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Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
US Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS 1786-P; Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Proposed Rule; Vol. 88, No. 145, July 31, 2023

Dear Ms. Brooks-LaSure:

On behalf of the 170+ hospitals and health systems in four states that make up the acute care membership of the Greater New York Hospital Association (GNYHA), we appreciate this opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS's) hospital outpatient prospective payment system (OPPS) and ambulatory surgical center payment systems proposed rule for calendar year 2024.

Our comments address the following CMS proposals:

- Price transparency
- Market basket update
- Medicare coverage for Intensive Outpatient Programs
- Inpatient-Only List
- Payment for buffer stock of essential medicines

Thank you for the opportunity to provide feedback on the OPPS proposed rule. Please direct questions on price transparency to Emily Leish or Matthew Felton, and questions on other topics to Rebecca Ryan.

Sincerely,

Elisabeth Wynn
Executive Vice President

GNYHA Comments on OPPS Proposed Rule

Price Transparency

GNYHA strongly supports efforts to improve price transparency information for consumers and help patients access more accurate information about their health care costs when making treatment decisions. We strive to work with the Centers for Medicare & Medicaid Services (CMS) and our member hospitals in pursuit of this important goal. While the proposed change to the hospital price transparency (HPT) policies requiring use of a CMS template to display Machine-Readable File (MRF) data has the potential to facilitate standardization and add clarity for hospitals, other proposals, such as additional data fields, a certification requirement, and the implementation timeframes are very problematic. We believe CMS is significantly underestimating the workforce, financial burdens, and implementation timeframes needed to comply with the proposed HPT provisions. **We therefore urge CMS to consider a phased approach to the revisions**, beginning with migrating to a standardized CMS template based on current requirements, and postponing finalizing additional requirements such as incorporating new fields and certification requirements only after further consultation with hospitals as to administrative and technological burdens and feasibility. Additionally, we emphasize the need for an extended implementation date of at least six months from the finalized CMS template assuming no additional fields are added, and at least 18 months if additional fields and information are to be incorporated into the MRF.

Standardized Template Can Add Value. GNYHA supports the overall goal of standardizing the MRF and associated data elements used by hospitals. We agree with CMS that standardization can help clarify the reporting requirements for hospitals and improve the usability of files for stakeholders. However, migrating even existing data elements to a new standardized format is a time and labor-intensive endeavor that will require significant restructuring of existing data elements. We urge CMS to revise the template to include only current MRF data elements and allow hospitals to focus resources on becoming familiar with and accurately converting current files to the new standardized format.

New Data Elements Are Overly Burdensome and Unworkable in Proposed Timeframe. The CMS template as proposed includes several new data fields. **We believe CMS is grossly underestimating the hours required to adapt existing data and develop comprehensive information for newly proposed data elements within the CMS template layout.** The addition of new data elements is overly burdensome and unworkable in the proposed timeframe.

Our members are particularly concerned with the proposed new fields that require information on the contracting method used to establish a payer-specific negotiated charge and the associated note fields. Populating these fields requires manually extracting detailed information and methodology from payer contracts for each and every identified service—this is not data that can be electronically extracted, even for hospitals with sophisticated contract management systems. For larger hospitals there can be more than 50,000 services under a payer agreement. Populating the proposed contracting method and note fields cannot be automated and will require significant manual effort.

We are also hearing concerns about having the appropriate workforce for the required effort. Understanding commercial insurance contracts is a defined and honed skill and only a discrete number of employees within

a hospital possess the requisite expertise, making it challenging to find multiple suitable candidates internally. Identifying the contracting method and crafting descriptions within the payer notes explaining the calculations used by the contract requires expertise. The same is true for the proposed new requirement to calculate consumer friendly expected allowed amounts. While a specialist with specific education, training, and experience in working with insurance contracts may be able to perform this task, it is crucial to recognize that this work is more than basic data entry and requires a skill set that cannot be easily taught or outsourced. One member hospital estimates that converting to the new CMS template with payer-specific notes would require seven full-time employees with the appropriate level of payer contracting expertise. And given that the requirement to maintain the CMS template is ongoing, hospitals will need to ensure they retain employees with appropriate expertise. Many hospitals may need to engage outside vendors at great additional expense.

In terms of timing, feedback from our members indicates that creating comprehensive payer notes describing the contract calculation alone could take between six to twelve months. Transitioning to the new template as proposed could take as much as 12-18 months. Furthermore, there are concerns that these note descriptions have the potential to be overly complex, lengthy, and open to misinterpretation.

Given the significant time and resource implications of the additional data elements, combined with the questionable utility of the information, **we request that the CMS template be standardized to include only existing data elements.** This would allow hospitals to become acclimated to the new MRF format, ensuring that existing data can be encoded correctly.

Compliance Cost Estimates are Significantly Understated. **There is a fundamental disconnect between CMS and hospitals as to the Overall Estimated Burden on Hospitals and Cost Estimates.** As evidenced by one hospital's projected need for 7 full-time equivalents to implement the proposed HPT policies, CMS's mean cost per hospital primary estimate of $2,787 and high estimate of $4,181 is grossly inadequate. We implore CMS to engage with hospitals to more accurately and comprehensively understand the associated financial and administrative burdens of proposed HPT policies before finalizing any requirements.

We also suggest CMS engage hospitals in further exploration of ways to best provide consumers with access to cost-estimates and continue to evaluate and refine which stakeholders are best positioned to provide different types of information. This evaluation should include an analysis of data that is now and will soon be available to consumers through health plans because of other state and federal transparency initiatives. CMS has deemed hospital online price estimator tools suitable for communicating standard charges in a consumer-friendly manner[1], while the Transparency in Coverage (TIC) rule and the No Surprises Act are both designed to empower consumers with pricing information and protect them from unexpected medical bills. We continue to have concerns that these different initiatives are producing conflicting information that will further lead to public confusion on health care pricing and urge CMS to reexamine the need for different stakeholders to produce the same pricing information.

Longer Implementation Period is Needed. We further emphasize the need for **additional time** for hospitals to come into compliance with the new requirements. A March 1, 2024, target date is not realistic, especially

[1] 88 FR 49862

given that the CMS template is not yet finalized. We feel very strongly that the template with new fields should not be implemented at this time. However, should CMS proceed with the template as proposed and with the new fields, we underscore that hospitals will need a meaningful implementation runway from the date the CMS template is released, and recommend 18 months.

Scope of Items and Services Should be Defined. **If and when CMS does decide to expand the list of required data elements in the MRF we strongly encourage CMS to consider applying the requirements to a defined set of items and services.** As the set of required data elements expands so does the associated file size, which creates a production burden for hospitals and makes the files increasingly more cumbersome for users. Limiting the services to which more expansive data elements are applied would better serve the goal of providing consumers with access to meaningful and usable data. Additionally, any new data elements should be gradually incorporated into the file over time, enabling hospitals to create and encode the information accurately.

Certification Should be Postponed. Finally, given the resource burdens described, we have significant concerns with the proposed requirement to certify the accuracy of the MRF. Our member hospitals have and will continue to work diligently and in good faith to meet the new regulatory requirements. However, in addition to real timing constraints, the introduction of a new format with new data elements, and the need to manually craft contract calculation descriptions, significantly increases the likelihood of errors. Given that a substantial portion of data will need to be created for the first time, it will be extremely challenging to thoroughly populate and validate every element for accuracy before March 1, 2024. Therefore, we request CMS postpone the proposal for MRF certification (within the file and through submission) until hospitals have had adequate time to familiarize themselves with the new format and adapt their data accordingly.

Market Basket Update

CMS proposes an OPPS payment increase of 2.8% in CY 2024, which includes a market basket update of 3.0% and a -0.2% productivity adjustment, and is the same methodology used to determine the fiscal year (FY) 2024 inpatient prospective payment system (IPPS) market basket. As we stated in our comment letter in response to the FY 2024 IPPS proposed rule, **CMS's proposed update factor is inadequate given the unprecedented cost growth that acute care hospitals have experienced and will continue to experience in the wake of the COVID-19 public health emergency (PHE) and fails to account for substantial market basket forecast errors. GNYHA strongly recommends that CMS issue an interim final rule to adjust the IPPS update using a methodology that more accurately reflects actual hospital cost growth in the final rule and apply this increased rate update in the CY 2024 OPPS final rule.**

For GNYHA's IPPS proposed rule comment letter, we conducted an extensive analysis showing 1) why CMS's market basket methodology fails to accurately measure input prices during times of high inflation for the purpose of updating hospital payment rates, and 2) how CMS can alter its methodology to improve payment accuracy. Below we summarize our main points from our IPPS comment letter. Additional background and details on our methodology can be found in our original letter, available here.

Summary of GNYHA's IPPS Comments on the Market Basket Methodology

Hospitals Face Dangerously Low Medicare Margins

Even prior to the COVID-19 pandemic, hospitals have faced declining Medicare margins resulting from years of cuts paired with inadequate rate updates. In its March report to Congress, the Medicare Payment Advisory Commission projected that hospital Medicare margins would decrease to roughly -10% in FY 2024 and concluded that 2024 IPPS and OPPS payment updates based on current law would be inadequate to ensure Medicare beneficiary access to hospital services.

Hospitals Have Experienced Unprecedented Cost Growth

GNYHA's analysis of 2015-2022 Medicare cost report data showed that in 2021 and 2022, hospitals' total allowable operating cost growth was 9.2% and 9.3%, respectively. While Medicare's payment updates were lower than actual cost growth in each year of the analysis, the difference was particularly acute in 2021 and 2022, with market basket updates of 2.4% and 2.7%, respectively. While inflation has begun to decrease, hospitals are still trying to catch up from the years in which their costs skyrocketed but their Medicare payments modestly increased. And while some pandemic-related costs have subsided, structural changes have led to permanently higher labor costs, with compensation costs growing by 14.3% nationwide in 2022. The stresses of the pandemic further deepened labor shortages, particularly for nurses, which has led to an increased reliance on contract labor and the need to increase salaries to retain permanent staff.

CMS's Market Basket Methodology Led to Significant Underpayments in 2021 and 2022

The current market basket methodology does not accurately capture growth in input prices during times of high inflation or properly account for labor cost increases. Importantly, the market basket methodology relies on the employment cost index (ECI) to measure compensation growth, yet the ECI does not separately capture inflation in contract labor compensation, which has increased dramatically in recent years.

Using the Same Methodology for 2024 will Lead to Another Underpayment Due to the Cumulative Effect of Past Inflation Rates

CMS must effectively "reset" the 2024 rates before considering whether to return to its usual market basket methodology to not only provide a reasonable rate increase for hospitals in 2024 but to establish a proper base for future rate increases. GNYHA recommends that CMS use case mix-adjusted Medicare inpatient costs per discharge from the Medicare cost reports to better capture the true growth in hospital input prices. These data represent cost growth for Medicare beneficiaries after adjusting for both changes in intensity and changes in volume and are therefore in line with the statutory requirements for the market basket percent increase. GNYHA's analysis found that adjusted costs per discharge increased 8.3% between 2021 and 2022. CMS could reasonably average this increase with the 2020-2021 increase of 0.96% to derive a 4.6% market basket adjustment for 2024.

CMS should also correct for unusually high forecast errors

GNYHA analyzed the forecasted and actualized change in prices produced by IHS Global Insights from 2012 to 2022 and found that the magnitude of this forecast error has grown each quarter since the start of 2021. We found that the 2022 Q3 forecast error of three percentage points is nearly three times larger than the next largest forecast error across 2012-2022. Yet, there is currently no mechanism to correct for forecast error in the operating component of the IPPS or therefore, the OPPS, and each year of understated price growth compounds the problem, as payment updates build upon the prior year's base payments. Therefore, CMS should adopt either a one-time adjustment to its 2024 payment update of three percentage points to

account for the documented FY 2022 forecast error or institute a permanent forecast error adjustment policy for IPPS and OPPS operating payments that captures cases of extreme forecast error, which are only expected to occur in the wake of economic shock. CMS could take a similar approach as it does in the capital portion of the IPPS and in the Skilled Nursing Facility PPS where it adjusts for forecast error associated with the most recent year with complete data when that error exceeds a threshold. GNYHA recommends that CMS structure the adjustment in the IPPS and OPPS so that it is only triggered if the forecast error exceeds 1.5 percentage points in either direction.

Summary of GNYHA Recommendations

CMS should revise its IPPS market basket update through an interim final rule in the following ways:

1) **Base the update on the case mix-adjusted Medicare costs per discharge from the Medicare cost reports and average the percent changes between 2020 and 2021 and between 2021 and 2022, which would result in a 4.6% market basket increase in FY 2024**
2) **Implement a 3% forecast error adjustment to adjust for the underpayment in the prior year with the most recent actual data (i.e., correcting the FY 2022 forecast error in FY 2024).**

Combining these two recommendations—a 4.6% market basket update and a 3% forecast error adjustment—would result in a FY 2024 IPPS adjusted market basket increase of 7.6%. CMS should then apply the same methodology when finalizing the OPPS market basket update.

Medicare Coverage for Intensive Outpatient Programs

GNYHA supports CMS's proposed implementation of the Consolidated Appropriations Act, 2023, requirement to provide Medicare benefits for Intensive Outpatient Program (IOP) services. Medicare coverage of IOP services is an important step toward improving access to behavioral health services in the outpatient setting.

CMS proposes to revise the methodology for calculating partial hospitalization program (PHP) services and apply the same PHP per-diem rates to IOP services, creating separate four-service and three-service payment rates. GNYHA agrees that CMS should pay the same rates for services whether they are billed as part of an IOP or a PHP. CMS also proposes to revise its current policy by applying the three-service payment rate to days with three *or fewer* services, acknowledging that occasionally patients cannot complete a full day of treatment due to extenuating circumstances. GNYHA supports this proposal (which would apply to both PHPs and IOPs), which recognizes that hospitals still incur costs when patients have incomplete service days.

Inpatient-Only (IPO) List

GNYHA supports CMS's proposal not to remove any services from the IPO list for CY 2024 and to add nine services with newly created codes to the IPO list that can only be safely performed in the inpatient setting. CMS also requested information on whether four gastrointestinal services that are currently on the IPO list could be safely performed in the outpatient setting on the Medicare population and whether they meet CMS's criteria for IPO list removal. These codes are as follows:

- CPT code 43775 (Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)
- CPT code 43644 (Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and roux-en-y gastroenterostomy (roux limb 150 cm or less))
- CPT code 43645 (Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption)
- CPT code 44204 (Laparoscopy, surgical; colectomy, partial, with anastomosis)

Our member hospitals have expressed that while performing some of these services in the outpatient setting may be appropriate for certain younger, healthier patients with minimal comorbidities and strong home support systems, it would be inappropriate for the typical Medicare patient. These complex procedures come with risks such as dehydration or, rarely, a major bleed that could lead to post-operative admissions. We are particularly concerned that the surgeries described by CPT 44204 (Laparoscopy, surgical; colectomy, partial, with anastomosis) would pose significant risk to Medicare beneficiaries if performed in the outpatient setting given this population's higher rate of comorbidities, by increasing the risk of ileus and anastomotic leak, which could lead to sepsis. Therefore, these procedures should remain on the IPO list to ensure Medicare beneficiaries can seek these services in the inpatient setting to reduce these risks and improve clinical outcomes.

Payment for Buffer Stock of Essential Medicines

CMS proposes to make separate payments under the IPPS (and possibly under the OPPS in future years) to cover hospitals' additional costs to establish and maintain access (including through contractual arrangement) to a three-month buffer stock of domestically manufactured essential medicines for cost reporting periods beginning on or after January 1, 2024. Through this proposed policy, CMS aims to address shortages of critical medical products, particularly over the past few years. **GNYHA agrees that a more reliable and resilient drug supply chain is needed to prevent shortages of essential medicines and safeguard the care hospitals provide to their communities. However, we are concerned that the proposed policy could be limited in its effectiveness, have unintended consequences, and pose an additional reporting burden on hospitals.**

Effectiveness of Potential Payment Policy

CMS asks stakeholders about the effectiveness of the proposed policy at improving supply chain resiliency for essential medicines. First, we believe the proposed payment incentive would be insufficient to fully achieve CMS's policy aims. While the additional payments would help cover the costs of establishing and maintaining a buffer stock relative to "just in time" inventory management models, it would fall short of the amount needed to establish and maintain a sufficient buffer stock for all patients. Specifically, CMS proposes to pay for the "IPPS shares" of the additional reasonable costs of a hospital to establish and maintain access to a buffer stock. However, this method only accounts for Medicare fee-for-service (FFS) payments paid under the IPPS and ignores other payers. Depending on a hospital's payer mix, this methodology might be insufficient to incentivize the intended behavior, especially because the payments would not cover the costs of the essential medicines themselves. The funding formula would also unfairly disadvantage safety net hospitals that serve high proportions of Medicaid beneficiaries but relatively few Medicare FFS beneficiaries. **If CMS finalizes the policy, it should expand the proposed payment to cover the cost of maintaining a buffer stock of essential medicines that would be used to care for all**

patients. At a minimum, CMS should consider the costs for Medicare Advantage enrollees in addition to FFS enrollees.

Second, we believe that even with an improved payment structure, many hospitals would not be able to establish a three-month buffer supply due to limitations on physical space, particularly for medicines with cold chain storage requirements, and may not be able to absorb the costs of the drugs themselves in three-month quantities to establish the initial supply. While beyond the scope of CMS's authorities, it may be more efficient for the Federal government to contract with distributors and wholesalers to maintain a buffer supply through the Administration for Strategic Preparedness and Response's (ASPR) Strategic National Stockpile (either instead of or in addition to the proposed policy). However, it would be essential to maintain full transparency with hospitals so that they can adequately prepare for emergencies and shortages to the extent possible while knowing which quantities of drugs would be available to them if needed from a national stockpile. The Federal government must also be willing to invoke its authorities under the Defense Production Act as needed when national or hospital-level stockpiles prove insufficient.

CMS should also consider whether a 60-day buffer stock would be sufficient for some or all of the essential medicines. GNYHA believes that in general, 60 days should allow hospitals enough time to increase their stockpiles to address any potential supply issues beyond the 60 days, even during an emergency. This would further reduce costs and perhaps increase the likelihood of a hospital participating. It could also help reduce medicinal waste due to the shelf life of certain essential medicines.

Unintended Consequences

CMS should ensure that by incentivizing buffer stocks of essential medicines, it does not inadvertently cause shortages for hospitals that are unable to establish and maintain these stockpiles. ASPR should maintain the Strategic National Stockpile to help avoid such situations by strengthening its ability to distribute these drugs to areas with an acute need from an emergency or disaster.

Additionally, CMS should consider that during drug shortages, hospitals would need to dip into their buffer stock for those specific drugs and could therefore fall below their required three-month buffer stock. In such situations, hospitals should still qualify for the additional payments while they are rebuilding their reserves.

CMS should also clarify the formula it will use to determine what constitutes a three-month buffer stock for each hospital, especially considering that drugs may be used more quickly during an emergency. During the peak of the COVID-19 pandemic, for example, hospitals were required to stockpile certain amounts of personal protective equipment (PPE) based on PPE usage during the height of New York's April 2020 surge, but as hospitalizations peaked in different areas of New York State at different times, this formula produced very different results for hospitals across regions and thus needed to be revised. CMS must develop and communicate a fair formula with stakeholder input to ensure an adequate stockpile and clarify requirements for hospital compliance.

Lastly, because the proposed payment is intended to cover hospitals' additional resource costs, CMS should not implement such adjustments in a budget-neutral manner. While CMS does not intend to make the policy budget-neutral in the IPPS, it states that if it applies this policy to the OPPS in the future, it would be required to do so in a budget-neutral manner. **If CMS does finalize this policy and extend it to the OPPS**

in the future, GNYHA urges CMS to seek new funding so that hospitals that may not have the space or resources to maintain a buffer supply of essential medicines are not unfairly harmed by the policy through a budget-neutral payment cut.

Increased Hospital Reporting Burden

Under CMS's proposal, hospitals would need to devote significant resources to report this information on a supplemental Medicare cost report worksheet. This would require hospitals to maintain separate records for buffer stock and non-buffer stock and domestically- versus non-domestically produced drugs.

Furthermore, hospitals would need to determine the source of the essential medicines to report to CMS the additional costs of maintaining domestically manufactured products compared to non-domestic ones. This may be challenging as hospitals do not usually have information from manufacturers on their manufacturing and supply chain process and may even be considered proprietary. Even if hospitals had access to this information, the definition of "domestically manufactured" is unclear. For example, while drug manufacturers may finish and package their essential drugs in the US, they may source some or all of the active pharmaceutical ingredients and key starting materials overseas. US manufacturers may also have arrangements with foreign contract manufacturers to produce some or all their products. If CMS finalizes its proposal, **it should work with the Food and Drug Administration and pharmaceutical manufacturers to ensure providers can efficiently and easily identify the origin of the drugs and to streamline reporting requirements to the extent possible.**