Legislative Analysis

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PHARMACIES PARTICIPATING WITH A 340B PROGRAM

Senate Bill 1179 (S-5) as passed by the Senate
Sponsor: Sen. Sam Singh
House Committee: [Pending]
Senate Committee: Oversight
Complete to 12-18-24

SUMMARY:

Senate Bill 1179 would amend Part 177 (Pharmacy Practice and Drug Control) of the Public Health Code to prohibit a drug manufacturer, wholesaler, or wholesale distributor-broker from doing any of the following:

- Denying, restricting, prohibiting, conditioning, discriminating against, or otherwise limiting the acquisition of a ***340B drug*** by a ***340B entity***.[1]
- Denying, restricting, prohibiting, conditioning, discriminating against, or otherwise limiting 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.
- Designating a person to act on behalf of the manufacturer, wholesaler, or wholesale distributor-broker to do either of the above.

However, a manufacturer, wholesaler, or wholesale distributor-broker could engage in the prohibited conduct if otherwise authorized by Michigan law or federal law.

340B drug would mean a covered outpatient drug as defined in federal law.[2]

340B entity would mean a covered entity as defined in federal law.[3]

Every July 1 beginning in 2026, a 340B entity would have to submit a report to the Department of Licensing and Regulatory Affairs (LARA) and the House and Senate fiscal agencies that includes all of the following:

- The name of the 340B entity.
- A copy of the entity's annual ***340B program*** recertification.
- If a community health needs assessment is required under section 501(r)(3)(A) of the federal Internal Revenue Code, a copy of that assessment.
- An affidavit affirming that the 340B entity is in compliance with 42 USC 256b(a)(5)(A)(i).
- An affidavit affirming that the 340B entity is in compliance with 340B program audits.
- A description of any adverse ***340B program audits*** within the preceding 12 months.
- A description of the impact of the 340B program on the patients and community served by it.

[1] For more information about the 340B Drug Pricing Program, see https://www.hrsa.gov/opa.
[2] Specifically, 42 USC 1396r-8: https://www.law.cornell.edu/uscode/text/42/1396r-8
[3] Specifically, 42 USC 256b: https://www.law.cornell.edu/uscode/text/42/256b

340B program would mean the federal 340B drug pricing program authorized under 42 USC 256b.

340B program audit would mean an audit performed under 42 USC 256b.

Every July 1 beginning in 2026, a drug manufacturer would have to submit a report to LARA and the House and Senate fiscal agencies on any prescription drug that exceeds $40 for one course of treatment and that has had an increase of more than 15% in its wholesale acquisition cost during the previous 12 months. The report would have to include all of the following:

- The name of the manufacturer.
- The name of the drug.
- Whether the drug has a brand name or generic name, whether the drug is a biological drug product or an interchangeable biological drug product, and any variation of the name of the drug.
- The year the drug was introduced into the market.
- The wholesale acquisition cost of the drug at the time it was introduced.
- The current wholesale acquisition cost of the drug and the schedule of wholesale acquisition cost increases for the preceding five years.
- The cost of producing one course of treatment of the drug, including whether or when it needs compounding immediately before dispensing.
- The expiration date of the drug's patent.
- Each form of the drug dispensed, including 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.

LARA would have to post each report described above on its publicly accessible website.

The bill cannot take effect unless Senate Bill 952 is also enacted. That bill would create the Hospital Price Transparency Act, which would prohibit hospitals from attempting to collect debts if they are not in compliance with certain price transparency requirements.

Proposed MCL 333.17757c

BACKGROUND:

The 340B Drug Pricing Program is a federal program that requires pharmaceutical manufacturers that participate in Medicaid to sell outpatient drugs to organizations that care for uninsured or low-income patients at reduced prices.[4]

FISCAL IMPACT:

Senate Bill 1179 would have an indeterminate, though likely minimal fiscal impact on state and local government units. The bill would require 340B entities, which may include publicly funded hospitals, to submit reports to the Department of Licensing and Regulatory Affairs (LARA) and the House and Senate fiscal agencies. The bill would require LARA to post the reports on the department website. Publicly funded hospitals that are 340B entities may

[4] https://www.aha.org/fact-sheets/fact-sheet-340b-drug-pricing-program

experience additional administrative costs associated with the production of reports. LARA may experience additional administrative costs associated with the posting of reports. Any costs incurred by hospitals and the department are likely to be minimal.

The bill would likely have no fiscal impact on the Department of Health and Human Services (DHHS) or Michigan's Medicaid program.

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■ This analysis was prepared by nonpartisan House Fiscal Agency staff for use by House members in their deliberations and does not constitute an official statement of legislative intent.