SUBSTITUTE FOR

HOUSE BILL NO. 4347

A bill to require drug manufacturers to report certain information to the department of insurance and financial services; to provide for the powers and duties of certain state officers and entities; to allow for the promulgation of rules; and to prescribe civil sanctions.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 1. This act shall be known and may be cited as the "drug manufacturer data reporting act".

Sec. 3. As used in this act:

(a) "Department" means the department of insurance and financial services.

(b) "Director" means the director of the department or his or her designee.

(c) "Drug manufacturer" means a manufacturer as that term is defined in section 17706 of the public health code, 1978 PA 368, MCL 333.17706.

(d) "Prescription drug" means that term as defined in section 17708 of the public health code, 1978 PA 368, MCL 333.17708.

(e) "Wholesale acquisition cost" means that term as defined in 42 USC 1395w-3a(c)(6)(B) or any other list price for a prescription drug that is contained within a list of prescription drugs and prices maintained by a drug manufacturer.

Sec. 7. (1) A drug manufacturer shall submit a report to the director within 30 days after increasing the wholesale acquisition cost of a qualified prescription drug by 15% or more in a given year or 40% or more over a 3-year period. The report must contain all of the following information:

(a) The name of the qualified prescription drug.

(b) Whether the qualified prescription drug is a brand name or generic prescription drug.

(c) The effective date and the percentage of the change in the wholesale acquisition cost.

(d) Aggregate, company-level research, and development costs for the previous calendar year.

(e) The cost of researching and developing the qualified prescription drug with money made available to the drug manufacturer, or a predecessor drug manufacturer, through a federal, state, or other governmental program.

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

(g) The name of each of the drug manufacturer's prescription

drugs that lost patent exclusivity in the United States in the previous 5 calendar years.

(2) The quality of information that a drug manufacturer submits to the director under this section must be consistent with the quality of information that the drug manufacturer includes on the United States Securities and Exchange Commission's Form 10-K.

(3) As used in this section, "qualified prescription drug" means a prescription drug with a wholesale acquisition cost of $500.00 or more for a 30-day supply.

Sec. 9. (1) Subject to subsection (2), a drug manufacturer shall notify the director in writing if the drug manufacturer is introducing a new prescription drug to the market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D Program. The drug manufacturer shall provide the notice required under this section within 3 calendar days following the release of the prescription drug into the commercial market. A drug manufacturer may make the notification pending approval by the United States Food and Drug Administration if commercial availability is expected within 3 calendar days following the approval. The director may request additional information from the drug manufacturer under this section if the director determines that the information provided by the drug manufacturer is unacceptable.

(2) The notice required under subsection (1) must include all of the following information:

(a) Whether the United States Food and Drug Administration granted the prescription drug a breakthrough therapy designation or a priority review.

(b) If the prescription drug was not developed by the drug

manufacturer, the date of and price paid for the acquisition of the prescription drug by the drug manufacturer.

(c) The costs for researching and developing the prescription drug with money made available to the drug manufacturer, or a predecessor drug manufacturer, through a federal, state, or other governmental program.

Sec. 11. (1) The reports and notices required under this act must be filed with the department in a form and manner required by the department.

(2) The department shall prepare an annual report based on the information received by it under this act. The report must contain aggregate data and must not contain any information that the director determines would cause financial, competitive, or proprietary harm to a drug manufacturer. The director shall file the report described in this subsection with each of the following:

(a) The house and senate standing committees on health policy.

(b) The house and senate fiscal agencies.

(c) The house and senate policy offices.

Sec. 13. The reports and information received by the department under this act from drug manufacturers are exempt from disclosure under the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246.

Sec. 15. A drug manufacturer that violates this act may be ordered to pay a civil fine of not more than $100,000.00 per month for each month that a report is not filed by the drug manufacturer in accordance with this act. A violation of this act may be prosecuted by the prosecutor of the county in which the violation occurred, or by the attorney general.

Sec. 17. The department may promulgate rules under the

administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328, that are necessary or required to implement this act.

Sec. 19. This act takes effect January 1, 2023.

Enacting section 1. This act does not take effect unless House Bill No. 4353 of the 101st Legislature is enacted into law.