

October 29, 2020

The Honorable Lamar Alexander
U. S. Senate
455 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Greg Walden
U. S. House of Representatives
2185 Rayburn House Office Building
Washington, DC 20515

Dear Senator Alexander and Representative Walden:

On behalf of the American Hospital Association's (AHA) nearly 2,000 340B member hospitals, we write to express our strong support of the 340B Drug Pricing Program. Hospitals are committed to ensuring that the 340B program can continue to fulfill its original intent of helping providers stretch limited resources to expand and improve access to comprehensive health care services for patients and communities. The increasingly high cost of pharmaceuticals continues to underscore the importance of the 340B program in helping achieve this goal.

The AHA remains opposed to any efforts that would diminish the scope of the program or significantly reduce its benefits, as the program is essential – now more than ever – to eligible hospitals. Congress should focus its energy on protecting the 340B program by providing strong oversight of drug manufacturers' constant efforts to undermine the program.

Since the bipartisan establishment of this important program in 1992, Congress has repeatedly recognized the program's vital role in supporting care for Americans by acting to expand the scope of the program. Currently, the 340B program includes certain organizations that receive funding from specific federal programs as well as children's hospitals, critical access hospitals, sole community hospitals, rural referral centers, and public and nonprofit disproportionate share hospitals that serve a large number of low-income and indigent patients. These entities must meet a variety of strict requirements to participate in the program, including yearly recertification of their program eligibility; audits from both the Health Resources and Services Administration (HRSA), which oversees the program, and drug manufacturers; and maintaining auditable inventories of all 340B and non-340B prescription drugs.

The 340B program allows providers that care for a large number of low-income and uninsured patients to stretch their scarce federal resources to provide better access to care, including, but not limited to, improved access to outpatient prescribed



pharmaceuticals. Hospitals use the savings generated from their participation in the 340B program to provide enhanced services to their patients, including but not limited to providing financial assistance to patients unable to afford their prescriptions; funding other medical services, such as obstetrics, diabetes education, oncology services and other ambulatory services; providing clinical pharmacy services, such as disease management programs or medication therapy management; establishing additional clinics; creating new community outreach programs; and offering free vaccines. Both the Government Accountability Office (GAO)¹ and independent academic research² have separately concluded that 340B hospitals provide high levels of uncompensated and unreimbursed care to their patients.

However, the benefits of improved access to care afforded to a 340B hospital is felt not only by the hospital's uninsured and low-income patient population, but also by the entire community the hospital serves. A recent analysis of IRS Form 990 Schedule H found that 340B hospitals provided over \$64.3 billion in community benefits in 2017, which includes financial support of community-building activities and in-kind contributions to local community groups and other community-oriented benefits.³ It also is apparent that neither this level of community benefits nor the range of services provided by 340B hospitals would be possible without support from the 340B program, especially as one in four 340B hospitals operate on a negative margin.⁴

Despite overwhelming evidence of the program's proven track record of helping providers stretch limited resources to better serve their communities, opponents of the program continue their relentless efforts to scale it back or significantly reduce the benefits eligible hospitals and their patients receive from the program. Several major drug manufacturers have taken actions to disrupt 340B contract pharmacy arrangements ranging from limiting the distribution of certain 340B drugs to demanding, burdensome and detailed reporting of 340B drug claims distributed through hospitals' contract pharmacies. Since 2010, HRSA has allowed 340B participants to contract with outside pharmacies to dispense drugs to their eligible patients in an effort to expand the reach of this vital program, and the agency has stated that such arrangements are permitted by the 340B statute. Contract pharmacies serve as an extension of the 340B covered entity allowing them to provide their patients access to prescription drugs outside of the four walls of their hospital or community clinic. For hospitals, these arrangements allow them to better serve their vulnerable communities by increasing access to more affordable health care services, especially in rural areas, where many hospitals do not operate their own in-house pharmacy.

¹ <https://www.gao.gov/assets/700/692587.pdf>

² <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2681653>

³ <https://www.aha.org/guidesreports/2020-09-10-340b-hospital-community-benefit-analysis>

⁴ <https://www.aha.org/news/blog/2019-11-22-report-misrepresents-340b-program-deflect-sky-high-drug-prices>

Therefore, the AHA is outraged that several major drug manufacturers have decided to limit distribution of 340B drugs to contract pharmacies, especially at a time when hospitals are responding to the immense financial and operational challenges posed by the COVID-19 public health emergency. **Instead of supporting the hospitals caring for communities ravaged by the public health crisis or working to address the inadequacies of the fractured pharmaceutical supply chain unearthed by this pandemic, these drug companies have decided that this is the right time to turn their attention to decimate a program that is actively working to help patients and communities in an effort to increase their already excessive profits.** These actions will undoubtedly force hospitals to divert critical resources away from caring for patients during this pandemic. It is deplorable that these 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..

The AHA firmly believes these unprecedented actions by some drug companies to limit the distribution of certain 340B drugs to hospitals and health systems violates the 340B statute. Under the terms of the statute and the Pharmaceutical Pricing Agreement (PPA) these manufacturers have entered with HRSA, the manufacturers must charge covered entities no more than the 340B ceiling price for any covered outpatient drug. Failure to do so is in direct violation of the 340B statute and the PPA.

The AHA has urged the Department of Health and Human Services (HHS) to use its existing authority to immediately direct offending drug companies to cease charging hospitals and covered entities more than the 340B ceiling price for drugs being dispensed by a contract pharmacy and issue refunds for each overcharge instance. We also have requested that the matter be referred to the HHS Office of Inspector General for assessment of civil monetary penalties. Likewise, there have been similar calls for action in bipartisan letters to the administration signed by a majority of congressional members.

However, the actions against 340B contract pharmacies are sadly not the only effort by drug companies to thwart the purpose of the program. In the latest attack on the 340B program, drug manufacturers are attempting to convert the means by which covered entities access discounted 340B pricing from an upfront discount to a back-end rebate. This approach complicates a covered entity's access to discounts, requires that financially-strapped organizations provide upfront financing and await reimbursement, and adds considerable burden and cost to the health care system. This new rebate model violates federal policy.

Specifically, it appears that the drug manufacturers – through Kalderos as its sponsored third-party vendor – are changing their PPAs without approval from HHS or HRSA. Kalderos and its clients are attempting to masquerade this fundamental change to the 340B program as simply a new software management tool. In addition, this rebate model is in direct violation of HRSA's own guidance that established the 340B program

The Honorable Lamar Alexander
The Honorable Greg Walden
October 29, 2020
Page 4 of 4

as an up-front discount program. This fundamental change to a new rebate model threatens the integrity of the 340B program and the savings that covered entities rely on to provide care to millions of low-income Americans. This harmful action directly subverts Congress' intent when it established the program.

We appreciate your continued interest in this vital program, and we recommend Congress use its oversight authority to investigate these harmful actions taken by drug companies against hospitals, and the patients and communities they serve. In addition, we respectfully request that you continue to encourage the administration to exercise its existing authority to address these abuses. It is important that we protect the 340B program and the vital benefits it affords to patients and communities across America, especially as hospitals are coping with the COVID-19 pandemic.

Please contact me if you have questions, or feel free to have a member of your team contact Aimee Kuhlman, senior associate director of federal relations, at 202-626-2291 or akuhlman@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President