

# CO-SIGN BIPARTISAN LETTER URGING HHS TO PROTECT THE INTEGRITY OF THE 340B DRUG DISCOUNT PROGRAM

**DEADLINE:** COB Thursday, June 23rd

**Supported by:** 340B Health, National Association of Community Health Centers, America's Essential Hospitals, Hemophilia Alliance

**Current Co-Signers:** Adams, Barragán, Beyer, Bishop, Blumenauer, Bost, Castor, Cleaver, Davis, DeGette, Fitzpatrick, García, Hartzler, Hayes, Langevin, Lawrence, Lynch, Norton, Pappas, Ruppertsberger, Schakowsky, Sewell, Smith, Suozzi, Tonko, Underwood, Wild, Williams, Wittman

Dear friends,

Please join Reps. Spanberger, McKinley, Matsui, Johnson, Axne, and Katko on the below bipartisan letter to HHS Secretary Becerra, HRSA Administrator Johnson, and HHS Inspector General Grimm urging them to begin enforcement actions against pharmaceutical companies that refuse to honor 340B discounts on prescription drugs.

In the summer of 2020, six pharmaceutical companies began withholding 340B discounts from safety-net providers and federal grantees. Both the current Administration and the previous Administration reviewed the companies' actions and found them to be illegal. In March 2021, [226 bipartisan U.S. Representatives](#) wrote to HHS saying the drug companies' actions were unlawful and urged the agency to penalize the drug companies and protect safety net providers from exorbitant price hikes.

Unfortunately, HHS has still not levied any sanction on the companies, who have refused to comply with the law and continue to overcharge safety net providers. HHS's inaction over the past 15 months has emboldened at least 11 more companies to begin withholding discounts, bringing the total number of non-compliant companies to 17 and threatening the integrity of the entire program.

The 340B program is an essential source of support for federally qualified health centers, Ryan White HIV/AIDS Clinics, safety net hospitals, and other federal grantees. Every time that a pharmaceutical company overcharges one of these providers for a drug, that company is taking resources from the health care safety net Congress intended to support.

It's time to renew our call that the agencies take an enforcement action to protect and preserve this important program

Sincerely,

Abigail D. Spanberger

David B. McKinley P.E. Doris Matsui

Dusty Johnson

Cindy Axne

John Katko

June XX, 2022

The Honorable Xavier Becerra

Secretary

Department of Health and Human Services

200 Independence Ave SW

Washington, DC 20201

Dear Secretary Becerra:

As leading supporters of the 340B drug pricing program, we urge you to take quick action to protect the integrity of the program and ensure its benefits reach providers and their vulnerable patients, as Congress intended.

Specifically, we urge the Department of Health and Human Services (HHS) and its Office of the Inspector General (OIG) to use current statutory authority to impose civil monetary penalties against all drug manufacturers who have unlawfully overcharged safety net health care providers. Manufacturers have received multiple warnings that their overcharges are unlawful, but still refuse to comply. Further delay of enforcement actions emboldens more manufacturers to begin overcharging safety net providers, threatening the integrity of the entire 340B program.

In February 2021, a majority of the U.S. House of Representatives signed a letter urging HHS to act in response to six drug manufacturers' refusal to honor 340B discounts on their products. Unfortunately, since we sent that letter more than a year ago, at least 11 more manufacturers have announced similar policies restricting access to the 340B program and overcharging providers. These companies' actions have increased costs for federal grantees and other safety net providers and have reduced patient access to care in vulnerable communities.

We appreciate that HHS has taken steps to protect the 340B program. HHS sent warning letters to eight drug manufacturers and referred seven of those companies to the OIG to evaluate whether to impose civil monetary penalties.<sup>[1]</sup> The OIG is authorized to impose civil monetary penalties against manufacturers that knowingly and intentionally overcharge 340B hospitals and health centers.<sup>[2]</sup> However, more than eight months after receiving the first referrals, the OIG has yet to take any enforcement action and these manufacturers continue to unlawfully overcharge safety net providers.

Therefore, we urge OIG to conclude its review of the seven referrals as soon as possible and begin imposing civil monetary penalties against manufacturers it finds in violation of the law. We also request HHS initiate enforcement actions against the remaining ten drug companies that have implemented overcharge policies but have not yet been referred to the OIG. These actions are essential to bring manufacturers back into compliance with their responsibilities under the statute and to deter other manufacturers from pursuing similar unlawful courses of action.

Every day that drug manufacturers violate their obligation to provide these discounted drugs, vulnerable communities, federal grantees, and safety net health care providers are deprived of resources Congress intended to provide. Thank you for your prompt attention to this urgent matter.

Sincerely,

CC: Christi A. Grimm  
Inspector General  
Department of Health & Human Services  
Office of Inspector General  
330 Independence Avenue, SW  
Washington, DC 20201

Carole Johnson

Administrator

Health Resources and Services Administration

U.S. Department of Health and Human Services

5600 Fishers Lane

Rockville, MD 20857

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<sup>[1]</sup> HRSA Correspondence to Stakeholders, Letters to United Therapeutics Corporation, Sanofi, Novo Nordisk, Novartis Pharmaceuticals Corporation, Eli Lilly and Company, AstraZeneca Pharmaceuticals, Boehringer Ingelheim, and Merck Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, <https://www.hrsa.gov/opa/program-integrity/index.html>.

<sup>[2]</sup> 42 U.S.C. § 256b(d)(1)(B)(vi); 42 C.F.R. §10.11(a).