HOUSE BILL No. 1150

DIGEST OF INTRODUCED BILL

Citations Affected: IC 12-7-2-22; IC 12-15-35.7.

Synopsis: Prescription drug cost reporting. Requires the office of the secretary of family and social services to identify any prescription drug under the Medicaid program for which the annual wholesale cost or the per course cost of treatment of the drug is at least $10,000, and directs the office to notify the manufacturer that the manufacturer is required to prepare a report on the drug to the drug utilization review board (board). Specifies requirements of the report. Authorizes the board to request additional information, establish forms, and specify other requirements that a manufacturer must meet in the filing of the report. Requires the board to: (1) keep proprietary information confidential; and (2) summarize the submitted reports and submit a report to the general assembly for inclusion on the general assembly's Internet web site.

Effective: July 1, 2017.

Taylor J

January 9, 2017, read first time and referred to Committee on Public Health.

Introduced

First Regular Session of the 120th General Assembly (2017)

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 2016 Regular Session of the General Assembly.

HOUSE BILL No. 1150

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

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

SECTION 1. IC 12-7-2-22, AS AMENDED BY P.L.12-2016, SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2017]: Sec. 22. "Board" means the following:

(1) For purposes of IC 12-10-10, IC 12-10-10.5, and IC 12-10-11, the community and home options to institutional care for the elderly and disabled board established by IC 12-10-11-1.

(2) For purposes of IC 12-11-14, the meaning set forth in IC 12-11-14-3.

(3) For purposes of IC 12-12-7-5, the meaning set forth in IC 12-12-7-5(a).

(4) For purposes of IC 12-15-35, the meaning set forth in IC 12-15-35-2.

(5) For purposes of IC 12-15-35.7, the meaning set forth in IC 12-15-35.7-2.

SECTION 2. IC 12-15-35.7 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2017]:

Chapter 35.7. Reporting on Pharmaceutical Drugs

Sec. 1. This chapter applies to the manufacturer of a prescription drug for which the:

(1) annual wholesale acquisition cost made available in Indiana; or

(2) per course cost of treatment;

of the prescription drug under the Medicaid program is at least ten thousand dollars ($10,000).

Sec. 2. As used in this chapter, "board" refers to the drug utilization review board created under IC 12-15-35.

Sec. 3. As used in this chapter, "Medicaid program" includes the:

(1) Medicaid fee-for-service program; and

(2) Medicaid risk based managed care program.

Sec. 4. (a) The office of the secretary shall identify any prescription drug covered under the Medicaid program for which the:

(1) annual wholesale acquisition cost made available in Indiana; or

(2) per course cost of treatment;

of the prescription drug under the Medicaid program is at least ten thousand dollars ($10,000).

(b) The office of the secretary shall notify the manufacturer of a prescription drug identified under subsection (a) that:

(1) the manufacturer's prescription drug meets the description set forth in subsection (a); and

(2) the manufacturer is required to submit the annual report required under section 5 of this chapter.

(c) The office shall provide the board with a list of the identified manufacturers and drugs.

Sec. 5. (a) The annual report required under this section must include information beginning at least five (5) years preceding the filing date of the investigational new drug application with the federal Food and Drug Administration through the approval date of the new drug application. A manufacturer may provide information for additional periods not specified in this subsection.

(b) A manufacturer must include the following in the report:

(1) The total costs for the production of the drug, including any of the following:

(A) The total research and development costs paid by the manufacturer.

(B) The total research and development costs paid by any

predecessor in the development of the drug.

(C) The total costs of clinical trials and other regulatory costs of the drug paid by the manufacturer.

(D) The total costs of clinical trials and other regulatory costs of the drug paid by any predecessor for the drug.

(E) The total costs for materials, manufacturing, and the administration attributable to the drug by the manufacturer.

(F) The total costs to a person other than the manufacturer or predecessor for research and development, including any:

(i) amount from federal, state, or other governmental programs; or

(ii) form of subsidies, grants, or other support.

(G) Any other costs to acquire the drug, including the cost for the purchase of patents, licensing, or acquisition of any corporate entity owning any rights to the drug while in development.

(2) The total marketing and advertising costs for the promotion of the drug, including advertising and marketing to consumers and health care providers.

(3) A history of the:

(A) average wholesale price; and

(B) wholesale acquisition cost;

increases for the drug, including the months each increase took effect under clause (A) or (B).

(4) The profit attributable to the drug:

(A) in dollars; and

(B) by percentage of the total manufacturer profits;

that were derived from the sale of the drug.

(5) The total amount of assistance the manufacturer has provided through patient prescription assistance programs.

(6) The total cost to the manufacturer of drugs or research projects that failed to succeed through the process to market approval.

(c) The manufacturer must document and itemize the information required in subsection (b).

(d) An independent third party auditor must review the report under this section and verify the information before the manufacturer may file the report.

(e) Before May 1 of each year, the manufacturer shall file the report with the board on the forms and in the manner prescribed

by the board.

(f) The board may request additional information from a manufacturer that the board considers necessary to meet the requirements of this chapter.

(g) The board may establish forms and requirements that a manufacturer must use or meet in the filing of a report under this section.

Sec. 6. (a) The board may not disclose any information contained in the reports submitted under this chapter that the board determines to be proprietary or otherwise confidential. The board may not include any proprietary or confidential information in the report to the general assembly under subsection (b).

(b) The board shall annually report a summary of the information contained in the reports submitted under this chapter to the general assembly in an electronic format under IC 5-14-6. The executive director of the legislative services agency shall post the board's report on the general assembly's Internet web site.