Attachment A

**Biotechnology Innovation Organization**
1201 Maryland Avenue SW
Suite 900
Washington, DC, 20024
202-962-9200

March 3, 2022

The Honorable Susan Lontine
Chair, House Health & Insurance Committee
State Capitol, 200 E Colfax
Denver, CO 80203

Dear Representative Lontine and Members of the Committee:

The Biotechnology Innovation Organization (BIO) writes to express opposition to certain provisions in HB22-1122, 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.

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. In addition to 340B covered entities dispensing drugs directly to patients, the Health Resources and Services Administration (HRSA), which administers the program, has allowed covered entities to contract with outside pharmacies to dispense drugs to covered entities' patients. 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—both in terms of size and in the use of contract pharmacies—it is important to ensure all appropriate federal laws are being followed and all steps are taken to prevent fraud, waste, and abuse.

State bills that seek to prohibit identification of 340B claims would make it more difficult to identify illegal duplicate discounts and diversion of 340B drugs. A heightened risk for duplicate

[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.

discounts and diversion exists at contract pharmacies 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) has found 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]

By preventing PBMs from requiring pharmacies to identify 340B claims, this provision 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 the Center for Medicare and Medicaid Services (CMS) regulations[5] that dictate states include a provision within their Medicaid MCO contracts to identify 340B claims.[6] While HB22-1122 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 HB22-1122. Please feel free to contact me with any questions that may arise.

Sincerely,

Brian Warren
Director, State Government Affairs
Biotechnology Innovation Organization

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