DIGESTIVE HEALTH
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10770 COLUMBIA PIKE | SUITE 400 | SILVER SPRING, MD 20901

August 31, 2023

BY E-MAIL

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850
Re: Comments to CMS-1793-P

Dear Administrator Brooks-LaSure:

On behalf of the Digestive Health Physicians Association (DHPA), we thank you for the opportunity to comment on the Medicare Program Hospital Outpatient Prospective Payment System Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 (Proposed Rule).[1]

DHPA® is the only national medical association that exclusively represents the voices of gastroenterologists who have chosen to care for patients in the independent practice setting. DHPA includes over 100 member gastroenterology practices from 39 states in every region of the country. Our more than 2,500 physicians provide care to approximately three million patients annually and diagnose more than 25,000 new cases of colon cancer each year. Physicians in DHPA member practices are on the front lines diagnosing and treating serious diseases such as colorectal cancer, Crohn's disease, and ulcerative colitis.

DHPA submits this comment letter to make two points regarding the Proposed Rule. First, CMS should announce as part of the "remedy" for the 340B-acquired drug payment policy that the Agency is going to conduct a survey of drug acquisition costs and use the findings from that survey to establish an accurate payment level for 340B hospitals on a prospective basis rather than continue paying 340B hospitals at the unsupportable level of Average Sales Price (ASP) + 6 percent.

[1] 88 Fed. Reg. 44078 (July 11, 2023).

Taking such a step would be fully consistent with the Supreme Court's decision in *AHA v. Becerra*. In that case, the Supreme Court did not hold that ASP minus 22.5% was an inaccurate payment level for 340B hospitals, but only that CMS could not establish differentiated payment levels without first conducting a cost acquisition survey.[2]

Second, although we agree with CMS's proposal to decrease the OPPS conversion factor prospectively to ensure that hospitals do not reap a windfall from the inflated reimbursement levels they received for non-drug items and services from CY 2018 through CY 2022 when 340B hospitals were paid at ASP minus 22.5%, we believe that a 0.5% downward adjustment to the conversion factor over 16 years is too long a period for recouping the inflated reimbursement that CMS paid over a five-year period. CMS should modify its proposal so that the "fix" occurs over five years—the same length of time that the conversion factor was artificially inflated as a result of payment to 340B hospitals at ASP minus 22.5 percent.

I. CMS's Remedy for 340B-Acquired Drug Payment Policy Needs to Account for Serious Flaws in the 340B Program

DHPA is supportive of the 340B program as first envisioned, which aimed to provide discounted drugs to vulnerable uninsured and indigent patient populations. However, the program's rapid expansion over the last decade as well as flagrant abuses that have been documented in government reports and widely circulated publications have raised alarms about the integrity of the 340B program and whether hospitals are exploiting 340B pricing to generate significant profits that help them acquire competing independent physician practices.[3,4,5] This cannot be ignored as CMS structures the remedy that needs to be developed in light of the Supreme Court's decision in *AHA v. Becerra*.

A well-document example of abuse in the 340B program was reported by the *New York Times* in an investigative piece that found that Bon Secours Mercy Health in Virginia used profits from their 340B program at their community hospital to open new clinics at their suburban covered entities that, on paper, are subsidiaries of Richmond Community Health. Meanwhile,

[2] See *American Hospital Association et al. v. Becerra*, 142 S.Ct. 1896 (2022).
[3] There have been numerous GAO and OIG reports citing the shortfalls and noncompliance of covered entities in the 340B program: https://www.gao.gov/products/gao-15-442; https://www.gao.gov/assets/gao-18-521r.pdf; https://www.gao.gov/products/gao-20-108; https://www.gao.gov/products/gao-21-107; GAO, "Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, Sept. 2011; OIG, "Testimony Before the United States Senate Committee on Health, Education, Labor, and Pensions," May 2018.
[4] Kelter, Jamie. Hospitals often don't help needy patients, even those who qualify, *The Wall Street Journal*, Nov. 17, 2022.
[5] Cooper, Zack, Han, James, and Mahoney, Neal. Hospital Lawsuits Over Unpaid Bills Increased By 37 Percent In Wisconsin From 2001 To 2018, *Health Affairs*, Dec. 2021.

they began slashing departments, services, and staff at the community hospital.[6] Notably, Bon Secours closed the intensive care unit at the Community Hospital, which served the predominantly Black neighborhood nearby and was already considerably under-resourced.

This is not an isolated example. A 2021 study in the American Journal of Managed Care found that hospitals that entered the 340B program did not increase their provision of uncompensated care more than hospitals that are not in the program.[7] Essentially, "nonprofit" hospitals are using the 340B program to pad their bottom lines by charging huge markups for the discounted drugs to insurers and patients, then using those resources to buy up and consolidate local markets.[8]

With these profits, hospitals continue to accelerate health care consolidation by acquiring physician practices. A recent Avalere study commissioned by the Physicians Advocacy Institute found that the percentage of hospital-employed physicians grew by 11% from 2019 to 2022, resulting in more than half of all physicians (52.1%) being hospital-employed by January 2022.[9]

As CMS finalizes its "remedy" for 340B-acquired drug payment policy that will result in $9 billion in lump sum payments to 340B hospitals, the Agency must take steps—consistent with the Supreme Court's decision in *AHA v. Becerra*—to fix the fundamental flaw of paying 340B hospitals at ASP + 6 percent. Ignoring this flaw will perpetuate market distortions and further increase costs for patients as more care migrates from the lower cost physician office setting to the more costly hospital site of care.

[6] Thomas, Katie and Silver-Greenberg, Jessica., How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits., *New York Times*, Sept. 24, 2022.
[7] Desai, Sunita and McWilliams, J. 340B Drug Pricing Program and Hospital Provision of Uncompensated Care. *American Journal of Managed Care*, Oct. 11, 2021.
[8] Okon, Ted, "Hospitals and for-profit PBMs are diverting billions in 340B savings from patients in need," STAT (July 7, 2022), *available at* https://www.statnews.com/2022/07/07/for-profit-pbms-diverting-billions-340b-savings/.
[9] Physicians Advocacy Institute. COVID-19's Impact on Acquisitions of Physician Practices and Physician Employment 2019-2021 Prepared by Avalere Health, p.12 (April 2022) available at http://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/PAI-Research/PAI%20Avalere%20Physician%20Employment%20Trends%20Study%202019-21%20Final.pdf.

II. CMS's Remedy Should Include a Cost Acquisition Survey to Establish Accurate Reimbursement Levels for 340B-Acquired Drugs

The reason CMS finds itself in the position of having to pay 340B hospitals a "remedy" of $9 billion is not because setting payment at ASP minus 22.5% was too low, but because the Supreme Court concluded in *AHA v. Becerra* that the Agency was statutorily obligated to conduct a survey of hospitals' acquisition costs as a predicate for varying the payment rate for outpatient prescription drugs by hospital group.[10] The key point is that CMS has the authority—and we believe the obligation—to conduct such a survey and base 340B-acquired drug payment policy on the results of that study. It would be a mistake for a Final Rule entitled "Remedy for 340B-Acquired Drug Payment Policy" to lock in a payment rate that CMS knows is far in excess of 340B hospitals' acquisition costs without at least laying the foundation for a cost acquisition survey that will rectify the flawed payment level on a prospective basis.

We agree with CMS's statement in the Proposed Rule that "[b]ecause we did not use any survey of hospitals' acquisition costs, we believe it is necessary for the remedy to apply the default rate (generally ASP plus 6 percent) to comply with paragraph (14)(A)(iii) of section 1833(t) of the Act for those years, as interpreted by the Supreme Court."[11] Our disagreement is with CMS's next sentence:

> "Even if a retroactive rule were not necessary to comply with section 1833(t)(14) of the Act, we believe that failing to apply the default rate retroactively would be contrary to the public interest in this specific situation in part because it would leave the plaintiff 340B hospitals paid at a substantially lower rate, due to the magnitude of payment, **than we now believe to be proper under the statute** and that they have continually pressed in court since we first announced the adjustment."[12]

CMS knows that keeping reimbursement at ASP + 6% for 340B hospitals is not a "proper" rate and, in fact, results in a gross overpayment to those hospitals. CMS has previously cited to government studies which found that lowering reimbursement for 340B hospitals from ASP + 6% to ASP minus 22.5% *likely did not go far enough* to establish an appropriate

[10] *AHA v. Becerra*, 142 S. Ct. at 1900 (citing 42 U.S.C. § 1395l(t)(14)(A)(iii)(I), § 1395l(t)(14)(D)) ("If the agency has conducted a survey and collected that data, HHS may set reimbursement rates based on the hospitals' 'average acquisition cost' for each drug.").
[11] 88 Fed. Reg. at 44083.
[12] Id. at 44083 (emphasis added).

reimbursement level for 340B-acquired drugs.[13] A March 2016 Report from HHS-OIG estimated that discounts across all 340B providers average 33.6 percent of ASP.[14] And CMS has previously acknowledged that some reports have found 340B hospitals benefitting from discounts as high as 50 percent.[15] This data is consistent with MedPAC's finding that "payments hospitals receive for 340B drugs (even at ASP minus 22.5 percent) are higher than the drug's discounted acquisition cost under the 340B program (and these discounts are growing)."[16]

And yet, CMS says nothing in the Proposed Rule about the inaccuracy of ASP + 6% as the payment level for 340B hospitals. Nor does the Agency explain that it could get the payment level right by conducting a conducting a cost acquisition survey. We fail to understand how CMS can structure a "remedy" for 340B-acquired drug payment policy without addressing the fundamental issue of ensuring accurate payment levels under the 340B program.

To continue paying 340B hospitals at ASP + 6% without engaging in a cost acquisition survey would contradict clear Congressional intent that the 340B program "maximize scarce Federal resources as much as possible, reaching more eligible patients, and providing care that is more comprehensive."[17] Moreover, paying 340B hospitals at ASP + 6% will drive even more services, including drug treatment for patients with cancer, into the more-expensive outpatient hospital setting. As one national study estimated, the blended profit margin for Part B drugs (accounting for both Medicare and commercial business) is only about 16% for physicians, but 210% for 340B hospitals.[18] This has encouraged hospital-physician practice consolidation because hospitals can expand their profit margins on drugs provided by the acquired practices.[19]

[13] OPPS Final Rule for CY 2019, 83 Fed. Reg. 58818, 59018 (Nov. 21, 2018).
[14] OIG March 2016 Report; Government Accountability Office. "Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals," GAO-15-442 (June 2015) (estimating the amount of the 340B discount at 20 to 50 percent); HHS Office of Inspector General. "Part B Payments for 340B-Purchased Drugs," November 2015. Available at https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf.
[15] 83 Fed. Reg. at 59020.
[16] Medicare Payment Advisory Commission. "Report to the Congress: Medicare Payment Policy," March 2020. Available at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar20_entirereport_sec.pdf.
[17] H.R. Rep. No. 102-384(II), at 12 (1992).
[18] Raina H. Jain, Stephen M. Schleicher, Coral L. Atoria, Peter B. Bach, "Part B payment for drugs in Medicare: Phase 1 of CMS's proposed pilot and its impact on oncology care," Memorial Sloan Kettering Cancer Center Evidence Driven Drug Pricing Project, p. 5.
[19] Desai and McWilliams, "Consequences of the 340B Drug Pricing Program," New England Journal of Medicine, Feb. 8, 2018, *available at* https://www.nejm.org/doi/full/10.1056/nejmsa1706475 (last accessed Sept. 13, 2022).

In short, CMS should conduct the necessary study of acquisition costs, without delay, and use those findings to establish an accurate payment level for 340B hospitals on a prospective basis, rather than continue paying 340B hospitals at the unsupportable level of ASP + 6 percent. We have no doubt that payment of ASP minus 22.5%, or quite possibly at an even lower level, will be validated as more than adequate to cover 340B drug acquisition costs. As CMS stated in the Proposed Rule, such a result "would allow Medicare beneficiaries and the Medicare program to pay a more appropriate amount when hospitals participating in the 340B Program furnish[] drugs to Medicare beneficiaries that were purchased under the 340B Program."[20]

III. DHPA Agrees with CMS that the Remedy Must Be Applied in a Budget Neutral Manner to Avoid Providing Hospitals with a Windfall, But the Prospective Adjustment to the Conversion Factor Should Occur Over a Significantly Shorter Period of Time

We agree with CMS that the remedy payments it proposes to make to 340B hospitals for CY 2018 through September 27, 2022 are subject to budget neutrality requirements.[21] The application of budget neutrality principles to the remedy payments is mandated by the Medicare statute, warranted as a matter of sound public policy, and (as CMS recognizes) makes common sense.[22] CMS cannot reasonably pay the 340B hospitals $9 billion in lump sum payments without addressing the inflated payments that all hospitals received for CY 2018 through CY 2022 when payment rates were increased by 3.19% for non-drug items and services.[23]

Just as the reduction in payments for 340B-acquired drugs for that five-year period was "budget neutralized" through an increase in payments for non-drug items and services, "failing to budget neutralize the remedy payments would mean that the additional payments for non-drug items and services that were made from CY 2018 through CY 2022 to achieve budget neutrality for the 340B payment policy…would be a windfall."[24] We agree with CMS that hospitals who received the windfall by virtue of the 3.19% increase in the conversion factor for CY 2018 through CY 2022 "have no legitimate interest in permanently retaining that windfall."[25]

[20] 88 Fed. Reg. at 44078.
[21] Id. at 44080.
[22] Id. at 44081-82.
[23] CMS estimates that 340B providers have already received $1.5 billion in remedy payments through reprocessed claims for 340B drugs provided from January 1, 2022 through September 27, 2022, thus bringing the total repayment to these providers to $10.5 billion. Id. at 44084.
[24] Id. at 44082.
[25] Id.

We do not take issue with CMS addressing the windfall through a prospective, downward adjustment of the conversion factor, but we strongly disagree with CMS's proposal to extend the recoupment period over 16 years that will allow hospitals to retain a portion of the windfall all the way to CY 2041. On the one hand, CMS proposes a timeframe of 60 calendar days for Medicare Administrative Contractors (MACs) to make $9 billion in lump sum payments to 340B hospitals (to be completed by early CY 2024), and yet the Agency's solution for the five-year windfall (2018-2022) is to reclaim those monies over a 16-year period through a 0.5% annual reduction to the conversion factor that will not even begin until CY 2025.

CMS recognizes that the additional payments hospitals received for non-drug items and services from 2018 through 2022 were "payments the hospitals should not have received but did anyway."[26] As such, we believe it is inappropriate to make such a small annual adjustment to the conversion factor that would take more than three times as long (16 years) to recoup the inappropriately paid monies than the number of years the incorrect payments were in effect (5 years).

Respectfully, CMS sets up a straw man as its justification for proposing a 0.5% annual reduction to the conversion factor for a 16-year period. CMS says that such a minimal reduction "would balance the need to address the past payments for non-drug items and services to ensure budget neutrality while also ensuring the offset is not overly burdensome on impacted entities, especially those in rural communities, which we believe would be the case if we were to apply an adjustment for the full offset amount in a single year."[27]

We agree with CMS that it would be inappropriate to offset the entire windfall in one year, but there is a significant difference between a single-year adjustment and CMS's proposal of stretching the adjustment over 16 years. We believe the most reasonable approach would be to recoup the windfall over a five-year adjustment period—the same length of time that hospitals received the benefit of the 3.19% increase in the conversion factor triggered by the payments for 340B-acquired drugs at ASP minus 22.5 percent. CMS should not be rewarding hospitals—who know full well that they received billions of dollars from Medicare to which they were not entitled—with the time-value of that money for an 16 additional years.[28]

[26] Id. at 44086.
[27] Id. at 44087.
[28] Nor do we believe it would be appropriate, as CMS identifies as an alternative option, to delay the start of the offset from CY 2025 to CY 2026 to "provide hospitals with additional time to make necessary arrangements." Id. at 44089. From the moment the Supreme Court issued its decision in *AHA v. Becerra* in June 2022, the hospitals knew that they would not be permitted to keep the windfall they had received from CY 2018 through CY 2022 as a result of the inappropriately inflated conversion factor.

Another alternative would be for CMS to offset a fixed dollar amount each year over a fixed period of time. As noted above, the most reasonable approach would be a five-year period that aligns with the five-years that hospitals received the benefit of the 3.19% increase in the conversion factor for non-drug items and services. This would mean dividing the $7.8 billion by five in order to offset $1.56 billion per year from CY 2024 through CY 2028 by making an adjustment to the conversion factor to reflect an estimated $1.56 billion reduction in non-drug items and services spending for each year. We do not believe any longer time period would be appropriate.

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DHPA looks forward to serving as a resource to CMS as it works to finalize the 340B Remedy Proposed Rule. Please reach out to me directly with any questions or requests for additional information (scott.ketover@mngi.com, 612-870-5408).

Sincerely,

Scott R. Ketover, M.D.
DHPA President & Chair of Health Policy