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 170+ 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 remedy in response to the Supreme Court ruling in *American Hospital Association (AHA) v. Becerra*.

While we support several aspects of CMS's proposal, including providing lump-sum payments to 340B hospitals to correct the Medicare fee-for-service (FFS) underpayments, we are concerned that the proposed remedy does not address the Medicare Advantage (MA) impact. As a result, hospitals will be harmed in two ways: 1) 340B hospitals are unlikely to be repaid by MA plans for the underpayments resulting from CMS's 340B policy that was in effect from 2018-22, and 2) all hospitals will experience an additional cut to MA outpatient payments, as MA plans are likely to adopt the reduced outpatient FFS conversion factor. Our comments focus on options for CMS to address the MA impact in its finalized policy.

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

GNYHA is a dynamic, constantly evolving center for health care advocacy and expertise, but our core mission—helping hospitals deliver the finest patient care in the most cost-effective way—never changes.

GNYHA Comments on CMS's Proposed 340B Remedy

Last summer, the US Supreme Court unanimously struck down CMS's policy of paying lower reimbursement rates to 340B hospitals. Subsequently, the Court provided CMS the opportunity to develop a "remedy" to the unlawful cuts to hospitals effectuated over 2018-22. In response, CMS proposes to 1) provide a lump-sum repayment to 340B hospitals in the amount of the underpayment, which is the difference between the average sales price (ASP) +6% and the reduced rate of ASP -22.5% paid over 2018-22, and 2) prospectively recoup the budget-neutral offset over the same period (i.e., the additional payments made to hospitals for all other non-separately payable items and services under Medicare outpatient prospective payment system [OPPS]).

Support for Lump-Sum Repayments & Additional Considerations

GNYHA supports CMS's proposal to provide lump-sum payments to 340B hospitals to reverse the FFS underpayment and encourages it to make these payments by the end of calendar year 2023 if feasible. GNYHA also agrees with CMS's methodology of calculating the FFS underpayment using claims billed with the "JG" modifier, and we appreciate that CMS is including the additional amount that hospitals would have been paid from beneficiary coinsurance payments, which shields beneficiaries from additional costs and minimizes the administrative burden on 340B hospitals. However, we disagree with CMS's belief that it is not authorized to include interest on the amounts it improperly withheld from hospitals when calculating the lump-sum repayments. We urge CMS to pay interest starting from the time the Supreme Court made its final determination that the underpayments were unlawful.

However, the FFS impact is only half the story. Our understanding is that the MA plans generally followed CMS's FFS policy and based reimbursement to 340B hospitals over 2018-22 on the same reduced rate as under Medicare FFS. According to CMS's Medicare Monthly Enrollment Data, 48.2% of Medicare beneficiaries were enrolled in MA in 2022, which means that the 340B cuts were approximately twice as large in the aggregate as CMS acknowledges through its proposed remedy. For some hospitals in areas with high MA penetration rates, this impact is much more significant.

We also understand that the MA plan bids and resulting capitation amounts paid by CMS to the MA plans for the 2018-22 period generally reflected the reduced 340B rates, which means that CMS effectively paid less to MA plans over this period to cover hospital payments for 340B drugs. **Because both the cuts to MA plan capitation rates and the flow-through impact on MA plan payments to hospitals for 340B drugs were a direct result of the 340B policy that the Supreme Court found was unlawful and must be remedied, CMS must compensate hospitals for the MA underpayment.** CMS's "non-interference" principle is not appropriate and should not apply in this situation where an unlawful CMS policy was used to establish MA plan capitation rates.[1] CMS should consider its options to pay hospitals directly for the MA underpayment (bypassing the MA plans).

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[1] Section 1854(a)(6)(B)(iii) of the Social Security Act prohibits CMS from interfering in payment arrangements between MA organizations and contract providers.

Concerns with Prospective Cuts

GNYHA disagrees that CMS is required to prospectively recoup an amount equal to the higher rates paid for non-drug items and services from 2018-22 and believes that hospitals should not be penalized for CMS's own past mistakes in implementing an unlawful policy.

The Department of Health and Human Services (HHS) is under the mistaken impression that it is either authorized or required by law to seek a "budget neutrality adjustment." HHS has made an intentional *choice* in the proposed rule to rely on sections 1833(t)(2)(E) and 1833(t)(14) of the Social Security Act as its authority for making the remedial repayments—ostensibly so that it can then, in turn, insist that these two provisions "require" it to claw back money from hospitals and health systems in the name of "budget neutrality." However, those authorities do *not* support a repayment or the corresponding "adjustment." HHS should abandon this reverse-engineered effort to achieve recoupment and instead rely on its well-established authority to acquiesce in the Supreme Court's unanimous decision.

Likewise, HHS cannot independently rely on its section 1833(t)(e) "adjustment" authority under the prospective payment system or any common law authority to effectuate a retrospective "budget neutrality adjustment." HHS further lacks the legal authority to make the specific proposed $7.8 billion "adjustment." The Supreme Court recently held in *Biden v. Nebraska* that a statutory "adjustment" must be moderate or minor, and a $7.8 billion retrospective clawback from all OPPS entities is anything but moderate or minor. It is likely that HHS did not have time to factor in this Supreme Court decision when issuing its proposed rule, but its final rule must account for it.

Consequently, even if HHS had the legal authority to pursue a "budget neutrality adjustment" at all, then it must, at a minimum, drastically reduce or modify its proposal in the final rule to better align with the "minor" adjustments permitted by statute. In particular, in these "unique circumstances," as HHS rightly calls them, it should consider 1) making only a $1.8 billion "adjustment" to correspond to the cost-sharing repayments CMS proposes to make, and 2) not including calendar years 2020-22 in any "adjustment" because recouping funds that hospitals spent caring for patients during a once-in-a-century pandemic is not "equitable" under the statute.

While we appreciate CMS's willingness to implement an extended recoupment period of approximately 16 years, the cuts would still be challenging for many hospitals to absorb, particularly given the inadequate Medicare rate updates finalized over the past several years as hospitals face unprecedented inflationary and wage pressures. **CMS should therefore hold the hospital field harmless for the 340B policy in effect over 2018-22 and not implement its proposed budget neutrality offset. If it does implement the offset, it should delay the start of the recoupment period until at least 2026 to allow hospitals additional time to prepare for the repayments, especially as many are still struggling financially from the pandemic, and it should finalize the proposed extended repayment period of 16 years.**

Importantly, if CMS chooses to finalize a prospective recoupment policy, it must again consider the significant missing variable of the MA payment impact. GNYHA is concerned that the proposed 0.5% cut to the OPPS conversion factor would be reflected in CMS benchmarks and plan bids and would therefore carry over to the rates MA plans pay to hospitals. This impact would be especially devastating if CMS does not accept our recommendation to make lump-sum payments to hospitals to reflect the MA payment cuts for 340B drugs (i.e., hospitals would not be repaid for the MA underpayments for 340B drugs yet would

be subject an additional prospective cut on all other services). In such circumstances, we believe CMS would receive significant unscored savings in the amount of the lower premiums paid to plans, which is inconsistent with CMS's intent to approximate payments as if the 340B policy had never been in effect.

While GNYHA's strong preference is for CMS to abandon its plans for a prospective offset, CMS should, at a minimum, prevent the cut from flowing through to MA. CMS could accomplish this by making an adjustment on hospital cost reports rather than by reducing the OPPS conversion factor. Specifically, CMS would need to modify Worksheet E, Part A, so that the 0.5% rate cut could be applied to the applicable services. To do so, CMS would need to separate payments for services paid based on the conversion factor and those paid based on cost or fee schedule (such as separately payable drugs and devices). The Provider Statistical & Reimbursement System would also need to be modified accordingly. Given the large yearly settlement that hospitals would face, GNYHA strongly recommends that CMS allow for quarterly installment payments.

Alternatively, CMS could specify during the MA premium development process that any conversion factor reduction is a separate, FFS-only adjustment related to the 340B lawsuit, and that plan bids should be based on spending projections using the full rate update. CMS could accomplish the same result by directing the plans to use the conversion factor it proposed for "new hospitals" not subject to the 340B policy. However, GNYHA would prefer that CMS make any prospective adjustment through the cost report process rather than through a reduced conversion factor so that hospitals are not put at risk having to negotiate this issue with MA plans.

Summary of Recommendations

GNYHA is pleased that CMS is restoring the five years of Medicare FFS payment cuts to hospitals that rely on 340B program savings to provide discounted drugs and other important services to their communities. We urge CMS to ensure that no further harm is done by promptly paying 340B hospitals the funds they are rightfully owed and not recouping any funds from hospitals for payments made for non-drug services under the agency's 340B policy over 2018-22. CMS must also account for the impact on MA payments in its final remedy. GNYHA's preference is for CMS to make additional lump-sum payments directly to hospitals to account for the estimated MA payment cuts. If CMS is unable to make such payments, it must ensure that any prospective rate cut—if CMS ultimately finalizes one—does not flow through to MA payments. It can best accomplish this by adjusting hospital payments through the cost report settlement process, thereby avoiding the need for a conversion factor reduction.