The Hospital + Healthsystem Association of Pennsylvania

Leading for Better Health

September 11, 2023

The Honorable Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS–1793–P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: CMS–1793–P, Medicare Program; Hospital Outpatient Prospective Payment System

Dear Administrator Brooks-LaSure:

On behalf of The Hospital and Healthsystem Association of Pennsylvania (HAP), representing more than 230 hospitals and health systems statewide, 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) 2024.

For CY 2024, CMS proposes a market basket update of 3.0 percent less a productivity adjustment of 0.2 percentage points, resulting in a net update of 2.8 percent. This is simply not enough. HAP is greatly concerned about this inadequate update, especially when taken together with the underwhelming market basket increases from CY 2022 and 2023. It does not capture either the unprecedented inflationary environment or the other persistent financial headwinds hospitals and health systems are experiencing. It also fails to account for the fact that labor composition and costs have remained extraordinarily high and that, as a result, the hospital field has continued to face sustained financial pressures and workforce shortages.

Given all the above, HAP strongly urges CMS to find ways to account for these increased costs to ensure that beneficiaries continue to have access to quality outpatient care. We also urge the agency to reduce the productivity cut for CY 2024 as such a cut does not align with hospital and health systems' public health emergency experiences related to actual losses in productivity during the COVID-19 pandemic.

Additionally, CMS is proposing several changes to the hospital price transparency requirements related to standardization of and changes to CMS' monitoring and enforcement processes, and requests comment on how to better align the various price transparency policies going forward. HAP encourages CMS to work closely with the American Hospital Association (AHA) to improve the hospital price transparency rule, especially as it relates to better aligning these requirements with the Transparency in Coverage and No Surprises Act requirements.

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.

In addition, we incorporate, by reference, all of the comments provided in the AHA'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

HAP Comments—Outpatient Prospective Payment System
Proposed Rule for Calendar Year 2024

PAYMENT UPDATE

Along with the American Hospital Association (AHA), HAP remains deeply concerned that CMS is proposing a CY 2024 outpatient hospital payment update of only 2.8 percent despite persistent financial headwinds facing the hospital field. Without a more robust payment update in the final rule, hospitals' and health systems' ability to continue caring for patients and providing essential services for their communities may be jeopardized.

PROPOSED 340B DRUG PAYMENT POLICY

Proposed Payment for 340B-acquired Drugs and Biologicals—*HAP is pleased that CMS proposes to continue to apply the default rate, generally Average Sales Price (ASP) plus 6 percent, to 340B-acquired drugs and biologicals.* Therefore, drugs and biologicals acquired under the 340B program would be paid at the same payment rate as those drugs and biologicals not acquired under the 340B program.

Proposal to Use a Single Modifier—In the CY 2023 outpatient prospective payment system (OPPS) final rule, CMS required that hospital-based 340B-covered entities continue to use the 340B-related modifier it used previously, either the "JG" (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes) or "TB" (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities) modifier.

In this CY 2024 proposed rule, CMS now states that it believes that utilizing a single modifier will allow for greater simplicity, especially because both modifiers are used for the same purpose—to identify separately payable drugs and biologicals acquired under the 340B program. Therefore, CMS proposes that all 340B-covered entity hospitals paid under the OPPS would report the "TB" modifier, effective January 1, 2025, even if the hospital previously reported the "JG" modifier.

The "JG" modifier would remain effective through December 31, 2024. Hospitals that currently report the "JG" modifier could choose to continue to use it in CY 2024 or choose to transition to use of the "TB" modifier during that year. Beginning on January 1, 2025, the "JG" modifier would be deleted, and hospitals would be required to report drugs and biologicals acquired through the 340B program using the "TB" modifier.

Additionally, beginning January 1, 2025, CMS would revise the "TB" modifier descriptor to no longer include "…for select entities" as all entities would report this modifier after this date.

HAP strongly believes that there no longer is a need to report either modifier because the OPPS Drug Payment Policy which relied on the modifiers has been ruled

unlawful and is no longer in effect. As suggested by the AHA in its comment letter, there are other more efficient ways for CMS to obtain information it may be seeking.

340B Remedy Proposed Rule—On July 11, CMS published its proposed rule regarding the remedy for OPPS 340B Drug Payment Policy for CYs 2018–2022. This rule follows last year's unanimous Supreme Court decision, which found unlawful the OPPS payment cuts for certain hospitals that participated in the 340B Drug Pricing Program.

As reflected in HAP's comment letter submitted August 28, 2023, we strongly supported CMS' proposal to repay 340B hospitals that were unlawfully underpaid from 2018 to 2022 in a single-lump sum payment. This will help to ensure that Pennsylvania hospitals can continue providing care to their patients and communities.

However, HAP is greatly disappointed with the choice to propose "budget neutrality adjustments" to offset this legally required remedy. As persuasively explained in the AHA comment letter, the statutes that the Department of Health and Human Service (HHS) relies on in its proposed rule do not give it the authority to make a "budget neutrality adjustment." Nor do they require budget neutrality as a matter of law. Contrary to suggestions in the proposed rule, HHS has both the legal obligation and legal flexibility to not seek a clawback of funds that hospitals received as a result of HHS' own mistakes and that hospitals have long since spent on patient care—including during the COVID-19 pandemic. ***Accordingly, HHS must not pursue any "budget neutrality adjustment" in the final rule. At the very least, it must pursue a far smaller one than the proposed $7.8 billion "adjustment."***

UPDATES TO REQUIREMENTS FOR HOSPITALS TO MAKE PUBLIC A LIST OF THEIR STANDARD CHARGES

CMS proposes additional changes to the hospital price transparency rule and requests comments on how to better align price transparency policies in the future. ***HAP supports the AHA efforts to work with CMS to improve the hospital price transparency rule, especially as it relates to better aligning these requirements with the Transparency in Coverage and No Surprises Act requirements.*** Hospitals have long been committed to providing patients information and support to make informed decisions, though earlier solutions required more cumbersome, manual processes with significant technical barriers, such as those related to obtaining cost-sharing information from insurers. Today, the landscape has shifted. Not only are patient price estimator tools commonly available on both hospitals' and insurers' websites, but uninsured and self-pay patients are receiving good faith estimates (GFE) prior to scheduled care, with the industry and CMS hard at work developing the technical standards to implement GFEs and advanced explanation of benefits (AEOB) for insured patients. In addition,

researchers and others have access to large datasets of hospital and insurer rates through both the hospital and insurer machine-readable files.

Alignment across these policies is paramount to ensure the data and estimates available are accurate and meaningful to patients and to minimize duplication of effort and excess cost in the system. HAP is concerned that both the administration and Congress are considering changes to the hospital price transparency rule simultaneously.

While well intentioned, if even a portion of these efforts are adopted, patients, policymakers, researchers, and others would face an even more daunting task of deciphering conflicting data from the myriad price transparency sources. In addition, each time changes are made to the requirements, hospitals must invest additional time and resources to come into compliance. ***HAP strongly recommends CMS work with Congress to ensure any legislative changes are made in accordance with any finalized administrative requirements to avoid conflicting requirements as hospitals seek to adhere to both the regulatory and statutory changes.***

Some specific comments on the agency's proposals and requests for comment follow.

Standardization—CMS proposes requiring a standardized format for the hospital price transparency machine-readable file requirements. The proposed changes appear to be in part a result of feedback the agency has received from hospitals and other stakeholders on the initial guidance for implementing the machine-readable files. The new format would include additional required fields, such as information on the contracting method used to derive a negotiated rate and an expected allowed amount for non-dollar rates. CMS proposes allowing hospitals two months to transition to the new standardized format following finalization of these requirements. ***While HAP appreciates CMS' willingness to address issues raised by hospitals with the current format, we echo the AHA concerns about the additional burden the new requirements would place on hospital staff and the short timeline for implementation.***

Hospitals, often in partnership with vendors, developed their machine-readable files based on their understanding of CMS' guidance and to accommodate the different types of contracts insurers and providers have. One common concern hospitals have shared with CMS is how to assign a single rate for a service when the contract with the payor does not include a simple fee schedule but is rather based on multiple factors. In response to this concern, CMS is now proposing that hospitals include far more information in their machine-readable files that would detail both the methodology used to derive a negotiated rate, as well as the amount the hospital expects to be paid based on that methodology. ***The additional fields detailing the methodology (e.g., percentage, algorithm) would be incredibly burdensome to***

produce while meaningless for anyone outside of the hospital and insurer relationship to interpret. Moreover, it would introduce new access issues to the files based on their expanded size. Instead, we recommend CMS keep the currently required data elements but revise the definition of negotiated rate to allow for dollar amounts beyond a simple fee schedule. That dollar amount could be an established rate when one exists or it could be what CMS is referring to as the *consumer-friendly expected allowed amount*, which is, and may be better described as, the average historic allowed amount. This would address hospitals' concerns about the narrow and restrictive negotiated rate definition without introducing unnecessary burden and size to the machine-readable files.

CMS also is proposing additional modifier and drug data fields that are superfluous and burdensome to produce. CMS proposes that hospitals specify in a new field any relevant modifiers that would change the negotiated rate. Many items and services can be billed with multiple modifiers that impact the calculated payment creating an almost endless number of permutations that would need to be included in the machine-readable file if CMS finalizes this requirement.

For drugs, CMS proposes that hospitals indicate the drug unit and type of measurement as separate data elements, which is information already captured in the item description. The inclusion of these new data fields would significantly increase the cost to comply with the new requirements while not providing additional insights to the data users beyond what is already available in other fields. They also would vastly increase the size of the machine-readable files, making them more cumbersome to utilize. ***HAP urges CMS not to finalize these data elements in the standardized format.***

Finally, we strongly request that CMS allow hospitals up to 18 months to adopt the new standards following the release of final technical guidance. Hospitals have already dedicated significant resources toward complying with the machine-readable file requirements. Some AHA members report spending $15,000–$25,000 per hospital on vendors to build the initial machine-readable files, and $10,000–$20,000 to maintain the files and update them annually. A different hospital system producing its own file without vendor help reports spending 1,600 hours annually, across 23 individuals, to produce their machine-readable files.

Given the complexity of these files, detailed guidance is going to be required to properly ensure that the new standard format is implemented consistently across hospitals and to avoid excessive updates to the guidance in the future. This will require collaboration between CMS and hospital technical experts and is unlikely to be completed by the time the final requirements are released. The implementation period for the standard files should not begin until this guidance is complete as attempting to meet the requirements before the guidance is released would be inefficient. Once the guidance is released, we recommend allowing hospitals up to 18

months to adopt the new format. Hospitals are only required to update their files annually and often need up to six months to prepare the file for the next year. Therefore, any time less than 18 months could result in duplicating a hospital's effort for the year, resulting in significant added cost and staff time that would be better deployed to other patient care and patient experience endeavors.

Changes to Monitoring and Enforcement Practices—CMS proposes several changes to its monitoring and enforcement practices, including requiring a hospital official to certify the accuracy and completeness of the hospital's machine-readable file. ***HAP urges the agency not to finalize this proposal.*** CMS also is proposing an accuracy and completeness affirmation within the standardized file, which would serve the same purpose but would be completed during the development of the file. A second, duplicative certification after the file has been developed would be administratively burdensome with no additional utility. Therefore, should CMS finalize the affirmation within the standard format, it should not require a separate attestation during the monitoring process.

HAP agrees with the AHA's opposition to the proposed addition of § 180.70(a)(2)(v) that would require hospitals and health systems to submit certain documentation to CMS. Specifically, the proposed rule suggests that CMS may require hospitals to submit "contracting documentation to validate the standard charges the hospital displays." Courts have long held that certain contracting information—especially negotiated rate data—is commercially sensitive information that is shielded from disclosure by numerous legal protections. *E.g., West Penn Allegheny Health Sys., Inc. v. UPMC,* 2013 WL 12141532 (W.D. Pa. Sept. 16, 2013) (trade secrets protection); *Medical Ctr. at Elizabeth Place, LLC v. Premier Health Partners*, 294 F.R.D. 87 (S.D. Ohio 2013) (discovery protections); 73 Fed. Reg. 30,664-01, 30,675–75 (May 28, 2008) (FOIA Exemption 4). There is no indication in section 2718(e) of the Public Health Services Act (i.e., the statutory text on which the agency relies for this documentation requirement) that Congress authorized CMS to override these well-established legal protections by regulatory fiat. To be clear, the AHA does not oppose CMS requiring submission of other information (e.g., verification of the hospital's licensure status or license number). But requiring hospitals to submit private contractual information crosses a critical legal line and that aspect of the proposed rule should not be finalized.

CMS proposes several other changes to the enforcement process. First, CMS proposes to allow notifications to health system leadership of any compliance activity within their system, as well as notification to the specific hospital's leadership, to better accommodate health systems with a central office responsible for compliance. ***HAP supports this proposal.***

CMS also proposes requiring hospitals to confirm receipt of warning notices to accelerate hospital attention to the issue identified and streamline further communication with CMS. We

appreciate CMS' desire to streamline this process and avoid unintentional delays due to communications issues. ***To that end, HAP recommends CMS also copy the primary contact listed on the 855A Enrollment Form.*** This individual already expects to be an intermediary between CMS and the hospital and could help to ensure the letter reaches the appropriate individuals within the hospital in a timely manner.

Publication of Compliance Actions and Outcomes—CMS proposes several changes to the public disclosure of information regarding the agency's oversight of hospital compliance with the rule. Specifically, CMS proposes to give itself authority to make public additional information related which to hospitals are being reviewed for compliance (either as part of routine oversight or in response to a public question or complaint), any compliance actions taken against a specific hospital, the status of the compliance action(s) and the outcome of the action(s). While we respect CMS' role as the sole arbiter of compliance and some stakeholders' desire for additional transparency regarding the agency's compliance actions, we are concerned that some of the information that could be released as a result of this proposal could be misconstrued. Specifically, we would expect that some stakeholders may misinterpret CMS' guidance and believe that hospitals under a routine compliance review are noncompliant and use that information to confuse the public and policymakers about the true state of compliance. Similarly, we know there will be situations where CMS may have questions about a hospitals' compliance and engage in follow-up with the hospital only to ultimately conclude that the hospital is indeed compliant. We based this on our understanding that there have been many productive collaborations between hospitals and CMS during review processes to date that have involved education on both sides around what information is and should be displayed in the machine-readable files. ***Should CMS finalize this proposal and eventually release this information, HAP urges the agency to make it clear that hospitals are <u>not</u> deemed non-compliant when under review.*** Alternatively, we recommend CMS set up a regular cadence under which it will review hospitals' machine-readable files and publicize that information, making it clear that all hospitals are reviewed on a set schedule and further taking stigma away from the review process.

Price Transparency Alignment—*HAP appreciates CMS' recognition of the several overlapping federal price transparency policies and interest in how changes to the hospital price transparency requirements could help achieve alignment.* Hospitals and health systems are dedicated to improving price transparency for patients. We remain concerned, however, that the numerous and sometimes conflicting requirements at both the state and federal levels create an overwhelming landscape of pricing information that not only is challenging for patients to navigate but also adds excessive costs and workforce burden to the health care system.
As we enter the next phase of price transparency regulation implementation, with most of the federal requirements already executed or on the horizon, we strongly recommend CMS focus on

streamlining current policies to remove complexity from the patient experience by narrowing the options for patient estimates and other pricing information and ensuring those estimates are as accurate as possible. This will allow the policies to achieve their intended purpose—to help patients understand and compare their expected costs prior to care—while also minimizing duplication and excess burden on the health care system.

Our specific recommendations for aligning the policies are as follows.

- ***Streamline the hospital machine-readable file requirements to minimize duplication of effort and the potential for conflicting information, while preserving public access to negotiated rates.*** Specifically, HAP recommends that CMS maintain the requirement that payors post all negotiated rates with providers while allowing hospitals to focus solely on chargemaster rates and cash prices. In doing so, consumers, third party vendors, researchers, and other interested parties would retain access to negotiated rate information while the risk of potentially conflicting information would be reduced. This also would eliminate duplication of effort and therefore reduce unnecessary costs and burden in the health care system.

- ***Rely on the No Surprises Act GFE and AEOB requirements to provide patients with the most accurate estimates for their course of care.*** We believe that once fully implemented, the No Surprises Act GFE and AEOB policies will have the greatest impact on patients. These estimates will be tailored to the patients' unique characteristics and expected care pathways and, in the case of insured patients, take into account their health care coverage, including where they are in their deductible. In addition, patients will automatically receive these estimates as part of their pre-care paperwork without additional effort on their part.

  The AHA is deeply engaged with CMS and other stakeholders in workgroups to ensure that the insured GFEs and AEOBs will be implemented in a way that will create meaningful estimates in an efficient manner. However, there are still several issues that are slowing down the process, including determining which entity is responsible for collecting and collating estimates from various providers involved in a patient's episode of care. There are two general approaches this process could take: 1) each provider submits its own pre-service estimate to the insurer who collates them and applies its coverage rules to generate the AEOB, consistent with how the explanation of benefit (EOB) process works today, or 2) where a single "convening" provider assumes responsibility for collecting estimates from different providers and transmitting the bundle of estimates to the insurer. ***To accelerate the process and avoid unnecessary costs and duplication of effort, HAP supports the AHA's recommendation for CMS to clarify that it is the insurers' responsibility to***

collect and collate all the estimates from the various providers to generate the patient's estimate.

The AEOB process is intended to essentially provide patients an EOB in advance of care. AEOBs, like EOBs, are not simply a compilation of claims from unique providers. They are the result of the insurer processing the individual claims and applying its coverage rules, including considering where the individual is within their deductible and maximum out-of-pocket cost limits. These coverage rules—such as whether the insurer bundles some set of services into a single reimbursement or even covers certain items in a given circumstance—are all elements that must be known to generate the AEOB. Insurance companies already have the workflows and technology to not only collect and collate claims from different providers, but also to apply their coverage rules and adjustments.

As we previously expressed, requiring a single convening provider for AEOBs would create enormous administrative burdens for providers, utilize a process that diverges from the claims process used to create patient bills, and could potentially lead to delays in care. To ensure that the estimates are most reflective of a patient's final bill and do not create unnecessary burdens on the care delivery process, the HAP urges CMS not to require a single provider to compile pre-service estimates before they are sent to the insurer.

- ***Finally, HAP recommends that CMS only require GFEs and AEOBs for scheduled services, while relying on the shoppable service/price estimator requirements of the Hospital Price Transparency and Transparency in Coverage rules to provide pre-service information to shopping patients.*** GFEs and AEOBs should provide individualized, and therefore highly accurate, pricing information for scheduled services where patient characteristics and the course of care are known. However, generating them is labor and time intensive and their usability is often dependent on clinical information and other personal information that is not known for nonscheduled patients. Therefore, we recommend the agency be thoughtful in applying these requirements where they will provide the most value and rely on the more scalable shoppable service/price estimator tool requirements to meet the needs of patients who are evaluating different options (i.e., shopping). In addition, we recommend CMS engage with Congress to preserve hospitals' ability to meet the shoppable service requirement with a price estimator tool. These tools are currently the best mechanism for patients to access price estimates. Changing this policy would move the field in the wrong direction, requiring patients to navigate machine-readable files that can be confusing for them to navigate.

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 2024 identifying payment at 40 percent of the OPPS rate. CMS is also proposing to correct an unintended reimbursement disparity for Intensive Cardiac Rehabilitation (ICR). The Medicare Improvements for Patients and Providers Act of 2008 requires, starting in 2010, that ICR services provided in physician offices be paid at 100 percent of the OPPS rate. When the site-neutral payment provisions of Section 603 of the Bipartisan Budget Act of 2015 (BiBA) where implemented, payments for ICR services furnished in off-campus, non-grandfathered provider-based departments of a hospital have been reduced to the "PFS-equivalent" rate of 40 percent of the OPPS rate.

The rule proposes to pay for these non-grandfathered ICR services at 100 percent of the OPPS rate.

While HAP appreciates CMS' acknowledgement and correction of the ICR issue, we strongly urge prompt repayment for ICR services during the years in which they were inappropriately reimbursed.

We also continue to 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.

HAP reiterates its comments from the previous years' proposed rule and incorporates, by reference, all of the comments provided in AHA'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 2024***

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.

In previous rulemaking, 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 ambulatory surgical center (ASC) and is on the list of approved ASC services or has been proposed by CMS for addition to the ASC list

CMS is not proposing to remove any procedures from the IPO list for CY 2024 but does propose to add nine procedures related to thoracolumbar, lumbar and thoracic vertebral body tethering, skull mounted cranial neurostimulators, epiaortic and epicardial ultrasound/placement of transducer, and transcatheter valve implantation/replacement.

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

BEHAVIORAL HEALTH

HAP appreciates and is supportive of the behavioral health updates proposed by CMS including the implementation of a new Medicare benefit for Intensive Outpatient Programs, updates to Medicare payment rates for partial hospitalization program (PHP) services and clarification that Medicare covers PHP for the treatment of substance use disorders, new and increased payment for remote mental health services, and a delay of the in-person service requirement for remote mental health services furnished by hospital staff.

Pennsylvania providers appreciate the agency's efforts to better align payment with the level of care delivered to patients receiving these services. HAP also appreciates

CMS' consideration for the complexities that arise when trying to meet in-person visit requirements after years of remote services and the unintended impact that reinstating these requirements would have on continuity of care.