ALLIANCE of SAFETY-NET HOSPITALS

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April 1, 2024

The Honorable Tammy Baldwin
United States Senate
Washington DC 20510

The Honorable Shelley Moore Capito
United States Senate
Washington DC 20510

The Honorable Benjamin L. Cardin
United States Senate
Washington DC 20510

The Honorable Debbie Stabenow
United States Senate
Washington DC 20510

The Honorable Jerry Moran
United States Senate
Washington DC 20510

The Honorable John Thune
United States Senate
Washington DC 20510

Dear Senators:

I am writing on behalf of the Alliance of Safety-Net Hospitals in response to your request for information about the 340B Drug Pricing Program and for stakeholder feedback on the bipartisan discussion draft of the Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of (SUSTAIN) 340B Act. The Alliance of Safety-Net Hospitals (ASH) is a coalition of like-minded community safety-net hospitals without dedicated sources of public funding that work together to advocate policy decisions on government health care programs, most notably Medicare and Medicaid, that ensure equitable access to care for the medically vulnerable residents of the communities they serve and adequate public resources for the community safety-net hospitals that serve those communities.

All ASH hospitals are eligible for and participate in the 340B program.

ASH greatly appreciates Congress's continuing interest in the 340B program. In our view, 340B is a true lifeline to patients in need, a vital tool for ensuring the ability of community safety-net hospitals and other participating providers to care for the generally low-income patients and communities they serve.

In this letter we address several specific aspects of the draft Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of (SUSTAIN) 340B Act and then offer some general observations about the 340B program.

Comments About Specific Aspects of the Draft Bill

ASH would like to address five specific aspects of the draft bill: patient definition, child sites, contract pharmacies, transparency requirements, and the status of physicians who serve 340B hospitals' patients.

Patient Definition

The first aspect of the draft bill we would like to address is "patient definition." ASH believes the current guidance for determining eligibility, established by the Department of Health and Human Services' Health Resources and Services Administration (HRSA) in 1996, remains appropriate in 2024.

The most important part of the current definition seeks to ensure that qualified patients do, in fact, have established relationships with the 340B-eligible providers serving them. ASH believes the current tests to determine the legitimacy of those relationships remain adequate and should not be altered. In 2015 HRSA proposed a narrower definition of what constitutes a "patient" and the provider community responded to that proposed definition with persuasive arguments that HRSA ultimately accepted when it withdrew its proposed changes. Individuals may legitimately have established relationships, some long-term and some short, with more than one provider from more than one hospital from more than one health system. People use specialists, and sometimes those specialists are not affiliated with the provider who directed them to specialty care. The 340B program enables providers to extend care options to individuals who often have few such choices and we believe that is a good thing that federal policy should continue to encourage.

Participation in the 340B program, moreover, should continue to be determined on the provider level and not the patient level because of the underlying rationale for the program: that providers that care for especially large numbers of low-income patients most need the support of prescription drug discounts to help serve those patients and others like them.

Child Sites

The second aspect of the draft bill we would like to address is so-called child sites. Community safety-net hospitals and others like them that are covered entities under the 340B program are caring for many patients in outpatient settings. An important aspect of these outpatient settings, these child sites, is that they help 340B hospitals bring doctors into their communities. Because so many of the patients 340B hospitals serve are insured by Medicaid and Medicare, which pay clinicians less than commercial insurers, these areas are not necessarily attractive places for physicians to establish their practices. 340B hospitals help make them attractive places by providing or helping to finance facilities, providing ancillary services, and supplementing provider salaries. We believe 340B policy should encourage the development of such child sites and not make operating them burdensome and should continue to enable 340B hospitals to stretch their resources in ways that bring more and better and more accessible care to their communities.

Another important aspect of nurturing the development and operation of child sites is the distance such sites may be from the 340B hospital. Currently there is no defined distance limit, nor does the draft propose such a limit. Today the program uses Medicare guidelines and ASH believes this remains appropriate. Imposing a distance limit on the development of child sites could risk access to care and to 340B-covered prescription drugs, especially in rural areas.

Contract Pharmacies

The third aspect of the draft bill we would like to address is contract pharmacies. The purpose of the 340B program is to help covered entities get needed prescription drugs into the hands of low-income individuals they serve on an outpatient basis. It should not matter whether the drugs themselves are dispensed directly by the 340B provider or a pharmacy that dispenses the prescription drugs under contract on the provider's behalf. In fact, it is critical that providers others than hospitals participate in dispensing 340B-covered prescription drugs. According to the group 340B Health, 53 percent of DSH hospitals, rural referral

centers, and children's hospitals and 88 percent of critical access hospitals do not operate their own retail pharmacies and fewer still have their own specialty pharmacies, making access to community pharmacies, working under contract with 340B providers, absolutely essential to the success of the program.

ASH appreciates that the draft bill imposes no limits on covered entities' use of contract pharmacies. The pharmaceutical industry would have it otherwise and has even attempted to take it upon itself to impose such limits. It has no authority to do so, and we encourage Congress to make it clear in any future legislation that governing is the responsibility of the government and not the pharmaceutical industry.

Transparency and Reporting Requirements

The fourth aspect of the draft bill we would like to address is transparency and reporting requirements. It is essential that Congress and regulators recognize some of the extraordinary challenges inherent in attempting to develop and impose new reporting requirements on 340B covered entities. It also is important to note that much of the data the draft bill would seek is already reported by hospitals on their Medicare cost reports and that some of the reporting requirements it envisions would be duplicative of current efforts.

The biggest challenge we find in some of the draft bill's proposed requirements is the lack of a common vocabulary. Even asking a simple question like "How much uncompensated care does a hospital provide?" is exceedingly complex. There is no single definition of uncompensated care. In some states and for some purposes it includes only free care while in others it may include Medicaid shortfall – an important consideration because the adequacy of Medicaid payments differs considerably from state to state. A single federal definition could be very different than the standard in individual states, through their Medicaid programs, necessitating the development and implementation of parallel and in many ways duplicative accounting and reporting systems – at considerable expense. Accounting for uncompensated care or charity care on an individual site basis would be exceptionally costly and exceptionally burdensome – if even possible – taking time, talent, and money away from the central 340B objective of helping providers that serve large numbers of low-income patients and investing it instead in accounting systems, technology, and staff to operate those accounting systems and that technology. New requirements along such lines could make it no longer feasible to establish new care sites and possibly even necessitate closing some of those already in operation.

ASH urges Congress to proceed with great caution when considering imposing new reporting requirements on 340B covered entities and their child sites. Such an approach could be highly burdensome in time and in money, and depending on how well definitions are drawn, it could end up painting a highly inaccurate picture of how much uncompensated and charity care covered entities provide.

The Status of Physicians

The fifth and final aspect of the draft bill we would like to address is the requirement that 340B hospital prescribers be employees or "bona fide contractors" of those hospitals. This requirement would pose a number of problems for 340B covered entities.

Some states, including California, Texas, and New York, do not permit hospitals to employ physicians. Their hospitals can – and do – own clinics, including child sites, where many physicians work and they sometimes subsidize the physicians' earnings but they do not employ them. That leaves the extremely tenuous concept of a "bona fide contractor," which would be very complicated to define and could result in some physicians choosing not to continue working with such hospitals – a potentially devastating loss to the communities they were serving.

If the objective of such a requirement is to ensure that the physicians working with providers' 340B programs are qualified for such work this can be done in other, better, less burdensome ways. Hospitals routinely review the credentials of prescribers that wish to work with them and enter into credentialing agreements with those they conclude are qualified for such a role. This, ASH believes, should adequately demonstrate the readiness of prescribers to participate in the program.

ASH's Perspective on the 340B Drug Pricing Program

The 340B program was created by Congress in 1992 with providers like ASH's community safety-net hospitals in mind: caregivers that serve low-income communities and especially large numbers of low-income, uninsured, and underinsured patients. The program enables these hospitals, and other providers like them, to maximize their resources when working to serve their communities. It helps improve access to high-cost prescription drugs for low-income patients and helps put additional resources into the hands of qualified providers so those providers can do more for their low-income patients: provide more care that their patients might otherwise not be able to afford, offer more services that might otherwise be unavailable in those communities, and do more outreach into communities consisting primarily of low-income residents.

A quick look at the work 340B covered entities do today shows the wisdom of these decisions made more than 30 years ago. According to the organization 340B Health, 340B hospitals – of which ASH's community safety-net hospitals are a subset – account for 77 percent of all hospital care provided to Medicaid patients and for 67 percent of all hospital uncompensated and unreimbursed care. They also often provide medical services that almost inevitably lose money, doing so because their communities need those services – services like trauma and burn care, behavioral health services, obstetrics, HIV/AIDS care, and more.

These mission-driven hospitals usually operate with a number of disadvantages in comparison to the typical American hospital: they have very small operating margins and few financial resources in the form of reserves or endowments. The 340B program, along with government programs like Medicare DSH, Medicaid DSH, and many others, enables them to rise to the challenge of serving their communities despite the inherent disadvantages of their circumstances.

Also important: 340B prescription drug discounts are provided by pharmaceutical companies and not funded by the federal government, enabling the program to generate perhaps the greatest return on investment of any program created and operated by the federal government.

ASH encourages you to preserve and protect the program, retain its core mission, and enable its participating providers to continue doing what they do best: care for their low-income patients.

We appreciate your consideration of the views we have expressed in this letter and welcome any questions you may have about them.

Sincerely,

Ellen J. Kugler, Esq.
Director