

United States Senate
WASHINGTON, DC 20510

September 17, 2020

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

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,

/s/ Tammy Baldwin
Tammy Baldwin
United States Senator

/s/ Debbie Stabenow
Debbie Stabenow
United States Senator

/s/ Benjamin L. Cardin
Benjamin L. Cardin
United States Senator

/s/ Patty Murray
Patty Murray
United States Senator

/s/ Ron Wyden
Ron Wyden
United States Senator

/s/ Jon Tester
Jon Tester
United States Senator

/s/ Doug Jones
Doug Jones
United States Senator

/s/ Gary C. Peters
Gary C. Peters
United States Senator

/s/ Rob Portman
Rob Portman
United States Senator

/s/ Shelley Moore Capito
Shelley Moore Capito
United States Senator

/s/ John Thune
John Thune
United States Senator

/s/ Susan M. Collins
Susan M. Collins
United States Senator

/s/ Jerry Moran
Jerry Moran
United States Senator

/s/ M. Michael Rounds
M. Michael Rounds
United States Senator

/s/ Joni K. Ernst
Joni K. Ernst
United States Senator

/s/ John Boozman
John Boozman
United States Senator

/s/ Robert P. Casey, Jr.
Robert P. Casey, Jr.
United States Senator

/s/ Mark R. Warner
Mark R. Warner
United States Senator

/s/ Angus S. King, Jr.
Angus S. King, Jr.
United States Senator

/s/ Charles E. Schumer
Charles E. Schumer
United States Senator

/s/ Chris Van Hollen
Chris Van Hollen
United States Senator

/s/ Elizabeth Warren
Elizabeth Warren
United States Senator

/s/ Cindy Hyde-Smith
Cindy Hyde-Smith
United States Senator

/s/ Roger F. Wicker
Roger F. Wicker
United States Senator

/s/ Kevin Cramer
Kevin Cramer
United States Senator

/s/ Thom Tillis
Thom Tillis
United States Senator

/s/ Sherrod Brown
Sherrod Brown
United States Senator

/s/ Kirsten Gillibrand
Kirsten Gillibrand
United States Senator