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September 11, 2023

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1793-P
P.O. Box 8010
Baltimore, MD 21244-1810

RE: CMS-1793-P – Medicare Program: Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022; published at Vol. 88, No. 131 Federal Register 44078-44096 on July 11, 2023.

Submitted electronically via <http://www.regulations.gov>

Dear Administrator Brooks-LaSure,

UnityPoint Health appreciates this opportunity to provide comments on this proposed rule related to the remedy for the 340B-acquired drug payment policy for calendar years 2018–2022. UnityPoint Health is one of the nation’s most integrated health care systems. Through more than 32,000 employees and our relationships with 370+ physician clinics, 36 hospitals in urban and rural communities, and 13 home care areas of service throughout our 8 markets, UnityPoint Health provides care throughout Iowa, west-central Illinois, and southern Wisconsin. On an annual basis, UnityPoint Health is responsible for a service area of over 2.3 million people and has generated \$344.6 million in community impact.

As a large nonprofit, integrated health care system in the Midwest, the UnityPoint Health network of Disproportionate Share Hospitals, Sole Community Hospitals, Critical Access Hospitals, and Rural Health Clinics provide vital access to health care services. The 340B Drug Pricing Program has served as a critical federal resource for our safety-net providers and the patients we serve in Iowa, Illinois, and Wisconsin. *Not including our affiliated 20 critical access hospitals, we have 12 hospitals (9 covered entities) under the 340B Drug Pricing Program.*

In addition, UnityPoint Health is committed to payment reform and is actively engaged in numerous initiatives which support population health and value-based care. UnityPoint Accountable Care is the accountable care organization (ACO) affiliated with UnityPoint Health and has value-based contracts with multiple payers, including Medicare. UnityPoint Accountable Care currently participates in the CMS Medicare Shared Savings Program (MSSP), and it contains providers that have participated in the Center for Medicare and Medicaid Innovation (CMMI) Global and Professional Direct Contracting Model, Next Generation ACO Model and the Pioneer ACO Model. *In our Medicare ACO contract, UnityPoint Accountable Care currently has more than 6,000 providers, including 15 hospitals (11 covered entities) –*

one of which is an academic medical center - under the 340B Drug Pricing Program.

Aside from traditional Medicare, UnityPoint Health participates as a provider in several Medicare Advantage (MA) health plans. Additionally through HealthPartners UnityPoint Health, we jointly operate our own MA health plan.

UnityPoint Health appreciates the time and effort of CMS in developing this remedy in response to the Supreme Court’s unanimous decision in American Hospital Association v. Becerra, 142 S. Ct. 1896 (2022). **As a member of the American Hospital Association and 340B Health, UnityPoint Health supports the formal comment letters submitted by those organizations.** Additionally, we respectfully offer the following comments.

PROPOSED REPAYMENT METHODOLOGY (From CY 2018 Through September 27, 2022)

After consideration of several options, CMS proposes a remedy that includes: (1) a one-time lump sum repayment to hospitals for underpayments for outpatient drugs purchased under the 340B program between CYs 2018 and 2022; (2) within the repayment, an additional amount that hospitals would have received in beneficiary cost-sharing; and (3) a methodology for calculating what 340B hospitals are owed, which minimizes administrative burden.

Comment: UnityPoint Health fully supports the proposed one-time lump sum repayment to hospitals, the inclusion of the additional beneficiary cost-sharing amount, and the methodology used to calculate what 340B hospitals are owed. Thank you! These aspects of the proposed rule advance all of the relevant legal and public policy interests—adherence to the Supreme Court’s decision, full and prompt repayment to 340B hospitals, administrative simplicity, patient protection, respect for the hospital field’s ongoing financial challenges, and equity. UnityPoint Health hospitals are eligible to participate in the 340B Drug Pricing Program by virtue of high volume of Medicaid and low-income Medicare patients as well as rural locations. We rely on our 340B savings to meet the needs of low-income and rural patients in our communities. **UnityPoint Health urges CMS to swiftly finalize these portions of the proposed rule, so that hospitals and health systems can be repaid in 2023.**

BUDGET NEUTRALITY ADJUSTMENT

CMS proposes to apply a budget neutrality adjustment to the remedy payments - “we believe a budget neutrality adjustment is statutorily required and, even if not statutorily required, warranted as a matter of sound public policy.”

Comment: UnityPoint Health disagrees with CMS’ application of the proposed budget neutrality adjustment as it is not statutorily required and is in fact contrary to sound public policy. Rather, CMS made the choice to propose “budget neutrality adjustments” to offset this legally-required remedy resulting from its unlawful underpayments to 340B covered entities. As persuasively explained in the American Hospital Association’s (AHA) comment letter¹, the statutes that CMS relies on in the proposed rule do not give it the authority to make a “budget neutrality adjustment.” Nor do the statutes require

¹ AHA letter, Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022 (RIN 0938-AV18) (July 11, 2023), to Administrator Chiquita Brooks-LaSure, dates August 2, 2023.

budget neutrality as a matter of law. Contrary to suggestions in the proposed rule, CMS has both the legal obligation and legal flexibility, as well as the backing of sound public policy, to not seek a claw-back of funds that hospitals received as a result of CMS' own mistakes and that hospitals have long since spent on patient care—including during the COVID-19 pandemic.

UnityPoint Health urges CMS to consider the impact to health care and communities should it elect to apply a “budget neutrality adjustment”. It bears repeating that the purpose of the 340B Drug Pricing Program as enacted in 1992 was to help eligible safety net providers “stretch scarce Federal resources as far as possible reaching more eligible patients and providing more comprehensive services.” **Any reductions in this program divert resources from providers that care for underserved and vulnerable populations. With thin operating margins, 340B savings often maintain vulnerable service lines (such as behavioral health, maternal and child health, and/or emergency services), enable preventive/outreach services (such as financial assistance for medications, medication therapy management, meds-to-beds programs, and/or dental clinics), and simply keep doors open (such as salaries for nurses and other frontline care staff).** For UnityPoint Health, our rural providers will be hardest hit by any reduction. These providers have already seen 340B savings decreased by up to 50% due to the unlawful actions of 25 drug manufacturers who are imposing additional restrictions on the use of contract pharmacies contrary to HRSA guidance. These restrictions have significantly impacted access to covered outpatient medications by UnityPoint Health patients, oftentimes making those 340B-priced medications inaccessible. Since budget neutrality is not required, any further erosion of these savings seems ill-timed and will impact patient care. While the exact impact will vary by community and local need, what is certain is that this will disproportionately impact those communities and populations that can least afford it.

For the reasons explained above and in the AHA’s comment letter, UnityPoint Health urges CMS to not pursue any “budget neutrality adjustment” in the final rule. This does not negate UnityPoint Health’s appreciation for CMS’ attempt to draft an “offset [that] is not overly financially burdensome on impacted entities,” including by proposing a prospective 16-year offset period with a delayed start. Should CMS choose to pursue a “budget neutrality adjustment,” (1) these features should not be abandoned; (2) any “adjustment” implementation should be delayed until CY 2026 (at the earliest) to enable hospitals and health systems like UnityPoint Health to further recover financially from the pandemic; and (3) due to these “unique” circumstances, the magnitude of the proposed \$7.8 billion “adjustment” should be reduced to a far smaller amount.

MEDICARE ADVANTAGE ORGANIZATION (MAO) REPAYMENTS

Many commercial MAOs pay hospitals according to the traditional Medicare payment rates. On December 20, 2022, CMS sent a memorandum² to MAOs about the Supreme Court decision, American Hospital Association v. Becerra, and the district court’s September 28, 2022, order vacating the differential payment rates for 340B-acquired drugs in the CY 2022 OPPS final rule. To date, MAOs have not acted to rescind the differentiated rates nor has CMS contemplated MAOs within the recoupment proposal.

² Memorandum, *Hospital Outpatient Prospective Payment System Update on Payment Rates for Drugs Acquired through the 340B Program - INFORMATIONAL for MAOs*, from Jennifer R. Shapiro, Director, Medicare Plan Payment Group, accessed at <https://www.cms.gov/files/document/cmsopps340bupdate508g.pdf>

Comment: Failure to include MAOs within the proposed remedy shifts benefit from the SMI Trust Fund to private entities – the MAOs themselves. **UnityPoint Health encourages CMS to take all possible measures to ensure MAO compliance with the remedy so that these entities do not receive an inadvertent windfall.** CMS should continue to press MAOs to make their own legally-required repayments, including the use of its prompt payment authorities under 42 U.S.C. 1395w-27(f) to ensure MAO compliance with this remedy. *For UnityPoint Health, Medicare Advantage plans comprise approximately 40 percent of the underpayments associated with the 340B payment rate reductions. At a minimum, the agency must account for the MAO windfall that will result from the proposed -0.5% adjustment to payment rates,* especially if the MAOs continue to refuse to pay the difference between the unlawful 340B payment amounts and what hospitals are owed. In the absence of any action, this will double the adverse impact of the proposed recoupment on hospitals and erosion to the SMI Trust Fund will continue to increase throughout the 16-year repayment period if Medicare Advantage continues its projected growth (e.g., the Congressional Budget Office anticipates MA enrollment growing to approximately 60% vis-à-vis traditional Medicare enrollment by 2032).

MEDICARE ACCOUNTABLE CARE ORGANIZATION (ACO) BENCHMARKS

When Medicare ACOs succeed in both delivering high-quality care and spending health care dollars more wisely, such ACOs may be eligible to share in the savings they achieve for the Medicare program. In downside risk arrangements, ACOs are also responsible for shared losses. To assess annual financial performance, CMS calculates a historical financial benchmark to determine eligibility for earned shared savings or losses payments. With the court-ordered restoration of the 340B rates, ACOs now have benchmark years, which include 340B underpayments that reduce per-member-per-month (PMPM) targets, and performance years, which include restored 340B rates that increase PMPM targets.

Comment: UnityPoint Accountable Care (UAC) is pleased to have participated in Medicare ACO models since their inception. For CY 2022, UAC participated in the CMMI Global and Professional Direct Contracting (GPDC) Model, and upon the sunset of the GPDC Model in CY 2023, we began participation in the MSSP ENHANCED Track. While the 340B Remedy proposal to provide a lump sum payment helps our participating providers, **UAC believes that ACOs should be held harmless in this remedy proposal, including those ACOs participating in CMMI models.** CMMI has indicated that it is aware of the issue and “assessing the feasibility of making adjustment if such a change was merited.”³. We appreciate that CMMI and CMS are exploring the impact of the Supreme Court decision and how this can be harmonized to support the transition to value from volume by ACOs.

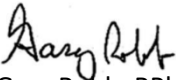
As CMS considers how to mitigate impact to value-based models, UAC offers two suggestions. First, **UAC urges CMS to treat the entire lump sum repayment as a non-claims-based expenditure for ACOs in the repayment year.** Second, the proposed rule fails to address the impact of underpayments to ACOs who are being paid at ASP +6% for 340B-acquired drugs in performance years while historic benchmark years reflect the ASP -22% payment. By omitting a remedy to address this payment differential, ACOs must

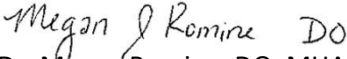
³ UAC submitted a CMMI help desk question. In response to whether CMS has considered adjusted the benchmark for the change in 340B, it was stated “CMS is aware of the issue and its potential impact to ACO benchmarks. Given the impact would implicate multiple components of the model, we are assessing the feasibility of making adjustments if such a change was merited.”.


continue to perform against artificially deflated benchmarks as long as baseline years include CYs 2018-2022. From 2021 to 2022, UAC's 340B-acquired drug PMPM spend increased 38%. This surge was driven by a unit cost increase of 31.7% from reduced 340B-acquired drug reimbursement and translates to nearly \$10 million (1% of total spend) that was excluded from the benchmark. **UAC has been modeling this impact⁴, and requests that CMS work with ACO stakeholders to craft a solution to negate the PMPM 340b-acquired drug spend gap between benchmark and performance years, such as benchmark redeterminations.**

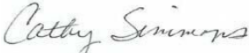
We are pleased to provide input on this proposed rule and its impact on our hospitals and health system, our beneficiaries, and communities served. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Executive Director, Government & External Affairs at cathy.simmons@unitypoint.org or 319-361-2336.

Sincerely,


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⁴ UAC submitted a Timely Error Notice to CMMI on August 31, 2023, in contest of our GPDC Model close-out process. As part of that notice, UAC included an attachment, "340B Fee Schedule Policy Change Impact to 2022 GPDC Financial Calculations" that specified 340B impact for 2022.