HOUSE BILL NO. 4878

September 11, 2025, Introduced by Rep. VanderWall and referred to Committee on Health Policy.

A bill to require the reporting of certain information and to prescribe conduct related to drugs and the federal 340B program; to prescribe civil sanctions; to allow for the promulgation of rules; and to provide for the powers and duties of certain state officers and entities.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 1. As used in this act, the words and phrases defined in sections 3 to 4 have the meanings ascribed to them in those sections.

Sec. 3. (1) "Biological drug product" means that term as defined in section 17702 of the public health code, 1978 PA 368, MCL 333.17702.

(2) "Department" means the department of licensing and regulatory affairs.

(3) "Hospital" means that term as defined in section 20106 of the public health code, 1978 PA 368, MCL 333.20106.

(4) "Interchangeable biological drug product" means that term as defined in section 17704 of the public health code, 1978 PA 368, MCL 333.17704.

(5) "Manufacturer" means that term as defined in section 17706 of the public health code, 1978 PA 368, MCL 333.17706.

(6) "Medicaid" means the program for medical assistance administered by the department of health and human services under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b.

(7) "Person" means an individual, partnership, corporation, association, governmental entity, or other legal entity.

(8) "Pharmacy" means that term as defined in section 17707 of the public health code, 1978 PA 368, MCL 333.17707.

Sec. 4. (1) "340B drug" means a covered outpatient drug as that term is defined in 42 USC 1396r-8.

(2) "340B entity" means a covered entity as that term is defined in 42 USC 256b.

(3) "340B program" means the federal 340B drug pricing program authorized under 42 USC 256b.

(4) "Wholesale distributor-broker" means that term as defined in section 17709 of the public health code, 1978 PA 368, MCL 333.17709.

(5) "Wholesaler" means a wholesale distributor as that term as

defined in section 17709 of the public health code, 1978 PA 368, MCL 333.17709.

Sec. 5. (1) Except as otherwise provided in subsection (2), a manufacturer, wholesaler, or wholesale distributor-broker shall not do any of the following:

(a) Deny, restrict, prohibit, condition, discriminate against, or otherwise limit the acquisition of a 340B drug by a 340B entity.

(b) Deny, restrict, prohibit, condition, discriminate against, or otherwise limit the acquisition of a 340B drug by, or the delivery of a 340B drug to, a pharmacy that is under contract with or otherwise authorized by a 340B entity to receive a 340B drug on behalf of the 340B entity.

(c) Designate a person to act on behalf of the manufacturer, wholesaler, or wholesale distributor-broker to engage in the conduct described in subdivision (a) or (b).

(2) A manufacturer, wholesaler, or wholesale distributor-broker may engage in the conduct prohibited under subsection (1) if otherwise authorized by a law of this state or federal law.

Sec. 7. (1) Beginning July 1, 2026, and each July 1 thereafter, a manufacturer shall submit a report to the department and the house of representatives and senate fiscal agencies on any prescription drug that exceeds $40.00 for the cost of 1 course of treatment and that has had more than a 15% increase in its wholesale acquisition cost during the preceding 12 months. The report must be submitted in a form and manner required by the department and include all of the following:

(a) The name of the manufacturer submitting the report.

(b) The name of the prescription drug included in the report.

(c) Whether the prescription drug has a brand name or generic

name, whether the prescription drug is a biological drug product or an interchangeable biological drug product, and any variation of the name of the prescription drug.

(d) The wholesale acquisition cost of the prescription drug and the schedule of wholesale acquisition cost increases for the preceding 5 years.

(e) The year the prescription drug was introduced into the market.

(f) The wholesale acquisition cost of the prescription drug at the time the prescription drug was introduced into the market.

(g) The cost of producing 1 course of treatment of the prescription drug, including, but not limited to, whether or when the prescription drug needs compounding immediately before dispensing.

(h) The expiration date of the patent for the prescription drug.

(i) Each form of the prescription drug dispensed, including, but not limited to, by oral pill, tablet, capsule, suppository, liquid, tincture, topical cream or ointment, or topical patch or other wearable, or by intravenous, port, peripherally inserted central catheter, or other method.

(2) The department shall post the information received by the department from the reports required under this section on the department's website in an area that is accessible to the public.

Sec. 9. If a 340B entity acquires an entity that is not a 340B entity, a drug prescribed for a patient of the acquired entity before the date of the acquisition cannot be claimed as a 340B drug.

Sec. 11. (1) A 340B entity that is a hospital shall ensure

that any savings received under the 340B program are invested in patient services or community benefit programs provided or performed at the hospital or by a coordinating hospital-affiliated entity.

(2) As used in this section:

(a) "Coordinating hospital-affiliated entity" means a legal entity that a hospital enters into an agreement with, and provides funding to, to provide patient services.

(b) "Patient services" means services provided by health care and nonclinical professionals to diagnose, treat, and manage an individual's health needs.

Sec. 13. A 340B entity shall ensure that it does not receive a duplicate discount or rebate as provided in 42 USC 256b(a)(5)(A)(i).

Sec. 15. (1) Subject to this section, beginning November 15, 2026, and each November 15 thereafter, a 340B entity that is a hospital shall report the following information to a qualified hospital organization for transactions that are conducted during the previous calendar year by the hospital or on the hospital's behalf and that are related to the hospital's participation in the 340B program:

(a) The aggregated acquisition costs for drugs obtained under the 340B program.

(b) The aggregated payment amount received for drugs obtained under the 340B program and dispensed or administered to patients.

(c) The number of pricing units dispensed or administered for drugs described in subdivision (b).

(d) The aggregated payments made to each of the following:

(*i*) To contract pharmacies to dispense drugs obtained under the

340B program.

(*ii*) To any other entity that is not a 340B entity and is not a contract pharmacy for managing an aspect of the 340B entity's 340B program.

(e) The aggregated payments made for any other expense related to administering the 340B program.

(2) The information required under subsection (1)(b) and (c) must be reported by payer type, including, but not limited to, commercial insurance, Medicaid, and Medicare.

(3) The information required under subsection (1)(a) to (c) must be reported at the national drug code level for the 50 most frequently dispensed or administered 340B drugs by the hospital under the 340B program.

(4) A hospital shall submit with the report required under subsection (1) all of the following for the year covered by the report:

(a) The aggregate amount spent by the hospital on community investments, delineated by the following categories:

(*i*) Subsidized health care services.

(*ii*) Financial assistance.

(*iii*) Community health improvement services and community benefit operations.

(*iv*) Cash and in-kind contributions.

(*v*) Community building activities.

(*vi*) Education for health care professionals.

(*vii*) Research that is not funded through a grant.

(*viii*) Medicaid shortfall.

(*ix*) Medicare shortfall.

(b) A copy of the community health needs assessment conducted

under the patient protection and affordable care act, Public Law 111-148, as amended by the health care and education reconciliation act of 2010, Public Law 111-152.

(c) A copy of any financial assistance policy from the hospital.

(5) A qualified hospital organization shall aggregate and deidentify the information collected under this section into an annual report that shall not identify the name of the hospital that submitted the information. The report must categorize information by each type of hospital that is eligible for the 340B program. Not later than December 31, 2026, and each December 31 thereafter, the qualified hospital organization shall make the report available to the public, including by posting the report on a publicly accessible website.

(6) The department shall enter into a contract with a hospital organization to implement this section.

(7) As used in this section:

(a) "Hospital organization" means a trade association operating in this state that represents hospitals.

(b) "Qualified hospital organization" means a hospital organization that has entered into a contract with the department under subsection (6).

Sec. 19. (1) If the department believes that a violation of this act has occurred, the department shall, within 30 days of that determination, notify the person involved. The department shall give the person the opportunity to correct the violation using informal methods. If, after 60 days after the person's receipt of the notice, the department determines that the person has not corrected the violation, the department shall refer the matter to

the attorney general for the enforcement of the civil fine provided under subsection (2).

(2) A person that violates this act is subject to a civil fine of not more than $500.00. The attorney general may bring an action to collect the fine. A fine collected must be deposited in the general fund. Each day that a violation continues after the violation is referred to the attorney general under subsection (1) is considered a separate violation.

Sec. 21. The department may promulgate rules under the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328, to implement this act.