Legislative Analysis

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340B DRUG PRICING TRANSPARENCY

House Bill 4878 as introduced
Sponsor: Rep. Curt S. VanderWall
Committee: Health Policy
Complete to 9-23-25

SUMMARY:

House Bill 4878 would create a new act to require reporting about drug price increases and set rules for conduct related to the federal ***340B program***. It would prescribe civil penalties, give duties to state agencies, and apply to drug manufacturers, wholesalers, pharmacies, hospitals, and ***340B entities***.

> ***340B program*** would mean the federal 340B drug pricing program authorized under 42 USC 256b, and ***340B entity*** would mean a *covered entity* under the same federal law.[1]

The federal 340B Drug Pricing Program[2] requires pharmaceutical manufacturers to offer certain drugs at discounted prices to 340B entities such as hospitals or clinics serving low-income or vulnerable patients. These entities then may use the savings from discounts to stretch resources and serve more patients.

Prohibited conduct

The new act would prohibit manufacturers, wholesalers, or wholesale distributor-brokers from denying, restricting, prohibiting, conditioning, discriminating against, or otherwise limiting the acquisition of a ***340B drug*** by a 340B entity or by a pharmacy under contract with or authorized by a 340B entity to receive a 340B drug on behalf of the 340B entity (or the delivery of a 340B drug to such a pharmacy). It also would prohibit delegating that conduct to someone else. However, these prohibitions would not apply if state or federal law explicitly authorizes the conduct

> ***340B drug*** would means a covered outpatient drug as defined in 42 USC 1396r-8.[3]

Manufacturer reporting

Beginning July 1, 2026, and July 1 each year thereafter, manufacturers would have to report to the Department of Licensing and Regulatory Affairs (LARA) and the House and Senate fiscal agencies on any prescription drug that costs more than $40 for one course of treatment and has had its wholesale acquisition cost increase by more than 15% over the past 12 months. The report would have to include all of the following:

- Manufacturer name.
- Drug name, including any variations.
- Whether the drug is brand name or generic.

[1] https://www.law.cornell.edu/uscode/text/42/256b
[2] See https://www.hrsa.gov/opa
[3] https://www.law.cornell.edu/uscode/text/42/1396r-8

- Whether it is biological or interchangeable biological drug product.
- Past five years of wholesale acquisition cost data.
- The year the drug was introduced.
- Its initial price (wholesale acquisition cost).
- The current production cost of one course of treatment (including whether compounding is needed).
- Patent expiration.
- All forms in which the drug is dispensed (pill, tablet, capsule, liquid, cream, ointment, patch, intravenous, etc.).

LARA would have to post the reported data on its website in a way the public can access.

Hospital reporting

Annually, beginning November 15, 2026, hospitals that are 340B entities would have to report the following information concerning transactions conducted by them or on their behalf in the previous calendar year to a qualified hospital organization (a Michigan trade association that represents hospitals and contracts with LARA under these provisions):

- Aggregated acquisition costs for drugs obtained under the 340B program.
- The aggregated payment amount received for drugs provided to patients and the number of pricing units dispensed or administered for those drugs. (This information would have to be reported by payer type, including at least commercial insurance, Medicaid, and Medicare.)
- The aggregated payments made to contract pharmacies to dispense drugs under the hospital's 340B program or other third parties to manage an aspect of the program.
- The aggregated payments made for other program-related expenses.

Information described in the first two bullets above would have to 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.

The following information also would have to be submitted with the report:

- The aggregate amount spent by the hospital on community investments, broken into the following categories:
    - Subsidized health care services.
    - Financial assistance.
    - Community health improvement services and community benefit operations.
    - Cash and in-kind contributions.
    - Community building activities.
    - Education for health care professionals.
    - Research not funded through a grant.
    - Medicaid shortfall.
    - Medicare shortfall.
- A copy of the community health needs assessment conducted under the federal Patient Protection and Affordable Care Act.
- A copy of the hospital's financial assistance policy, if any.

A qualified hospital organization would have to aggregate and anonymize the data described above into an annual report that categorizes information by each type of hospital eligible for the 340B program and publish the report by December 31 annually.

Enforcement

If LARA believes that someone has violated the new act, it would have to notify them within 30 days, allow them 60 days to correct the violation informally, and, if not corrected, refer the matter to the attorney general for enforcement. A person that violates the new act would be subject to a civil fine of up to $500, and each day a violation continues after referral to the attorney general would be a separate violation. The attorney general could bring an action to collect the fine.

Other provisions

If a 340B entity (such as a hospital) acquires another entity that was not previously a 340B entity, any prescriptions for patients of the acquired entity written before the acquisition date could not be retroactively claimed as 340B drugs.

Hospitals that are 340B entities would have to ensure that savings from the 340B program are invested in patient services or community benefit programs, provided either at the hospital or through an affiliated entity it contracts with and provides funding to.

LARA could develop and issue rules to implement the new act.

FISCAL IMPACT:

House Bill 4878 would have an indeterminate fiscal impact on the Department of Licensing and Regulatory Affairs. The bill would require drug manufacturers to submit reports to LARA and require LARA to post information from the reports on its website. The department would also be required to enter a contract with a hospital organization to implement certain reporting requirements outlined in the bill. LARA would likely incur costs associated with these activities as well as the promulgation of rules, though the magnitude of these costs is unknown. To the extent violations of the new provisions occur, additional fine revenue may be realized and enforcement costs incurred. The bill may also impact hospitals that are operated by units of state and local government, which include Hurley Hospital in Flint, Michigan Medicine in Ann Arbor, and Helen Newberry Joy Hospital in Newberry. Any potential costs incurred by these hospitals for compliance with the bill's requirements are indeterminate.

Legislative Analyst: Leah R. Doemer
Fiscal Analyst: Una Jakupovic