HOUSE BILL NO. 5108

October 15, 2019, Introduced by Reps. Witwer, Hood, Kennedy, Brixie, Stone, Rabhi, Chirkun, Sowerby, LaGrand, Liberati, Cherry, Ellison, Haadsma, Yancey, Garrett, Tyrone Carter, Bolden, Hoadley, Garza, Sabo, Pohutsky, Robinson, Pagan, Manoogian, Kuppa, Brenda Carter, Hertel, Cynthia Johnson, Hope, Wittenberg, Shannon, Clemente and Love and referred to the Committee on Health Policy.

A bill to amend 1978 PA 368, entitled

"Public health code,"

(MCL 333.1101 to 333.25211) by adding sections 17748e, 17748f, and 17748g.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 17748e. (1) Subject to subsection (2), beginning October 1, 2019, a manufacturer of a prescription drug that has a wholesale acquisition cost that is more than $40.00 for a course of treatment

and that is made available in this state shall notify a qualified purchaser that is registered under subsection (5) if the manufacturer is increasing the wholesale acquisition cost of the prescription drug by 12% or more during any 24-month period.

(2) The manufacturer shall provide the notice required under subsection (1) at least 60 days before the planned effective date of the increase in the wholesale acquisition cost. The notice must include all of the following:

(a) The effective date of the increase in the wholesale acquisition cost.

(b) The wholesale acquisition cost of the prescription drug as of the date of the notice and the dollar amount of the increase in the wholesale acquisition cost as of the effective date of the increase.

(c) Whether a change or improvement to the prescription drug necessitates the increase in the wholesale acquisition cost and a description of any change or improvement.

(3) Beginning October 1, 2019 and each quarter thereafter, a manufacturer that increases the wholesale acquisition cost of a prescription drug described in subsection (1) shall report all of the following information to the commission in a form and manner required by the commission:

(a) The amount of the increase in the wholesale acquisition cost of the prescription drug.

(b) A description of the specific financial and nonfinancial factors considered by the manufacturer in increasing the wholesale acquisition cost of the prescription drug and an explanation of how the factors justified the increase in the wholesale acquisition cost of the prescription drug.

(c) If the prescription drug was manufactured by the manufacturer within the 5 years preceding the date of the increase in the wholesale acquisition cost of the prescription drug, a schedule of the increases in the wholesale acquisition cost of the prescription drug for the previous 5 years.

(d) If the prescription drug was acquired by the manufacturer within the 5 years preceding the date of the increase in the wholesale acquisition cost of the prescription drug, all of the following information:

(*i*) The wholesale acquisition cost of the prescription drug at the time it was acquired by the manufacturer and in the year before it was acquired by the manufacturer.

(*ii*) The name of the company from which the prescription drug was acquired by the manufacturer, the date it was acquired, and the purchase price.

(*iii*) The year the prescription drug was introduced to the market and the wholesale acquisition cost of the drug at the time of introduction.

(e) If the prescription drug is under patent, the patent's expiration date.

(f) Whether the prescription drug is a multiple source drug, an innovator multiple source drug, a noninnovator multiple source drug, or a single source drug, as those terms are defined in 42 USC 1396r-8.

(g) Whether there has been a change or improvement to the prescription drug. If there has been a change or improvement to the prescription drug, the manufacturer shall provide documentation of the increase with the report required under this subsection.

(h) The volume of sales of the prescription drug in the United

States for the year preceding the date of the increase of the wholesale acquisition cost of the prescription drug.

(4) The commission shall post on a publicly available website the information received by it under subsection (3) within 60 days after receiving the information. The commission shall post the information in a manner that discloses the information for each prescription drug. However, if the commission determines that any information received by it under subsection (3) from a manufacturer is confidential or proprietary and the information would cause competitive harm to the manufacturer if disclosed, the commission shall refrain from posting that information on the publicly available website or otherwise disclosing that information to the public.

(5) A qualified purchaser that wishes to receive notice under subsection (1) shall register with the commission. The commission shall make available to a manufacturer a list of qualified purchasers that have registered with the commission under this subsection for the purpose of providing notice under subsection (1).

(6) A manufacturer that violates this section is subject to an administrative fine of $100,000.00 per day for every day that the information is not provided in accordance with this section.

(7) As used in this section and sections 17748f and 17748g:

(a) "Commission" means the drug consumer protection commission created in section 17748g(1).

(b) "Course of treatment" means the recommended daily dosage units of a prescription drug pursuant to its prescribing label as approved by the FDA for a course of treatment that is 30 days or less.

(c) "Excessive price" means a price that is defined as unlawful under section 3(1)(z) of the Michigan consumer protection act, 1976 PA 331, MCL 445.903.

(d) "Qualified purchaser" means any of the following persons that purchase the prescription drug or provide reimbursement for the prescription drug:

(*i*) An insurer as that term is defined in section 106 of the insurance code of 1956, 1956 PA 218, MCL 500.106.

(*ii*) A health maintenance organization, as that term is defined in section 3501 of the insurance code of 1956, 1956 PA 218, MCL 500.3501.

(*iii*) A pharmacy benefit manager.

(*iv*) A department of this state.

(e) "Unconscionable" means any of the following:

(*i*) Excessive and not justified by the cost of producing the prescription drug or the cost of the appropriate expansion of access to the prescription drug to promote public health.

(*ii*) Results in consumers for whom the prescription drug is prescribed having no meaningful choice about whether to purchase the prescription drug because of the importance of the prescription drug to their health and insufficient competition in the market for the prescription drug.

(f) "Wholesale acquisition cost" means that term as defined in 42 USC 1395w-3a.

Sec. 17748f. (1) Beginning October 1, 2019, a manufacturer of a prescription drug that is made available in this state shall notify the commission if the manufacturer is introducing a new prescription drug into the market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the

Medicare prescription drug, improvement, and modernization act of 2003, public law 108-173. The manufacturer shall provide the notice in writing and within 3 days after the prescription drug is commercially available. However, a manufacturer may provide the notice pending the approval of the FDA if commercial availability is expected within 3 days after the FDA's approval.

(2) Subject to subsection (3), within 30 days of providing the notice required under subsection (1), the manufacturer shall report all of the following information to the commission in a form and manner required by the commission:

(a) If the prescription drug was not developed by the manufacturer, the date the prescription drug was acquired and the purchase price.

(b) A description of the marketing and pricing plans that are used to launch the new prescription drug in the United States and internationally.

(c) The estimated volume of patients that may be prescribed the prescription drug.

(d) Whether the prescription drug was granted breakthrough therapy designation or priority review by the FDA before final approval.

(3) If the information described in subsection (2) is available in the public domain, the manufacturer may limit the information it includes in its report to the commission under subsection (2).

(4) The commission shall post on a publicly available website the information received by it under subsection (2) on at least a quarterly basis. The commission shall post the information in a manner that discloses the information for each prescription drug.

(5) A manufacturer that violates this section is subject to an administrative fine of $100,000.00 per day for every day that the information is not provided in accordance with this section.

Sec. 17748g. (1) The drug consumer protection commission is created within the department.

(2) The commission consists of the following 13 members appointed by the governor after considering the recommendations of the senate majority leader, the senate minority leader, the speaker of the house of representatives, and the house minority leader:

(a) Six individuals who represent consumer health advocacy groups.

(b) One individual who represents pharmacy benefit managers.

(c) Three individuals who represent health insurers, health maintenance organizations, or other persons who provide prescription drug benefits.

(d) The director of the department or his or her designee.

(e) The director of the department of health and human services or his or her designee.

(f) The director of the department of insurance and financial services or his or her designee.

(3) The members first appointed to the commission must be appointed within 15 days after the effective date of this section.

(4) Members of the commission shall serve for terms of 4 years or until a successor is appointed, whichever is later, except that of the members first appointed 1 shall serve for 1 year, 3 shall serve for 2 years, and 3 shall serve for 3 years.

(5) If a vacancy occurs on the commission, the governor shall make an appointment for the unexpired term in the same manner as the original appointment.

(6) The governor may remove a member of the commission for incompetence, dereliction of duty, malfeasance, misfeasance, or nonfeasance in office, or any other good cause.

(7) The governor shall call the first meeting of the commission. At the first meeting, the commission shall elect from among its members a chairperson and other officers as it considers necessary or appropriate. After the first meeting, the commission shall meet at least quarterly, or more frequently at the call of the chairperson or if requested by 4 or more members.

(8) A majority of the members of the commission constitute a quorum for the transaction of business at the meeting of the commission. A majority of the members present and serving are required for official action of the commission.

(9) The business that the commission may perform must be conducted at a public meeting of the commission held in compliance with the open meetings act, 1976 PA 267, MCL 15.261 to 15.275.

(10) Except as otherwise provided in section 17748e(4), a writing prepared, owned, used, in the possession of, or retained by the commission is subject to disclosure under the freedom of information act, 1976 PA 442, MCL 15.231 to 15.246.

(11) Members of the commission shall serve without compensation. However, members of the commission may be reimbursed for their actual and necessary expenses incurred in the performance of their official duties as members of the commission.

(12) Upon receiving a report filed under section 17748e or 17748f, the commission shall review the contents of the report to determine whether a manufacturer is charging an excessive price for a prescription drug or whether a manufacturer's increase in the wholesale acquisition cost of a prescription drug is

unconscionable. In making its determination, the commission may hold public hearings to hear from consumers of the prescription drug and consult with scientists, health researchers, and any individual with knowledge or expertise in the pricing of prescription drugs or the pharmaceutical industry.

(13) If the commission determines that a manufacturer has charged an excessive price for a prescription drug or that the increase in the wholesale acquisition cost of a prescription drug is unconscionable, the commission shall submit a written summary of its findings to the office of the attorney general and request that the attorney general investigate under section 3j of the Michigan consumer protection act, 1976 PA 331, MCL 445.903j.

Enacting section 1. This amendatory act takes effect 90 days after the date it is enacted into law.

Enacting section 2. This amendatory act does not take effect unless Senate Bill No.____ or House Bill No.____ (request no. 01297'19) of the 100th Legislature is enacted into law.