DIGESTIVE HEALTH
PHYSICIANS ASSOCIATION®

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September 13, 2022

BY E-MAIL

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments to CMS-1772-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 and Ambulatory Surgical Center Payment Systems Proposed Rule for Calendar Year 2023 (OPPS/ASC 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 2,400 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 of providing innovative treatments for serious diseases such as colorectal cancer, Crohn's disease, and ulcerative colitis.

DHPA submits this comment letter to make three main points regarding Medicare payments to 340B hospitals arising from the Supreme Court's June 2022 decision that the U.S. Department of Health and Human Services ("HHS") and, by extension, CMS acted unlawfully in implementing a lower payment formula of Average Sales Price (ASP) minus 22.5% for reimbursement of drugs to 340B hospitals because the Agency had failed to undertake a survey of acquisition costs to support the reimbursement level it had set for that group of hospitals. [2]

[1] 87 Fed. Reg. 44502 (July 26, 2022).
[2] *American Hospital Association et al. v. Becerra*, 142 S.Ct. 1896 (2022).

The three points we make are of profound consequence to the sustainability of high quality, cost-efficient and convenient care delivery furnish in the independent ASC setting:

1. As was the case in 2018, when CMS implemented the more appropriate payment level of ASP minus 22.5% for 340B hospitals, the ASC payment system should be insulated from any change CMS makes to OPPS payments in light of the Supreme Court's decision in *AHA v. Becerra* that reduce the OPPS conversion factor for CY 2023;

2. ASC payments for CYs 2018-2022 (when CMS paid 340B hospitals at ASP minus 22.5%) should not be subject to any retroactive recoupment; and

3. CMS should undertake, without delay, the survey of acquisition costs required by the Medicare statute and base Medicare payments to 340B hospitals on that survey starting with CY 2023. As CMS recognized through the payment policy it had in effect for 2018 through 2022, a cost survey is necessary to ensure that 340B hospitals not be reimbursed by Medicare for Part B drugs far in excess of their acquisition costs. To pay 340B hospitals at ASP + 6% would exacerbate the unleveled playing field that independent gastroenterology (and other specialty) practices confront and fuel further anti-competitive behavior and physician acquisitions by hospitals.

Background on 340B Payment Policy

First enacted in 1992 to assist indigent and uninsured patients seeking treatment in safety net hospitals, the 340B drug discount program has grown tremendously in recent years, as has been documented by numerous studies.[3] In 2020, total 340B program sales reached $38.8 billion when measured at the discounted 340B price, which is more than three times the level of 340B sales compared to just five years prior.[4] Until CMS issued its 2018 OPPS Final Rule, 340B hospitals

[3] The 340B drug pricing program continues to expand at astonishing, double-digit rates, with data from the Health Resources and Services Administration showing that 340B discounts grew from $6.9 billion in 2012 to $24.3 billion in 2018. "340B Program Purchases Reach $24.3 Billion—7%+ of the Pharma Market—As Hospitals' Charity Care Flatlines," Drug Channels (May 14, 2019), *available at* https://www.drugchannels.net/2019/05/exclusive-340b-program-purchases-reach.html (last accessed Sept. 2, 2022);
Medicare Payment Advisory Commission March 2020 Report, Chapter 3, p. 56, *available at* https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar20_entirereport_sec.pdf (last accessed Sept. 2, 2022);
HHS Office of Inspector General: Part B Payments for 340B-Purchased Drugs, p.8, *available at* https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf (last accessed Sept. 2, 2022).

were not required to pass on these substantial drug savings to *any* of their patients (not even uninsured or indigent patients). Rather, many 340B hospitals used these resources to acquire competing physician practices.[5]

Hospitals acquisitions of physician practices are terribly problematic for our health care system—dramatically increasing the cost of care for Medicare and private patients as well. Two examples—the cost of drug administration and colonoscopies—illustrate how serious this situation is. Medicare pays $325.64 for drug administration (CPT Code 96413) in the hospital outpatient department (HOPD) setting, but *less than half that amount* ($140.16) when administered in a physician office. Similarly, Medicare pays $1,059.06 for a colonoscopy (CPT Code 45380) in an HOPD, but only half that amount ($537.08) in an independent ASC. That is why DHPA, whose mission is to promote and protect the delivery of high quality, cost-efficient care in the independent practice setting as a competitive counterbalance to more expense care furnished in hospitals, welcomed CMS's reform to reduce 340B drug reimbursement for Medicare beneficiaries.

CMS's implementation of a reimbursement formula of ASP minus 22.5% for 340B hospitals, beginning in 2018, was a modest reform given that numerous studies commissioned by the federal government and other stakeholders demonstrate that 340B hospitals acquire drugs at discounts far in excess of 22.5 percent.[6] There can be little question that the 340B program has strayed far from its goal of providing a safety net for our country's most vulnerable patients. And to make matters worse, this broken system now helps drive up health care system costs by reducing competition.

Payment of ASCs for 2023

In the 2023 OPPS Proposed Rule, CMS indicates that it intends to revert drug reimbursement to 340B hospitals to ASP+6% in 2023 to comply with the Supreme Court's decision in *AHA v. Becerra*.[7] By making that payment increase, CMS asserts it will be compelled to decrease the OPPS conversion factor ("CF") by 4.1 percent. (We note that CMS offers no explanation for why this 4.1% decrease is significantly greater than the corresponding 3.2% increase to the CF when

[4] Berkley Research Group: "Measuring the Relative Size of the 340B Program" June 2020: https://media.thinkbrg.com/wp-content/uploads/2020/06/17122436/BRG-340B-Measuring_2020_cleaned.pdf (last accessed Sept. 2, 2022).

[5] Avalere White Paper: Hospital Acquisitions of Physician Practices and the 340B Program (June 8, 2015), *available at* https://avalere.com/insights/avalere-white-paper-hospital-acquisitions-of-physician-practices-and-the-340b-program (last accessed Sept. 2, 2022).

[6] As the Medicare Payment Advisory Commission notes, "payments hospitals receive for 340B drugs (even at ASP–22.5 percent) are higher than the drug's discounted acquisition cost under the 340B program (and these discounts are growing)." Moreover, the HHS Office of Inspector General found that Medicare paid 340B hospitals 58% more than the 340B discounted prices. This means hospitals are still reaping substantial margins on Part B drugs even with the payment of ASP minus 22.5%.

[7] 87 Fed. Reg. at 44505, 44507, 44647-49.

CMS changed reimbursement for 340B hospitals to ASP minus 22.5% in 2018). This reduction to the OPPS CF could subsequently cascade into the ASC payment system, which is based on the OPPS CF. CMS seeks comment on how to best redistribute the $1.96 billion for 2023 to affected hospitals, as well as on how to "remedy" differential payments for 2018 through 2022 when 340B hospitals were reimbursed at ASP minus 22.5 percent.

To start, it would be entirely inappropriate and unfair to ASCs, which are paid under a separate payment system, to shoulder the burden of significant payment reductions for an error CMS made in the OPPS payment system that has nothing to do with any of the services ASCs provide. ASCs do not administer separately payable Part B drugs; rather, they provide surgeries and procedures such as colonoscopies, cataract replacement, and orthopedic and pain surgeries.

We note that when CMS changed 340B payments for CY 2018 to ASP minus 22.5, **the Agency did not allow that change in payment to separately payable drugs under the OPPS to impact the ASC CF.**[8] **CMS should take the same approach for 2023, even if the Agency changes the payment level for 340B hospitals to ASP + 6 percent.** Regardless of what CMS decides to do with respect to OPPS drug payments—whether in 2023 or beyond—the Agency should continue to insulate the ASC CF from any change due to the payment change for the separately payable drugs under the OPPS.

More fundamentally, the reason CMS finds itself in the position of having to change the reimbursement formula for 340B drugs is not because setting payment at ASP minus 22.5% was inaccurate, but because the Supreme Court concluded that the Agency violated its statutory obligation by not conducting a survey of acquisition costs before developing the separate payment classification for 340B hospitals.[9] **The appropriate action CMS should take in response to the Supreme Court decision is not to change payment to 340B hospitals to the unsupportable level of ASP + 6%, but to conduct the necessary study of acquisition costs, without delay, and use those findings to establish payment for 340B hospitals for CY 2023 and beyond.** 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.

CMS should act with all deliberate speed to engage in the cost study much like it did after the U.S. District Court for the District of Columbia ruled in favor of the 340B hospitals in the *AHA v.*

[8] See OPPS Final Rule for CY 2018, 82 Fed. Reg. 52356, 52496, 52558 (Nov. 13, 2017) (reflecting that CMS did not apply the ASC budget neutral scalar to items and services, such as Part B drugs, that are paid separately under the OPPS).

[9] *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.").

Becerra case in late 2018. Following the loss in the district court, the Agency recognized that it was "important to begin obtaining acquisition costs for specified covered outpatient drugs to set future payment rates based on cost for certain 340B Hospitals."[10] There is an even more compelling need to do so now that the Supreme Court has issued its ruling that differential payments can only be made to different groups of hospitals if based on a cost acquisition survey.

To permit 340B hospitals to be paid at ASP + 6% for 2023 (or for any year) would be fundamentally at odds with the commitment to "ensure that the Medicare program pays for specified covered outpatient drugs, purchased under the 340B Drug Pricing Program, at a reasonable payment amount to ensure access to care is maintained, prudent payers of taxpayer dollars, and ensure that Medicare beneficiaries can also stretch their scarce resources."[11]

A payment policy that reflects a CMS-conducted study would provide an appropriate remedy for 2023 consistent with the Supreme Court's decision in *AHA v. Becerra* and could result in no increase in payment levels for 340B drugs. HHS acknowledged this very point in recent briefing on remand to the district court when it noted that the results of such a survey may indicate that no change in payment level is needed. **And if, for logistical reasons, CMS cannot complete the study before January 1, 2023, then current Medicare payments can be frozen in place for one or two quarters of 2023 until the study is completed and new payment policy can be established**.

Such a limited delay would be entirely appropriate in these unique circumstances, given that CMS knows that setting reimbursement at ASP + 6% for 340B hospitals would grossly overpay 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 reimbursement level for 340B-acquired drugs.[12] As one example, HHS-OIG estimated in a March 2016 Report that discounts across all 340B providers

[10] Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709), OMB 0938-1374, *available at* https://omb.report/omb/0938-1374 (last accessed Sept. 8, 2022).
[11] Id; See also CMS Response to 340B Survey Comments, Hospital Survey for Specified Covered Outpatient Drugs (SCODs) (CMS-10709), OMB: 0938-1374, *available at* https://omb.report/icr/202008-0938-005/doc/103575401 (last accessed Sept. 8, 2022).
[12] OPPS Final Rule for CY 2019, 83 Fed. Reg. 58818, 59018 (Nov. 21, 2018).

average 33.6 percent of ASP.[13] And CMS has previously acknowledged that some reports have found 340B hospitals benefitting from discounts as high as 50 percent.[14]

To adjust 340B hospitals to ASP + 6% at the start of CY 2023 without taking into account the results of a cost acquisition survey, which we urge CMS to begin immediately, 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."[15] To revert back to ASP + 6% for 340B hospitals without the benefit of the cost acquisition survey results would drive 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.[16] This has encouraged hospital-physician practice consolidation because hospitals can expand their profit margins on drugs provided by the acquired practices.[17]

The answer to the Supreme Court's decision in *AHA v Becerra* is not for CMS to give up on getting drug reimbursement right for 340B hospitals and simply pay all hospitals at ASP + 6%, but, instead, to conduct the cost acquisition survey required under the Medicare Act in order to permit differential payment. We are not aware of any statutory prohibition that would prevent CMS from adopting this approach in order to avoid paying 340B hospitals at a rate that is not justified under any possible cost acquisition data analysis.

And, as noted above, we cannot overstate the fundamental unfairness of ASCs, which are not involved with the dispute over drug reimbursement, having to finance legal errors made by CMS. ASCs already confront significant payment cuts due to a discretionary "scaler" that CMS has been using to reduce payments to ASCs when procedures migrate from the more expensive hospital setting to the ASC setting. Since the new ASC payment system was implemented in 2008, ASCs have suffered a 15% payment reduction because of the scaler. It would be harmful to patient care if ASCs, already suffering from significant cuts as a result of the unnecessary ASC scaler, are also

[13] 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).
[14] 83 Fed. Reg. at 59020.
[15] H.R. Rep. No. 102-384(II), at 12 (1992).
[16] 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.
[17] 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).

subjected to additional cuts from exigencies in the OPPS fee schedule that the Supreme Court found to be unlawful. Costs to physician practices and ASCs continue to escalate due to worker shortages, rampant inflation, and continued pandemic-related measures. CMS should not exacerbate these serious challenges through application of its unrelated 340B payment policy under the OPPS fee schedule.

CMS Does Not Have the Statutory Authority to Remedy the 340B Payment Issue under the OPPS Payment System in a Way that Would Result in Retrospective Recoupment of Funds from ASCs.

Nothing in the statute supports the notion that CMS can retroactively recoup payments made to providers under prospective payment systems. Prospective payment systems, by their inherent nature, are applied *prospectively* and budget neutrality decisions made for previous years (e.g., 2018 through 2022) cannot be revisited. The plain text of the Medicare Act authorizes CMS to establish a "prospective" payment system for the *following* year based on *estimated* expenditures for that next year.[18]

The law does not provide CMS with the ability to evaluate spending already made for prior years and—in the name of "budget neutrality"—change future reimbursement policy to extract claw backs or recoupment, even if those estimated expenditures determined in advance of a given year do not ultimately match actual spending. When the U.S. Court of Appeals for the District of Columbia dealt with the issue of budget neutrality under the Medicare Act, the Court noted that budget neutrality under the OPPS is a *prospective* exercise by avoiding increases or decreases in "overall projected expenditures for the *next* year."[19]

Simply put, budget neutrality no longer applies once expenditures are actual. Indeed, if budget neutrality were required of actual expenditures and not limited to a prospective assessment, CMS would be in the position of constantly revisiting and significantly revising payment policy. That would lead to a volatile and unpredictable payment system, which would wreak havoc on the health care system and set a dangerous precedent for CMS to pursue radical, retroactive recoupments in the future. Not surprisingly, we have not identified a single instance in which CMS has offset the cost of fixing pricing errors made under the OPPS by retroactively recouping prior payments made to providers; and, likewise, we did not find any instance in which a pricing error under one payment

[18] 42 U.S.C. 1395(t).
[19] *American Hospital Ass'n et al. v.* Azar, 964 F3d 1230, 1234 (DC Cir 2020) (emphasis added).

system (e.g., the OPPS payment system) led to CMS fixing that error by recouping payments from providers under a different payment system (e.g., the ASC payment system).

The 3.2% budget neutrality adjustment made in 2018 and thereafter reflected CMS's *estimate* of the adjustment needed to achieve budget neutrality in payments that were to be made for the *upcoming* year. We are not aware of an instance in which CMS retroactively corrected perceived overpayments to entire provider groups by using its authority under *prospective* budget neutrality requirements, and the Agency should not do so here. As an example, when CMS increased payments to rural hospitals in 2007 because those hospitals were mistakenly excluded from a cancer hospital adjustment, CMS did not retroactively recoup overpayments to other hospitals.[20] And in 2015, CMS realized that OPPS payments for 2014 and 2015 had been too high due to packaging of clinical laboratory tests into its OPPS payments. CMS reduced the CF in 2016 to prevent further overpayments but it did not "recoup" overpayments for the past years of 2014 and 2015.[21] This prospective approach was appropriate, given that there is no statutory language that would authorize retrospective recoupment.

Setting aside CMS's lack of statutory authority to demand and recoup past payments, such action is unnecessary to make whole the 340B hospitals that were unlawfully underpaid (if, in fact, a cost acquisition study shows that the 340B hospitals should have been paid at a level higher than ASP minus 22.5%). In light of the ruling in *AHA v. Becerra*, CMS could pay the 340B hospitals out of the Federal Judgment Fund[22] the difference between ASP minus 22.5% and what those hospitals would have received if the ASP payment reform had not been in effect for 2018 through 2022.

Importantly, the payment to 340B hospitals out of the Federal Judgment Fund would not simply be the difference between ASP minus 22.5% and ASP + 6%. To pay on that differential would result in an overpaying the 340B hospitals, because those hospitals (like all hospitals) benefitted from the 3.2% increase to the CF for all hospital services. **Specifically, any amount CMS pays to the 340B hospitals for 2018 through 2022 should come out of the Federal Judgment Fund and should net out the difference between the two ASP payment rates (ASP minus 22.5% and ASP + 6%) and the 3.2% increase to all services provided through the CF change.**

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[20] *H. Lee Moffitt Cancer Center and Research Institute Hospital, Inc. v. Azar*, 324 F. Supp. 3d 1, 15 (D.D.C. 2018) (noting that the OPPS's budget neutrality requirement may not apply "where HHS has elected to make the cancer-hospital adjustment . . . well after the services are rendered, not by adjusting prospectively-set rates"); see also 2007 OPPS/ASC Final Rule for CY 2007, 71 Fed. Reg. 67960, 68010 (Nov. 24, 2006).
[21] OPPS/ASC Final Rule for CY 2016, 80 Fed. Reg. 70,298, 70,354 (Nov. 13, 2015).
[22] See 31 C.F.R. § 256.1.

Under no circumstance, however, would the Medicare Act permit CMS to make any offsets to achieve actual or retrospective budget neutrality. Nor does the statute permit CMS to apply budget neutrality principles to any remuneration that the Agency might provide 340B hospitals with respect to purported underpayments for prior years. For CMS to do otherwise would be to recoup payments that were lawfully made for non-drug items and services under the OPPS.

Lastly, it would be unconscionable to expect providers, who deliver care in independent ASCs, are paid under a different payment system, and have struggled to serve patients and keep their doors open during the challenges of a worldwide pandemic and lockdowns, to return monies to the government (either through repayment or recoupment) based on errors made in the government's formulation of payment policy under a different payment system. Clinicians furnishing care in ASCs were properly paid under the ASC fee schedule for 2018 through 2022 and did not benefit from a higher OPPS CF, as the ASC system was insulated from that change. ASCs, therefore, should not pay a penalty if CMS changes payment policy on 340B drugs now or in the future. In any event, such a dramatic and unprecedented step could not be taken by the Agency without express authorization from Congress.[23] No such authorization has been granted here.

DHPA looks forward to serving as a resource to CMS as it works to finalize the OPPS/ASC Fee Schedule for CY 2023. Please reach out with any questions or requests for additional information to DHPA's Chair of Health Policy, Dr. Scott Ketover (scott.ketover@mngi.com, 612-870-5408), or to DHPA's legal counsel, Howard Rubin (Howard.Rubin@katten.com, 202-625-3534).

Sincerely,

Latha Alaparthi, M.D.
President

Scott R. Ketover, M.D.
Chair, Health Policy

cc: Kevin Harlen, DHPA Executive Director
Howard Rubin, Esq., Katten Muchin Rosenman LLP

[23] See, e.g., TMA, Abstinence Education, and QI Programs Extension Act of 2007, Pub. L. No. 110-90, § 7, 121 Stat. 984, 986–97 (2007) (authorizing CMS to reduce 2010–2012 IPPS payment rates to offset any overpayments in 2008–2009); American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 631(b), 126 Stat. 2313 (2013) (authorizing CMS to reduce 2014–2017 IPPS payment rates to offset $11 billion in overpayments from 2008–2013).