

September 15, 2020

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

Dear Secretary Azar:

I write to you with concerns over the actions taken in recent weeks by pharmaceutical manufacturers towards health providers negatively impacting their 340B programs. These actions come during the ongoing public health emergency when providers' need for additional resources to serve the poor and underserved has never been greater. The aggressive actions of the manufacturers will limit 340B arrangements with contract pharmacies within the 340B Drug Pricing Program. I ask that, under your direction, the Health Resources and Services Administration (HRSA) notify these companies that their actions are counter to the guidance governing the program and they must cease and reverse these policies.

The 340B program was created in 1992 to provide much needed savings to enable entities to stretch scarce federal resources as far as possible reaching more eligible patients and providing more comprehensive services. In 1996, HRSA set forth guidance that created contract pharmacies (61 FR 43549, August 23, 1996) specifically to allow covered entities "participating in the 340B Drug Pricing Program to contract with a pharmacy to provide services to the covered entity's patients. HRSA further clarified the guidance most recently in 2010 (75 Fed. Reg. 10272, March 5, 2010) stating, "Covered entities will be permitted to use multiple pharmacy arrangements as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition."

In the past few weeks, several pharmaceutical manufacturers notified covered entities of various policy changes that would impact their usage of contract pharmacies under the program. Most recently, both Astra Zeneca and Eli Lilly announced to providers and wholesale pharmacy contact partners that they only will process 340B pricing through a single contract pharmacy site for covered entities. This follows the notice from Novartis, Merck, and Sanofi their intention to collect and analyze 340B covered entities' contract pharmacy claims data to mitigate duplicate 340B drug discounts and "ineligible rebates." These actions are either in direct violation of the HRSA guidance and/or the various 340B entity contracts.

It has been reported that HRSA is undertaking an investigation into these issues, as these policies are counter to the intention of the 340B Program as well as the governing policies of the program, I request that you notify the manufacturers of the possible violations and instruct them to reverse the stated policies as the investigation moves forward.

Thank you for working to ensure access to affordable medications for low income patients. I appreciate your attention to this matter and look forward to working together to address this pressing issue.

Sincerely,

A handwritten signature in blue ink, appearing to read "Joe Manchin III". The signature is fluid and cursive, with a large initial "J" and a long horizontal stroke at the end.

Joe Manchin III  
United States Senator