter. A civil penalty imposed under this section may not exceed thirty thousand dollars ($30,000) for each day that the reporting entity is found not to have complied with any section of this chapter.

(c) The department may audit the data submitted to the department by a reporting entity under sections 13 through 19 of this chapter in a form and manner specified by the department. The reporting entity shall pay all costs associated with the audit.

(d) The department may require a reporting entity to submit a corrective action plan, in a form and manner specified by the

department, to correct deficiencies in data reported under sections 13 through 19 of this chapter.

(e) The department may:

(1) hold one (1) or more public hearings; and

(2) subpoena any reporting entity;

concerning the reporting of data by a reporting entity under sections 13 through 19 of this chapter.

Sec. 23. (a) The department shall annually:

(1) prepare and make available on its Internet web site a report on emerging trends in prescription drug prices; and

(2) conduct a public hearing based on the findings in the report.

(b) The report prepared under subsection (a) must include:

(1) an analysis of manufacturer prices and price increases as reported under this chapter; and

(2) an analysis of information as reported by insurance issuers, pharmacy benefit managers, and wholesale drug distributors under this chapter;

so as to make clear the major components of prescription drug pricing along the supply chain and the impacts of prescription drug pricing on insurance premiums and consumer cost sharing.

(c) The data in the report prepared under subsection (a) may not reveal information specific to any individual reporting entity.

(d) Except as provided in this section, the department shall:

(1) keep confidential; and

(2) protect from public disclosure;

all information submitted by an individual reporting entity under this chapter.

(e) If the department shares information described in subsection (d) with any other state agency, the other state agency shall keep the information confidential and protect it from public disclosure.

Sec. 24. The provisions of this chapter are severable in the manner provided by IC 1-1-1-8(b).