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January 25, 2023

The Honorable Rob Nosse, Chair
House Committee on Behavioral Health and Health Care

Dear Representative Nosse and Members of the Committee:

The Biotechnology Innovation Organization (BIO) writes to express concerns with certain provisions in HB 1303, which is currently before your committee. Among other things, this bill would prohibit pharmacy benefit managers from requiring pharmacies to identify claims where a drug discounted under the federal 340B Drug Discount Program has been dispensed to a patient. BIO opposes this provision because it can make it more difficult for states, payers, and manufacturers to identify illegal duplicate discounts and diversion of 340B drugs.

We understand the intent of these provisions concerning claims modifiers is to stop PBMs from reimbursing pharmacies and clinics less for claims when 340B drugs are dispensed. We do not oppose that goal. Provisions in HB 2716, also before your committee, are similarly intended to ensure fair treatment of pharmacies and clinics dispensing 340B drugs. The approach in HB 2716 does not have the same unintended consequences as the approach in HB 3013, explained in detail below, and we urge the committee to replace the 340B provisions in HB 3013 with the provisions found in HB 2716.

The federal 340B Program was enacted in 1992 to provide steeply discounted drugs to certain qualified hospitals and clinics, collectively referred to as "covered entities," intended to support these facilities' care to uninsured and underinsured patients. Covered entities are able dispense discounted drugs to patients and receive reimbursement by commercial payers at the full price, keeping the difference and providing a revenue stream for the covered entity. However, under federal law, 340B drugs cannot be subject to Medicaid supplemental rebates when dispensed to Medicaid beneficiaries ("duplicate discounts"). Additionally, 340B drugs may only be dispensed to patients of a covered entity; dispensing 340B drugs to ineligible patients is prohibited and referred to as "diversion" from the 340B program.

Since 2014, purchases under the 340B Program have tripled, to $38 billion in 2020, an increase of 27% over 2019. This represents more than 8% of the total US drug market.[1] An October 2020 study found that from April 2010 to April 2020, contract pharmacy arrangements in the program grew by 4,228% from 2,321 in 2010 to 101,469 today.[2] Because of this explosive growth in the 340B Program, it is important to ensure all appropriate federal laws are being followed and all steps are taken to prevent fraud, waste, and abuse.

In addition to 340B covered entities dispensing drugs directly to patients, the Health Resources and Services Administration (HRSA), which implements the program, has allowed covered entities to contract with outside pharmacies to dispense drugs to covered entities' patients.

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[1] Fein, Adam, "The 340B Program Soared to $38 billion in 2020—Up 27% vs. 2019 ," Drug Channels, June 9, 2020. Accessed: https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html
[2] Vandervelde, Aaron, et al., For-Profit Pharmacy Participation in the 340B Program, BRG Group, October 2020.

However, a heightened risk for duplicate discounts and diversion at contract pharmacies exists because, unlike at covered entities' in-house pharmacies, many of the patients visiting contract pharmacies are not eligible for 340B drugs. The Government Accountability Office (GAO) reports that contract pharmacies are a significant source of diversion and duplicate discounts, in part, because they often do not identify patients as 340B-eligible until after the prescription has been dispensed.[3] In fact, the GAO also notes, "66 percent of the 380 diversion findings in HRSA audits involved drugs distributed at contract pharmacies."[4]

HRSA's main mode of enforcing the 340B program is through random audits. HRSA audits 200 covered entities per year (about 1.5% of the over 12,000 covered entities), and problems with duplicate discounts and diversion are common findings in audits, as well as working with "contract pharmacies" without any actual contract in place. Oregon facilities are found to have compliance issues approximately on par with the rest of the country. A report by the federal GAO in 2018 found that 72 percent of audits had findings of noncompliance.[5] Unfortunately, the HRSA audit program has limitations, as indicted in the title of GAO's 2018 report: "Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement."

By prohibiting pharmacy benefit managers from requiring pharmacies to identify claims where a drug discounted under the 340B Program has been dispensed to a patient, this bill would make it more difficult for payers and manufacturers to identify illegal duplicate discounts and diversion of 340B drugs. The claims modifier ban runs contrary to the spirit of the 340B statutory prohibition on duplicate discounts and makes identifying them even more difficult. This prohibition is also inconsistent with CMS regulations that dictate states include a provision within their Medicaid MCO contracts to identify 340B claims.[6] While HB 3013 carves out Medicaid claims, the same policy justifications exist: the easier it is easier to identify 340B claims, the less likely that duplicate discounts and diversion will occur.

For these reasons, we oppose the claims modifier provisions in HB 3013. Please feel free to contact me with any questions that may arise.

Sincerely,

Brian Warren
Senior Director, State Government Affairs

[3] *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO Report, June 2018.
[4] Ibid.
[5] Ibid.
[6] 42 CFR §438.3(s)(3), Medicaid Managed Care Final Rule, CMS.