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March 11, 2025

The Honorable Rob Nosse, Chair
House Behavioral Health and Health Care Committee
State Capitol, 900 Court St NE
Salem, OR 97301

Dear Representative Nosse and Members of the Committee:

The Biotechnology Innovation Organization (BIO) has an **oppose** position on **HB 2385**, which is currently before your committee. This bill would prohibit biopharmaceutical manufacturers participating in the federal 340B Drug Discount Program ("340B Program") from establishing requirements or standards intended to ensure compliance with federal laws. BIO has very serious concerns with these provisions, which would enact state requirements in an exclusively federal program and would preclude legitimate efforts to ensure transparency and integrity in the 340B Program.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, delay their onset, or prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life- saving medicines and vaccines for all individuals.

The 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 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.

The 340B program has grown exponentially in volume over the past decade. the 340B program has expanded in ways that no one could have foreseen. From 2015 to 2021, purchases under

the program grew at an average rate of 24% per year and as of 2023 totaled $66.3 billion.[1, 2] 340B is now the second largest pharmaceutical program in the nation behind Medicare Part D.[3] 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.[4] 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 issued sub-regulatory guidance to allow covered entities to contract with outside pharmacies to dispense drugs to covered entities' patients. However, a heightened risk for duplicate discounts and diversion at contract pharmacies exists because, unlike at covered entities' in-house pharmacies, most of the patients visiting contract pharmacies are not eligible for 340B drugs. The federal 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.[5] In fact, the GAO also notes, "66 percent of the 380 diversion findings in HRSA audits involved drugs distributed at contract pharmacies."[6]

HRSA's main mode of enforcing the 340B program is through random audits. They audit 200 covered entities per year, 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.[7] 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."

Adding further concern to compliance concerns with contract pharmacies, HRSA does not even cite audit findings of noncompliance if the noncompliance is by a contract pharmacy. In another report in 2021, GAO states "HRSA officials told GAO that, beginning in fall 2019, the agency started issuing findings only when audit information presents a clear and direct violation of the requirements outlined in the 340B Program statute. HRSA officials explained that guidance, which is used to interpret provisions of the 340B statute for the purposes of promoting program compliance among covered entities, does not provide the agency with appropriate enforcement capability. For example, *HRSA officials reported that there were instances among fiscal year 2019 audits in which the agency did not issue findings for a failure to comply with guidance related to contract pharmacies in part because the 340B statute does not address contract pharmacy use and, therefore, there may not have been a clear statutory violation*" (emphasis added).[8]

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[1] Fein, Adam, "What I (and Others) Told the Senate about the 340B Drug Pricing Program." Drug Channels, August 8, 2023. Accessed September 14, 2023. https://www.drugchannels.net/2023/08/what-i-and-others-told-senate-about.html
[2] Fein, Adam, The 340B Program Reached $66 Billion in 2023- Up 23% vs 2022: Analyzing the Numbers and HRSA's Curious Actions." Drug Channels. October 22, 2024. Accessed December 10, 2024.
[3] Blalock, Eleanor. Measuring the Relative Size of the 340B Program, BGR Group, June 2022.
[4] Vandervelde, Aaron, et al., For-Profit Pharmacy Participation in the 340B Program, BRG Group, October 2020.
[5] *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO Report, June 2018.
[6] Ibid.
[7] Ibid.
[8] Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements, GAO Report, December 2020.

We strongly oppose this bill's provisions intended to prohibit biopharmaceutical manufacturers participating in the 340B Program from establishing requirements or standards to ensure compliance with federal laws. The use of contract pharmacies in the 340B Program simply has not been adequately policed by HRSA. It is for this reason that some manufacturers have put in place requirements for covered entities that use multiple contract pharmacies. This particular issue is currently being litigated in several federal courts, as there is no statutory requirement for manufacturers to extend 340B prices to contract pharmacies. Contract pharmacy was created through sub-regulatory federal guidance (guidance that HRSA itself has acknowledged is legally unenforceable[9]). This bill's provisions are nearly identical to bills in nearly *two dozen* other states this year, which are part of an effort by covered entities to inappropriately enshrine *their* interpretation of federal law into state statutes. Yet the belief that manufacturers have no ability to establish standards and must provide discounted 340B drugs to all contract pharmacies, regardless of a history of noncompliance, has been rejected by multiple courts.

Even beyond the exclusive federal jurisdiction of the 340B program and the multiple pending federal lawsuits, the policy contained in these provisions is flawed. Biopharmaceutical manufacturers have participated in the 340B Program for 30 years and, in doing so, provided hundreds of billions of dollars in financial support to covered entities. However, when evidence exists that certain arrangements (i.e., contract pharmacies) result in increased rates of illegal duplicate discounts and diversion of 340B drugs, it is untenable to preclude manufacturers from implementing *any* standards. In doing so, the state would be facilitating contract pharmacies' noncompliance with federal statute.

For these reasons, we respectfully oppose HB 2385 and urge your NO vote on this measure. If you have any questions, please do not hesitate to contact me at bwarren@bio.org.

Sincerely,

Brian Warren
Vice President, State Government Relations

[9] "HRSA Urges Pharma to Continue 340B Discounts at Contract Pharmacies," *Inside Health Policy*, August 20, 2020.