April 26, 2024

Michael E. Chernew, Ph.D.
Chair, Medicare Payment Advisory Commission
425 I Street NW, Suite 701
Washington, DC 20001

Re: Presentation on "Initial findings from analysis of Medicare Part B payment rates and 340B ceiling prices"

Dear Dr. Chernew:

On behalf of over 1,500 hospital and health system members that participate in 340B, we are writing to provide comments in response to the April 12, 2024, presentation MedPAC received on "[i]nitial findings from analysis of Medicare Part B payment rates and 340B ceiling prices." We recognize that the initial presentation of the analysis was not intended to lead to immediate recommendations to Congress, but given commissioners' discussion following the presentation and previous recommendations by MedPAC to lower Part B payments for 340B providers,[1] we wish to express our opposition to any recommendation that would reduce Medicare Part B payments to 340B hospitals from the current rate.

Low-income and underserved patients disproportionately rely on 340B providers for essential care. 340B hospitals serve a vital role in our healthcare system and the 340B program was designed to stretch scarce federal resources by allowing providers serving disproportionate shares of low-income, rural, and underserved patients to leverage the savings created by the program to support and sustain quality patient care. 340B disproportionate share (DSH) hospitals account for more than three-fourths of all Medicaid hospital services and more than two-thirds of all hospital uncompensated care while operating under tight financial margins.[2] Moreover, 340B hospitals are essential for addressing health disparities, particularly in communities of color, by offering specialized services for chronic conditions, HIV/AIDS, and behavioral health.

As described in the April 12 presentation, between 2018 and 2022 the Centers for Medicare & Medicaid Services (CMS) lowered Part B payments for most 340B drugs under the outpatient prospective payment system (OPPS) from the statutory average sales price (ASP) + 6% to ASP - 22.5%. In 2022. the U.S. Supreme Court held that CMS's process for setting separate reimbursement rates for 340B hospitals was not conducted in accordance with the 340B statute, rejecting the government's argument that Congress could not have intended that paying the same

[1] MedPAC Comment Letter to CMS, CMS-1772-P, Sept. 12, 2022, https://www.medpac.gov/wp-content/uploads/2022/09/09122022_OPPS_FY2023_MedPAC_COMMENT_v2_SEC.pdf

[2] Dobson DaVanzo, 340B DSH Hospitals Serve Higher Share of Patients with Low Incomes (2022), https://www.340bhealth.org/files/340B_and_Low_Income_Populations_Report_2022_FINAL.pdf; Dobson DaVanzo, 340B DSH Hospitals Increased Uncompensated Care in 2020 Despite Significant Financial Stress (2022), https://www.340bhealth.org/files/Dobson_DaVanzo_Op_Margins_and_UC_FINAL.pdf.

rate to 340B and non-340B hospitals amounted to overpayment, noting that "enacting this statute in 2003, Congress was well aware that 340B hospitals paid less for covered prescription drugs."[3]

As one commissioner pointed out during the April 12th meeting, this is not the first time the Commission has discussed the possibility of reducing Part B payments for 340B hospitals that meet the 340B eligibility criteria. In 2016, MedPAC recommended that Congress "reduce 340B hospitals' Medicare payment rates for separately payable Part B drugs by 10 percent of the ASP [and] direct the savings from reducing Part B drug payment rates to beneficiaries and to the Medicare uncompensated care pool, and distribute all uncompensated care payments" based on a hospital's provision of charity care.[4] In discussion following the April 12th presentation, commissioners described the motivation behind the 2016 recommendation as "concerns that the 340B monies were not being distributed necessarily to the neediest hospitals." Then, as now, we do not believe it would be appropriate for MedPAC to recommend reducing payments to hospitals that meet the eligibility criteria, which Congress has already determined reflect hospitals and other providers that serve disproportionately low-income, rural, and underserved patients.

I. *Reducing Part B payments for 340B drugs during implementation of the Inflation Reduction Act could further undermine 340B*

We do not support Part B payment reductions for 340B drugs such as those MedPAC has recommended in the past, but it is important to note that the Commission's previous and current analyses of 340B payment rates did not take into consideration the impact of the Inflation Reduction Act (IRA) on 340B. The implementation of the IRA is expected to impact 340B savings for drugs that make up a significant share of Medicare spending. In fact, 340B Health has estimated that the IRA is expected to have a $929 million negative impact on hospitals' 340B savings, for the drugs selected for 2026.[5]

The IRA will result in Medicare paying less for selected drugs, which will significantly reduce 340B savings on these drugs. Medicare spending on Part B drugs is highly concentrated, with the top 15 drugs making up nearly half of such spending.[6] A Government Accountability Office (GAO) report also found that Medicare represented at least half the market for 22 of the most expensive Part B drugs in 2015.[7] Given that the IRA will significantly impact 340B savings relating to drugs used for Medicare patients, reducing reimbursement for 340B drugs during implementation would only further erode the benefit 340B provides to patients and the safety net. We strongly urge MedPAC

[3] *Am. Hospital Ass'n., et al. v. Becerra et al.,* 142 S. Ct. 1896 (2022).
[4] Medicare Payment Advisory Commission, "Report to the Congress: Medicare Payment Policy," March 2016, xiv, https://www.medpac.gov/wp-content/uploads/2021/10/march-2016-report-to-the-congress-medicare-payment-policy.pdf.
[5] 340B Health analysis of drug list from the Centers for Medicare and Medicaid Services (CMS) using data from members, Health Resources and Services Administration (HRSA), IQVIA, CMS, and SSR.
[6] Medicare Part B Spending by Drug, data for 2020. Analysis excludes vaccines. https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-spending-by-drug
[7] GAO. Medicare Part B. Medicare Represented at Least Half the Market for 22 of the 84 Most Expensive Drugs in 2015. 18 Dec 2017. https://www.gao.gov/products/gao-18-83

not to recommend a reduction in Part B payments for 340B drugs given the ongoing changes brought about by the IRA.

II. *Any recommendation to reduce payments would redirect the benefit of pharmaceutical discounts away from 340B hospitals, which are the intended beneficiaries due to their high level of services to low-income individuals*

When CMS reduced reimbursement for 340B drugs following its 2018 policy change, it also increased payments to all hospitals under OPPS for non-drug items and services in accordance with budget neutrality rules.[8] As a result, savings from pharmaceutical manufacturers' discounts that Congress intended to help fund 340B hospitals' services to low-income and rural patients were diverted to boosting Medicare payments for non-drug services to all OPPS providers, including those do not meet 340B eligibility criteria of providing care to a high number of low-income individuals.

CMS justified the 2018-2022 policy change by arguing that reducing payment rates would "make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs."[9] However, the rationale expressed by CMS is not appropriate for 340B drugs, where the acquisition cost is established by federal law at a below market price with the express purpose of subsidizing services provided by safety net providers. We support comments made by some commissioners during the April 12th meeting explaining that 340B was intended to support certain types of providers serving disproportionately low-income and rural populations and to support services and programs that would not always be sustainable in these environments without the 340B savings.[10]

III. *Reducing payments under Part B would risk undoing a critical component of 340B to help hospitals offset underpayments and unreimbursed care*

Targeting 340B hospitals for lower reimbursement rates by Medicare would thwart a key purpose of 340B to help hospitals offset underpayments by Medicaid. Medicaid has underpaid providers for decades. In 2020, hospitals received payment of only 88 cents for every dollar spent caring for Medicaid patients.[11] Payment reductions would undermine 340B hospitals' ability to maintain crucial initiatives and jeopardize access to care for vulnerable populations. We support comments by several commissioners' who noted that 340B is serving the purpose for which Congress intended it, and that "hospitals still [have] substantially negative margins" and that in the absence of 340B "it would be even more negative than it is."[12] This impact would significantly undercut 340B hospitals' ability to sustain their current levels of care.

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[8] 82 Fed. Reg. 52356, 52504, 52623 (Nov. 13, 2017).
[9] 86 Fed. Reg. 42018, 42134 (Aug. 4, 2021).
[10] MedPAC Meeting Transcript, April 12, 2024, page 95-96, https://www.medpac.gov/wp-content/uploads/2023/10/April-2024-meeting-transcript.pdf (comments by Dr. Chernew and Dr. Ryu on the patient benefit of 340B).
[11] American Hospital Association. Fact Sheet: Underpayment by Medicare and Medicaid. https://www.aha.org/fact-sheets/2020-01-07-fact-sheet-underpayment-medicare-and-medicaid.
[12] MedPAC Meeting Transcript, April 12, 2024, page 97, https://www.medpac.gov/wp-content/uploads/2023/10/April-2024-meeting-transcript.pdf (comments by Dr. Ryu).

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We share concerns expressed by one MedPAC commissioner during the April 12th meeting that 340B providers are "among the most stressed because of the populations they serve and [to] put an additional burden on [them] by taking 340B out of the mix would be a mistake."[13] We encourage MedPAC to evaluate the impact that changes in Medicare payment policy would have on 340B before recommending any fundamental changes to 340B.

Thank you for your consideration of these comments. Please contact me at maureen.testoni@340bhealth.org if you have any questions.

Sincerely,

Maureen Testoni
President and CEO
340B Health

[13] MedPAC Meeting Transcript, April 12, 2024, page 87, https://www.medpac.gov/wp-content/uploads/2023/10/April-2024-meeting-transcript.pdf (comments by Mr. Poulson).