American Hospital Association™
Advancing Health in America

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October 30, 2020

RADM Krista Pedley
Director
Office of Pharmacy Affairs
Health Resources & Services Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Admiral Pedley:

On behalf of the American Hospital Association's (AHA) nearly 2,000 340B member hospitals, we are writing to you to express our concerns regarding recent actions taken by the major drug manufacturers to thwart the purpose of the 340B program.

In this latest assault on the 340B program, drug manufacturers are looking to convert the means by which covered entities access discounted 340B pricing from an upfront discount to a back-end rebate. This approach complicates covered entities' access to discounts, requires financially strapped organizations provide upfront financing and await reimbursement, and adds considerable burden and cost to the health care system. This fundamental change threatens the integrity of the 340B program and the savings on which covered entities rely to provide care to millions of low-income Americans. Suffice to say, this harmful action directly subverts Congress' intent when it established the program more than 25 years ago to allow 340B providers to "stretch scarce federal resources to reach more eligible patients and provide more comprehensive services."

We urge you to intervene and stop the drug manufacturers from employing these pernicious tactics to drastically change the 340B drug program, and ensure that 340B drugs remain available and accessible to vulnerable communities.

In September, Kalderos, a third-party analytics vendor sponsored by the major drug manufacturers, launched a new program called 340B Pay. Under this program, 340B providers would no longer have point-of-purchase access to 340B prices. Instead, providers would be required to first purchase drugs at higher, non-340B prices; providers would then submit requests for rebates after the drugs are dispensed. In addition, providers would need to submit detailed claims information to Kalderos and the pharmaceutical companies, which would then unilaterally validate which claims are

eligible for 340B pricing and not subject to a Medicaid rebate. After completion of this intentionally cumbersome process, the manufacturer would determine the appropriate rebate amount; only then would payment be remitted to 340B providers.

Kalderos and its clients are attempting to masquerade this fundamental change to the 340B program as simply a new software management tool. But this new rebate model violates federal policy. Specifically, federal statute is clear that drug manufacturers are to enter into a pharmaceutical pricing agreement (PPA) with the Department of Health and Human Services (HHS) in exchange for having their drugs covered by Medicaid and Medicare Part B[1]. It appears that the drug manufacturers – through Kalderos as its sponsored third-party vendor – are in fact changing their PPAs without approval from HHS or the Health Resources and Services Administration (HRSA), the sub-agency that oversees the 340B program. In addition, this rebate model is in direct violation of HRSA's own guidance that established the 340B program as an up-front discount program.[2]

Furthermore, this new rebate-pricing model would add significant burden and cost to the health care system. Providers would need to reconfigure IT systems to collect and report this data and divert significant staff resources away from caring for patients and toward submitting to Kalderos and drug manufacturers required claims data along with any additional follow-up information.

At the same time, the drug manufacturers and Kalderos are *adding* costs to the health care system through increased administrative burden; they are also intentionally withholding from 340B-covered entities the financial resources used to provide their communities with critical health care services.

The drug manufacturers and Kalderos' approach decimates the entire point of the 340B program: 340B-covered entities do not have the financial resources to extend access to care without these discounts. If they are required to pay drug manufacturers full price for drugs upfront, vulnerable communities across the country could be in jeopardy of losing medication therapy management programs, opioid treatment centers and mental health counseling services. The drug companies are exploiting the current COVID-19 health care crisis to subvert the 340B program while government regulators have their attention focused on addressing the pandemic. Our communities would lose a key resource to care for their most vulnerable citizens so that drug manufacturers and their third-party vendors can continue to rake in astronomical profits.

Drug manufacturers continue to flaunt the 340B statute and guidance with the sole purpose of increasing their profits. These callous and unconscionable actions come at a time when hospitals throughout the nation are under severe stress by the need to

[1] https://www.hrsa.gov/sites/default/files/opa/programrequirements/phsactsection340b.pdf
[2] 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).

prepare for, and/or care for, COVID-19 patients, while coping with the financial damages inflicted by the pandemic. HHS' own general counsel in his recent letter to Eli Lilly regarding the 340B contract pharmacy issue echoed this very concern regarding 340B hospitals' precarious financial health.[3] Specifically, the letter highlighted that one drug company's income increased more than 14 percent, from $1.4 billion during the second quarter of 2019 to $1.6 billion for the second quarter of 2020, while during this same period "most health care providers, many of which are covered entities under section 340B, were struggling financially and requiring federal assistance from the Provide Relief Fund established by the CARES Act."

We therefore urge you to order drug manufacturers and their vendor Kalderos to immediately halt their conversion of the 340B program to a back-end rebate program.

They should not be permitted to put their profits ahead of the health of vulnerable patients and communities across the country that rely on 340B providers for access to needed drugs for their well-being.

Please contact me if you have questions, or feel free to have a member of your team contact Molly Collins, AHA's director of policy, at 202-626-2326 or mcollins@aha.org or Aimee Kuhlman, AHA's senior associate director of federal relations, at 202-626-2291 or akuhlmanl@aha.org.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development

cc: Jim Parker, Senior Advisor to Secretary for Health Reform
U.S Department of Health & Human Services

[3] https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf