

U.S. Sen. Baldwin: Leads bipartisan effort in urging action to address practices of pharmaceutical companies undermining 340B Program

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WASHINGTON, D.C. – U.S. Senator Tammy Baldwin (D-WI), a member of the Senate Committee on Health, Education, Labor and Pensions (HELP), is leading a bipartisan group of her colleagues in calling for enforcement action to address practices of pharmaceutical companies that threaten to undermine the 340B Drug Pricing Program during the COVID-19 public health emergency.

The 340B program requires drug companies to sell discounted prescription drugs to safety net hospitals, rural health facilities, and other entities that provide care in underserved communities. Savings from the 340B program ensure that these “covered entities” are able to continue to serve their patients. However, drug manufacturers have recently announced new burdensome requirements on covered entities beyond the scope of the 340B program, or they have announced that they will no longer provide discounts for medications shipped to pharmacies that dispense drugs to patients on behalf of covered entities.

In their letter to Health and Human Services Secretary Alex Azar, the bipartisan group of Senators urge the administration to take immediate enforcement action to halt these tactics and ensure safety-net providers are able to continue providing life-saving medications to patients across the country.

The Senators write, *“In the midst of the ongoing COVID-19 pandemic, where providers have seen drops in revenue and available resources, it is critically important that 340B covered entities, including federally qualified health centers (FQHCs), FQHC Look-Alikes, children’s hospitals, Ryan White HIV/AIDS clinics, and other safety-net hospitals and providers are able to continue to serve the individuals who seek out their care. As these threats to the Program progress, we fear the potential exacerbation of these shortfalls in resources for providers at a time when they are needed most.”*

The bipartisan letter was also signed by Senators Rob Portman (R-OH), Debbie Stabenow (D-MI), Shelley Moore Capito (R-WV), John Thune (R-SD), Ben Cardin (D-MD), Patty Murray (D-WA), Susan Collins (R-ME), Ron Wyden (D-OR), Jerry Moran (R-KS), Jon Tester (D-MT), Mike Rounds (R-SD), Doug Jones (D-AL), Joni Ernst (R-IA), Gary Peters (D-MI), John Boozman (R-AR), Bob Casey (D-PA), Cindy Hyde-Smith (R-MS), Mark Warner (D-VA), Roger Wicker (R-MS), Angus King (I-ME), Kevin Cramer (R-ND), Chuck Schumer (D-NY), Thom Tillis (R-NC), Chris Van Hollen (D-MD), Elizabeth Warren (D-MA), Sherrod Brown (D-OH), and Kirsten Gillibrand (D-NY).

This bipartisan effort is supported by the American Hospital Association (AHA), America’s Essential Hospitals, American Association of Medical Colleges (AAMC), 340B Health, Ascension Wisconsin, Children’s Wisconsin, Marshfield Health System, Gunderson Health System, Advocate Aurora, Rural Wisconsin Health Cooperative, and Sixteenth Street Community Health Centers in Milwaukee.

“The AHA thanks this bipartisan group of senators for their important effort to protect the 340B program, and the vulnerable communities it benefits, from big drug companies’ efforts to harm the program,” **said Tom Nickels, AHA Executive Vice President.** “The AHA continues to call on the Department of Health and Human Services to take action against drug companies and to protect the patients and communities the 340B program helps serve.”

“Drug manufacturers are flouting their statutory obligations by restricting access to safe, affordable medications for low-income Americans who also are among those most affected by COVID-19,” **said Bruce Siegel MD, MPH, President and CEO**

of America's Essential Hospitals. “We applaud the bipartisan Senate signatories, led by Sens. Baldwin, Thune, Stabenow, Portman, Cardin, and Capito, for their swift action to urge the administration to stop big pharma’s ill-timed and illegal efforts to narrow the 340B program.”

“The AAMC appreciates Senators from both sides of the aisle working together to protect the 340B program and patients,” **said Karen Fisher, JD, Chief Public Policy Officer of the Association of American Medical Colleges.** “Particularly in the midst of the COVID-19 pandemic, it is unwarranted that several major drug companies are attempting to undermine this important program that allows safety net hospitals, including many teaching hospitals, to provide critical health care services to vulnerable patients in communities across the country.”

“340B has a long history of bipartisan support in Congress. Drug companies must stop denying discounts on expensive outpatient drugs in violation of the 340B statute. We appreciate the efforts of these Senate leaders in making that message crystal clear,” **said Maureen Testoni, President and CEO of 340B Health.**

“Wisconsin rural hospitals and communities need a strong 340B Program, now more than ever. The current program saves Medicare money and achieves the Congressional purpose to reach more eligible patients and providing more comprehensive services,” **Tim Size, Executive Director of Rural Wisconsin Health Cooperative.**

“Coordinated efforts by drug manufacturers to place arbitrary limits on the number of contract pharmacies they will serve or to eliminate discounted 340B pricing will significantly impact the health of our most vulnerable patients. Some medications will not be available for uninsured patients through the sliding fee scale. And without the savings accrued from 340B pricing, health centers will no longer be able to offer affordable pharmaceuticals to low-income patients — thereby directly jeopardizing the health of the uninsured or underinsured. We need immediate support from Congress and HRSA to stop recent actions from drug manufacturers and prevent others from following suit,” **said Dr. Julie Schuller, President and CEO of Sixteenth Street Community Health Centers.**

“We appreciate the Senator’s continued support of safety net providers. From our Medical Mission events, providing free care in our communities, to supporting new moms through Blanket of Love in Milwaukee – the 340B Program helps us care for our communities. Ascension continues to experience substantial increases in the costs to acquire needed medication, and we applaud the bipartisan effort to urge HRSA to take enforcement action to protect the 340B Program,” **said Bernie Sherry, Ministry Market Executive at Ascension Wisconsin.**

The full letter is available [here](#) and below. An online version of this release is available [here](#).

Dear Secretary Azar:

We write to express our concerns regarding recent actions from pharmaceutical manufacturers that threaten to undermine the role of contract pharmacies in the 340B Drug Pricing Program. In the midst of the ongoing COVID-19 pandemic, where providers have seen drops in revenue and available resources, it is critically important that 340B covered entities, including federally qualified health centers (FQHCs), FQHC Look-Alikes, children’s hospitals, Ryan White HIV/AIDS clinics, and other safety-net hospitals and providers are able to continue to serve the individuals who seek out their care. As these threats to the Program progress, we fear the potential exacerbation of these shortfalls in resources for providers at a time when they are needed most. While we understand that the Health Resources and Services Administration (HRSA) is further investigating these actions, we urge HRSA to take immediate and appropriate enforcement action to halt these tactics and ensure safety-net providers are able to continue providing life-saving medications to patients across the country.

As you are aware, on September 1, 2020, Eli Lilly announced that the company would no longer allow 340B covered entities to receive discounts for products that are shipped to a contract pharmacy, with an exception for insulin. This follows similar actions from AstraZeneca, which announced in August that it would refuse 340B pricing to hospitals with on-site pharmacies for any drugs dispensed through

contract pharmacies. Similarly, other companies have imposed additional and burdensome reporting requirements on all contract pharmacy claims. For covered entities, and in particular rural hospitals and other rural covered entities that rely disproportionately on contract pharmacies, these changes could have long-lasting repercussions that will challenge a covered entity's ability to support its community now during this pandemic and in the future.

The Public Health Service Act requires that manufacturers wishing to participate in Medicaid and Medicare Part B enter into agreements with the Department of Health and Human Services (HHS) that "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." Further, HRSA has recognized the importance of contract pharmacies by acknowledging such arrangements in current guidance. We believe these recent actions by pharmaceutical manufacturers run counter to the statute and create a dangerous and negative precedent for the 340B Program and the providers and patients it serves.

To ensure pharmaceutical manufacturers continue to comply with the 340B statute and provide discounts to safety-net providers, we call on HRSA to take appropriate, prompt enforcement action to address violations of the Public Health Service Act. We appreciate your attention to this important issue and look forward to partnering with you and stakeholders to ensure the 340B program continues to support access to quality health services with proper oversight and transparency.

Sincerely,