Kansas Hospital ASSOCIATION

To: The Honorable John Thune
The Honorable Jerry Moran
The Honorable Tammy Baldwin
The Honorable Benjamin L. Cardin
The Honorable Shelley Moore Capito

From: Audrey Dunkel, VP Government Relations

Date: July 28, 2023

Re: 340B Drug Discount Program RFI

Thank you for the opportunity to provide input on potential changes to the 340B program on behalf of our 123 community hospital members and 91 340B hospitals.

The purpose of the 340B program, as noted in the RFI, is to enable eligible entities to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services. Drug manufacturers participating in the Medicare program must provide drugs at a discounted price to 340B qualifying entities. The 340B program allows those cost savings to be used to maintain and improve access to care for the patients those entities treat. This looks different for different types of hospitals. Critical Access Hospitals and sole community hospitals are often the only source of care in their areas. 340B dollars help maintain hospital services in these parts of the state and allow hospitals to fund service sites closer to their patients. In the case of larger hospitals, which qualify for the program because of the number of low-income and uninsured patients they serve, 340B resources are often invested in the expansion of high-demand programs like infusion services and obstetrics, as well as recruiting doctors in needed specialties that would otherwise not be available. Academic medical centers use 340B dollars to provide innovative care for the sickest patients, paving the way for new and better treatments for heart disease and cancer that revolutionize healthcare.

When viewed from a purely financial standpoint, drug companies generate significant profit from the healthcare industry without the same opportunity to contribute to care for low-income and remote populations as providers have through the Medicare and Medicaid program and EMTALA (Emergency Medical Treatment and Labor Act). A review of the financials in the Wall Street Journal last week for the six companies HRSA sent noncompliance letters to last year revealed that the operating margins for the drug manufacturers ranged from 11.4 percent to 51.17 percent. In comparison, the margins for the 91 340B hospitals in Kansas average negative 17.75 percent. The 18 drug manufacturers imposing restrictions on access to the 340B discounts accounted for nearly $650 billion in revenues in 2021, with planned biannual price increases

continuing outside the control of hospitals. In addition, a 2019 study found that research and development costs accounted for only 22% of pharmaceutical companies' spend, and more than double that rate of investments were attributable to advertising, corporate overhead, and profits. By comparison, 340B sales over the last several years have accounted for only 1-7% of the overall U.S. drug market. Clearly, drug manufacturers make significant profits despite the 340B discount requirements. Meanwhile, they continue to pursue efforts to withhold the benefits of the 340B program from providers and, ultimately, patients.

The 340B program allows covered entities to meet HRSA's desire to reach more eligible patients and provide more comprehensive services. Examples include:

- Rural clinic operations
- Infusion Center expansion
- Physician recruitment and retention
- Magnet Program for nursing excellence, recruitment and retention
- Patient experience – valet parking and easy lobby access
- Investment in obstetrical programs, which nationwide have struggled to meet the demand for their patients.
- Financing care for aged adults, which is also in demand in many areas and often operates at a significant deficit
- Childcare services to address workforce hurdles in many communities which would not be possible without 340B dollars
- Oncology services for patients in need of care without the ability to pay - the 340B program supports the hospital's ability to care for those patients with compassion and empathy, regardless of whether they can pay.

Many of these service lines would be endangered if the 340B program were to cease to exist, and any threat to the 340B program only threatens access to care for the people who live in our state. It is essential that this program not only persists but is also allowed to grow without threat. This program is truly exceptional and has a considerable influence on the health and well-being of individuals in all stages of their life.

If the COVID-19 pandemic has taught us nothing else, healthcare in this country and worldwide is a continuum, with all sectors playing a vital role in a healthy America. The 340B program is a critical component in supporting that continuum of care. Unfortunately, the 340B program has come under attack since 2020 from drug companies who have limited 340B entities to only one contract pharmacy and the drugs they will discount. The result has been billions of dollars taken out of the 340B program and retained by drug manufacturers. A 2023 study found that the impact of these drug company restrictions has resulted in the removal of an estimated $1.1 billion from the healthcare safety net in 1 year alone. Yet those lost savings to the safety net accounted for only 1% of U.S. sales for drug companies that imposed restrictions.

There needs to be more clarity regarding how the 340B program will be administered. This has led many hospitals to raise concerns with Congress. As such, 340B entities have been asked to respond to six questions. The Kansas Hospital Association, representing 91 covered hospital entities, would like to share our responses to those questions.

1. What specific policies should be considered to ensure HRSA can oversee the 340B program with adequate resources? What policies should be considered to ensure HRSA has the appropriate authority to enforce the statutory requirements and regulations of the 340B program?

Response: There is a significant difference between administering and enforcing a program. Programs like 340B that operate with a carrot (the ability for manufacturers to provide drugs for beneficiaries in the Medicare and Medicaid programs) and stick (exclusion from providing drugs to Medicare and Medicaid beneficiaries) generally need to be willing and able to engage the stick in the face of non-compliance. While CMS and HRSA both fall under the umbrella of HHS, direct authority to employ the stick does not fall within HRSA's, making enforcing the program they administer impossible. Further, HHS has not shown an interest in forcing compliance by eliminating non-compliant drug companies from the Medicare and Medicaid rosters. This leaves the program at the mercy of the goodwill of the participants, which has worn thin in the last few years, leaving providers faced with reducing programs or potentially closing their doors as millions of dollars are withheld from them by the drug manufacturers.

The solution to the enforcement problem includes the following: HRSA must have direct enforcement authority for the program, or the program needs to move to CMS, which would then have the authority to enforce the program. In addition, enforcement needs to include monetary penalties and payback requirements, regardless of which agency administers the program. In addition, the agency needs to move forward with the Alternative Dispute Resolution process.

2. What specific policies should be considered to establish consistency and certainty in contract pharmacy arrangements for covered entities?

Response: The idea that allowing only one contract pharmacy per qualified entity meets the overarching goal of access to care for beneficiaries in areas with more significant numbers of uninsured and Medicare and Medicaid beneficiaries is, quite frankly, ridiculous. Most 340B hospitals must meet a specific threshold to participate in the program –serving a disproportionate share of poor and uninsured compared to their peers. Additionally, Critical Access Hospitals participate in the program by providing care in rural and frontier communities, as well as to the impoverished. This results in patients traveling from their home communities for care at the hospital but filling their prescriptions where it is most convenient for them – in their home community. Hospitals want to contract with pharmacies that are most convenient to their patients to ensure medication compliance and better health outcomes. Today's pharmaceutical distribution system is very complex. Unfortunately, entities like PBMs and insurers often require prescriptions, especially those with greater 340B value, to be filled with their pharmacies of choice. Payer contracts should not limit a patient's ability to use their pharmacy of choice, and covered entities should not be limited in a hospital's ability to contract with our patient's pharmacy of choice by the manufacturers.

Mail-order prescriptions are also becoming more commonplace. Particularly for pharmacies that fill specialty prescription medications, these pharmacies are often only located in a handful of states throughout the United States, requiring 340B hospitals to contract with pharmacies located a significant distance away to access 340B pricing for those specialty medications for their patients. In addition, large corporations require contracting with central processing pharmacies when the utilization occurs locally. These multiple distribution sources were likely part of allowing multiple contract pharmacies for 340B entities. Limiting the number of contract pharmacies only limits access to care, especially in rural communities where patients travel significant distances to receive care. We believe these situations drive drug manufacturers' concern about the far-flung contractual arrangements. Instead of limiting the number of contract pharmacies 340B providers can use, it would

be better to prohibit 3rd parties from requiring contractual arrangements with out-of-state pharmacies that are unnecessary to access the needed medications. Further, the use of multiple contract pharmacies should continue to be allowed to help meet the needs of the patients and benefit the missions of the covered entities as the 340B program was intended to do.

Congress should consider enacting separate legislation, such as the bipartisan House legislation 340B Pharmaceutical Access to Invest in Essential, Needed Treatments & Support Act (340B PATIENTS Act), which would prohibit drug companies from imposing their restrictions on where and how 340B hospitals and their patients access 340B medications. Additionally, legislation should give HHS the authority to impose civil monetary penalties on a drug company that refuses to sell or deliver 340B drugs as requested by a hospital, including through community or specialty pharmacies.

3. What specific policies should be considered to ensure that the benefits of the 340B program accrue to covered entities for the benefit of the patients they serve, not other parties?

Response: Without question, the DSH threshold requirement for participating providers guarantees that the benefits from providers go to providing access to care. However, the accountability lens needs to view not only healthcare providers but also the manufacturers, insurers, and 3rd party entities along the healthcare continuum. First, PBMs and the insurance companies that often own them should not be able to profit from the 340B program by taking a portion of the 340B savings. Anything beyond a minimal processing fee should be prohibited. The same applies to contract pharmacies – the cost of the drug and a minimal service fee should apply. In addition, PBMs and other third parties should not be allowed to recoup 340B savings from contract pharmacies. These redistributions of the 340B program resources should cease to maintain the program's vision.

Congress should consider enacting legislation such as H.R. 2534 (PROTECT 340B Act) that prohibits discriminatory actions by PBMs against 340B entities and their pharmacy partners. Such legislation should also authorize civil monetary penalties against PBMs that implement discriminatory policies, as well as authorize HHS to contract with a third-party entity to collect and review data from state Medicaid agencies to prevent Medicaid duplicate discounts

4. What specific policies should be considered to ensure that accurate and appropriate claims information is available to ensure duplicate discounts do not occur?

Response: 340B entities invest significant time and resources to avoid duplicate discounts. Hospitals estimate that up to 19 percent of the 340B resources are spent on staff and contractors to administer the program and ensure compliance. Kansas entities are confident that when Medicaid fee for service is the provider, their systems exclude the hospital from receiving 340B benefits. Unfortunately, the complexity of Medicaid under managed care and the existence of beneficiaries with multiple sources of coverage may allow drugs related to those beneficiaries to slip through the process. HRSA audits can often help identify and recover processing errors in these situations.

While there may be options for creating databases to address this problem, an in-depth cost-benefit analysis of the actual dollars that currently result in duplicate discounts versus the cost of implementing such a database should be carefully considered. In addition, if the answer is to invest resources into systems that redundantly check for compliance, there must be an open and competitive

market for these systems with thoroughly vetted limitations to ensure covered entities are not being taken advantage of. Any new process must be neutral and free of bias from stakeholders with conflicting interests (PBMs, pharmaceutical companies).

While Kansas policy is straightforward and KDHE works closely with Kansas providers, there is complexity with each state having its own practice. A resource or database for all information needed for all state policies to prevent duplicate discounts is necessary. HRSA's vendor, Apexus, provides a similar resource to 340B Covered Entities. However, it is noted in that tool that it should not be relied upon as up-to-date and accurate, requiring each 340B entity (which by the nature of their qualification often have limited resources) to review, understand, and implement practices consistent with up to 50 different state policies.

In addition, PBM transparency is needed. States and 340B entities are doing their part. Still, in the instances where PBMs manage MCOs, limited transparency hinders information that could be useful to understand Medicaid duplicate discount risk better. It should be noted that the statute addresses only Medicaid duplicate discounts. At the same time, PBMs and drug companies often use the term "Duplicate Discounts" when talking about commercial rebates they have negotiated amongst themselves, which have nothing to do with 340B, causing confusion in identifying the true "cost" of duplicate discounts.

5. What specific policies should be considered to implement common sense, targeted program integrity measures that will improve the accountability of the 340B program and give healthcare stakeholders greater confidence in its oversight?

Response:

A. Develop tiers or steps for verification for program utilization
   i. Tier 1 - Using cost report data already available, providers with negative operating margins would not be required to do further reporting.
   ii. Tier 2 - Providers with positive operating margins should have their uncompensated care reviewed from the S-10. Further reporting would only be necessary if the uncompensated care is within the net resources provided by the 340B program.
   iii. Tier 3 – For providers with positive operating margins whose 340B benefits exceed their uncompensated care, IRS Form 990 should be reviewed to determine where dollars are spent to benefit the community.
   iv. Tier 4 - Tier 4 - Academic medical centers whose 340B benefits exceed tier 2 and or tier 3 should be allowed to show investments in specialized clinical programs, medical education programs, residencies (GME), preceptors, other training/education and associated expenses directly related to the unique role and mission of an academic medical center within a region.

B. Include a 340B impact statement in the Community Health Needs Assessment for hospitals that must complete one.

While it is believed that all Kansas hospitals will be able to show appropriate utilization of 340B resources with one of the methods above, hospitals who fall short in documenting their community benefit shall be required to annually report to HRSA additional programs they have implemented to reach vulnerable populations.

Transparency should focus on pharmaceutical companies and PBMs. 340B Hospitals are already subject to HRSA audits, with findings posted publicly. They are required to register in a public database (OPAIS) all participating 340B entity locations, any contract pharmacy relationships, and any Medicaid billing numbers and NPIs they use. Many also often publish their 340B savings and how savings are used publicly, in alignment with AHA 340B Good Stewardship principles.

Once again, thank you for the opportunity to provide input on the 340B drug discount program on behalf of our membership.