NATIONAL ASSOCIATION OF Manufacturers

April 20, 2026

Chantelle Britton
Director, Office of Pharmacy Affairs
The Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Rockville, MD 20857

Re: Request for Information: 340B Rebate Model Pilot Program (Docket No. HRSA-2026-93942)

Dear Director Britton,

The National Association of Manufacturers (NAM) appreciates the opportunity to submit comments to the Department of Health and Human Services (HHS) Health Resources and Service Administration (HRSA), Office of Pharmacy Affairs (OPA) in response to its Request for Information (RFI) regarding the potential implementation of a 340B Rebate Model Pilot Program (Docket No. HRSA-2026-93942).

The NAM is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturers have a deep commitment to providing health benefits to their workers, even as rising health care costs remain a top challenge for the industry. These benefits are an effective tool to attract and retain employees and to maintain a healthy and productive workforce. Manufacturers know that keeping employees and their families healthy is the right thing to do for the workers who keep America and its economy strong. Seventy percent of manufacturers cited rising health care and insurance costs as their primary concern in the NAM's most recent Manufacturers' Outlook Survey.[1] Despite this challenge, 95% of manufacturing employees are eligible for health insurance benefits, 80% of whom participate, which underscores the urgent need for action to reduce health care costs for manufacturers and manufacturing workers alike.[2]

The NAM has long been concerned with the rapid and massive expansion of the 340B program. While manufacturers support original congressional intent of the program—to increase access to low-cost prescription drugs and medical care for low-income and underserved populations—such expansion has been to increase profits for hospitals and other covered entities. On September 8, 2025, the NAM submitted a comment letter in response to HRSA's request for public comment on its 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program (Docket No. HRSA-2025-14619), included in this comment letter as Appendix A, and request that you consider the information included therein as manufacturers' response to this RFI.

Of note, the second paragraph on the second page of our September 2025 letter includes data that shows the 340B program's contribution to the increase in premiums for employer-

[1] National Association of Manufacturers, Q1 2026 Manufacturers' Outlook Survey (March 12, 2026). Available at https://nam.org/wp-content/uploads/securepdfs/2026/03/NAM_Q1_2026_Outlook_Write_Up.pdf.

[2] Kaiser Family Foundation, *2025 Employer Health Benefits Survey* (Oct. 22, 2025). Available at https://files.kff.org/attachment/Employer-Health-Benefits-Survey-2025-Annual-Survey.pdf

sponsored insurance (ESI). Manufacturers' responses to the NAM's Q4 2025 Manufacturers' Outlook Survey demonstrated the extent of premium increases they faced for 2026. Ninety-four percent of manufacturers responded that they expected, or had already seen, an increase in health insurance premiums for 2026. Of those, 11% saw premiums rising by more than 20%, an unsustainable increase that neither manufacturers nor manufacturing workers and their families can afford.[3] While the 340B program is not solely responsible for these premium increases, it has contributed significantly to the rising costs of health care for manufacturers in America.

The NAM appreciates the OPA's consideration of these comments, including the feedback outlined in Appendix A, and urges the expeditious establishment of a 340B rebate model pilot program. The NAM would be pleased to work with OPA on a pilot program to ensure manufacturers and their workers are not disadvantaged by the 340B program, while ensuring original congressional intent to expand care for low-income and underserved populations.

Sincerely,

Jess Wysocky
Director, Health Care Policy

Jake Kuhns
Vice President, Domestic Policy

3 National Association of Manufacturers, Q4 2025 Manufacturers' Outlook Survey (December 17, 2025). Available at https://nam.org/wp-content/uploads/securepdfs/2025/12/NAM_Q4_2025_Outlook_Write_Up.pdf.

APPENDIX A

NATIONAL ASSOCIATION OF Manufacturers

Jake Kuhns

*Vice President,
Domestic Policy*

September 8, 2025

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Re: HHS Docket No. HRSA-2025-14619: 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program

Dear Administrator Engels,

The National Association of Manufacturers ("NAM") appreciates the opportunity to submit comments to the Department of Health and Human Services ("HHS") Health Resources and Service Administration ("HRSA"), Office of Pharmacy Affairs ("OPA") in response to the request for public comment on its 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program.

The NAM is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Small and medium-sized manufacturers make up the majority of manufacturing businesses in the United States and employ approximately 40% of manufacturing workers. Manufacturers have a deep commitment to providing health benefits to their workers, even as rising health care costs remain a top challenge for the industry. Sixty percent of manufacturers, and 67% of small manufacturers, cited health care costs as their primary concern in the NAM's most recent Manufacturers' Outlook Survey.[1] Despite this challenge, 93% of manufacturing employees are eligible for health insurance benefits, which underscores the urgent need for action to reduce health care costs for manufacturers and manufacturing workers alike.[2]

Employer sponsored insurance ("ESI") is the bedrock of the United States' health care system—in 2024, 154 million people were covered through ESI.[3] In 2023, the NAM released a study, *Manufacturers on the Front Lines of Communities: A Deep Commitment to Health Care*, which took an in-depth look at the progress made by manufacturers in offering ESI, as well as the challenges they continue to face.[4] The study found that ESI helps manufacturers effectively attract talent, retain employees, and maintain a healthy and productive workforce. Manufacturers are committed to continuing to offer health insurance to their employees and recommend steps be taken to ease the burden they face.

---

[1] National Association of Manufacturers, Q2 2025 Manufacturers' Outlook Survey (May 30, 2025). Available at https://nam.org/2025-second-quarter-manufacturers-outlook-survey/.
[2] Kaiser Family Foundation, *2024 Employer Health Benefits Survey* (Oct. 9, 2024). Available at https://files.kff.org/attachment/Employer-Health-Benefits-Survey-2024-Annual-Survey.pdf
[3] *Id.*
[4] National Association of Manufacturers, *Manufacturers on the Front Lines of Communities: A Deep Commitment to Health Care* (July 2023). Available at https://documents.nam.org/IIHRP/2023%20Health%20Care%20Reportsingles.pdf.

One such step is the 340B Rebate Model Pilot Program. The 340B program, intended to provide lower cost medicines and expand care for low-income and underserved patients, has rapidly and massively expanded beyond this intent. Many covered entities have taken advantage of the program to increase their profits, which has become a cost driver of ESI. In fact, 340B is now the second largest federal health care program and is on pace to eclipse Medicare Part D in the coming years.[5] The 340B program allows participating hospitals to charge patients' commercial insurance the full list price for drugs acquired at 340B prices, which makes patients and employers ineligible to receive a rebate, as it would be a duplicate discount. Patients and employers end up paying more while hospitals keep the spread of full reimbursement by commercial insurance for drugs acquired at the low 340B price.

The expansion of this program was associated with approximately $23 billion in additional employer-based healthcare expenses in 2023, of which employees paid about $4.5 billion per year in added insurance premiums.[6] That equals approximately $137 in additional annual premium costs for single coverage and $415 for family coverage, or about 8% of the overall increase in employer-based premiums over that period. An IQVIA study found that the 340B program increases drug costs for self-insured employers and their workers by 4.2% due to the manufacturer rebates that are lost when drugs are purchased at the 340B discount price.[7] This equals a $5.2 billion increase in healthcare costs for self-insured employers and the 103.4 million workers they employ.[8] The study also found that states with a higher density of 340B-affiliated hospital sites have employer premiums that are about 4.5% higher than lower-density states. Overall, the program has led to a massive increase in expenses for employers without the corresponding health outcomes for the patient population it was intended to serve.

Manufacturers believe the 340B program is an important tool in expanding care for underserved communities and urge fundamental changes that would restore this program to its core purpose. Abuse of the program in the name of hospital profits has hurt manufacturers and their employees, contributing to the ever-increasing costs of health care for the industry.

This pilot program is a critical first step in enhancing program integrity and transparency in a way that makes the 340B program work for everyone. As the 340B program currently operates, manufacturers lose out on negotiated rebates due to factors including duplicate discount issues, limited operational oversight, and lack of regulation. The rebate model pilot program will increase transparency, which will help inform reforms to the 340B program and enable manufacturers to take advantage of negotiated rebates and lower health care costs.

Additionally, the rebate model pilot program will demonstrate that a rebate model is feasible, not just for drugs in the Medicare Drug Price Negotiation Program, but for all 340B drugs. The NAM appreciates that OPA is working with pharmaceutical manufacturers to determine the specifics of the pilot program. Such collaboration will ensure greater transparency to the 340B program.

While this pilot program is needed, it will not be fully sufficient in reforming the 340B program, and manufacturers will continue to advocate for additional reforms. As a next step, manufacturers

---

[5] BRG, Measuring the Relative Size of the 340B Program. Available at https://media.thinkbrg.com/wp-content/uploads/2022/06/30124832/BRG-340B-Measuring-Relative-Size-2022.pdf

[6] National Pharmaceutical Council, The 340B Drug Purchasing Program and Commercial Insurance Premiums. Available at https://www.npcnow.org/sites/default/files/2025-05/340B%20and%20Employer%20Costs%20White%20Paper.pdf

[7] IQVIA, The Cost of the 340B Program Part 1: Self-Insured Employers. Available at https://www.iqvia.com/locations/united-states/library/white-papers/the-cost-of-the-340b-program-part-1-self-insured-employers

[8] Ibid.

recommend and respectfully request that OPA consider quick expansion of the pilot program to all 340B drugs, which would ensure the integrity of the 340B program by increasing transparency and protecting congressional intent. Thoughtful implementation of a program-wide rebate model would support the goals of the 340B program, as safety net hospitals and clinics would continue to be able to stretch their limited resources further and continue to serve vulnerable patients with access to more affordable drugs. The rebate model would also create transparency and accountability to ensure 340B drug prices are used appropriately and the program is not abused.

The NAM appreciates OPA's consideration of these comments and looks forward to working with you to ensure the 340B program is fully transparent and no longer taken advantage of at the expense of manufacturers and manufacturing workers.

Sincerely,

Jake Kuhns
Vice President, Domestic Policy