

October XX, 2020

Secretary Alex Azar
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington DC, 20201

Dear Secretary Azar,

We write to express our grave concern about measures being considered by drug manufacturers that threaten safety net providers' lawful access to discounted drugs through the 340B Program. It is doubly troubling that these actions, which threaten the needs of the most vulnerable patients and the integrity of the health care safety net, are occurring in the midst of a global pandemic. We urge you to take action to prevent significant changes to the program that could enable widespread noncompliance with manufacturers' statutory responsibility to provide discounted drugs to safety net providers.

Following the creation of the Medicaid Drug Rebate Program, Congress enacted the 340B Drug Pricing Program in 1992 with the intent to "stretch scarce federal resources to reach more eligible patients and provide more comprehensive services." As you know, Section 340B of the Public Health Service Act requires drug manufacturers, in exchange for having their drugs covered by Medicaid and Medicare Part B, to enter into a pharmaceutical pricing agreement with the Department of Health and Human Services (HHS). The Health Resources and Services Administration (HRSA) administers and oversees the program, including the authority to issue guidance and ensure compliance with 340B program requirements.

340B program covered entities – including Federally Qualified Health Centers, Ryan White HIV/AIDS Clinics, safety net hospitals, rural hospitals, and children's hospitals – help improve access to affordable prescription drugs and essential health services in underserved areas. Right now, these providers are also working to protect the health and safety of their patients as we combat COVID-19. The safety net providers in our districts have been good stewards of the 340B program, and it is critical they can continue to participate in the program to meet their communities' health care needs.

We are deeply concerned by reporting that Kalderos, a third-party vendor, is working with pharmaceutical manufacturers seeking to change how covered entities receive 340B drugs by shifting from a discount to a rebate formula. On September 8th, Kalderos announced the launch of 340B Pay, a software system it claims, "allows manufacturers, covered entities and Medicaid agencies to work together to effectuate discounts compliantly and efficiently." However, unilaterally forcing 340B participants to purchase drugs at list price and then request rebates would give drug manufacturers tremendous leverage over covered entities.

This action is also inconsistent with HRSA's long-standing guidance that the 340B program is an up-front discount program. HRSA issued guidance in both 1993 and 1994 stating that discounts must be made available to 340B covered entities.^[1] In addition, HRSA has previously only allowed the use of a rebate model in a limited case, and only after issuing guidance through the notice-and-comment process and soliciting feedback from stakeholders.^[2]

This platform could make participation in 340B more difficult for covered entities, effectively reshaping the 340B program in a way that only serves manufacturers' and these third-party vendors' financial interests. These tactics open the door for significant compliance issues, threatening to put manufacturers in violation of their statutory obligation to provide 340B pricing.

With these concerns in mind, we request the following information by November 1, 2020:

1. Has Kalderos, any other third-party vendor, or any drug company sought input from HHS regarding the use of a rebate model covered entities?
2. What guidance has HHS provided to Kalderos, any other third-party vendors, or drug companies regarding the use of a rebate model for covered entities?
3. What oversight, if any, would HRSA have into the operations of 340B Pay or similar third-party platforms that provide manufacturers with significantly more authority over the 340B program and jeopardize their compliance with 340B statutory requirements?
4. What steps would be taken to ensure that drug companies not deny 340B pricing to covered entities and that covered entities would be able to access 340B pricing in a timely manner and without facing unnecessary administrative or financial burden?

We are deeply concerned that the use of a rebate model could threaten the ability of covered entities to access 340B savings and provide accessible, affordable prescription drugs and critical health care services to millions of low-income Americans the 340B program is intended to serve. To protect safety net providers and their patients, we urge you to make clear that manufacturers may not implement a 340B rebate model without approval from HRSA. Further, we urge HRSA not to approve the use of a rebate model without first soliciting feedback and publishing guidance through the notice-and-comment process, consistent with past actions by HRSA.

Thank you for your prompt attention to these matters.

Sincerely,

Abigail D. Spanberger

Cindy Axne

Doris Matsui

David B. McKinley

Dusty Johnson

John Katko

^[1] Limitation on Prices of Drugs Purchased by Covered Entities, 58 Fed. Reg. 27289, 27291 (May 7, 1993); Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25110, 25113 (May 13, 1994).

^[2] See Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992— Rebate Option, 63 Fed. Reg. 35239 (June 29, 1998).