

**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:**

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

3       Sec. 3. As used in this act:

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

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

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

4 (d) "Prescription drug" means that term as defined in section  
5 17708 of the public health code, 1978 PA 368, MCL 333.17708.

6 (e) "Wholesale acquisition cost" means that term as defined in  
7 42 USC 1395w-3a(c)(6)(B) or any other list price for a prescription  
8 drug that is contained within a list of prescription drugs and  
9 prices maintained by a drug manufacturer.

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

15 (a) The name of the qualified prescription drug.

16 (b) Whether the qualified prescription drug is a brand name or  
17 generic prescription drug or a biological drug product or  
18 biosimilar drug product.

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

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

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

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

1 (g) The name of each of the drug manufacturer's prescription  
2 drugs that lost patent exclusivity in the United States in the  
3 previous 5 calendar years.

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

8 (3) As used in this section, "qualified prescription drug"  
9 means a prescription drug with a wholesale acquisition cost of  
10 \$500.00 or more for a 30-day supply.

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

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

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

1 (b) If the prescription drug was not developed by the drug  
2 manufacturer, the date of and price paid for the acquisition of the  
3 prescription drug by the drug manufacturer.

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

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

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

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

18 (b) The house and senate fiscal agencies.

19 (c) The house and senate policy offices.

20 (3) The department shall post the annual report described in  
21 subsection (2) on the department's website in a location that is  
22 accessible to the public and in a manner that is easy to navigate.

23 Sec. 13. The reports and information received by the  
24 department under this act from drug manufacturers are exempt from  
25 disclosure under the freedom of information act, 1976 PA 442, MCL  
26 15.231 to 15.246.

27 Sec. 15. A drug manufacturer that violates this act may be  
28 ordered to pay a civil fine of not more than \$100,000.00 per month  
29 for each month that a report is not filed by the drug manufacturer

1 in accordance with this act. A violation of this act may be  
2 prosecuted by the prosecutor of the county in which the violation  
3 occurred, or by the attorney general.

4 Sec. 17. The department may promulgate rules under the  
5 administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to  
6 24.328, that are necessary or required to implement this act.

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

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