LUGPA
Integrated Practices Comprehensive Care

Submitted via regulations.gov

September 13, 2022

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Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1772-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CY 2023 Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Proposed Rule (CMS-1772-P)

Dear Administrator Brooks-LaSure,

On behalf of the Large Urology Group Practice Association (LUGPA), we appreciate the opportunity to comment on the above captioned Calendar Year (CY) 2023 Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems Proposed Rule (the "Proposed Rule").1 LUGPA currently represents 150 urology group practices in the United States, with more than 2,100 physicians who, collectively, provide approximately 35% of the nation's urology services.

First, LUGPA writes to provide input on any readjustment for CY 2023, as well as any potential remedies for CY 2018-2022 that the agency may adopt following the Supreme Court's recent decision that CMS acted unlawfully in implementing a differential payment policy for drugs and biologicals purchased by 340B hospitals without having conducted a survey of hospitals' acquisition costs.[2] In particular, LUGPA urges CMS to ensure that the ASC payment system is not affected by any prospective adjustment for CY 2023 that may be necessitated by *American Hospital Association v. Becerra*, and to refrain from adopting a remedy for CY 2018-2022 payments that would involve the retrospective recoupment of funds from non-340B providers, as this approach is not supported by the governing statute. LUGPA also urges CMS to revive the alternative 340B payment methodology for Part B drugs acquired under the 340B program, and to ensure that the implementation of any future differential payment is in accordance with the Supreme Court's recent decision.

[1] 87 Fed. Reg. 44502 (July 26, 2022).
[2] 142 S. Ct. 1896 (2022).

LUGPA also writes in support of CMS's continued application of the productivity-adjusted hospital market basket, as well as CMS's proposals regarding addition of C-APC 5372, and reassignment of certain procedure codes from APC 5375 to APC 5376.

Our comments, which are discussed in more detail below, can be summarized as follows:

- LUGPA requests that CMS confirm that as the agency prospectively reverses the alternative 340B payment methodology, Ambulatory Surgical Centers will not be adversely impacted.
- LUGPA urges CMS to ensure that the methodology determined to remedy underpayments between 2018-2022 does not inadvertently impact non-340B eligible providers who receive no benefit from this program, including Ambulatory Surgical Centers.
- LUGPA urges CMS to commission a hospital acquisition cost survey for 340B drugs so that it may continue to pay for 340B drugs at a rate that more closely approximates the costs incurred by 340B providers, ensuring that the 340B program functions as it was intended, to subsidize care, rather than to create large margins for hospitals between the purchase and administration price for certain drugs across the board
- LUGPA supports CMS's application of the hospital market basket index to update the ASC payment system as a commonsense payment policy that promotes safe, convenient, and cost- effective care.
- LUGPA supports CMS's proposal to add proposed C-APC 5372 (Level 2 Urology and Related Services).
- LUGPA supports CMS's proposal to reassign certain procedure codes from APC 5375 to APC 5376.

I. BACKGROUND ON LUGPA

The Large Urology Group Practice Association (LUGPA) was formed in 2008 as a way to facilitate communication between independent urology-focused (GU) groups of ten or more providers. This served the complementary priorities of: (1) the promotion of clinical and operational benchmarking to guide best practices; (2) the establishment and promulgation of quality guidelines; and (3) the utilization of resources for advocacy and communication in the legislative and regulatory arena. Since that time, LUGPA has expanded its mission to incorporate any group practice that provides integrated and comprehensive GU services to patients affected by genitourinary diseases and conditions. LUGPA has gained membership steadily; it currently includes over 150 urology group practices in the United States, representing more than 2,100 physicians who, collectively, provide approximately 35% of the nation's Medicare fee-for-service

urology services.[3] Furthermore, LUGPA's members provide the majority of the GU care delivered in the independent physician office setting.[4]

As health care reform efforts in the US have evolved to redirect focus towards the development and promotion of outcome driven, "best-practice" patient care delivered in the most cost-effective setting, LUGPA practices have consistently been leaders in innovative and adaptive care models. Expanding both the range of procedures and the complexity of care that can be safely and effectively provided in the independent physician setting has resulted in demonstrable reduction in the cost of care delivery as well as improved outcomes. In addition, LUGPA practices have been at the forefront of adopting team-based healthcare, with broad incorporation of other physician specialists and a variety of advanced practice providers, maximizing both convenience and accessibility to comprehensive and advanced care. LUGPA practices have embraced value-based care models, and the organization was among the first to create a physician-focused payment model. As such, LUGPA has served consistently in developing and promoting high-quality, cost-effective alternatives for care as a counterbalance to the inflationary trend associated with the vertical consolidation of health care services by hospital systems.

LUGPA's mission has been to provide and maximize access to the resources, technology, management tools and advocacy efforts to optimize the ability of independent practice urologists and their clinical partners to provide integrated, comprehensive care for patients with acute and chronic GU conditions. During the global Public Health Emergency (PHE), LUGPA's mission was expanded to provide crucial resources to independent physician practices so as to enable continuity of outpatient services, even as the nation's inpatient capacity was overrun by patients stricken with COVID-19. Through these and other efforts, LUGPA helped ensure that vulnerable populations continued to be able to access critical urological services.

LUGPA will continue to work on behalf of its membership to ensure that the integral role of independent GU practices is recognized and optimized as we evaluate and deploy legislative and regulatory strategies designed to reduce cost, improve quality, and expand access to US health care services.

II. 340B ALTERNATIVE PAYMENT POLICY

In the CY 2018 OPPS/ASC Final Rule, CMS finalized a policy to pay for Part B drugs acquired under the 340B program at Average Sales Price (ASP) - 22.5% instead of ASP + 6%. CMS stated that its goal in adopting the payment policy change was to make Medicare payments for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs, while recognizing the intent of the 340B program to allow covered entities to stretch scarce resources for the benefit of their vulnerable patient populations. CMS continued this payment policy for CYs 2019-2022.

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[3] CMS PUF Data: Medicare Physician & Other Practitioners - by Provider and Service. Accessed at: https://data.cms.gov/provider-summary-by-type-of-service/medicare-physician-other-practitioners/medicare-physician-other-practitioners-by-provider-and-service/data, 9/1/2022

[4] *Id.*

Hospital groups challenged CMS's 2018 policy, and, on June 15, 2022, the Supreme Court found that HHS acted unlawfully in varying payment rates for drugs and biologicals among groups of hospitals without having conducted a survey of hospitals' acquisition costs.[5] While the Supreme Court's decision concerned payment rates for CYs 2018 and 2019, its reasoning necessarily has implications for payment rates in CYs 2020-2022, as well as CY 2023. However, the Court's decision did not address the proper remedy for 340B hospitals for the relevant years covered in the lawsuit, nor did it prescribe how HHS should approach resolving the remaining years.

For CY 2023, CMS states that it is proposing to continue its policy of paying ASP - 22.5% for 340B-acquired drugs. According to CMS, when the Court's issued its decision on June 15, 2022, the agency had already developed the policies, calculated the payment rates intended for the CY 2023 Proposed Rule, which included application of an adjustment to maintain budget neutrality. CMS states that there was insufficient time remaining in the proposed rule development process for the agency to change the policy and accompanying rates in response to the Court's decision. As such, the rates, tables, and addenda in this proposed rule reflect the proposal to pay for drugs differently if they were acquired through the 340B program, namely at ASP - 22.5%, with the anticipated savings redistributed to all other items and services in a budget neutral manner.

However, CMS further notes that, "in light of the Supreme Court's recent decision in *American Hospital Association v. Becerra*, [it] fully anticipate[s] applying a rate of ASP + 6 percent to such drugs and biologicals in the final rule for CY 2023 and making a corresponding decrease to the conversion factor consistent with the OPPS statute and our longstanding policy that this adjustment is made in a budget neutral manner."[6] CMS clarifies that, due to budget neutrality, reverting to ASP + 6% for 340B drugs would require a readjustment of approximately $1.96 billion to decrease the OPPS conversion factor. Notably, any readjustment to the OPPS conversion factor has the potential for collateral impact to ASC payment rates.

In the CY 2023 Proposed Rule, CMS solicits public comments on several aspects of the above. First, CMS solicits comments on how best to redistribute the $1.96 billion offset to the OPPS conversion factor to affected hospitals (i.e., how to implement the "remedy" in response to the court decision). CMS also solicits "public comments on the best way to craft any proposed, potential remedies affecting calendar years 2018-2022 given that the Court did not resolve that issue." Last, CMS solicits comments on whether to continue a differential payment policy for 340B-acquired drug for future years (e.g., ASP - 22.5% vs. ASP + 6% as for all other drugs).

A. <u>LUGPA requests that CMS confirm that as the agency prospectively reverses the 340B alternative payment methodology, Ambulatory Surgical Centers will not be adversely impacted.</u>

When CMS adopted the 340B drug payment reductions in the CY 2018 OPPS final rule, CMS announced that it would do so in a budget neutral manner within the OPPS through "offsetting the

[5] 142 S. Ct. 1896 (2022).
[6] 87 Fed. Reg. at 44505.

conversion factor for nondrug services."[7] As a result, savings from the 340B payment reduction would be "redistributed pro rata through an increase in rates for non-drug items and services under the OPPS."[8] At the same time, CMS clarified that "the budget neutral weight scalar is not applied in determining payments for [340B-acquired drugs],[9] and as such, "scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount…such as drugs and biologicals that are separately paid…."[10]

In light of the fact that the ASC PPS was not affected by the 340B payment reductions since they were implemented in CY 2018, we ask that CMS confirm in the final rule that ASC PPS rates will remain unaffected by CMS's implementation of the Supreme Court's decision in *AHA v. Becerra*, either through the conversion factor or relative weights. While some ASCs are owned by hospital systems (and even 340B eligible hospitals), many are owned partially or wholly by independent physician groups who have no 340B eligibility, direct or indirect. It would be fundamentally unfair to penalize physician practices that have not and cannot benefit from the 340B program because the agency's actions were found to be unlawful. Many physician practices continue to experience significant financial difficulties caused by the pandemic and exacerbated by inflationary pressures. Indeed, if the final OPPS/ASC payment rates vary significantly from the payment rates included in the Proposed Rule, this would raise obvious concerns of fair notice, and we are troubled that stakeholders have not been provided a full opportunity to meaningful comment on the merits of various proposals considered by the agency.

B. <u>CMS should not implement a remedy for CY 2018-2022 that involves retrospectively recouping funds from non-340B providers.</u>

Any attempt to retrospectively recoup funds from non-340B providers for CY 2018-2022 is not supported by the governing statute. The concept of budget neutrality does not provide any sort of justification for retrospective recoupment, as the statute only contemplates that the Secretary will ensure budget neutrality *prospectively*.[11] For CY 2018-2022, the Secretary correctly applied a positive adjustment to non-340B claims in order to achieve budget neutrality based on prospective estimates undergirding those rulemakings. Thus, any remedy must not explicitly or implicitly recoup non-340B payments, which were properly made for the relevant years. The agency cannot use budget neutrality as a crutch to claw back needed funds that have already been spent by providers rendering care in the midst of a once in a lifetime pandemic, and LUGPA is not aware of, nor has the agency cited any legal authority for the retroactive recoupment of payments.

Separate and apart from the legal obstacles, retrospective recoupment is unnecessary. There are other options available to the agency to remedy this issue. CMS could pay the 340B hospitals out

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[7] 82 Fed. Reg. 59216, 59364 (Dec. 14, 2017).
[8] Id.
[9] *Id.* at 59356.
[10] *Id.* at 59418.
[11] See 42 U.S.C. §1395l(t)(9)(B) (emphasis added).

of the Federal Judgment Fund[12] 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 the 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 overpayment to the 340B hospitals, because those hospitals (like all hospitals) benefitted from the 3.2% increase to the conversion factor 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 conversion factor change.

C. CMS should continue its differential payment policy for 340B-acquired drugs consistent with the Supreme Court's decision.

As mentioned above, the Supreme Court held that CMS cannot vary reimbursement rates for drugs purchased by one group of hospitals without conducting the required survey of hospitals' acquisition costs.[13] Here, this means that CMS cannot implement payment rates for 340B-acquired drugs that reflect the acquisition costs for the relevant providers without conducting an acquisition cost survey. As such, LUGPA urges CMS to conduct a comprehensive survey of hospital acquisition costs and continue its differential payment policy for 340B-acquired drugs.

The explosive growth of the 340B program in the last decade strongly suggests that hospitals are exploiting 340B pricing to generate significant profits with little oversight on how they are spent. The Medicare Payment Advisory Commission (MedPAC) found that the 340B program grew relatively slowly between 1992 and 2005 to include roughly 583 participants.[14] However, by 2014, the 340B program exploded and grew by 367% in just nine years after the enactment of the Medicare Modernization Act (MMA) of 2003. Hospitals recognized that 340B program participation enabled them to maximize profits under the new ASP-based payment methodology established under the MMA. This can be seen most clearly in the oncology space, where the share of chemotherapy infusions administered in 340B hospital outpatient departments increased by 770% between 2004 and 2014, rising from 3% to 23.1%.[15] There should be no doubt that participation in the 340B program represents a lucrative membership club for hospitals.

Reduction in the Medicare payment amount for 340B-acquired drugs merely reflects the significantly discounted acquisition cost that 340B covered entities enjoy on Part B drugs and avoids contributing to an artificial windfall for 340B covered entities associated with a payment of ASP + 6%. 340B hospitals will continue to have access to heavily discounted drug prices.

We also believe that the payment reduction for 340B-acquired drugs, among other policies, are critical in stemming the tide of consolidation of physician services within the hospital setting while

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[12] See 31 C.F.R. § 256.1.
[13] *AHA v. Becerra*, 142 S. Ct. 1896 (2022).
[14] Report to the Congress: Overview of the 340B Drug Pricing Program. MedPAC, May 2015.
[15] Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014. Milliman, April 2016.

safeguarding the high quality, cost-efficient care furnished to Medicare beneficiaries by independent medical practices.

III. LUGPA Supports CMS's Application of the Hospital Market Basket Index to Update the ASC Payment System as a Commonsense Payment Policy that Promotes Safe, Convenient, and Cost- Effective Care.

In the CY 2019 OPPS/ASC final rule, CMS adopted a policy that applied the productivity-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023). [16] During this interim period, CMS would assess whether there was a migration of the performance of procedures from the hospital setting to the ASC setting as a result of the use of a productivity-adjusted hospital market basket update, as well as whether there were any unintended consequences from the policy.

Pursuant to this policy, for CY 2023, CMS proposes to utilize the hospital market basket update of 3.1 percent, reduced by the productivity adjustment of 0.4 percent, resulting in a productivity-adjusted hospital market basket update factor of 2.7 percent for ASCs meeting the quality reporting requirements.[17] This would result in a proposed CY 2023 ASC conversion factor of $51.315.[18] Based on this proposed update, CMS estimates that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2023 would be approximately $5.4 billion, an increase of approximately $130 million compared to estimated CY 2022 Medicare payments.[19] LUGPA supports CMS's proposed update to the ASC conversion factor, as well as CMS's continued use of the hospital market basket to update the ASC payment system.

LUGPA also urges CMS to use the hospital market basket to update ASC payment amounts for CY 2024 and subsequent years. The underlying statute does not require the adoption of any one specific annual update factor for the ASC payment system, but it does provide that in the absence of any such update factor as determined by CMS, payments must be increased by CPI-U.[20] Although we understand that CMS's use of the hospital market basket is temporary and set to expire in CY 2023, we cannot comprehend why CMS would revert to CPI-U regardless of what the agency concludes following its assessment of the five-year hospital market basket update policy.

LUGPA believes that the use of the hospital market basket update is a commonsense update factor to use since it directly incorporates the cost of healthcare resources and inputs, as opposed to the CPI-U that barely reflects the costs of healthcare, which have consistently risen faster than the cost of consumer goods. Even if CMS's assessment concludes the worst-case scenario, that the hospital market basket update had no impact on migrating procedures to the ASC setting, we do not see how that justifies updating a healthcare payment system with price changes that are virtually

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[16] 83 FR 59075 through 59080.
[17] 87 Fed. Reg. at 44725.
[18] *Id*.
[19] 87 Fed. Reg. at 44505.
[20] See Social Security Act, § 1833(i)(2)(C)(i).

irrelevant with respect to the rising cost of healthcare. Reverting to the statutory default of CPI-U when CMS plainly has the authority to use a superior update factor effectively represents an abdication of CMS's responsibility to ensure access to ASC services through adequate payment to participating providers.

Therefore, we urge CMS to apply the hospital market basket update to the ASC payment system on a permanent basis to better align payments with the rising costs of healthcare and to help provide payment certainty to ASC providers.

IV. LUGPA Supports CMS's Proposal To Add C-APC 5372 (Level 2 Urology and Related Services).

Each year, in accordance with Section 1833(t)(9)(A) of the Act, CMS reviews and revises the services within each APC group and APC assignments. For CY 2023, CMS proposes to add one C-APC under the existing C-APC payment policy: proposed C-APC 5372: Level 2 Urology and Related Services.[21] CMS states that this APC was selected because, like other C-APCs, it includes primary, comprehensive services, such as major surgical procedures, that are typically reported with ancillary and adjunctive services.[22] Furthermore, similar to other clinical APCs that have been converted to C-APCs, there are currently higher APC levels (Levels 3-8 Urology and Related Services) within the clinical family or related clinical family of this APC that have previously been converted to C-APCs.[23]

LUGPA supports the addition of C-APC 5372: Level 2 Urology and Related Services and asks that the agency finalize this proposal.

V. LUGPA Supports CMS's Proposal to Reassign Certain procedure Codes from APC 5375 to APC 5376

In the Proposed Rule, CMS states that, pursuant to its review of CY 2021 claims data, it has identified eight procedures from APC 5375 whose geometric mean ranged between the geometric means for APC 5375 and APC 5376.[24] CMS states that the geometric means of these services are closer to the geometric mean of APC 5376, which is $8,788.53, than the geometric mean of APC 5375, which is $4,826.23. As such, for CY 2023, CMS proposes to reassign these eight procedures from APC 5375 to APC 5376 for the Urology and Related Procedure APC series.

LUGPA supports CMS's proposal and agrees with CMS that this reassignment "improves the resource cost and clinical homogeneity for the procedures within APC 5375 and APC 5376."[25]

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[21] 87 Fed. Reg. at 44517.
[22] *Id*.
[23] *Id*.
[24] 87 Fed. Reg. at 44572.
[25] *Id*.

On behalf of LUGPA, we would like to thank CMS for providing us with this opportunity to comment on the Proposed Rule. Please feel free to contact Dr. Kapoor at (516)-342-8170 or dkapoor@impplc.com if you have any questions or if LUGPA can provide additional information to assist CMS as it considers these issues.

Respectfully submitted,

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