The Hospital + Healthsystem Association of Pennsylvania

Leading for Better Health

September 13, 2022

The Honorable Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1772-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: CMS-1772-P, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; Proposed Rule, July 26, 2022

Dear Administrator Brooks-LaSure:

On behalf of The Hospital and Healthsystem Association of Pennsylvania (HAP), which represents approximately 235 member hospitals, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system proposed rule for calendar year (CY) 2023.

HAP appreciates CMS' decision to end its unlawful policy to significantly cut payments to 340B hospitals for 2023 following the Supreme Court's recent unanimous ruling in favor of hospitals. The end of this harmful policy will help ensure that 340B hospitals can provide comprehensive health care services to the patients and communities they serve. Given that CMS has recognized that its policy was unlawful, HAP urges the administration to promptly reimburse those hospitals affected by these cuts for all years that the policy was in place. At the same time, no hospital should be penalized for the agency's implementation of an unlawful policy; CMS should not attempt to recoup funds from the rest of the hospital field, especially as hospitals and health systems continue to deal with rising inflation and skyrocketing costs for supplies, equipment, drugs, and labor.

We also reiterate our position against continuing site-neutral payment reductions. CMS should reverse its unlawful and harmful policy reducing payment for outpatient clinic visits in excepted provider-based hospital outpatient departments.

The following comment letter also addresses changes to:

- Inpatient-only list
- Hospital Outpatient Quality Reporting Program
- Prior Authorization Program Changes
- Organ Procurement and Research

In addition, we incorporate, by reference, all of the comments provided in the American Hospital Association's response to the proposed rule.
Thank you for your consideration of HAP's comments about this proposed rule regarding outpatient payment and other provisions related to hospitals and the patients they serve in Pennsylvania.

If you have any questions, contact Kate Slatt, vice president, innovative payment and care delivery, at (717) 561-5317.

Sincerely,

Jeffrey Bechtel
Senior Vice President, Health Economics and Policy

Attachment

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HAP Comments—Outpatient Prospective Payment System
Proposed Rule for Calendar Year 2023

UPDATES TO OUTPATIENT PROSPECTIVE PAYMENT SYSTEM PAYMENT RATES

CMS is proposing to update Outpatient Prospective Payment System (OPPS) payment rates for hospitals that meet applicable quality reporting requirements by 2.7 percent. This update is based on the projected hospital market basket percentage increase of 3.1 percent, reduced by a statutorily required productivity adjustment 0.4 percentage points.

HAP is deeply concerned that the proposed market basket update of 3.1% is woefully inadequate and does not capture the unprecedented inflationary environment hospitals and health systems are experiencing. Therefore, we urge CMS to take action to increase the market basket in the final rule to better account for these extraordinary circumstances in order to ensure that beneficiaries continue to have access to quality outpatient care. We also are concerned about the proposed reduction for productivity, and ask CMS to elaborate in the final rule on the specific productivity gains that are the basis for the proposed 0.4 productivity offset. Such a cut does not align with hospital and health systems' public health emergency (PHE) experiences related to actual losses in productivity during the COVID-19 pandemic.

HAP urges the agency to implement a market basket increase that is more aligned with the current environment that hospitals are, and will be, operating in during 2023.

PAYMENTS TO 340B HOSPITALS

CMS announced that the agency "fully anticipate(s) applying" a payment rate of Average Sales Price (ASP) plus 6 percent to 340B-acquired drugs and biologicals in 2023 in light of the Supreme Court's recent decision in *American Hospital Association v. Becerra.* The payment rate of ASP plus 6 percent also would apply to such drugs and biologicals when furnished in non-excepted off-campus provider-based departments (PBD) paid under the Medicare Physician Fee Schedule (PFS).

Because of the timing of the court's decision during mid-June, the agency did not have sufficient time to formally propose this policy in the rule. As such, CMS continues to propose the current payment rate of ASP minus 22.5 percent, which it notes will be restored in the calendar year (CY) 2023 final rule to ASP plus 6 percent with the requisite changes to the proposed conversion factor.

HAP supports the agency's position that it "fully anticipates" reverting to its prior policy of paying ASP plus 6 percent for 340B-acquired drugs during CY 2023 and urge it to finalize this policy in the OPPS final rule.

CMS also has requested comments on a remedy in *American Hospital Association v. Becerra*. As we explain below, the Supreme Court's decision dictates that the only possible remedy is to:

1. Revert to the prior lawful policy of paying ASP plus 6 percent for CY 2023, regardless of whether a drug was acquired through the 340B program
2. Promptly repay any hospital the difference between ASP plus 6 percent and what they were actually paid for drug claims as a result of this unlawful policy for CYs 2018–2022
3. Hold the entire hospital field harmless for this illegal policy for CYs 2018–2022, which means no recoupment of funds received during this period

HAP strongly encourages CMS to agree to this remedy in the ongoing American Hospital Association v. Becerra litigation and to ensure that payments to hospitals are appropriately restored in the agency's CY 2023 OPPS final rule.

COMPLETE AND PROMPT REPAYMENT IS NECESSARY

To correct the unlawful policy that the Supreme Court struck down, **HAP strongly urges CMS to promptly repay 340B hospitals the difference between ASP plus 6 percent 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' unlawful policy has deprived 340B hospitals of payment, even as hospitals across the country struggled to care for their patients and communities amidst a once-in-a-century pandemic.

Additionally, **HAP maintains that the survey of 340B acquisition costs initiated during CY 2020 was defective and, as such, cannot be used** to set future payment rates, or to delay or deny repayment for CYs 2021 or 2022. That survey does not comport with the law and was never relied upon by the agency as the basis for continuation of its unlawful policy. It is not a fair, proper, or legal basis for the agency to delay or deny repayment.

RETROSPECTIVE RECOUPMENT WOULD BE UNFAIR, UNLAWFUL AND UNPRECEDENTED

In the past, CMS has raised the specter of invoking "budget neutrality" to retrospectively recoup funds from hospitals that received them because of its unlawful policy. However, the agency 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 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 put vulnerable patients and communities at further 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.

Finally, it is important to keep in mind that the agency exempted a number of 340B hospitals from its unlawful policy, including rural sole community hospitals (SCH), freestanding children's hospitals and freestanding cancer hospitals. Not only would it appear that these hospitals would be subject to clawbacks, but it would be impossible to fairly implement a budget neutrality policy if these entities were not subject to the same recoupments as other hospitals.

HAP firmly believes that neither these exempted hospitals—nor any others—should be subject to clawbacks based on an illegal policy that has already disrupted the entire hospital field during arguably the most vulnerable period in its history.

CONCERNS REGARDING CY 2023 CONVERSION FACTOR ADJUSTMENT AND REPORTING OF CLAIMS MODIFIERS

For CY 2023, CMS states that it "fully anticipates" restoring payment to 340B hospitals at a rate of ASP plus 6 percent for separately payable drugs. In undoing the agency's unlawful policy, CMS is proposing a new budget neutrality adjustment to the OPPS conversion factor to account for this increase in payment. HAP has concerns, however, that the agency's calculation of this adjustment is incorrect and will result in further underpayment to all hospitals. These payments are critical for hospitals to cover the costs associated with caring for Medicare patients. In fact, according to the most recent report by the Medicare Payment Advisory Commission, hospitals' Medicare margins were **negative** 8.5 percent during 2020, even after accounting for federal relief during the pandemic.

Hospitals simply cannot afford to endure further underpayments. **Therefore, HAP urges CMS to correct the proposed adjustment to ensure that the appropriate amount is added back into the CY 2023 OPPS conversion factor and no hospital is underpaid.**

On a related matter, we also ask CMS to abandon its policy of requiring certain hospitals to report the informational "JG" and "TB" modifiers to identify separately payable drug claims.

When the agency first proposed its unlawful 340B payment policy in the CY 2018 OPPS proposed rule, it required certain hospitals to report these modifiers on drug claims. But given that the agency fully anticipates to abandon its current 340B payment policy, there is no need for the agency to continue to collect such information from hospitals. In fact, abandoning the use of these modifiers would be consistent with CMS' ongoing commitment to reduce regulatory burden for providers. **Therefore, HAP urges CMS to no longer require hospitals to report these modifiers for CY 2023 and subsequent years.**

In conclusion, we appreciate CMS' decision to restore payment to 340B hospitals for CY 2023 in light of the Supreme Court's decision in *American Hospital Association v. Becerra*. However, we strongly 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 who were paid as part of the agency's own unlawful policy.

HAP previously submitted comments detailing the association's position and perspective with respect to 340B payment policy on August 12, 2022. Those comments have been restated above.

USE OF JUNE 2020 COST REPORT AND CY 2021 CLAIMS DATA FOR CY 2023 OPPS AND AMBULATORY SURGICAL CENTER RATE SETTING DUE TO THE PUBLIC HEALTH EMERGENCY

Typically, CMS uses the most recently available claims data for rate setting, which for CY 2023 rate setting purposes would be CY 2021 claims data. However, the most recent available cost report data include periods that overlap with CY 2020. CMS believes that the CY 2020 cost report data are not the best overall approximation of expected outpatient hospital services, because half of the cost reports that typically would be used for CY 2023 rate setting have cost reporting periods that overlap with parts of the CY 2020 and would include data from the start of the public health emergency (PHE). In order to mitigate the impact of some of the temporary changes in hospitals' cost report data from CY 2020, CMS is proposing to use cost report data from the June 2020 Healthcare Cost Report Information System, which only includes cost report data through CY 2019, predating the PHE. This is the same cost report extract used to set OPPS rates for CY 2022. As a result, CMS is proposing to use CY 2021 claims data with cost report data through CY 2019 (prior to the PHE) to set CY 2023 OPPS and ambulatory surgical center (ASC) payment system rates. **HAP strongly supports CMS' proposal and appreciates its recognition of the unusual impact of the PHE on the cost report data specifically.**

PROPOSED ADDITION TO THE PRIOR AUTHORIZATION PROGRAM

Citing its statutory authority to control "unnecessary increases in the volume of covered outpatient department (OPD) services," CMS in the CY 2020 OPPS final rule established a prior authorization process as a condition of payment for certain hospital-based services. Table 80 in the proposed rule lists all the service categories and services to which prior authorization currently applies.

In the proposed rule, CMS suggests adding one new service category, Facet Joint Interventions, to the prior authorization list, effective for dates of services on or after March 1, 2023. The Facet Joint Interventions service category would consist of facet joint injections, medial branch nerve blocks, and facet joint nerve destruction. The proposed rule also includes a list of Current Procedural Terminology (CPT) codes that CMS proposes for inclusion in the Facet Joint Interventions service category.

While previous years' additions of services to the prior authorization program were given an effective date of July 1, CMS notes that it proposes March 1, 2023, as the effective date because the Medicare Administrative Contractors, CMS, and hospital outpatient departments (HOPD) already have experience with the prior authorization process. In addition, CMS notes this new service category can be performed by some of the same provider types who furnish other services currently subject to the HOPD prior authorization process.

In its rationale for adding the Facet Joint Interventions service category to the prior authorization program, CMS concludes that both the facet joint injections/medial branch block CPT codes and nerve destruction CPT codes, with 2.5 percent and 7 percent annual increases, respectively, demonstrated higher average annual increases in claim submissions between 2012 and 2021 than the 0.6 percent annual increase for all outpatient department services during the same time period.

In addition, the agency notes that the U.S. Department of Health and Human Services Office of the Inspector General has published multiple reports indicating questionable billing practices, improper Medicare payments, and questionable utilization of facet joint interventions. During March 2022, the Department of Justice reported a $250 million fraud scheme involving physicians allegedly subjecting their patients to medically unnecessary facet joint injections in order to obtain illegal prescriptions for opioids. CMS also reviewed clinical and industry-related literature and did not find any indication that justifies the increases. CMS therefore concludes that increases are due to financial motives.

HAP strongly urges the agency not to move forward with this proposal but instead to engage with stakeholders and conduct a thorough analysis of what other processes, clinical factors, or changes could be driving these increased volumes.

Additionally, HAP urges CMS to require the clear delineation of data-driven justifications by health plans over which it has oversight authority, including Medicare Advantage and plans on the Federal Exchange.

PROPOSED INPATIENT PROSPECTIVE PAYMENT SYSTEM AND OPPS PAYMENT ADJUSTMENTS FOR ADDITIONAL COSTS OF DOMESTIC NIOSH-APPROVED SURGICAL N95 RESPIRATORS

CMS recognizes that hospitals may incur additional costs when purchasing domestic NIOSH-approved surgical N95 respirators. Therefore, CMS is proposing payment adjustments under the inpatient prospective payment system (IPPS) and OPPS that would reflect, and offset, the additional marginal resource costs that hospitals face in procuring domestically made NIOSH-approved surgical N95 respirators.

Under this proposal, these payments would be provided biweekly as interim lump-sum payments to the hospital and would be reconciled at cost report settlement. The rule also outlines the information that would be collected on the cost report to determine payments under this proposal, which would apply to cost reporting periods beginning on or after January 1, 2023.

HAP appreciates CMS' recognition of the need for financial support as future surges may occur and strongly supports this bi-weekly payment option with a defined cost report reconciliation process.

MEDICARE'S SITE-NEUTRAL PAYMENT POLICIES

In this rule, CMS proposes to continue its payment cuts for non-grandfathered (non-excepted) off-campus PBD in CY 2023 identifying payment at 40 percent of the OPPS rate.

However, CMS acknowledges that access to care in rural communities is challenged by this payment policy and are proposing to exempt rural SCHs from the site-neutral policy. The rule proposes that SCHs be paid the full OPPS payment rate when a clinic visit is furnished in a grandfathered (excepted) off-campus PBD of a rural SCH.

CMS is also requesting comments on whether it would be appropriate to exempt other rural hospitals from this site-neutral payment policy.

While HAP supports exempting the SCHs, by continuing the cut, we believe CMS has undermined clear Congressional intent and exceeded its legal authority, despite the

U.S. Supreme Court declining to review the unfavorable ruling by the appeals court that deferred to the government's inaccurate interpretation of the law last year.

HAP reiterates its comments from the previous years' proposed rule and incorporates, by reference, all of the comments provided in the American Hospital Association's response to the proposed rule. We continue to urge CMS to:

1. ***Immediately restore the higher payment rates for clinic visits furnished by excepted off-campus PBDs that existed before CMS adopted the unlawful payment cuts***
2. ***Promptly repay hospitals the difference between the amounts they would have received under those higher rates and the amounts they were paid under the unlawful payment rates***
3. ***Abandon the proposed continuation of the payment cut in 2023***

CHANGES TO INPATIENT-ONLY LIST

CMS designates certain procedures that can only be performed in an inpatient setting for various reasons such as the acuity of the procedure, history of the patient, or postoperative recovery time. The list is typically reviewed by CMS annually.

Last year, CMS finalized five criteria for determining whether a service or procedure should be removed from the inpatient-only (IPO) list:

1) Most outpatient departments are equipped to provide the services to the Medicare population
2) The simplest procedure described by the code may be furnished in most outpatient departments
3) The procedure is related to codes that CMS has already removed from the IPO list
4) A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis
5) A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by CMS for addition to the ASC list

CMS is proposing to remove 10 procedures (maxillofacial reconstruction services, escharotomy, and arthrodesis) and add eight services (hernia repair, total disc arthroplasty, and mesh implementation for delayed closer defects) to the IPO list.

HAP appreciates the use of appropriate criteria to assess systemically what procedures should be taken off the list as current standards of practice continue to change. HAP supports the changes to the IPO list as proposed.

ORGAN PROCUREMENT AND RESEARCH

Last year, CMS proposed several changes to organ acquisition payment policies with the expressed goal of making Medicare's share of organ acquisition costs more accurate. These proposals would have affected organ acquisition payment policies for transplant hospitals, donor hospitals, and organ procurement organizations (OPO). Due to the voluminous comments received, CMS refrained from finalizing any policies related to the count of Medicare usable organs as only organs transplanted into Medicare beneficiaries and the count of organs procured for research when calculating Medicare's share of organ acquisition cost.

In this rule, CMS is proposing a method of accounting for research organs that it believes will improve payment accuracy and lower the costs to procure and provide research organs to the research community.

CMS is also proposing to address potential financial barriers to organ donation after cardiac death, which may increase organ procurement and promote equity within the transplant ecosystem. Specially, CMS proposes to clarify that organ acquisition costs include certain hospital costs incurred for services provided to deceased donors.

In addition, CMS is requesting information to promote transparency and inform potential future organ acquisition payment policy. Specifically, CMS is requesting information on possible alternative methodologies for counting organs to calculate Medicare's share of organ acquisition costs for transplant hospitals and OPOs.

Like the AHA, HAP remains concerned with CMS' proposals related to Medicare usable organs and organ acquisition payments to THs. Excluding research organs from the count of Medicare's share of organ acquisition costs would disincentivize innovative scientific organ research. In addition, CMS' alternative methodology for counting organs in the calculation of Medicare's share would jeopardize hospital transplant programs, which of course rely on these funds. Taken together, these proposals would entail payment cuts endangering transplant programs' ability to provide care and, subsequently, access to organ transplantations for vulnerable patients. We strongly urge CMS to withdraw these proposals.

HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM

The Hospital Outpatient Quality Reporting (OQR) Program is a pay-for-reporting quality program for the hospital outpatient department setting. The Hospital OQR Program requires hospitals to meet quality reporting requirements, or receive a reduction of 2.0 percentage points in their annual payment update if these requirements are not met.

In the CY 2023 OPPS/ASC proposed rule, CMS proposes minor changes including:

- Voluntary, rather than mandatory reporting of measure OP-31/ASC-11, Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery beginning with the CY 2027 payment determination (CY 2025 reporting period)
- Shifting the quarters of data on which OQR payment determinations are based to align with patient encounter quarters for chart-abstracted measures in the OQR with the calendar year two years prior to the payment determination year beginning with the CY 2024 reporting period
- Adding hospitals with less than four quarters of data subject to validation receiving an extraordinary circumstances exception for one or more quarters and with a two-tailed confidence interval that is less than 75 percent to the validation targeting criteria used for identifying hospitals for measure data validation

While HAP appreciates CMS' acknowledgement that mandatory reporting of the cataracts measure is operationally burdensome and therefore will allow for voluntary reporting of the measure, the measure continues to suffer from the same deficiencies as when it was first proposed for adoption including:

- ***The measure is operationally difficult for hospitals to collect and report***
- ***The results of the survey used to assess the pre-operative and post-operative visual function of the patient were not consistently shared across clinicians, making it difficult for hospitals to have knowledge of the visual function of the patient before and after surgery***
- ***Clinicians used inconsistent surveys to assess visual function, as the measure allows the use of any validated survey***

Until CMS can resolve these issues, HAP does not support he required reporting of this measure in any future year.

OVERALL HOSPITAL QUALITY STAR RATING

The Overall Hospital Quality Star Rating was first introduced and reported at CMS' Hospital Compare website during 2016. In this rule, CMS proposes to amend regulatory language to clarify a change to data periods used for refreshing data finalized in the CY 2021 rule. The change would clarify that the phrase "from a quarter within the prior year" refers to any time within the previous 12 months, not just the calendar year.

The rule also notes that, while CMS intends to refresh the star ratings during 2023, it may exercise its authority to suppress the star rating "should the COVID-19 PHE substantially affect the underlying measure data".

Finally, the rule provides additional information in regards to its policy to include Veteran's Health Administration (VHA) hospitals in the star ratings program.

HAP supports the proposed changes to the Overall Hospital Quality Star Rating program and encourages CMS to continue to evaluate the impact of the PHE on its quality programs.

REMOTE OUTPATIENT MENTAL HEALTH SERVICES

CMS proposes to designate certain mental health services performed remotely by clinical hospital staff using telecommunications technology to beneficiaries in their homes as covered services for which payment is made under the OPPS. To pay for these services, CMS would create three new HCPCS codes for diagnosis, evaluation, or treatment of a mental health or substance use disorder (one code describing the initial 15–29 minutes, one describing the initial 30–60 minutes, and an add-on code for each additional 15 minutes). These codes would specify that the beneficiary must be in their home and that there is no associated professional services billed under the PFS. Hospital clinical staff would be required to be physically located in the hospital when furnishing remote services.

HAP appreciates CMS' willingness to establish permanent payment for certain remote outpatient mental health services and, in doing so, clarify the pathway to maintain access to these services after the end of the PHE. During the course of the PHE, Pennsylvania hospitals have provided remote outpatient services in order to remove barriers to care and increase access to needed services. Many Pennsylvania counties do not have an adequate number of providers to meet their community's needs. Remote services allows providers to serve a larger geographic community to meet some of those needs. Furthermore, remote services bring treatment to patients where they are. Across Pennsylvania, transportation is a barrier to patients receiving life-saving services. In urban communities, bus fare or parking/expense of travel is often an issue for vulnerable patients. In rural communities, transportation becomes a barrier for people who have limited social support and access to vehicles. Unsurprisingly, even as the public health restrictions are easing and patients are returning to more pre-pandemic activities, Pennsylvania hospitals continue to have more patients requesting/preferring telehealth services than people requesting in-person.

Pennsylvania hospitals welcome the opportunity to continue to service patients remotely. CMS proposes to assign the new HCPCS codes to APCs based on the PFS facility payment rates for similar CPT codes due to the agency's belief that the costs associated with these remote services more closely resemble those under the PFS rather than the OPPS because the hospital is not accruing all the costs associated with in-person services. However, the proposal still requires that hospital clinical staff to be physically located in the hospital when furnishing remote services.

HAP recommends that CMS continue to analyze and assess the sustainability of the proposed payment rate to ensure long-term access to necessary remote services. Additionally, we urge CMS to continue to assess whether the clinician needs to be physically located in the hospital to provide high-quality, HIPAA-compliant services as the location of the clinician impacts the cost of care.