August 31, 2023

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1793-P

Submitted electronically to: http://www.regulations.gov

Re: Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 (Docket Number: CMS-1793-P)

Dear Administrator Brooks-LaSure:

Premier Inc. appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the *"Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 (Docket Number: CMS-1793-P)"* proposed rule which was published in the July 11, 2023 *Federal Register*.

I. BACKGROUND ON PREMIER INC.

Premier Inc. is a leading healthcare improvement company and national supply chain leader, uniting an alliance of more than 4,350 U.S. hospitals and approximately 300,000 continuum of care providers to transform healthcare. Premier's sophisticated technology systems contain robust data from nearly half of U.S. hospitals and 200,000 ambulatory clinicians. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,460 manufacturers to source the highest quality and most cost-effective products and services. Premier is also a leader in identifying, fulfilling and closing gaps in diverse sources for critical product categories, a strategy that proved to be critical as the country looked to increase domestic manufacturing and identify new sources of critical supplies.

A 2006 Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government, and other entities to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare and ensuring healthcare providers have access to the right supplies, at the right time, to treat patients.

II. 340B DRUG DISCOUNT PROGRAM

Congress created the 340B Drug Pricing Program in 1992 to allow certain safety net hospitals and other healthcare entities (known as covered entities) to purchase outpatient drugs at a discount from drug manufacturers "to stretch scarce Federal resources" and to expand healthcare services to vulnerable populations. For nearly three decades, the 340B program has been critical in helping covered entities expand access to lifesaving prescription drugs and comprehensive healthcare services to low-income, underinsured and uninsured individuals in communities across the country.

The savings produced by the 340B program have become essential to covered entities in meeting the needs of the communities and patients they serve. Under the program, drug manufacturers are required to offer lower prices on covered outpatient drugs to covered entities (e.g., those with a Medicare disproportionate share percentage of more than 11.75 percent) and other settings, enabling them to reinvest the difference between the discounted price and the amount paid by Medicare in healthcare services for underserved and uninsured patients. The ability to reinvest these savings is more critical than ever as our nation continues to face unprecedented healthcare challenges stemming from the COVID-19 pandemic.

In the 2018 Outpatient Prospective Payment System (OPPS) rule, CMS adopted a policy to pay hospitals for separately payable, non-pass-through drugs (other than vaccines and those furnished by rural sole community hospitals, inpatient prospective payment system (IPPS) exempt cancer hospitals, and children's hospitals) purchased through the 340B program at the average sales price (ASP) -22.5 percent, rather than ASP+6 percent. Consistent with statutory requirements, CMS applied a budget neutrality adjustment to all hospitals through an increase in the OPPS conversion factor which had the effect of increasing payments for all OPPS services paid through Ambulatory Payment Classifications (which excludes separately payable drugs).

III. LITIGATION

CMS' 340B payment policy has been subject to ongoing litigation since the policy was adopted. The litigation culminated with a decision by the United States Supreme Court on June 15, 2022 that held the Secretary may not vary payment rates for drugs and biologicals among groups of hospitals in the absence of having conducted a survey of hospitals' acquisition costs.[1] The Supreme Court remanded the case back to the Circuit Court that, in turn, remanded the case back to the District Court to determine a remedy.

On Sept. 28, 2022, the District Court vacated CMS' 340B reimbursement rate for the remainder of 2022 without requiring any offset for budget neutrality.[2] In response to this order, CMS changed its systems to make payment at ASP+6 percent for claims received with a date of service after Sept. 27, 2022. Some of CMS' Medicare Administrative Contractors (MACs) allowed for reprocessing of all 2022 claims at the revised ASP+6 percent rate.

On Jan. 10, 2023, the District Court issued a remand to CMS giving it the opportunity to determine the proper remedy for the reduced payment amounts to 340B hospitals under the payment rates in effect for 2018 through Sept. 27, 2022.[3] In response to the District Court's remand, CMS published a proposed rule on July 11, 2023 proposing a remedy for those hospitals harmed by CMS' 340B policy for the period of time the unlawful regulation was in effect.

In summary, CMS proposed to:

- Repay 340B hospitals for money owed from Jan. 1, 2018 through Sept. 27, 2022 through a lump sum payment less amounts already paid through claims reprocessing that occurred for services furnished between Jan. 1, 2022 through Sept. 27, 2022.
- Provide the repayment amount to hospitals inclusive of any additional beneficiary coinsurance and not allowing hospitals to collect additional coinsurance.

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[1] 142 S. Ct. 1896 (2022).
[2] See Am. Hosp. Ass'n v. Becerra, 18-cv-2084 (RC), 2022 WL 4534617.
[3] Am. Hospital Ass'n v. Becerra, 18-cv-2084 (RC), 2023 WL 143337.

- Maintain budget neutrality for these additional payments to 340B hospitals through a -0.5 percentage point adjustment to the OPPS update that applies to non-drug OPPS services beginning Jan. 1, 2025 until such time as the full amount of the additional payment is recouped (currently estimated at 16 years).

IV. REPAYING 340B HOSPITALS

CMS proposes to make a one-time lump sum payment to each 340B hospital that would be the same as if CMS manually reprocessed claims for Jan. 1, 2018 through Sept. 27, 2022 at a rate of ASP+6 percent. The proposed rule indicates that 1,649 340B hospitals received approximately $10.5 billion less in payments than had Medicare paid these claims at ASP+6 percent. CMS believes that about $1.5 billion of this amount has already been paid to 340B hospitals for reprocessed claims with dates of service in 2022.

To determine the aggregate amount due to 340B hospitals, CMS determined the difference in payment for separately payable drugs at ASP-22.5 percent and ASP+6 percent where the claim included the “JG” modifier that was used to apply the payment adjustment for drugs acquired under the 340B program. CMS proposed to issue an instruction to the MACs to provide a one-time lump sum payment within 60 calendar days of receipt of its instruction. If this rule is finalized, CMS anticipates making the additional payments to 340B hospitals at the end of 2023 or the beginning of 2024. The proposed rule indicates that CMS would pay the hospital the full amount owed including additional beneficiary coinsurance while prohibiting the hospital from collecting the additional coinsurance from the beneficiary.

Premier strongly supports CMS’ proposal to make a lump sum payment to 340B hospitals for the amounts they are owed based on the difference between ASP-22.5 percent and ASP+6 percent for the period Jan. 1, 2018 through Dec. 31, 2021. This proposal is consistent with Premier’s past public comments on this issue where we indicated “CMS should provide 340B eligible hospitals with a lump sum payment equal to the difference in payment that these hospitals would have received if CMS had paid ASP+6 percent.”

Premier’s only qualifier on this issue relates to the amounts owed to hospital for 2022 as we recommend that CMS allow processes already begun by the MACs for 2022 claims for 340B acquired drugs to continue. Following the District Court’s Sept. 28, 2022 order, some MACs only allowed for payment of ASP+6 percent for 340B acquired drugs prospectively for the remainder of the year. Other MACs allowed hospitals to submit adjustment claims for the retroactive period while still others reprocessed past claims with no action on the part of the hospital.

CMS acknowledges this point in the proposed rule. The proposed rule indicates that CMS believes that about $1.5 billion of the $10.5 billion owed to hospitals has already been paid to 340B hospitals for reprocessed claims with dates of service in 2022.[4] As there is already in place a system for making repayments to hospital on their 2022 claims, Premier recommends that CMS continue that system without requiring hospitals to resubmit claims to receive payment amounts due in 2022. Rather, Premier requests that CMS provide an instruction to the MACs that would require them to do a mass adjustment on any outstanding claims where the hospital has not already been provided with a refund of the amounts owed. Such an instruction would result in rapid refunds of amounts due to the hospital with a minimum of administrative burden on CMS, the MACs and hospitals.

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[4] 88 FR 44083.

V. BUDGET NEUTRALITY ADJUSTMENTS

Prior CMS Precedent Applying Budget Neutrality:

CMS proposes beginning in 2025, to reduce payments for non-drug items and services to all OPPS providers (except new providers that enrolled in Medicare beginning in 2018) by 0.5 percent each year until the total offset is reached, which CMS estimates to be approximately 16 years. CMS believes that budget neutrality is required under sections 1833(t)(2)(E) and 1833(t)(14) of the Act when the budget neutrality adjustment would not be de minimis and is not expressly exempted by statute. CMS does not believe Congress intended the statute to permit regulated entities to achieve policy outcomes through litigation that would be statutorily unavailable to them through the regular rulemaking process - especially policy outcomes that increase total Medicare expenditures.

Premier strongly disagrees with these budget neutrality assertions that are inconsistent with past CMS precedent as demonstrated below. CMS has applied budget neutrality as a prospective concept (e.g., CMS uses past year information to make a prediction about the future and it does NOT revise that adjustment for later events or information unless expressly authorized by Congress). This has been longstanding CMS policy in many contexts. For instance, with regard to Medicare payment of outliers, CMS routinely indicates in its annual Inpatient Prospective Payment System (IPPS) rules:

> *Our current estimate, using available FY 2022 claims data, is that actual outlier payments for FY 2022 were approximately 6.73 percent of actual total MS–DRG payments [compared to 5.1 percent estimated]…Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2022 are equal to 5.1 percent of total MS–DRG payments…We believe it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment.*[5]

In this instance, the difference in the amount of outlier payments (6.73 percent) and the 5.1 percent amount removed from the IPPS standardized amounts to fund outliers is 1.63 percentage points. On a payment system with aggregate payments well in excess of $100 billion, 1.63 percent could easily exceed 1.6 billion - hardly a “de minimis” amount.

In another example this point, beginning in 2014, CMS packaged clinical diagnostic laboratory tests into its OPPS payments with exceptions for specific circumstances that would allow the test to continue to be paid separately. In 2015, CMS observed that spending for hospital outpatient services increased in 2014 significantly without a comparable reduction in spending for outpatient department laboratory services. After analyzing this issue, CMS determined they underestimated the frequency of clinical diagnostic laboratory services that would continue to be paid separately. In effect, they packaged more costs for clinical diagnostic laboratory services into the OPPS payments than would be saved by no longer separately paying separately for most laboratory services. As CMS could not discover this problem until after 2014 was over, the overstated OPPS rates continued into 2015.

Under the authority of section 1833(t)(3)(C)(iii) of the Act, CMS made an adjustment to OPPS rates for 2016 so the overpayment would not carry forward into future years. CMS adopted a reduction of 2.0 percentage points to the CY 2016 conversion factor to redress inflation in the OPPS payment rates and prevent CY 2016 payment rates from including $1 billion in excess packaged payment - again, not a “de

[5] (88 FR 2722).

minimis" amount. However, CMS made very clear that its statutory authority did not extend to recouping any past additional payments:

> *Comment: Several commenters suggested that the purpose of the proposed adjustment was to recoup overpayments in CY 2014 and CY 2015, and that recouping overpayments made in prior years was inconsistent with a prospective payment system.*
>
> *Response: The proposed -2.0 percent adjustment to the conversion factor would not recoup ''overpayments'' made for CYs 2014 and 2015. When we classified laboratory tests as OPPS packaged services in 2014, we increased the conversion factor to account for that change, which resulted in excess payment being built into the rates. The proposal to apply a -2.0 percent adjustment to the conversion factor is intended to address the effects of the OPPS classification changes on OPPS payments for CY 2016 that do not reflect real changes in service-mix. If we do not adjust the conversion factor, the excess payment built into the rates would carry through to the CY 2016 OPPS rates.*[6]

CMS reiterates a similar point in this same rule when it says, "The proposed adjustment to the conversion factor would affect OPPS payments for CY 2016, not CY 2014."[7]

In these circumstances, CMS has not revised Medicare payments retroactively when providers were the beneficiaries of the additional payments. However, there are other circumstances where CMS has not revised its estimates after-the-fact when practitioners or providers were disadvantaged by CMS underestimating a potential budget neutrality adjustment. For instance, CMS, in consultation with the CPT Editorial Panel and the Relative Value Update Committee, created codes respectively in 2013 and 2015 for Transitional Care Management (TCM) and Chronic Care Management (CCM) - non-face-to-face services where the physician is managing the patient's care.

While these services were not explicitly paid previously, CMS argued that it was part of an Evaluation and Management (E/M) service but there was no way to determine how to reduce the value of E/M to pay for these additional services. In this case, CMS had to estimate utilization to determine the potential increase in spending from additional payment for these services. CMS' preemptive budget neutrality adjustment for these services vastly overestimated utilization. As CMS does not revise budget neutrality after the fact, these adjustments resulted in permanent reductions to MPFS payments.

CMS will only revisit a past budget neutrality adjustment when it is explicitly authorized to do so by Congress. For instance, CMS made an adjustment for FYs 2008-2010 to make implementation of the MS-DRGs budget neutral after accounting for increased spending due to documentation and coding. Congress reduced those adjustments for two of the three years but required CMS to recoup excess spending in FY 2008 and FY 2009 by FY 2012 if CMS estimated higher spending than was adjusted for documentation and coding.

As CMS noted later in the *Federal Register,* spending due to documentation and coding was higher than its original estimates. Excess spending due to documentation and coding remained in the IPPS rates for FY 2010 through 2012 because of delays by CMS in prospectively applying reductions to rates for those years until it could evaluate documentation and coding for prior years. CMS did not have the authority to recoup excess spending due to documentation and coding for FYs 2010 through 2012 stating:

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[6] 80 FR 70354.
[7] 80 FR 70355.

> *We note again that delaying full implementation of the prospective portion of the adjustment required under section 7(b)(1)(A) of Public Law 110–90 until FY 2013 resulted in payments in FY 2010 through FY 2012 being overstated. These overpayments could not be recovered by CMS as section 7(b)(1)(B) of Public Law 110–90 limited recoupments to overpayments made in FY 2008 and FY 2009.*[8]

The amounts that were included in IPPS rates that CMS indicated that it was prohibited from recouping was $11 billion - again, not a "de minimis" amount and more than is at issue for the 340B budget neutrality adjustment. Congress explicitly authorized that CMS recoup $11 billion between FY 2014 and FY 2017 to account for the additional money CMS indicated was included in IPPS rates from 2010 to 2012. CMS acknowledged that there was additional spending in the IPPS rates due to documentation and coding and its own delay in implementing a prospective adjustment is what resulted in the excess spending for FY 2010 through FY 2012 that it was not authorized to recoup until enactment of the American Tax Relief Act of 2012. Basically, CMS acknowledged overpayments in two prior years that it could not recoup until it received explicit authorization from Congress.

As can be concluded from the above discussion, CMS has explicitly acknowledged that the budget neutrality is a prospective concept and it cannot revise payments prospectively or retroactively to address later information that may have affected earlier estimates. For this reason, ***Premier not only opposes CMS' prospective recoupment adjustment of -0.5 percentage points annually beginning in 2025 but we believe it is both inconsistent with the law and CMS' longstanding past precedent regarding application of budget neutrality adjustments.***

Lack of Court Rulings on Budget Neutrality

Premier further notes that CMS is addressing a policy that was not previously addressed by any court of law. The Supreme Court only ruled that the Secretary may not vary payment rates for drugs and biologicals among groups of hospitals in the absence of having conducted a survey of hospitals' acquisition costs. It explicitly decided not to address arguments regarding budget neutrality when it stated "At this stage, we need not address potential remedies."[9]

Further, as noted above, the District Court's September 28, 2022 order vacating CMS' 340B reimbursement rate for the remainder of 2022 did so without requiring any offset for budget neutrality.[10] Clearly, if the District Court believed that budget neutrality was a requirement of the statute, it would not have vacated only CMS' rule related to additional payment to 340B hospitals, it also would have required an offset for budget neutrality. As the District Court clearly did not make such an order, CMS cannot now insist that budget neutrality is a requirement of law.

Use of the Terms "Windfall" and "Overpayment"

While CMS appears to concede that a budget neutrality offset is not a requirement of law ("even if the remedy rule were exempt from budget neutrality requirements as a matter of statutory interpretation"), it would still pursue recoupment as:

[8] 78 FR page 50514.
[9] See footnote 1.
[10] See footnote 2.

> *to avoid a windfall to providers would also be consistent with agency's longstanding inherent and common-law (and common-sense) recoupment authority through which 'the Secretary generally has the duty and power to protect against overpayments to providers.'*

Premier objects to CMS' characterization of these additional payments as a "windfall" or "overpayments" to providers. These payments were not made wrongfully and are not overpayments. At the time these payments were made, they were made consistent with rules in effect at the time. CMS cites *U.S. v. Lahey Clinic Hospital* as support for its position. However, a review of this case indicates that the alleged overpayments occurred as a result of the defendant billing Medicare for tests a la carte that could have been billed as a panel or billing for tests that were not medically necessary.[11]

In this case, the alleged overpayments resulted from the actions of the provider, not the government. The situation in *Leahy* is hardly comparable to what has occurred in the 340B case where it was CMS that took the actions that resulted in the hospitals receiving additional payments. The terms "overpayment" and "windfall" are clearly inapplicable and offensive in that they suggest untoward behavior by the hospitals that led to the result when the situation that disturbs CMS was created by its own illegal action to undertake a rule that was unanimously struck down by the Supreme Court.

Impact on Beneficiaries

CMS further implies that budget neutrality is required because "unexpected increases in Medicare Part B or D expenditures may thus require increases to beneficiary premiums and coinsurance."[12] Premier does not follow the relevance of this point. CMS is rightly protecting beneficiaries from having to pay additional coinsurance for past years on claims already paid. Therefore, in the immediate term, CMS is directly protecting Medicare beneficiaries from additional payment liability.

The only remaining implication of this statement is that the immediate payment to 340B hospitals of payments owed to them will deplete the Part B Trust Fund potentially resulting in a higher Part B beneficiary premium. While this may be accurate in the immediate term, it is unclear how CMS plans to apply a -0.5 percentage point adjustment to the OPPS update over 16 or more years can address that problem given that it is an attenuated recoupment and will largely affect *future* beneficiaries who were unaffected by these policies. It will have no impact on current beneficiaries. At minimum, CMS must explain in more detail how this policy would mitigate impact on current Medicare beneficiaries.

Interaction with Medicare Advantage

Premier remains very concerned that if any windfall arises as a result of CMS' 340B policies, it will be to Medicare Advantage (MA) plans. Many MA plans reduced 340B drug payments to hospitals to match CMS' policy. However, we have no indication that MA plans will now reverse the policy and pay a lump sum to hospitals. Further, if CMS finalizes its recoupment policy, MA plans will be able to set their bids on a fee-for-service baseline that includes the 0.5 percent payment reduction without having ever provided hospitals with the additional 340B payments - again, a windfall to MA plans.

The only information we have on this issue comes from a Dec. 20, 2022 memorandum from Jennifer Shapiro to the MA Plans. In that memorandum, Ms. Shapiro indicates that MA plans "must pay non-contract providers or facilities for services and items at least the amount they would have received under Original

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[11] U.S. v. Lahey Clinic Hospital, Inc., 399 F.3d 1
[12] 88 FR 44081

Medicare payment rules." However, this memorandum does not address the obligations of MA plans to contract hospitals. Ms. Shapiro writes:

> *MAOs that contract with a provider or facility eligible for 340B drugs can negotiate the terms and conditions of payment directly with the provider or facility and CMS cannot interfere in the payment rates that MAOs set in contracts with providers and facilities.*[13]

Premier recognizes that CMS' authority with respect to contracted hospitals with MA plans is limited under section 1852(a)(2) of the Act. Nevertheless, Premier urges CMS to inform MA plans of developments in Medicare fee-for-service payment policy and encourage them to take actions consistent with how hospitals have been paid for drugs acquired under the 340B program.

VI. CONCLUSION

In closing, Premier appreciates the opportunity to submit these comments on the *"Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 (Docket Number: CMS-1793-P)*." Premier looks forward to working with CMS to strengthen the 340B program by ensuring that hospitals and other 340B entities are appropriately compensated for past 340B payment shortfalls and can fulfill Congressional intent of the program, which is to expand care for vulnerable populations.

If you have any questions regarding our comments or need more information, please contact me at soumi_saha@premierinc.com or 732-266-5472.

Sincerely,

Soumi Saha, PharmD, JD
Senior Vice President of Government Affairs
Premier Inc.

[13] Memorandum from Jennifer R. Shapiro to All Medicare Advantage Organizations on December 20, 2022: Hospital Outpatient Prospective Payment System Update on Payment Rates for Drugs Acquired through the 340B Program - INFORMATIONAL for MAOs (cms.gov)