March 29, 2024

The Honorable John Thune
United States Senate
511 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
United States Senate
731 Hart Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
United States Senate
170 Russell Senate Office Building
Washington, DC 20510

The Honorable Tammy Baldwin
United States Senate
141 Hart Senate Office Building
Washington, DC 20510

The Honorable Jerry Moran
United States Senate
521 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ben Cardin
United States Senate
509 Hart Senate Office Building
Washington, DC 20510

Dear Senators Thune, Stabenow, Capito, Baldwin, Moran, and Cardin,

The Community Practice Coalition applauds your proactive approach in formulating a discussion bill aimed at improving and fortifying the implementation of the 340B program, as well as your dedication to engaging with stakeholders for their input. Our coalition, encompassing a wide range of medical specialties, including oncology, rheumatology, urology, and women's health, collectively serves hundreds of thousands of patients across the nation annually.

As community healthcare providers, we assert that the 340B program has contributed to the increasing consolidation within the U.S. healthcare system. This has provided substantial resources to larger health systems, allowing them to acquire independent physician practices, thereby diminishing competition. Additionally, these health systems can leverage the HOPD designation to impose higher charges compared to the same services offered in an independent physician practice setting.

The 340B program was initially designed to enable covered entities to maximize limited federal resources by purchasing outpatient drugs at reduced prices to benefit uninsured and indigent patients. However, mounting evidence of program misuse suggests a departure from its original purpose. Fortunately, the legislative reforms you have proposed, including those areas where you specifically sought feedback, present clear opportunities to address these shortcomings and realign the program's focus toward its intended beneficiaries.

Patient Definition

As you know, the 340B statute lacks a specific definition of 'patient,' thereby facilitating misuse. Individuals with minimal or no affiliation to the 340B hospital acquire drugs purchased at a substantial discount, often for administration at locations a considerable distance from the 340B hospital itself. Consequently, 340B hospitals can generate significant and inappropriate revenue from individuals who lack genuine ties to the hospital.

Our groups believe the bill should clarify that a legitimate 340B patient must have a clear clinical connection to the 340B hospital. For example, the patient should have received care at the 340B hospital by that hospital’s employees within 30 days to be considered a 340B eligible

patient. Based on the intent of the original statute, simply picking up a prescription at a contract pharmacy should not satisfy the definition of a 340B patient.

HRSA should be entrusted with new audit powers to assess hospital compliance with the new Patient Definition and enforce regulations, ensuring that discounts are exclusively granted for legitimate patients with genuine clinical ties to the hospital.

Child Sites

Numerous 340B hospitals have acquired physician practices, preserving their original off-site physical locations and, in many cases, even retaining their original practice names while providing drug administration at these "child sites," which then qualify for 340B discounts from manufacturers. This practice certainly generates revenue benefits for the hospital but may not directly benefit the intended patient population. Recent investigations by various newspapers have revealed that many of these acquired child sites failed to improve patient access or resources within their communities. These sites are often established in suburban, economically affluent areas that do not cater to the lower-income areas that the 340B provisions originally intended to serve.[1]

Your legislation calls for the reform of “child sites,” which we welcome. Congress must first define child sites and then appropriately track utilization from child sites.

It is notable that Congress has addressed child sites as it pertains to Medicare payments, and similar lessons can be learned regarding the 340B eligibility of such sites. The Bipartisan Budget Act of 2015 included a critical reform to deter provider consolidation and protect the Medicare program from excessive billing. That provision prohibits hospitals from acquiring physician practices and subsequently billing for identical procedures at off-campus facilities at higher hospital outpatient rates. Those off-campus facilities are directed to bill Medicare at the physician office rate, just as before their acquisition.

Unfortunately, research has found that most hospitals evade this provision by billing the care in these off-campus outpatient facilities as if the care were being delivered at the main hospital campus, where the higher rate is permitted.[2] Hospitals have been able to skirt the law’s intent due to CMS’s inability to discern whether care was provided at an off-campus site of an acquired practice.

Our coalition supports bipartisan legislation introduced by Rep. Joyce (R-PA) and Sarbanes (D-MD) (H.R. 3237), which resolves this problem by requiring each provider's off-campus outpatient department to obtain and include a unique national provider identifier for service claims. This provision was included in the Lower Cost, More Transparency Act, which passed the House in December 2023 with a strong bipartisan vote of 320-71 and was scored by CBO as saving $403 million over ten years.

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[1] 340BReport.com, “New York Times Investigative Story Aftermath: Leading Local Paper Dives into 340B, Emphasizing its Importance for Community Health Centers.” October 4, 2022. Ted Slafsky and Sarah True. October 2022

[2] HHS OIG, “CMS is Taking Steps to Improve Oversight of Provider-Based facilities, But Vulnerabilities Remain.” June 2016. HHS OIG, “Incorrect Place-of-Service Claims Resulted in Potential Medicare Overpayments Costing Millions.” May 2015

Similarly, off-campus "child sites "must not be treated as if they were providing care offered by the mothership 340B hospital. In addition to implementation of the discrete NPI requirement, Congress should consider three additional options with respect to child sites:

1. In order to benefit from 340B, child sites must be operating in medically underserved areas or low-income areas.

2. Provide a 5-year delay for newly acquired child sites from participating in 340B; 340B revenue should not be a driving force for hospital acquisition of physician practices.

3. Make 340B certification child sites contingent on a bona fide level of charity care (e.g., 3.8% currently provided by private hospitals)[3] by both the 340B hospital and separately for the child site.

Transparency Must Include a Survey of Hospital Acquisition Costs of 340B Drugs for Determining Medicare Payment

We are encouraged by the draft legislation's emphasis on enhanced transparency, which entails documenting the extent of charity care offered and the utilization of savings by 340B hospitals. Nevertheless, the bill fails to employ this information in a manner that guarantees Medicare's appropriate payment to 340B hospitals for these discounted medications.

The Medicare statute requires CMS to survey adjusting hospital payments. CMS's failure to survey hospital acquisition costs to date was cited by the Supreme Court in its ruling against CMS in AHA vs. Becerra, wherein CMS had reduced reimbursement from ASP+6% to ASP - 22.5% for 340B drugs.

Thus, Congress has clearly been given a judicial mandate to compel CMS to conduct the necessary study of acquisition costs. The bill should then use those findings to establish the appropriate payment for 340B hospitals. The bill should explicitly direct CMS to undertake that survey and, if necessary, provide CMS with additional resources to conduct it.

We are confident these studies will substantiate the need for the proposed lower Medicare reimbursement rate for 340B drugs. The cost savings associated with this reform will protect the patients 340B was intended to benefit (through enhanced access, lower copayments, and Part B premiums) and the Medicare program's long-term solvency.

Conclusion

We thank you for your leadership in tackling this complex issue that is now ripe for reform and hope to be a resource to you on these matters.

Sincerely,

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Chair, Health Policy Committee
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[3] Bai et al. "Analysis Suggests Government and Nonprofit Hospitals' Charity Care is Not Aligned with Their Favorable Tax Treatment." Health Affairs, April 2021

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