September 11, 2023

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Submitted via regulations.gov

RE: CMS–1786–P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction Proposed Rule (Vol. 88, No. 145), July 31, 2023.

Dear Administrator Brooks-LaSure:

On behalf of our more than 200 member hospitals and health systems the Florida Hospital Association ("FHA") appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system proposed rule for calendar year (CY) 2024.

CY 2024 OPPS Payment Update

For CY 2024, CMS proposes a market basket update of 3.0% less a productivity adjustment of 0.2 percentage points, resulting in a net update of 2.8%. This update, especially when taken together with the underwhelming CY 2022 and 2023 updates, continues to be woefully inadequate. It does not capture what hospitals and health systems need to continue to overcome the many challenges that threaten their ability to care for patients and provide essential services for their communities. **Therefore, we ask that in the final rule, CMS examine 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' PHE experiences related to actual losses in productivity during the COVID-19 pandemic.**

Since 2020, Florida's hospitals have experienced compounding challenges resulting in unprecedented financial challenges. The strain of COVID-19 accelerated a labor shortage that resulted in a 45% increase in labor costs. Those labor costs, along with inflated prices for drug and medical supplies resulted in an increase in expenses of more than 35% and a decline in operating margins of 66%. Nationally, 2023 saw the highest level of hospital bond defaults in over a decade; margins remain volatile – in July hospitals reported a negative 1.6% margin; and the amount of charity care provided by hospitals continues to rise as COVID era Medicaid continuous coverage requirement expired.

Appropriately accounting for recent and future trends in inflationary pressures and cost increases in the hospital payment update is essential to ensure that Medicare payments for acute care services more accurately reflect the cost of

providing hospital care. Indeed, Medicare only pays 84% of hospital costs on average. According to a March 2023 MedPAC report to congress, Medicare margins fell to negative 8.2% in 2021 without COVID relief funds, after hitting an all-time low of negative 12.3% in 2020. In that same report MedPAC projects that 2023 margins will fall below negative 10%, the 20th straight year of Medicare paying below costs. These underpayments are simply not sustainable.

Market Basket

CMS should not continue to rely on historical data and its current market basket calculation methodology during such an atypical historical period. The proposed CY 2024 update of 2.8%, especially when taken together with the underwhelming CY 2022 and 2023 updates, continues to be woefully inadequate for the hospital field that experienced one of the worst financial years in 2022. For CY 2022, CMS finalized a market basket of 2.7%, based on estimates from historical data through March 2021. Because the market basket was a forecast of what was expected to occur, it missed the unexpected trends that actually did occur in 2022 with hospitals combatting high inflation and workforce shortages. **Indeed, including data through September 2022 yields a CMS estimate of 5.7% for the change in the actual CY 2022 market basket — a staggering 3.0 percentage points higher than the OPPS payment update that was given to hospitals.**

Productivity

Under the Affordable Care Act (ACA), the OPPS payment update is reduced annually by a productivity factor, which is equal to the 10-year moving average of changes in the annual economy-wide, private nonfarm business total factor productivity (TFP). This

measure was intended to ensure payments more accurately reflect the true cost of providing patient care. For CY 2024, CMS proposes a productivity cut of 0.2 percentage points.

The use of the private nonfarm business TFP is meant to capture gains from new technologies, economies of scale, business acumen, managerial skills and changes in production. However, in an economy marked by great uncertainty due to workforce shortages and demand and supply shocks, this assumption generates significant departures from economic reality. Indeed, the nonfarm business sector labor productivity decreased 2.7% in the first quarter of 2023 compared to the previous quarter. Compared to the same quarter a year ago, it has decreased 0.9%, the first time since 1948 that the four-quarter change series has remained negative for five consecutive quarters. **These unusual circumstances must be factored in by CMS as it finalizes the proposed role. FHA urges the agency to eliminate the productivity cut for CY 2024.**

Payments for 340B Drugs

FHA appreciates CMS' decision to continue its current policy to pay 340B hospitals the same rate as non-340B hospitals for separately payable drugs and biologicals purchased under the 340B drug pricing program. However, we urge the agency to abandon its position to require hospitals to report a 340B modified.

CMS established the use of the "JG" and "TB" modifiers as part of its unlawful policy that cut payments to 340B hospitals. Despite the end of this policy upon the Supreme Court's unanimous ruling, the agency has continued to require hospitals to report separately payable drugs purchased under the 340B program using either the "JG" or "TB" modifiers, depending on the type of 340B hospital. Now the agency is seeking to consolidate these two modifiers into one single "TB" modifier for all 340B hospitals. **While we appreciate that CMS is proposing such a change, the FHA instead urges the agency to abandon the use of the 340B modifier entirely.**

The use and implementation of modifiers adds significant administrative burden — it requires considerable investment in systems and staff time to ensure that the modifiers are appropriately appended to the claims. In this case, even though the agency is attempting to consolidate modifiers, hospitals currently billing the "JG" modifier will need to modify their systems and programs to accommodate this change. Forcing hospitals to undertake this cost and staff burden directly contravenes CMS' longstanding policy.

Behavioral Health Provisions

CMS proposes multiple provisions related to behavioral health in this rule, many of which are to implement aspects of the Consolidated Appropriations Act (CAA) of 2023. FHA appreciates CMS' work on these important issues that have long gone under-addressed and welcomes the thoughtful approach to behavioral health care that the agency has employed in this and other recent rules. We look forward to working with CMS to carry out these provisions and hope we can help the Administration further hone its oversight, coverage and payment for behavioral health services in the future.

Intensive Outpatient Program (IOP)

The CAA established a new Medicare benefit category for IOP services furnished by hospital outpatient departments (HOPDs), community mental health centers (CMHCs), federally qualified health centers (FQHCs) and rural health clinics (RHCs) to begin Jan. 1, 2024. To implement this part of the statute, CMS proposes several provisions, including updates to existing regulations regarding Partial Hospitalization Programs (PHPs). **FHA appreciates CMS' attention to this important advancement in access to behavioral health care provided by ambulatory facilities. It is our interpretation that the agency is appropriately implementing the benefit as directed by the statute; we urge the agency to robustly monitor utilization of IOP services as billed under Medicare Part B to ensure that there are no unintended consequences stemming from the design of the benefit as proposed in this rule.**

That said, we are disappointed that CMS does not discuss how remote services could factor into the newly establish IOP benefit. We understand from the CY 2023 OPPS final rule that remote PHP services were allowed to be delivered under waivers granted as part of the COVID-19 PHE, which ended in April of this year and that patients receiving care through a PHP could receive remote behavioral health services, but they would not be considered part of the PHP. We assume that CMS takes a similar stance in this rule, both for PHP and IOP services. **However, we encourage the agency to consider including at least some or a proportion of PHP or IOP services to be delivered remotely as a way to increase access to these benefits.** We also encourage CMS to ensure flexibility for coverage for remote services, relying on clinical discretion when appropriate.

Payment Methodology

CMS proposes four separate PHP per-diem rates and four separate IOP per-diem rates at the same rates as those proposed for PHP; in addition, the agency proposes to differentiate per-

diem payments based on whether the patient received the typical four services in a day versus three or fewer. **We believe it is appropriate to value the services the same regardless of whether they are billed as part of a PHP or an IOP; we also support CMS' revision to define incomplete service days as those when the patient receives three or fewer services due to extenuating circumstances that result in the patient being unable to complete a full day of treatment.**

Delayed In-person Service Requirements

CMS proposes to delay in-person service requirements for mental health services furnished remotely by hospital staff to beneficiaries in their homes until Jan. 1, 2025. In previous rulemaking, the agency adopted statutory requirements for beneficiaries to receive an in-person service within six months prior to the first and within 12 months after each remote mental health service, with certain exceptions. The requirements were originally set to take effect on the 152nd day after the end of the COVID-19 PHE.

FHA supports this delay and encourages CMS to work with Congress to permanently remove these requirements. These in-person service requirements are arbitrary and not based upon any clinical guidelines or evidence. While some patients certainly should receive in-person services complementary to their remote interactions, the decision to do so should be made by that patient and their clinician rather than mandated by a regulatory body. While CMS allows for this requirement to be waived if the patient and their physician determine that the risks and burdens outweigh the benefits, providers must include clear justification documented in the beneficiary's medical record including the clinician's professional judgment behind the decision. It is incongruous that providers must provide clinical evidence that the in-person visit is unnecessary while there is no clinical evidence that the in-person visit is necessary in the first place.

Outpatient Quality Reporting Program (OQR)

CMS proposes several updates to the current OQR program, including the removal of one measure, addition of three measures, and modifications of three existing measures.

Removal of the Left Without Being Seen (LWBS) Measure

FHA supports the removal of the LWBS measure from the OQR given the issues with this measure beginning with the CY 2024 reporting period. As noted in the proposed rule, this measure, which assess the percentage of patients leaving the emergency department without being evaluated by a physician, advanced practice nurse or a physician assistant, lacks

evidence to link it to improve patient outcomes and reflects factors beyond the control of hospital outpatient/emergency departments. We recommend that CMS consider removing OP-18, Median ED Time for Discharged ED patients.

Modification of COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) Measure

FHA agrees with CMS's rationale to modify the COVID-19 Vaccination Coverage among HCP to use the number of HCP "who are up to date" with their vaccination as recommended by the Centers for Disease Control and Prevention at the time of reporting and to ensure it is aligned with the other CMS quality reporting programs. While FHA supports the appropriate vaccination of HCP to guard against transmission and exposure to protect patients and staff, there continues to be a lack of evidence around the optimal cadence for the boosters, development of new vaccines and guidelines for which individuals should be getting the soon to be released vaccines, we do not see the value for hospitals to spend necessary resources collecting and reporting the data.

We recommend CMS withdraw the proposed mandatory reporting requirement and continue to collect up-to-date vaccination status on a voluntary basis. Once FDA and CDC have completed their recommendations on an updated vaccination schedule, CMS considers ways to minimize the burden of data collection and reporting by working with provider stakeholder, and can offer a single annual reporting period, then a new proposed rule should be offered.

If CMS continues to require this information and publicly report it, there needs to be caveat and education so consumers can understand the issues with the measure, for example, some HCPs are not vaccinated because of religious or medical reasons. Note, however, that hospitals may not have access to HCP reasons for not receiving the COVID-19 vaccine which will ultimately make it difficult to present a clear picture of a staff vaccination rate. Additionally, the time lag between data collection and the publicly reported rate of vaccination will result in a mismatch between the true rate of health care personnel who are up-to-date with their vaccinations and the rate that is displayed on Care Compare; CMS needs to clearly communicate what publicly reported data reflects.

Modification of Cataracts: Improvement in Patient's Visual Function within 90 days

While we note that CMS is addressing the concern raised in the CY2023 OPPS proposed rule about the lack of a standardized survey tool to collect data on patient improvement in visual function within 90 days of the procedure, this does little to address reporting burden this

measure places on providers compared to its ability to improve care for patients undergoing cataract procedures. **We recommend this measure be removed from the OQR**.

Modification of Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

FHA **supports** modifying the measures to change the age from 50 to 45 years to assess the percentage of patients receiving a colonoscopy screening without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years documented in their colonoscopy report.

Re-Adoption of HOPD Volume Data on Selected Outpatient Surgical Procedures

CMS should continue to explore meaningful ways to incorporate volume into quality reporting. In the proposed rule CMS notes that "experts on quality and safety have recently suggested that while volume alone may not indicate or lead to better outcomes, it is still an important component of quality." Throughout the background section describing this measure the agency is careful to qualify the connection between volume and quality as probable, but not certain. CMS should not finalize the proposal to re-adopt HOPD volume data in the OQD program until the measure goes through additional validity and reliability testing as well as review and endorsement by a CBE.

We would also note that the proposed method of data collection does not provide enough detail to aid patient decision making. For example, reporting a "gastrointestinal" ("GI") procedure does not tell a patient the kind of GI procedure that was performed. A provider who regularly completes routine GI procedures may have a better quality rating than a provider who specializes in a particular procedure. The measure as described in the rule would not give the patient sufficient detail about which provider has the expertise to provide the care the patient needs.

FHA supports quality measures that help patients make informed decisions about the best provider for their care needs. Given the current available information regarding volume and outcomes, and concerns for how the presentation of the information may be interpreted by patients, FHA urges CMS to conduct further study on the proposed measure before implementing within the OQR.

Adoption of Risk-Standardize Patient-Reporting Outcome-Based Performance Measure Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)

FHA believes there is value in understanding patient perceptions about improvement in their conditions after a procedure and **supports voluntary reporting of this measure** since the testing of this measure has not been completed. Hospitals have been voluntarily reporting a similar measure in the Inpatient Quality Reporting program but many of our members are struggling with how to best capture the feedback from the patients accurately and effectively. We suggest CMS monitor results from the voluntary report before adopting it in the OQR.

Adoption of Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computer Tomography in Adults

This measure was recently added to the Inpatient Quality Reporting (IQR) program for FY 2024 as one of the available eCQM measures. We have concerns about including it in the OQR program, given that hospital outpatient departments (HOPDs) do not individually participate in the Promoting Interoperability Program and don't have options of measures to report. Given the newness of this measure in the IQR program, **we recommend CMS pause adding this to the OCR until more hospitals have more experience in reporting the measure.**

Hospital Price Transparency

Updates to Requirements for Hospitals to Make Public a List of their Standard Charges

FHA supports price transparency and helping consumers gain access to the information they need to make choices and understand their costs for the recommended care. Florida hospitals have been posting prices on common services and procedures or linking to the state FloridaPriceFinder website for several years. Along with those resources, hospitals and health plans provide estimating tools to help patients understand prices and hospitals are providing estimates and financial assistance policies to those without health insurance so they have a good understanding of the cost of care.

We feel the current amount and level of detail CMS requires hospitals to provide is not the type of information that is useful to consumers directly. This level of detail is for employers and insurers to leverage to create standard prices for hospital services, instead of allowing each of the parties to negotiate fair prices for the volume and patient characteristics of the group.

Standardization

Given the publicity around hospital non-compliance, with various groups weighing in on whether a hospital is compliant or not, **FHA supports efforts to ensure the clarity, consistency, and standardization of the requirements for hospitals to post their prices in various formats.** Since the rule was issued, Florida hospitals have worked to comply, but it should be noted the delay in providing guidance, the lack of standardization and the enormity of providing this amount of data with this level of detail is time consuming and resource intensive.

As CMS notes in the proposed rule, hospital pricing is complex and each hospital has a different approach to how they price items and services. While the flexibilities provided initially allowed for hospitals to figure out how to report these data, there was a lack of clarify on how to address some of the contracting approaches that ultimately reflect what a consumer would pay. Providing templates, requiring the encoding and standardization help with compliance and the accusations that hospitals are not providing all the data. **However, we have concerns about the additional data elements now being required such as the modifier and drug data fields. These will be extremely difficult to produce given the numerous modifiers that may or may not change the price. FHA does not support finalizing these data elements in the standardized format.**

The changes CMS is proposing will take additional time and resources, and compliance with these proposed actions may not be possible within the timeframe outlined by CMS. As the initial requirements have revealed, detailed technical guidance is necessary to ensure the data are being pulled and reported accurately. **FHA requests that CMS allow at least 18 months after the final technical guidance is released for hospitals to adopt the new standard formats.**

CMS proposes several changes to the monitoring and enforcement practices, including a hospital official to certify the accuracy and completeness of the hospital's machine readable file and a second certification during the monitoring process. **FHA does not support requiring a separate affirmation during the monitoring process.**

FHA strongly opposes the requirement that hospitals submit contracting documentation to CMS. We believe this information is private and proprietary and is shielded from disclosure by numerous legal protections.

FHA supports the proposal to allow notifications to health system leadership of any compliance activity within their system, as well as notification to the specific hospital's leadership. We agree with the need to confirm receipt of warning notices but recommend CMS also copy the primary contact listed on the 855A Enrollment Form.

CMS proposes several changes to the public disclosure of information regarding the oversight of hospital compliance with the rule, including making information public about which hospitals are being reviewed for compliance, any compliance actions taken, the status of compliance actions and the outcome of compliance actions. Given the media and consumer groups focus on the transparency requirements, we are concerned that this information may be misconstrued and used inappropriately to paint a picture of noncompliance, when there might be questions that need to be answered, education of what is expected and corrections. **If CMS does finalize this proposal and releases this information, it must be clear that the hospitals are not deemed non-compliant when under review.**

Price Transparency Alignment

Given the Transparency in Coverage rule and the No Surprises Act, along with various congressional proposals and state initiatives on price transparency, we are concerned that the conflicting and duplicative requirements will create confusion and add additional costs to the system, without much value. **FHA recommends that 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.**

Thank you again for the opportunity to provide feedback on this proposed rule. If you have any questions please do not hesitate to reach out to Michael Williams, FHA's Senior Vice President of Federal Affairs at michaelw@fha.org.

Sincerely,

Mary C. Mayhew, President and CEO