LUGPA
Integrated Practices Comprehensive Care

March 25, 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 Large Urology Practice Group Association (LUGPA) commends you for your discussion draft bill intended to strengthen and improve the implementation of the 340B program and for your solicitation of stakeholder input. LUGPA represents 150 urology group practices in the United States, with more than 2,100 physicians who, collectively, provide more than one-third of the nation's urology services.

As we have stated previously, we believe the 340B program has contributed to the increasing consolidation of the U.S. health system by providing large health systems with enormous resources to buy up their independent physician practice competition. Furthermore, the health systems can then leverage the HOPD designation to charge more than the identical care would have cost had it been delivered by the (previously) independent physician practices.

The 340B program was explicitly designed to enable covered entities to stretch scarce federal resources by purchasing outpatient drugs for administration to uninsured and indigent patients at significantly reduced prices. However, ongoing and mounting evidence of program misuse suggests subversion of the program's original intent. Fortunately, the legislative reforms you have suggested, including those issues on which you specifically solicit feedback, offer straightforward opportunities to fix these deficiencies and redirect the utilization of the program to its intended beneficiaries.

Patient Definition

As you are aware, the 340B statute does not include a definition of 'patient,' and this has enabled significant abuse to occur involving individuals who have little or no relationship to the 340B hospital receiving drugs purchased at a massive discount, often many miles from the 340B hospital. As a result, 340B hospitals can generate enormous and undeserved revenue from individuals with no real connection to the hospital.

We 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.

875 N. Michigan Avenue
Suite 3100
Chicago, IL 60611
www.lugpa.org

Manufacturers should be able to recoup illegitimately provided discounts from hospitals for drugs provided to individuals who do not meet the Patient Definition. To enforce this provision, HRSA must be tasked with new audit authority to determine hospital compliance and enforcement such that discounts can only be provided for legitimate patients with a real clinical relationship with the hospital.

Child Sites

Many 340B hospitals have purchased physician practices, retained their pre-existing off-site locations (often even the name of the practice), and commenced providing drug administrations at these "child sites," which are then eligible for 340B discounts from manufacturers. This generates revenue for the hospital but does not necessarily benefit patients. Recent investigations by several newspapers found that many of these acquired child sites are not providing enhanced patient access or resources within their communities. These are often established in suburban, economically affluent areas that do not serve the lower-income areas that the 340B provisions were intended to reach.

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 concerning 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 the higher hospital outpatient rates. Those off-campus facilities are supposed to bill Medicare at the physician office rate, just as was done 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.[1] 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. LUGPA supports bipartisan legislation introduced by Rep. Joyce (R-PA) and Sarbanes (D-MD) (H.R. 3237), which resolves this problem by requiring each off-campus outpatient department of a provider to obtain and include a unique national provider identifier for claims for services. 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.

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.)[2] by the 340B hospital and separately for the child site.

1 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

2 Bai, et al. "Analysis Suggests Government and Nonprofit Hospitals' Charity Care is Not Aligned with Their Favorable Tax Treatment". Health Affairs, April 2021

Transparency must include a Survey of Hospital Acquisition Costs of 340B Drugs for Determining Medicare Payment

We are heartened that the draft legislation requires greater transparency, including documentation of the amount of charity care provided and how 340B hospitals use savings. However, the bill does not use this information in a manner that can ensure Medicare is paying 340B hospitals appropriately for these discounted drugs.

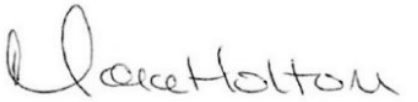
CMS's failure to survey hospital acquisition costs is the reason the Supreme Court ruled in the American Hospital Association v. Becerra case that the CMS rule to reduce Medicare reimbursement from ASP+6% to ASP-22.5% was illegal. The Medicare statute requires CMS to conduct a survey before adjusting hospital payments.

Congress has thus clearly been given a judicial mandate to compel CMS to conduct the necessary study of acquisition costs and 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 the survey. LUGPA is confident that 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, which was intended to benefit (through lower copayments and Part B premiums), as well as the Medicare program's long-term solvency. Finally, it could be a deterrent to further hospital acquisition and consolidation of physician practices.

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,



Evan R. Goldfischer, MD
President

Mara Holton, MD
Chair, Health Policy