February 19, 2024

Lilly USA, LLC

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

Re: House Bill 4028-2

Dear Oregon House and Senate Members,

Eli Lilly and Company (Lilly) opposes the provisions in Oregon House Bill 4028-2 (HB 4028-2) which purport to require pharmaceutical manufacturers to extend federal 340B discounts to contract pharmacies, including to for-profit entities.[1] We support the federal 340B drug pricing program that Congress created and have done so since its inception in 1992. However, we believe that patients should be the ones benefiting from deeply discounted 340B medicines. Not only would HB 4028-2 continue to allow for-profit pharmacies and large hospital systems to use the 340B program to generate profit at the expense of patients, but the bill raises significant legal concerns, both under the United States Constitution and in light of a recent ruling by the U.S. Court of Appeals for the Third Circuit.

1. **The contract pharmacy provisions of HB 4028-2 raise significant legal concerns and attempt to override a recent ruling by the Third Circuit.**

Congress created the federal 340B drug discount program in 1992 to help vulnerable and uninsured patients access outpatient prescription medicines at safety-net facilities. The 340B program requires that manufacturers who participate in the Medicaid program must "offer" their drugs at or below a certain discounted price, known as the "ceiling price," which is typically far less than a product's list price. Manufacturers must "offer" their drugs at these discounted prices to certain types of hospitals, called "covered entities."[2]

The 340B program is a comprehensive *federal* program that provides certain rights and imposes certain duties on regulated entities. HB 4028-2 seeks to further regulate manufacturers' participation in this exclusively federal program, and in a manner that directly conflicts with the explicit requirements both in the federal 340B statute, 42 U.S.C. § 256b, and in manufacturers' Pharmaceutical Pricing Agreements (PPAs) with the Secretary of the U.S. Department of Health and Human Services (HHS).[3] Specifically, the federal 340B statute lists fifteen specific entity types that are "covered entities." Contract pharmacies are not one such entity. In fact, nowhere in the 340B statute are contract pharmacies even mentioned. Moreover, a manufacturer's obligation to "offer" certain drugs to covered entities is memorialized in the manufacturer's PPA with the federal government. Again, nowhere in the PPA are contract pharmacies mentioned, and the Supreme Court has held that they are not third-party beneficiaries to this agreement between a manufacturer and the *federal* government.[4]

Crucially, the U.S. Court of Appeals for the Third Circuit recently weighed in on the proper functioning of the *federal* statutory scheme. The court squarely held that the "drug makers' restrictions on delivery to contract pharmacies do not violate Section 340B," that the government ***cannot*** require manufacturers to "[deliver] discounted drugs to an unlimited number of contract pharmacies," and that "drug makers' policies [with respect to contract pharmacies] are lawful." As the court explained,

---

[1] *See* HB 4028-2, which proposes adding a new section to the Oregon Code.
[2] 42 U.S.C. § 256b.
[3] Manufacturers must enter into an agreement with the Secretary of HHS as part of their participation in the federal 340B program. HHS, Health Services & Resources Administration (HRSA), "Manufacturer Resources." (2019). Manufacturer Resources | Official web site of the U.S. Health Resources & Services Administration (hrsa.gov)
[4] *See Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113–14 (2011).

although these policies stop covered entities from "squeez[ing] as much revenue out of [the 340B program] as they once could, drug makers need not help them maximize their 340B profits."[5]

HB 4028-2 attempts to override the Third Circuit's findings regarding the requirements of the federal 340B program by stating that manufacturers cannot "deny, restrict, prohibit or otherwise interfere directly or indirectly with the acquisition of a 340B drug or the delivery of a 340B drug to a pharmacy or drug outlet that has contracted with a covered entity to receive and dispense 340B drugs on behalf of the covered entity unless the acquisition or delivery is prohibited by the United States Department of Health and Human Services." But federal law does not allow covered entities to unilaterally authorize entities to purchase or receive such products. Such state action implicates the Supremacy Clause of the United States Constitution: The Supremacy Clause leaves no room for states to wade into this comprehensive federal regime and impose separate (let alone conflicting) requirements. In fact, similar laws in Arkansas and Louisiana are currently being challenged on federal preemption grounds.[6] These five cases are pending at the District Court level or with U.S. Court of Appeals for the Eighth Circuit.

States simply have no authority to add to the requirements of a uniquely *federal* program. The 340B program is entirely a creature of federal statute, and the sole basis for the federal government requiring any discounted sales to covered entities in the first place is as a condition for participating in other federal programs—Medicare and Medicaid. States, however, have no ability to require where or how discounted sales are made pursuant to the federal 340B program. For a state to nonetheless attempt to mandate who a manufacturer must provide federal statutory discounts to, and how such discounts are provided would violate the Takings and Due Process Clauses in the Fifth and Fourteenth Amendments of the United States Constitution. Doing so could also be inconsistent with the limitations of the Commerce Clause by directly regulating lawful transactions consummated out of state.

2. The Federal 340B program has grown significantly since its inception, with documented noncompliance attributable to contract pharmacy expansion. HB 4028-2 would exacerbate this noncompliance.

Not only does HB 4028-2 raise legal concerns, but it would also exacerbate the challenges that have resulted from the unrestrained growth of the 340B program. Since its formation, the federal 340B program has grown so big that it is now larger than Medicaid and second in size only to Medicare Part D.[7] It is projected to be the largest federal program by 2026.[8] Purchases at the 340B discounted price totaled $53.7 billion in 2022 – the list price value of these purchases was more than $106 billion.[9] Left unfixed, growth in the 340B program will burden manufacturers participating in the Medicare and Medicaid programs in a manner different than what Congress intended, raising significant implications for those federal programs, as well.

This growth is attributable – in part – to the rampant growth of contract pharmacy arrangements, under which a 340B covered entity contracts with a pharmacy to provide drugs to the covered entity's patients. In 2010, the Health Resources and Services Administration (HRSA) noted fewer than 1,300 unique contract pharmacies. In 2022, roughly 32,000 unique pharmacies were participating in the 340B

---

[5] *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Human Servs.*, Nos. 21-3167 & 21-3379 (3d Cir. Jan. 30, 2023).
[6] *See PhRMA v. McClain*, No. 22-3675 (8th Cir.); *Novo Nordisk v. McClain*, No. 4:23-cv-0969 (E.D. Ark.); *PhRMA v. Landry*, No. 6:23-cv-0997 (W.D. La.); *AstraZeneca v. Landry*, No 6:23-cv-1042 (W.D. La.); *AbbVie v. Landry*, No 6:23-cv-1307 (W.D. La.).
[7] Berkeley Research Group (BRG), "340B Program at a Glance." (2021). 340B_Forecast-Report-Infographic_2021.pdf (thinkbrg.com)
[8] BRG, "340B Program at a Glance." (2021). 340B_Forecast-Report-Infographic_2021.pdf (thinkbrg.com)
[9] Drug Channels, "The 340B Program Reached $54 Billion in 2022—Up 22% vs. 2021." Drug Channels: EXCLUSIVE: The 340B Program Reached $54 Billion in 2022—Up 22% vs. 2021

program through more than 168,000 contract pharmacy arrangements with covered entities.[10] In fact, one analysis suggests that contract pharmacies' 2021 gross profits attributable to 340B were over $3 billion.[11]

What is more, the oversight measures the federal Congress chose to impose in the 340B statute are often ignored by contract pharmacies. The statute prohibits covered entities from engaging in "diversion" by selling a 340B discounted drug to a person who is not a patient of a covered entity. It is therefore unlawful for a contract pharmacy to purchase or receive a drug at the 340B price and then sell the drug to a customer who is not a patient of any covered entity. The statute also prohibits "duplicate discounts" which occur when a covered entity purchases a drug at the 340B price, and the manufacturer also pays a Medicaid rebate to the state for the same drug. Yet federal agencies have repeatedly confirmed covered entities and contract pharmacies are not complying with these federal prohibitions, particularly in contract pharmacy arrangements. For example, the Government Accountability Office (GAO) and Office of Inspector General (OIG) have noted:

- "Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."[12]
- Contract pharmacies create "complications" in preventing duplicate discounts because "some covered entities that do dispense 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies did not report a method to avoid duplicate discounts."[13]
- There are "a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements."[14]
- "The *identified noncompliance* at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices."[15]

Notwithstanding these findings, the number of contract pharmacy arrangements has continued to grow, without the additional oversight or controls recommended by these federal government agencies.

3. The explosive growth of the federal 340B program has not directly benefited patients at the pharmacy counter. HB 4028-2 would not resolve drug affordability challenges for patients.

Data highlight that although 340B hospitals purchase drugs at steep discounts, many are not passing on the discounted price to patients, which can leave patients (and their insurers, if applicable) paying full price for their medicines.[16] In fact, the New England Journal of Medicine noted that "[f]inancial gains for

---

[10] Drug Channels, "Exclusive: Five Pharmacy Chains and PBMs Dominate 2022's Still-Booming 340B Contract Pharmacy Market." (2022). Drug Channels: Exclusive: Five Pharmacy Chains and PBMs Dominate 2022's Still-Booming 340B Contract Pharmacy Market

[11] Drug Channels, "Exclusive: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market." (2023). Drug Channels: EXCLUSIVE: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market

[12] U.S. Government Accountability Office (GAO), "Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement." (2011). GAO-11-836 Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement

[13] HHS Office of the Inspector General (OIG), "Contract Pharmacy Arrangements in the 340B Program." (2014). https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp

[14] HHS OIG, "Examining Oversight Reports on the 340B Drug Pricing Program. Testimony of Ann Maxwell, Assistant Inspector General for Evaluation and Inspections before the United States Senate Committee on Health, Education, Labor and Pensions." (2018). Examining Oversight Reports on the 340B Drug Pricing Program (05/18) (hhs.gov)

[15] GAO, "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement." (2018). https://www.gao.gov/assets/gao-18-480.pdf

[16] GAO, "Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement." (2011). GAO-11-836 Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement

[340B] hospitals have not been associated with clear evidence of expanded care or lower mortality among low-income patients."[17]

These findings have been reiterated in various government reports. For example, the GAO found more than half of the 340B hospitals surveyed did not provide low-income, uninsured patients discounts or only provided the 340B discount at some of their contract pharmacies (which include CVS, Walgreens, and Walmart).[18] The Office of Inspector General (OIG) highlighted that 340B hospitals are not required to provide the discounted 340B price to uninsured patients at contract pharmacies, and in fact, many do not. As a result, OIG acknowledged, "uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies."[19]

This is consistent with Lilly's experience. 340B hospitals are able to purchase many of our insulins for a penny per milliliter (mL), but that's not what uninsured patients pay. For example, one contract pharmacy we interviewed marked up the price of a vial of insulin over 330,000%, charging an uninsured patient over $500. That's why Lilly continues to provide 340B "penny priced" insulin to 340B hospitals for their contract pharmacy shipments, so long as the hospital agrees to provide the insulin to the patients at the 340B discounted price – i.e., 10 cents for a 10-mL vial.[20]

HB 4028-2 does not resolve these patient affordability challenges at 340B entities and contract pharmacies.

4. Lilly supports state policies that make medicines more affordable for patients.

Lilly continues to advocate for federal reform to the 340B program and supports state policies that ensure patients have affordable access to medicines. Specifically, Lilly supports federal 340B reforms that improve program transparency, provide more direct patient benefit, and promote better compliance with the statutory prohibition against duplicate discounts and diversion. These reforms would put patients back at the center of the 340B program. Because the 340B program is an exclusively federal program, Lilly believes a state's ability to implement these needed reforms is limited. However, Lilly supports state actions, including the below policies that ensure patients have affordable access to medicines:

- **Cost sharing based on net price (rebate pass through):** Requiring pharmacy benefit managers and health plans to share manufacturer rebates directly with beneficiaries at the point of sale to offset out-of-pocket costs.
- **Affordability program awareness:** Policies that ensure people are aware of and enroll in applicable state and federal health care programs to enable affordable access to medicines.
- **Cost-sharing assistance:** Polices that ensure patients fully benefit from manufacturer cost-sharing assistance at the pharmacy counter.

We commend Oregon for passing policies such as copay caps to help address patient affordability of medicines, and we encourage the legislature to evaluate other policies that have a more direct impact on patients' out-of-pocket experiences.

---

[17] New England Journal of Medicine, "Consequences of the 340B Drug Pricing Program." (2018). Consequences of the 340B Drug Pricing Program | NEJM

[18] GAO, "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement." (2018, p. 30-31). https://www.gao.gov/assets/gao-18-480.pdf

[19] HHS OIG, "Contract Pharmacy Arrangements in the 340B Program." (2014, p. 2). Contract Pharmacy Arrangements in the 340B Program Report (OEI-05-13-00431) 02-04-2014 (hhs.gov)

[20] 340B hospitals must also agree to not add any dispensing or administrative fee, not bill the patient's insurance company, and provide claims data to Lilly regarding these purchases. See How Lilly is Helping Discounts Reach People with Diabetes in 340B | Eli Lilly and Company

* * * * * * *

We appreciate the opportunity to express our views on HB 4028-2. Given HB 4028-2 does not advance patient drug affordability goals, and raises serious federal preemption concerns, we respectfully request that you oppose.

Sincerely,

William Reid
Vice President
State Government Affairs
Eli Lilly and Company

CC: Diane Hilligoss, Assistant General Counsel – Eli Lilly and Company