

Congress of the United States
Washington D.C. 20515

September 14, 2020

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

Dear Secretary Azar:

The 340B program plays an integral role in ensuring eligible health care organizations have access to vital lifesaving medications. As Members of Congress deeply committed to the important safety net mission of the 340B Drug Pricing Program, it is imperative that immediate action is taken to ensure covered entities continue to receive crucial 340B drug discounts.

Recently, several pharmaceutical companies have taken a series of actions to restrict federally required 340B drug discounts for eligible health care organizations/covered entities, which are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers. These providers have always served as a critical part of our health care safety net, ensuring that our most vulnerable populations have access to the care they need. Right now, they are on the front lines of our national response to COVID-19. These providers rely on 340B savings to ensure access to care for low-income and rural patients. The recent actions undermine the intended purpose of the 340B Drug Pricing Program. The Department of Health and Human Services (HHS) must take immediate action to stop these companies from either denying or limiting access to 340B pricing to hospitals, health centers, and clinics participating in 340B.

Congress enacted 340B with strong bipartisan support more than 25 years ago to reduce drug costs for safety-net providers that care for vulnerable populations. Congress clearly stated the law's purpose: "To stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." The savings created by 340B do not cost the American taxpayer a single dollar, as the savings come directly from discounts provided by the manufacturers. Specifically, the 340B statute requires manufacturers wishing to participate in Medicaid and Medicare Part B to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." There are no provisions in the statute that allow manufacturers to set conditions or otherwise impede a provider's ability to access 340B discounts.

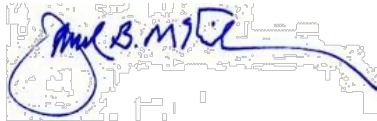
Despite this statutory requirement, several major drug manufacturers have recently announced that they will limit or restrict 340B pricing based on where the safety-net provider elects to have its 340B drugs shipped. These actions are in violation of the statutory requirement that drug companies charge no more than the 340B ceiling price when selling their products to 340B providers. They establish a dangerous precedent for other manufacturers to follow if immediate action is not taken.

Additionally, within the past two months, other manufacturers have sent requests to covered entities demanding extensive claims data that goes far beyond the scope of the 340B statute. These demands are not only needlessly burdensome for providers but also raise issues related to patient privacy. These companies are also threatening to limit or deny 340B pricing if these covered entities do not comply.

The actions of these companies violate the 340B statute and must be rejected. A failure to act will serve as an invitation to other manufacturers to follow suit, leading to a wholesale increase in prescription drug costs for our safety-net providers during a public health emergency. We urge you to use your authority to address these troubling actions and require these companies to comply with the law.

Thank you for your attention to these matters. Should you have any questions please contact Kirsten Wing with Representative David B. McKinley's office at Kirsten.Wing@mail.house.gov or Sherie Lou Santos with Representative Diana DeGette's office at SherieLou.Santos@mail.house.gov.

Sincerely,

A blue ink signature of David B. McKinley, featuring a stylized 'D' and 'M'.

David B. McKinley P.E.
Member of Congress

A blue ink signature of Diana DeGette, written in a cursive style.

Diana DeGette
Member of Congress

A blue ink signature of Greg Gianforte, featuring a stylized 'G' and 'J'.

Greg Gianforte
Member of Congress

A blue ink signature of Peter Welch, written in a cursive style.

Peter Welch
Member of Congress

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Dusty Johnson
Member of Congress

A blue ink signature of Doris Matsui, written in a cursive style.

Doris Matsui
Member of Congress

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Ralph Abraham
Member of Congress

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Earl Blumenauer
Member of Congress

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Tony Cardenas
Member of Congress

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Alma S. Adams, Ph.D.
Member of Congress

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Lisa Blunt Rochester
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André Carson
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Xochitl Torres Small
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Ann Wagner
Member of Congress