STATEMENT

In Opposition to Vermont H. 266

Position: The Pharmaceutical Research and Manufacturers of America ("PhRMA") respectfully opposes Vermont H. 266. H. 266 would require biopharmaceutical manufacturers to ship 340B drugs to all pharmacies that contract with 340B "covered entities" and by extension offer 340B pricing at these locations. This type of provision not only raises constitutional concerns but also exacerbates existing problems with the 340B program without ensuring that vulnerable patients needing discounted medicines will benefit.

Congress created the 340B program in 1992 to help vulnerable and uninsured patients access prescription medicines at safety-net facilities.

Through the program, biopharmaceutical manufacturers provide tens of billions of dollars in discounts each year to qualifying safety-net hospitals and certain clinics ("covered entities"), but patients are often not benefitting. Today, large tax-exempt hospital systems, chain pharmacies, and pharmacy benefit managers (PBMs) are generating massive profits from the 340B program even though its intended beneficiaries were true safety-net hospitals and clinics and the low-income and vulnerable patients they treat. The 340B program has strayed far from its safety-net purpose, and Congress needs to fix the program to ensure that it is reaching its intended populations.

There is no evidence that the 340B program is improving health care access for patients most in need.

There are no requirements that covered entities share 340B savings with low-income patients. Participation in the 340B program does not appear to have increased care or improved outcomes for patients in underserved areas. According to an Agency for Healthcare Research and Quality (AHRQ)-funded study, "financial gains for [340B] hospitals have not been associated with clear evidence of expanded care or lower mortality among low-income patients."[i] In fact, 65% of 340B (Disproportionate Share Hospitals) DSH hospitals provide less charity care as a percentage of operating costs than the national average for all hospitals.[ii]

An investigation by the New York Times found that "starting in the mid-2000s, big hospital chains ... [would] build clinics in wealthier neighborhoods, where patients with generous private insurance could receive expensive drugs, but on paper make the clinics extensions of poor hospitals to take advantage of 340B." In one case, a hospital system's facility based in a low-income area reported the highest profit margin in the state by allowing the entire hospital system to access 340B discounts, despite the fact that the hospital lacks basic medical equipment and specialists.[iii]

340B prescriptions filled at contract pharmacies are typically identified long after a patient has left the pharmacy—meaning that the system is set up to ensure corporations benefit but not patients. Therefore, it's not surprising that a study published in the American Journal of Managed Care determined "growth of contracts with 340B hospitals was less likely in areas with higher uninsured rates and in medically underserved areas."[iv]

A combination of lax eligibility standards for 340B hospitals, little oversight into how 340B funds are used, and the program having no requirements that covered entities share savings with patients are among the key factors that have contributed to the way the program has distorted the health care market at the expense of patients. Changes are needed to ensure the 340B program is working for patients instead of driving up costs for everyone while being coopted by big hospital corporations and for-profit companies to pad their bottom line.

<u>There is little evidence to suggest that patients have benefited from contract pharmacy growth.</u>

Since 2010, the number of contracts with pharmacies has grown by more than 12,000%, and between 2013 and 2024, over 200,000 contract pharmacy agreements were established.[v] Because the program has no transparency or guardrails on how hospitals and clinics use 340B profits, the money often is not going to help low-income and uninsured patients access medicines. An analysis of contract pharmacy claims for brand medicines only found evidence that patients were directly receiving a discount for 1.4% of prescriptions eligible for 340B.[vi] Additional studies have found that 65% of the roughly 3,000 hospitals that participate in the 340B program are not located in medically underserved areas,[vii] and in Vermont, 66% of contract pharmacies are located in rural areas despite 85% of the state's zip codes being considered rural.[viii;ix] Research has also found that more than 77% of 340B hospitals provide less charity care than the national average for all hospitals, and they often spend less on charity care and community investment than the estimated value of their tax breaks as nonprofits[x]. In fact, 100% of 340B hospitals in Vermont are below the national average for charity care levels.[xi]

<u>The 340B program has become a hidden tax on employers, patients, and state employees.</u>

Marking up the costs of 340B medicines for employer-sponsored commercial plans and patients with private insurance generates significant revenue for 340B hospitals. 340B hospitals collect 7 times as much as independent physician offices for the sale of medicines administered to commercially insured patients[xii] and average spending per patient in the commercial market on outpatient medicines was more than 2.5 times higher at 340B hospitals than non-340B hospitals.[xiii]

In addition, the current design of the program directly increases costs for employers by an estimated $6.6 billion, due to reduced rebates from manufacturers, and indirectly increases employer costs by incentivizing provider consolidation and use of higher cost medicines.[xiv] Employers in Vermont pay an estimated $43.9 million more in health care costs due to forgone rebates which leads to a $1.1 million reduction in state and local tax revenue.[xv] With no obligation

to invest profits from 340B markups at satellite facilities into underserved communities, 340B hospitals frequently purchase independent physician offices so they can then buy more medicines and increase their 340B profits.[xvi] Further, incentives in the 340B program increase the use of higher-cost medicines as hospitals participating in 340B generally obtain substantially larger profits from more expensive medicines.[xvii,xviii]

In an unprecedented report examining 340B hospital practices in its state, the North Carolina State Treasurer found North Carolina 340B hospitals charged state employees massive markups for oncology medicines. According to the report, North Carolina 340B hospitals charged state employees, on average, a price markup of 5.4 times the hospitals' discounted 340B acquisition cost for outpatient infused cancer medicines. This resulted in billing the North Carolina State Health Plan for Teachers and State Employees a price markup on cancer medicines that was 84.8% higher than North Carolina hospitals outside of the 340B program.[xix]

H. 266 will line the pockets of PBMs, pharmacy chains, and large hospital systems.

Many contract pharmacies charge a patient based on a drug's full retail price because they are not required to share any of the discount with those in need.[xx] Big-box retailers such as Walgreens, CVS Health, and Walmart are major participants in the 340B program through contract pharmacy arrangements. Because of vertical integration in the supply chain, PBMs now own the vast majority of pharmacies, meaning they also make a profit from contract pharmacy arrangements. In fact, the five largest for-profit pharmacy chains comprise 60% of 340B contract pharmacies, but only 35% of all pharmacies nationwide.[xxi] 340B covered entities and their contract pharmacies generated an estimated $13 billion in gross profits on 340B purchased medicines in 2018, which represents more than 25% of pharmacies' and providers' total profits from dispensing or administering brand medicines.[xxii] The 340B program reached $66.3 billion, a 23% growth increase from the previous year.[xxiii]

In 2023, the Minnesota Legislature passed legislation[xxiv] that requires the Minnesota Department of Health (MDH) to collect and aggregate data from Minnesota providers that participate in the federal 340B program. The Minnesota 340B report provides further evidence that for-profit middlemen are profiting from the 340B program. Payments to contract pharmacies and third-party administrators (TPAs) were over $120 million, representing approximately $16 of every $100 of gross 340B revenue generated paid to external parties. In fact, 10% of safety-net federal grantees reported a negative net 340B revenue due to payments made to middlemen. The top 10% of critical access hospitals and disease-specific grantees with the highest external operational costs lost at least half their gross 340B revenue to TPAs and contract pharmacies.[xxv]

The Minnesota 340B report also sheds light on the massive profits 340B tax-exempt hospitals retain from the 340B program. Minnesota providers participating in the 340B program earned a collective net[xxvi] 340B revenue of at least $630 million for the 2023 calendar year. Based on national data, MDH believes this figure may represent as little as half to one-third of the actual total 340B revenue for Minnesota providers due to lack of reporting from the covered entities for office administered drugs.[xxvii] Most entities did not report data for office administered drugs, which are estimated to account for 80%

of all 340B drug spending.[xxviii] The state's largest 340B hospitals benefitted most from the 340B program, accounting for 13% of reporting entities but representing 80%—more than $500 million—of net 340B revenue.[xxix]

The 340B program is a comprehensive federal program that is governed exclusively by federal law.

States do not have the authority to create new requirements that are not in the federal statute or that conflict with the statute. Whether manufacturers can be required to ship drugs to contract pharmacies for 340B providers is currently being litigated in multiple federal courts across the country.

Whether manufacturers can be required to ship drugs to contract pharmacies for 340B providers is currently being litigated in several federal courts across the country. In litigation about the federal 340B statute, U.S. Courts of Appeal for the Third Circuit and D.C. Circuit have specifically found that the federal statute does not require delivery to an unlimited number of contract pharmacies.

In January 2023, the U.S. Court of Appeals for the Third Circuit held that "[s]ection 340B [of the federal statute] does not require delivery to an unlimited number of contract pharmacies" and "Congress never said that drug makers must deliver discounted Section 340B drugs to an unlimited number of contract pharmacies." *Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs*., 58 F.4th 696 (3d Cir. 2023).

In May 2024, the U.S. Court of Appeals for the D.C. Circuit similarly held that manufacturers are not required to deliver to an unlimited number of contract pharmacies. Slip. Op. at 12, *Novartis Pharms. Corp. v. Johnson*, Nos. 21-5299, 21-5304 (D.C. Cir. May 21, 2024).

Despite ongoing activity at the federal level and in federal courts, a number of states have enacted legislation similar to H. 266 that has serious constitutional defects and is being challenged in court. In December 2024, the U.S. District Court for the Southern District of West Virginia enjoined one of those laws after finding that plaintiffs were likely to succeed on their claim that the law was preempted by federal law.

PhRMA respectfully opposes the provisions outlined above and appreciates your consideration prior to advancing H. 266.

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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are laser focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. Over the last decade, PhRMA member companies have invested more than $800 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.

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[xxvi] MDH defines “net” as the difference between the payments received for discounted drugs ($1.5 billion), and the cost of acquiring those drugs ($734 million) plus payments to external administrators ($120 million). (see p.7)
[xxvii] The Minnesota Legislature amended the transparency law in 2024 to explicitly require covered entities to report data for office-administered drugs. See 2024 Minnesota Statutes, Section 62J.461
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