GREATER NEW YORK HOSPITAL ASSOCIATION
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The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1772-P
P.O. Box 8010
Baltimore, MD 21244-1810

Dear Ms. Brooks-LaSure:

On behalf of the more than 160 voluntary and public hospitals that make up the acute care membership of the Greater New York Hospital Association (GNYHA), I appreciate this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the calendar year (CY) 2023 outpatient prospective payment system (OPPS) and ambulatory surgical center payment system. Our comments address the following topics:

- Market Basket Update
- Payments for 340B Drugs
- Exemption of Sole Community Hospitals (SCHs) from Site-Neutral Cuts
- Medicare's Share of Organ Acquisition Costs

If you have any questions or would like further information, please contact Rebecca Ryan at (212) 506-5514 / rryan@gnyha.org).

Thank you for considering our recommendations.

Sincerely,

Kenneth E. Raske
President

Market Basket Update

CMS proposes a payment increase of 3.08% in CY 2023, which includes a market basket update of 3.1%, a pass-through spending budget neutrality adjustment of 0.34%, and a -0.4% productivity adjustment. When coupled with the expected four-percentage-point budget neutrality reduction should CMS finalize its alternative 340B payment policy, GNYHA estimates that the payment increase would be only 0.83%. As we stated in our comment letter in response to the Federal fiscal year (FY) 2023 inpatient prospective payment system (IPPS) proposed rule, **CMS's proposed update factor vastly underestimates the cost growth that acute care hospitals have experienced and will continue to experience due to structural labor market changes triggered by the COVID-19 public health emergency (PHE). In addition, it does not account for substantial forecast errors.**

Inflation reached the highest levels observed in 40 years in 2021[1] and has remained elevated through 2022,[2] resulting in considerable increases in hospital costs compared to pre-pandemic levels. The increased inflationary environment has placed significant financial burdens on providers. According to the August 2022 Hospital Flash Report by Kaufman, Hall and Associates, the median hospital operating margin was -0.98% through July 2022, a 74% decrease from July 2021. Total expenses per adjusted discharge are nearly 11% higher than the same time last year, and expense increases were particularly high for labor (13.5% per adjusted discharge).[3] The increase in labor costs is driven by persistent labor shortages and an increased reliance on, and the rising price of, contract labor due to the COVID-19 PHE. Importantly, increases in contract labor costs are not captured by the labor cost component of the hospital market basket. In the FY 2023 IPPS final rule, CMS notes that in 2020 contract labor only accounted for 3% of labor *hours*, but this understates the impact of rising contract labor *costs*. Based on GNYHA's analysis of Medicare cost reports, contract labor among the continuous set of hospitals with an available cost report for 2015 through 2021 now comprises nearly 8% of total labor *costs*.

Further, an analysis by The University of Southern California–Brookings Schaeffer Initiative for Health Policy demonstrates that while provider input costs are rising faster than in the past, these rising input costs have not translated into increased payments.[4] In response to the FY 2023 IPPS proposed rule, GNYHA commented that CMS should address this discrepancy by revising its market basket update methodology by calculating the four-quarter moving average percent change between the estimates for the most recent four quarters and the estimates for the prior four quarters that CMS used initially in the calculation of the market basket update in the previous year. This change would help ensure adequate payment increases even in the presence of heightened inflation when initial forecasts tend to be artificially low.

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[1] https://www.usatoday.com/story/money/2022/04/12/inflation-rate-cpi-highest-40-years-prices/7284054001/

[2] https://www.usnews.com/news/economy/articles/2022-08-26/inflation-cools-in-july-as-powell-set-for-key-speech-on-interest-rates

[3] Kaufmann Hall National Hospital Flash Report. August 2022. https://www.kaufmanhall.com/sites/default/files/2022-09/KH-NHFR-2022-08_FINAL_9.2.22.pdf

[4] Fielder M. What Does Economy-Wide Inflation Mean for the Prices of Healthcare Services (and Vice Versa)? USC Schaeffer. Published April 1, 2022. Accessed June 17, 2022. https://healthpolicy.usc.edu/brookings-schaeffer/what-does-economy-wide-inflation-mean-for-the-prices-of-healthcare-services-and-vice-versa/

We once again urge CMS to consider revising its market basket update methodology to reflect the heightened inflationary environment more accurately, particularly given hospitals' deteriorating margins.

Payments for 340B Drugs

Earlier this summer, the US Supreme Court unanimously struck down CMS's policy of paying lower reimbursement rates to 340B hospitals. In response to the decision, **CMS stated in the OPPS proposed rule that it "fully anticipates" reverting to its prior policy of paying average sales price (ASP) +6% for 340B-acquired drugs in CY 2023. GNYHA supports this position and urges CMS to finalize this policy.**

CMS also requested comments on the appropriate remedy in *American Hospital Association (AHA) v. Becerra*. Based on the Supreme Court's decision, GNYHA believes the only appropriate and feasible remedy is to:

- Revert to the prior lawful policy of reimbursing all separately payable drugs at ASP +6% for CY 2023, regardless of whether a drug was acquired through the 340B program
- Promptly repay all 340B hospitals the difference between ASP +6% and what they were actually paid for drug claims as a result of this unlawful policy for CYs 2018-2022
- Hold the entire hospital field harmless for this illegal policy for CYs 2018-2022—meaning that there should be no recoupment tied to the higher payment rates for non-drug services provided during this period

GNYHA strongly encourages CMS to agree to this remedy in the ongoing *AHA v. Becerra* litigation.

Complete and Prompt Repayment is Necessary

To correct the unlawful policy that the Supreme Court struck down, CMS should promptly repay 340B hospitals the difference between ASP +6% and the amount actually paid to hospitals for 340B drugs (plus applicable interest) for *all* the years in which the agency acted unlawfully. The Supreme Court recognized that "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." Yet for five years, CMS's unlawful policy deprived 340B hospitals of payment, even as hospitals across the country struggled to care for their patients and communities during a once-in-a-century pandemic.

In devising the remedy, CMS cannot rely upon the survey of 340B acquisition costs initiated in CY 2020. The survey was defective because it did not meet the statutory requirement for CMS to survey a large enough sample of hospitals to generate a statistically significant estimate of average hospital drug acquisition costs for each specified outpatient drug. CMS only surveyed 340B hospitals (as opposed to all hospitals) and the vast majority either opted for the "Quick Survey" option that allowed CMS to substitute the Health Resources and Services Administration's 340B ceilings prices as reflective of their actual acquisition costs or did not respond. With only 7% of hospitals responding to the survey with their own data, CMS did not collect sufficient data to meet the statutory requirement and as such the data cannot be used to set future payment rates or to delay or deny repayment for CYs 2021 or 2022. The Government

even acknowledged during oral arguments in *AHA v. Becerra* that the surveys do not "produce results that are all that accurate."

Retrospective Recoupment Would be Unfair, Unlawful, and Unprecedented

In *AHA v. Becerra*, the Government argued that a judicial ruling invalidating the 2018 and 2019 reimbursement rates for 340B hospitals would require budget-neutral offsets elsewhere in the program, implying it would consider retrospectively recouping funds from hospitals that received them because of its unlawful 340B drug payment policy.

CMS should not penalize any hospital for the agency's own past mistakes in implementing an unlawful policy. Not only would retrospective recoupment be illegal, it would also be impossible to implement as a practical matter. Most of the funds that hospitals received were already spent during the pandemic, a crisis that even today is causing hospitals to struggle financially. Clawing back those funds would only further put patients and communities at risk.

Moreover, nothing in Federal law requires—or even permits—CMS to claw back funds to achieve budget neutrality. The law governing the OPPS makes it clear that budget neutrality applies *prospectively*—not retrospectively—as it addresses only future estimates and forward-looking periodic reviews. Therefore, CMS lacks the legal authority to recoup past payments to achieve budget neutrality and, to the best of our knowledge, there is no relevant instance where CMS has even tried to recoup prior OPPS payments.

GNYHA appreciates CMS's decision to restore drug payments to 340B hospitals at ASP+ 6% for CY 2023 in alignment with the Supreme Court's decision in *American Hospital Association v. Becerra*. We urge the agency to ensure no further harm is done to any hospital by promptly paying 340B hospitals the funds they are rightfully owed and not unfairly, unlawfully, and unprecedentedly recouping any funds from hospitals for payments made for non-drug services under the agency's unlawful 340B policy for the period 2018-2022.

Exemption of Sole Community Hospitals (SCHs) from Site-Neutral Cuts

Beginning in CY 2019, CMS used its authority to control "unnecessary increases" in the volume of certain services furnished in hospital outpatient departments (HOPDs) to expand upon the site-neutral cuts mandated by the Bipartisan Budget Act of 2015 (BBA). Specifically, CMS subjected off-campus HOPDs that were grandfathered ("excepted") under the BBA to reduced reimbursement rates for clinic visit services (i.e., these services were now paid at 40% of the OPPS rate, which is the rate CMS determined is equivalent to the rate paid under the physician fee schedule for the same services). CMS is now expressing concern that its expanded site-neutral policy could have the unintended consequence of limiting access to primary care in rural areas. Therefore, beginning in CY 2023, CMS proposes to exempt rural SCHs from the payment cuts for clinic visits furnished at off-campus provider-based sites that were excepted under the BBA.

GNYHA appreciates CMS's recognition that site-neutral payment policies can adversely impact access to vital health care services. GNYHA opposes site-neutral payments generally because they do not reflect the additional costs (and associated benefits) of furnishing services in HOPDs as opposed to in physicians' offices. However, at a minimum, we encourage CMS to expand the scope of its proposed exception policy to include additional HOPDs that provide primary care services in underserved areas. While CMS's

proposed exception policy would impact certain hospitals in rural areas, it would not benefit other rural hospitals or urban hospitals located in areas with access issues. An analysis of GNYHA's New York membership shows that 47% operate at least one off-campus site in a Primary Care Health Professional Shortage Area (PC-HPSA), indicating a shortage of primary care providers either for the geographic area or for a specific population within that geographic area. These same providers also provide a greater proportion of clinic visits off-campus (49%), as identified by the presence of a PO modifier on the claim, than providers that do not operate at least one site in a PC-HPSA (25%) and therefore may be disproportionately affected by CMS's site-neutral payment policy.

CMS should consider using an expanded exception policy to help hospitals maintain essential primary care services, particularly for beneficiaries residing in shortage areas, and to provide patients in these areas with sufficient choice of provider. One way that CMS could establish such an exception policy is to determine which excepted off-campus sites are in a PC-HPSA or treat a certain percentage of patients that reside in a PC-HPSA, and instead pay them at the full OPPS rate for evaluation and management services.

Request For Information (RFI): Changes to Medicare's Share of Organ Acquisition Costs

Transplant hospitals are currently reimbursed for Medicare's share of their organ acquisition costs reported on Worksheet D-4 of the Medicare cost report. To establish the "Medicare usable organ count," the Medicare cost report instructions state that transplant hospitals should include 1) organs transplanted into Medicare beneficiaries (including in some cases when Medicare is the secondary payer), 2) all organs excised from deceased donors that were sent to an organ procurement organization (OPO) for transplant at another hospital, 3) organs sent to other transplant hospitals, and 4) certain other organs.

CMS had expressed concern that the Medicare program has been reimbursing costs for organs that do not end up transplanted into Medicare beneficiaries. In the FY 2022 IPPS proposed rule, CMS proposed to require transplant hospitals that excise deceased donor organs to track the organs sent to OPOs and to determine whether the ultimate transplant recipients (who received the transplant surgery at a different hospital) are Medicare beneficiaries to accurately count these as Medicare usable organs in the cost report. CMS did not finalize its proposal due to concerns from stakeholders about the inability of transplant hospitals to track which donor organs are ultimately transplanted into Medicare beneficiaries at other hospitals. However, CMS is now requesting comment on a potential future policy that would go a step further and prohibit transplant hospitals from reporting *any* organs excised and sent to an OPO, even when the organ was transplanted into a Medicare beneficiary in another hospital. Under this proposal, Medicare reimbursement for transplant hospitals would be limited to the organs they transplant into Medicare beneficiaries.

Revising the Medicare usable organ count in this way would significantly reduce reimbursement to transplant hospitals and would have dangerous ripple effects on the entire organ donation and transplant system. While we understand CMS's concern that Medicare may be paying for some organ donation and transplantation costs that are unrelated to Medicare beneficiaries, it would be irresponsible to cut Medicare funding without identifying alternative funding sources to make the system whole and ensure continued access to lifesaving transplants.

The RFI Policy Would Underfund the Transplant System

Congress established the payment methodology for transplant hospitals to encourage donation and transplantation. The policy CMS is contemplating in the RFI would cut critical funding from the US transplant system, making it harder for CMS and the transplant community to achieve their goals of increasing transplant rates and reducing disparities in access to transplantation, and is counter to congressional intent. These goals come with additional costs such as investment in research to expand the number of transplantable organs, air and ground transportation to cover broader allocation distances, and medical expenses associated with the use of more marginal organs that require more complex post-transplant care. The alternate organ counting methodology would reduce the incentives and resources that transplant hospitals use to support deceased organ donation and could limit important investments in their transplant programs, including the use of organ perfusion technologies.

Impacts

CMS did not publish impact estimates of this potential future policy change. However, GNYHA estimates that if transplant hospitals are prohibited from counting any of their donated organs as Medicare usable, Medicare payments to these hospitals would be reduced by approximately $350-400 million annually. The impact on smaller transplant programs would be particularly dire—they could be forced to close or reduce operations. Given the interdependency of the organ donation and allocation system, any reimbursement changes that could lead to fewer donor organs available for transplant would impact all transplant hospitals and the patients they serve, including Medicare beneficiaries.

CMS also fails to acknowledge that fewer kidneys available for transplant would extend the time that end-stage renal disease beneficiaries would need to receive dialysis while on the transplant waitlist, which would increase dialysis costs for Medicare. According to the US Renal Data System 2021 Annual Data Report: Epidemiology of Kidney Disease in the United States, Medicare spent significantly less on kidney transplant patients in 2019 ($38,863) than it did on peritoneal dialysis ($81,091) or hemodialysis patients ($94,608).[5] The human impact of increased access to kidney transplant is even more compelling: The report found that transplant patients had much lower all-cause adjusted mortality rates than dialysis patients (46.8 per 1,000 patient-years vs. 156.6 per 1,000 patient-years).

Recommendation

Given the complexity of the organ acquisition process and its reimbursement mechanisms, CMS should thoroughly study the impacts of its proposed policy changes on not only the immediate finances of transplant hospitals but on the entire system, including how the proposed changes could impact the availability of donor organs. To study this issue properly, CMS should facilitate a workgroup that includes transplant hospitals and OPOs to conduct a comprehensive analysis and develop recommendations that address CMS's concerns, while ensuring continuity of the organ acquisition and transplant ecosystem.

[5] Medicare fee-for-service spending only.