Biotechnology Innovation Organization
1201 New York Avenue NW
Suite 1300
Washington, DC, 20005
202-962-9200

March 12, 2025

Senate Human Services Committee
State Capitol
600 East Boulevard Avenue
Bismarck, ND 58505

Dear Chair Lee and Members of the Senate Human Services Committee,

The Biotechnology Innovation Organization (BIO) respectfully asks for your opposition to H.B. 1473. BIO respectfully opposes H.B. 1473, as it distorts the 340B program beyond the scope of federal statute and makes it more difficult for the state, payers, and manufacturers to identify illegal duplicate discounts and diversion (and waste in the system).

The bill prohibits manufacturers from withholding 340B-discounted drug products from a pharmacy that has contracted with a 340B covered entity. **This restriction creates perverse incentives in an already opaque program, ultimately making it harder to hold covered entities accountable and ensure that the benefits they are trusted to deliver to patients aren't being diverted to intermediaries' profit margins.** Many contract pharmacies are for-profit corporations whose shareholders benefit from exponential growth in the 340B program. In 2023, the program reached approximately $66.3 billion, equating to approximately 20% of gross US sales of brand-name drugs.[1] According to an October 2020 study, the number of contract pharmacy arrangements in the program grew by 4,228% from 2,321 in 2010 to 101,469 in 2020,[2] and as of July 2023 this number increased to 194,016.[3] According to one analysis, "the average profit margin on 340B medicines commonly dispensed through contract pharmacies is an estimated 72% compared with just 22% for non-340B medicines dispensed through independent pharmacies."[4] This explosive growth has occurred because it is extremely profitable for pharmacies to share in the 340B discount provided to covered entities. The restrictions in H.B. 1473 would further benefit contract pharmacies' profit margins rather than the vulnerable patients the 340B program seeks to protect and serve.

Contract pharmacies are also known to be greater risk of diversion and duplicate discounts. Fraud, waste, and abuse within the 340B program often comes in the form of "duplicate discounts" and "diversion," which are prohibited by the 340B federal statute. A duplicate discount is when an entity illegally collects discounts under multiple programs for the same drug, such as receiving discounts from both the 340B Program and the Medicaid Drug Rebate Program. Diversion is when a non-eligible patient receives a 340B discounted drug. The US Government Accountability Office (GAO) notes that contract pharmacies are a significant source of diversion and duplicate discounts, in part due to the fact that they often do not identify patients as 340B-eligible until after the prescription has been dispensed.[5] The GAO also notes, "66 percent of the 380 diversion findings in HRSA audits involved drugs distributed at contract pharmacies. . ."[6] The GAO and the US Health and Human Services Office of Inspector General (OIG) have both

[1] Op Cit.
[2] Vandervelde, Aaron, et al., "For-Profit Pharmacy Participation in the 340B Program," BRG Group, October 2020. https://www.thinkbrg.com/insights/publications/for-profit-pharmacy-participation-340b/ (Accessed: April 25, 2023)
[3] Fein, Adam, "Exclusive: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market," July 11, 2023. Accessed July 13, 2023. https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html
[4] Vandervelde, October 2020.
[5] GAO Report, June 2018.
[6] Ibid.

Biotechnology Innovation Organization
1201 New York Avenue NW
Suite 1300
Washington, DC, 20005
202-962-9200

acknowledged in reports and before Congress that the complexity of contract pharmacy arrangements makes oversight difficult, in part, because the definition of "patient" is ambiguous,[7,8] leading to prohibited duplicate discounts and diversion. Both agencies have also noted that HRSA does not scrutinize contract pharmacy arrangements.

H.B. 1473 would increase the risk of fraud, waste, and abuse by preventing the identification of 340B claims. H.B. 1473 prohibits manufacturers from requiring data to identify 340B claims. However, claims data is essential to prevent fraud, waste and abuse in the program. Manufacturers and states rely on 340B claims data to prevent inappropriate duplicate discounts and diversion. Without this information, it is much more difficult for manufacturers to conduct audits to ensure that fraud, waste, and abuse are not taking place.

In FY 2024, HRSA found that 46% of the covered entities that were audited had adverse findings, including dispensing drugs at a contract pharmacy for prescriptions written at ineligible sites.[9] The Centers for Medicare and Medicaid Services (CMS) issued a bulletin in January 2020 that made "best practice" recommendations to states on minimizing duplicate discounts.[10] States are required to report data excluding 340B claims to CMS for the purposes of billing manufacturers for Medicaid drug rebates. In their recommendations, CMS notes that states should have a means to identify 340B drug claims. The Agency also confirmed that "HRSA encourages 340B covered entities to work with the [applicable] state to develop strategies to prevent duplicate discounts on drugs covered by Medicaid managed care plans."[11]

Further, as required by the Medicaid Managed Care Final Rule, 42 CFR §438.3(s)(3), "claims for 340B drugs that are the responsibility of the Medicaid managed care plan must be identified and excluded from the general managed care utilization data reported to the state for purposes of billing manufacturers for Medicaid rebates."[12]

The prohibition on claims data as outlined in H.B. 1473 runs counter to CMS' and HRSA's recommendations, increasing the likelihood for diversion and duplicate discounts, as prohibited by federal statute.

For these reasons, BIO opposes H.B. 1473 and urges the Legislature not to move forward with the bill. Please do not hesitate to contact us for any further information.

Sincerely,

/S/

Lilly Melander
Senior Director, State Government Affairs
Biotechnology Innovation Organization

---

[7] Ibid.
[8] "Contract Pharmacy Arrangements in the 340B Program," *Memorandum to HRSA Administrator Mary Wakefield*, Office of Inspector General, February 4, 2014.
[9] HRSA Program Integrity: FY 24 Audit Results. Retrieved: https://www.hrsa.gov/opa/program-integrity/fy-24-audit-results?order=field_opa_audit_entity&sort=asc
[10] Lynch, Calder, "Best Practices for Avoiding 340B Duplicate Discounts in Medicaid," *CMS Information Bulletin*, Centers for Medicare and Medicaid Services, January 8, 2020.
[11] Ibid.
[12] Best Practices, January 8, 2020.