HOUSE BILL NO. 4154

February 06, 2019, Introduced by Rep. Vaupel and referred to the Committee on Government Operations.

A bill to amend 1978 PA 368, entitled

"Public health code,"

(MCL 333.1101 to 333.25211) by adding section 17748e.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 17748e. (1) Beginning in 2019, a manufacturer shall file an annual report with the department of health and human services on costs associated with a prescription drug for the preceding calendar year if the prescription drug meets 1 of the following and

is distributed for sale in this state by the manufacturer:

(a) The prescription drug is remanufactured resulting in a decrease in the prescription drug's shelf life.

(b) The prescription drug has an annual wholesale acquisition price of $10,000.00 or more.

(c) The prescription drug has a wholesale acquisition price of $10,000.00 or more per course of treatment.

(d) The prescription drug has a wholesale acquisition price that has increased by a total of 25% or more during the 5 years immediately preceding the calendar year covered by the report or by 5% or more during the preceding calendar year.

(2) A report filed under subsection (1) must be filed on or before May 1 of each year, beginning May 1, 2019, in a form and manner prescribed by the department of health and human services and must contain an itemized account of all of the following information for the calendar year covered by the report:

(a) Total costs paid by the manufacturer and any predecessor manufacturer for manufacturing and distributing the prescription drug.

(b) Costs paid by the manufacturer or any predecessor manufacturer for researching and developing the prescription drug, including, but not limited to, all of the following:

(*i*) Costs for researching and developing the prescription drug with money made available to the manufacturer or predecessor manufacturer through a federal, state, or other governmental program or through a subsidy, grant, or other form of monetary support.

(*ii*) After-tax research and development costs for the prescription drug.

(*iii*) Costs of clinical trials for the prescription drug.

(c) Research and development costs paid by a third party for the prescription drug.

(d) Costs paid by the manufacturer or any predecessor manufacturer for acquiring the prescription drug, including, but not limited to, costs paid for purchasing a patent or licensing the prescription drug or costs paid to acquire a property right to the prescription drug.

(e) The costs paid by the manufacturer for marketing and advertising the prescription drug to consumers of the prescription drug, including any costs associated with offering and redeeming coupons or other discounts including rebates.

(f) The aggregate rebates paid by the manufacturer to pharmacy benefit managers that are related to the use of the prescription drug by health insurers.

(3) In addition to the itemized accounting of the costs described in subsection (2), a report filed under subsection (1) must contain all of the following information for the calendar year covered by the report:

(a) Each increase in the wholesale acquisition price of the prescription drug for that year, expressed as a percentage of the wholesale acquisition price, and the date on which each increase occurred.

(b) The price for the prescription drug that is charged to consumers of the prescription drug who are located in a country other than the United States, as required by the department of health and human services.

(4) A manufacturer must obtain an audit by an independent third party of a report prepared under this section before the

report is filed under subsection (1). The manufacturer shall select the third party from among a list of potential auditors made available by the department of health and human services.

(5) After completing an audit under subsection (4), the third party that conducted the audit shall file a summary of the audit with the department of health and human services on or before May 1 of the following year, in a form and manner prescribed by the department of health and human services. The manufacturer shall pay all costs associated with auditing and filing a summary under this subsection.

(6) The department of health and human services shall post on its internet website a searchable database with data from the reports filed under subsection (1) and any information that the department of health and human services determines is necessary to assist the general public in understanding the data.

(7) A manufacturer that fails to file the report required under subsection (1) is subject to an administrative fine of $100,000.00 per month for every month that the report is not filed in accordance with this section.

(8) The department of health and human services, in consultation with the department and the board, may promulgate rules to implement this section.