United States Senate
WASHINGTON, DC 20510

January 8, 2021

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 actions being considered by pharmaceutical manufacturers that would undermine the integrity of the 340B Drug Pricing Program and violate federal law. These actions would significantly threaten the ability of 340B covered entities to access 340B savings and could result in denial of 340B pricing altogether. The safety net health care providers who could suffer as a result of this move are a lifeline to patients across the country, and are on the frontlines of the ongoing pandemic and many other public health crises. We urge the Health Resources and Services Administration (HRSA) to take immediate action to clarify that implementation of a rebate model by manufacturers would violate a material condition of the 340B Drug Pricing Program.

Several drug manufacturers are reportedly considering using the services of Kalderos, a drug information technology company, to implement a rebate model that would replace the 340B Drug Pricing Program up-front discount. This model would require 340B covered entities to purchase covered drugs up front at higher "sticker" prices and then request payment of the rebate once the drugs are dispensed. According to its website, Kalderos "is contracting with several manufacturers," and once a manufacturer decides to use the Kalderos rebate program, 340B covered entities must participate "to receive the 340B price." [1] While the rebate model may be marketed as optional for 340B entities, the practical impact will leave 340B entities who depend on access to 340B savings to fund services for low-income and rural patients with little choice but to participate.[2] The rebate model would continue to single out and penalize 340B entities that rely on contract pharmacies, and there is no guarantee that these providers would eventually receive 340B savings.

Under the Public Health Service Act, manufacturers wishing to participate in Medicaid and Medicare Part B must enter into agreements with the Department of Health and Human Services (HHS) requiring them to "offer each covered entity covered outpatient drugs for purchase at or

[1] Kalderos, Webinar FAQs, September 2, 2020 webinar "addressing 340B rebates," available at: https://f.hubspotusercontent40.net/hubfs/7227094/Kalderos_Program%20Integrity%20through%20340B%20%20Rebates%20Webinar%20FAQs.pdf

[2] Last month, Kalderos announced changes to its rebate model after hearing concerns from covered entities. However, the Kalderos rebate program continues to undermine the integrity of the 340B program; the revised rebate model will still apply to all covered entities that use contract pharmacies. Kalderos press release, December 15, 2020, https://www.prnewswire.com/news-releases/kalderos-upgrades-340b-pay-platform-giving-covered-entities-more-options-301193543.html

below the applicable ceiling price if such drug is made available to any other purchaser at any price." In addition, last week, HHS's Office of General Counsel issued an advisory opinion reiterating that "manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price."[3] We are concerned that allowing manufacturers to replace the program's point-of-sale discount requirement with a new rebate model would not only negatively impact 340B providers and the millions of patients they serve, but would also undermine the integrity of the 340B program.

In the midst of a worsening COVID-19 pandemic, the transition to a rebate model would make participation in the 340B Drug Pricing Program more difficult and severely strain the resources of 340B entities and providers who have been on the frontline for months. Furthermore, many 340B 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, simply do not have the resources to purchase covered drugs at higher prices and then wait for an undetermined period of time for a rebate that is not guaranteed. Many covered entities have also raised concerns over potential negative implications of data sharing that would accompany rebate requests.

Last month, HRSA notified Congress that it is reviewing various proposals by drug manufacturers that limit access to 340B drugs to determine whether they violate the 340B statute and whether sanctions may apply.[4] We urge HRSA to include a review of the Kalderos rebate model as part of this effort. HRSA has long recognized that safety-net providers should not bear the burden of waiting for the discounts to which they are entitled under the 340B statute. We believe a rebate model violates both the spirit and the letter of the law, which requires manufacturers to offer 340B pricing to 340B-covered entities, and we call on HRSA to take action to prevent its implementation.

We appreciate your attention to this important issue.

Sincerely,

Patty Murray
United States Senator

Tammy Baldwin
United States Senator

[3] HHS Office of General Counsel, Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program, December 30, 2020.

[4] December 9, 2020, letter from Thomas Engels, Administrator, HRSA, in response to a September 17, 2020, letter from a bipartisan group of 28 senators on actions from pharmaceutical manufacturers that threaten to undermine the role of contract pharmacies in the 340B Drug Pricing Program.

CC: Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services

Jeremy Docken
Chief Executive Officer
Kalderos, Inc.