Federation of American Hospitals®

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President and CEO

September 11, 2023

The Honorable Chiquita Brooks-LaSure
Administrator Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

RE: CMS-1786-P; 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, 88 Fed. Reg. 49,552 (July 31, 2023).

Dear Administrator Brooks-LaSure:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC, and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services. The FAH appreciates the opportunity to provide our comments to the Centers for Medicare & Medicaid Services (CMS) regarding the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems proposed rule (Proposed Rule), as discussed below.

II. Proposed Updates Affecting OPPS Payments
B. Conversion Factor Update

Summary of Proposed CY 2024 Outpatient Hospital Update

CMS proposes an OPPS update based on a market basket update of 3.0 percent less 0.2 percentage points for total factor productivity as required by law. By law, CMS is required to update outpatient prospective payment system (OPPS) rates by the same update that applied under the inpatient prospective payment system (IPPS.)[1] As CMS has already finalized an update of 3.1 percent for the fiscal year (FY) 2024 IPPS,[2] it is clear that CMS will be adopting a calendar year (CY) 2024 final rule OPPS update of 3.1 percent (3.3 percent market basket less 0.2 percentage points for total factor productivity). Nevertheless, the FAH reiterates our prior comments that the update CMS will be applying to CY 2024 OPPS rates is too low and will not fully recognize hospital inflation.

As the FAH indicated in our comments on the FY 2024 IPPS proposed rule, this update will likely understate hospital inflation for the fourth consecutive year. This market basket update is a product of CMS' reliance on historical data to forecast FY 2024 hospital operating costs without adjustments designed to capture the profoundly aberrant and historic economic forces that are fueling rapid cost increases for goods and services. For example, the FY 2022 market basket update was a full 3.0 percentage points below the actual rate of increase while the FY 2021 market basket was 0.6 percentage points below the actual rate of increase.

Recent data suggests that the market basket for FY 2023 will mark the third consecutive year that the forecasted hospital market basket increase will be below the actual rate of increase. CMS released data in July 2023 indicating that the FY 2023 market basket increase will be 4.7 percent or 0.6 percentage points in excess of the 4.1 percent forecast market basket update hospitals received.

In addition, CMS proposed reducing the market basket update with a 0.2 percentage point total factor productivity adjustment. This total productivity adjustment is inappropriate in that it contemplates improbable and overstated gains in productivity for the hospital sector as noted by the CMS Office of the Actuary (OACT) itself and detailed below.

Background

Under section 1833(t)(3)(C)(iv) of the Act, CMS states that the:

> the "OPD fee schedule increase factor" for services furnished in a year is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) [the IPPS update] to hospital discharges occurring during the fiscal year ending in such year.

[1] Section 1833(t)(3)(C)(iv) of the Social Security Act.
[2] See page 982 of the display copy of the FY 2024 IPPS final rule at: 2023-16252.pdf (federalregister.gov) (scheduled to be published in the Federal Register October 28, 2023).

The update is subject to the productivity adjustment and further adjustments for hospitals that fail to submit quality information.[3] While CMS proposed to use a hospital market basket of 3.0 percent to update inpatient hospital rates for CY 2024, it has already finalized an FY 2024 IPPS update of 3.1 percent based on a market basket of 3.3 percent less 0.2 percentage points for total factor productivity. This market basket is based on the forecast of CMS' contractor, IHS Global Insight, Inc. (IGI). IGI's second quarter 2023 forecast (with historical data through the first quarter of 2023). Therefore, absent any intervention on the part of CMS to provide a different update under the OPPS than the IPPS or to account for forecast error, we are expecting that CY 2024 OPPS update will be 3.1 percent.

CMS' Understatement of Prior Year Hospital Inflation

In our public comments on the FY 2023 IPPS proposed rule, the FAH provided several sources of data that indicate that the historical data upon which the proposed FY 2023 forecast of the market basket was based was less than the rate of increase that hospitals were experiencing at that time.[4] The evidence in our IPPS letter revealed that CMS forecasts of the market basket during a time of high inflation and economic instability understate the actual rate of increase and CMS' own data show that as well. The below table shows how CMS' forecast of the market basket compares to the actual market basket based on later data since FY 2021:

IPPS Market Basket	FY 2021	FY 2022	FY 2023[5]
Forecast Used in the Update	2.4	2.7	4.1
Actual Based on Later Utilization	3.0	5.7	4.7
Difference	-0.6	-3.0	-0.6

These data show that CMS has understated the market basket by a combined 4.2 percentage points for these three years. While FY 2023 remains an estimate as the historical data is only through the first quarter of CY 2023 (second quarter of fiscal year 2023), CMS' own data indicates that it will likely have underestimated the hospital market basket for the third consecutive year.

One reason that CMS' market basket data may be reflecting lower increases in staffing costs compared to what hospitals are experiencing relates to use of contract labor. Hospitals have confronted worrying shortages of hospital workers during the COVID-19 public health emergency (PHE), necessitating an outsized reliance on contract staff – particularly travel nurses – to meet patient demand.

[3]Sections 1833(t)(3)(F) and (t)(17) of the Act.

[4] These data came from the KaufmanHall, National Hospital Flash Report, p.4 (Jan. 2021) and Premier, Inc. (PINC) AI™ Data: CMS Data Underestimates Hospital Labor Spending (Apr. 12, 2022) and demonstrated that the latest data that CMS uses for the market basket in the proposed rule seriously underestimated cost increases hospitals were experiencing using other data sources.

[5] OACT, second quarter 2023 release of the market basket information with historical data through the first quarter of 2023 (Market Basket Data | CMS) for the actual update based on later utilization. Data for FY 2023 remains an estimate as it only reflects data through the second quarter of FY 2023.

In 2019, hospitals spent a median of 4.7 percent of their total nurse labor expenses for contract travel nurses, which skyrocketed to a median of 38.6 percent in January 2022. A quarter of hospitals – those who have had to rely disproportionately on contract travel nurses in order to serve their communities during a global pandemic – saw their costs for contract travel nurses account for over 50 percent of their total nurse labor expenses. We understand that the Bureau of Labor Statistics' (BLS) Employment Cost Index (ECI) only captures the salary increases associated with employed staff, and thus wholly fails to capture the extraordinary growth in labor costs associated with hospitals' necessary reliance on nursing personnel that are contracted through staffing agencies during a time of labor supply shortages. This discrepancy may explain why the ECI data is so divergent from that being reported to Premier Inc (PINC) AI™. It is unreasonable to rely on the ECI data for labor expenses without appropriate adjustments that reflect the profound increase in hospital expenses for contract and travel nurses.

As we noted in our previous public comments, the FAH and American Hospital Association (AHA) provided a report from FTI Consulting that likewise recognized that hospital use of contracted staff has increased markedly since 2019. According to FTI:

> [H]ospitals face more competition than ever from travel and temporary nurse staffing firms that are attracting a greater share of the workforce with higher pay and more generous benefits, a trend driving up hospital labor costs. The cost of contract labor relative to total labor expenses increased five-fold in 2022 compared to 2019, primarily due to the need to replace departing staff nurses with travel or agency nurses. Median wages for contract nurses reached triple the median wages of employed nurses in March 2022.[6]

In this analysis, jointly undertaken by the FAH and AHA, we found that the ECI is unlikely to catch up with the overall level of hospital labor cost increases. Since contract labor use and general workforce composition will not likely revert to its earlier levels, growth in the ECI will continue to lag behind growth in hospital labor costs.[7] This report relies on many of the sources we provided in our FY 2023 IPPS proposed rule comments documenting that the ECI understates the growth in hospital labor costs because it does not account for contract labor being a higher proportion of total hospital costs.

This report builds on last year's work by finding that a closely related measure—the Employer Costs for Employee Compensation (ECEC) may better and more timely account for growth in hospital compensation costs than the ECI. As explained in the report, the ECI is constructed through a multi-step process that is intended to smooth short-term fluctuations in the labor pool. However, when the underlying hospital employment structures are changing rapidly and permanently, the ECI will understate labor costs by relying on a job type that is only in the

[6] FTI Consulting, Report: Assessing the Adequacy of Proposed Updates to the Hospital Inpatient Prospective Payment System, page 4.
[7] Federation of American Hospitals and the American Hospital Association, Hospital Employment Cost Index Undermeasures Labor Cost Growth in Recent Years, page 4.

sample for two consecutive quarters, using a sampling weight for when a job first enters the sample and holding the mix of occupations fixed before there is a rebasing.[8]

The ECEC, however, is dynamic and will reflect increases in compensation and changes in the mix of labor inputs on a timelier basis. For the wages and salaries component, the ECI and the ECEC show a growth rate of 13.3 percent and 20.0 percent respectively, a 6.7 percentage point gap between the fourth quarter of 2019 and the fourth quarter of 2022. The growth in the total compensation component, which CMS uses to track benefits, is slightly lower with the ECI and the ECEC recording growth of 12.4 percent and 16.6 percent, respectively, a 4.2 percentage point gap. Combining wages and salaries and employee benefits into a single composite measure shows the ECEC was 6 percentage points higher during this period than the ECI for items that account for 52.9 percent of the total hospital market basket. All else equal, if the hospital ECI growth had matched the hospital ECEC growth, this would have meant an additional three percentage point increase in the IPPS hospital market basket over this period. Given the parallel trends to CMS' own market basket data, these data clearly show that the ECI is too low, not that the ECEC is too high.

In the FY 2024 IPPS final rule, CMS rejects use of the ECEC as an alternative to the ECI as a measure of change in hospital wage costs because it includes both changes in compensation as well as changes in employment.[9] While CMS' response is accurate, such as it is, the response earlier indicates that the increase in hospital wages that are resulting from higher use of contract labor are also not being accounted for by the ECI.

Therefore, the choice is between two measures of the change in hospital compensation—each of which has a weakness. The ECI does not account for increases in hospital wage compensation associated with more expensive contract labor while the ECEC does not hold employment constant. Given the ECEC has better predicted the change in hospital compensation based on after-the-fact data, the FAH posits that the ECEC remains the better measure for CMS to rely on for determining the hospital update in a period of high inflation and unstable changes in prices.

Total Factor Productivity

Pursuant to section 1886(b)(3)(B)(xi)(II) of the Act, the Secretary reduces the IPPS market basket increase by the "10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as produced by the Secretary for the 10-year period ending with the applicable fiscal year)." The theory behind the offset for economy wide total productivity is that the hospital sector should be able to realize the same productivity gains as the general economy.

However, CMS itself takes issue with the assumption that hospitals can recognize the same kinds of productivity gains as the general economy. In a memorandum dated June 2, 2022, OACT stated: "over the period 1990-2019, the average growth rate of hospital TFP using the two

[8] See pages 6-7 of the FAH and AHA Report for more detail on this issue.
[9] See page 981 of the display copy of the FY 2024 IPPS final rule at: 2023-16252.pdf (federalregister.gov) (scheduled to be published in the Federal Register October 28, 2023).

methodologies ranges from 0.2 percent to 0.5 percent, compared to the average growth of private nonfarm business TFP of 0.8 percent." The memorandum also indicates that an assumed future rate of hospital industry productivity growth of 0.4 percent per year remains reasonable compared to an assumed rate of productivity growth in the private nonfarm business sector of 1.0 percent.[10]

The FAH shares OACT's skepticism regarding the offset to the hospital market basket for the 10-year average in economy-wide nonfarm total factor productivity. One reason that hospitals may not be able to realize the same growth in general economy wide productivity is that hospital services are highly labor intensive. As labor represents nearly 70 percent of the index, hospitals have little opportunity to obtain productivity gains from non-labor inputs as may be occurring in other industries that are less labor intensive.

The FAH understands that CMS is required by law to adjust the IPPS market basket update for total factor productivity. However, the FAH asks CMS to consider that the adjustment for total factor productivity reduces the update below what even OACT says is reasonable for hospitals to achieve when deciding on its application of an update for hospital inpatient and outpatient services for 2024.

Adjusting IPPS and OPPS Rates for Forecast Error

In our FY 2024 IPPS rule comments, the FAH noted that CMS applies a forecast error correction in the Skilled Nursing Facility (SNF) PPS and the capital PPS above a threshold difference between the market basket update and its actual value based on later data. For the SNF PPS, CMS makes a forecast error adjustment when the difference between the market basket used in the update and based on later data exceeds a threshold of 0.5 percentage points. For the capital IPPS, the threshold is 0.25 percentage points.

CMS rejected applying a similar forecast error adjustment for the FY 2024 IPPS rule update. According to CMS, "the capital PPS and SNF PPS forecast error adjustments were adopted very early in both payment systems and, unlike what commenters are requesting here for the IPPS, forecast errors over many years have been consistently addressed within each of the Capital PPS and SNF PPS.[11] The FAH recognizes that if CMS were to adopt a policy to correct for forecast errors above a threshold amount, the adjustment could reduce the increase in the annual update as well provide an increase. Nevertheless, we believe that three consecutive years of understatement in the hospital market basket necessitates applying an adjustment for forecast error for CY 2024.

[10] Paul Spitalnic, Stephen Heffler, Bridget Dickensheets and Mollie Knight, "Hospital Multifactor Productivity: An Update Presentation of Two Methodologies Using Data through 2019." Hospital Multifactor Productivity: An Updated Presentation of Two Methodologies Using Data through 2019 (cms.gov).

[11] See page 986 of the display copy of the FY 2024 IPPS final rule at: 2023-16252.pdf (federalregister.gov) (scheduled to be published in the Federal Register October 28, 2023).

II.A.3.d. Comment Solicitation on OPPS Packaging Policy for Diagnostic Radiopharmaceuticals

CMS is considering changes to the existing policy that packages the costs of diagnostic radiopharmaceuticals in the total cost and payment of the related APC. CMS has heard concerns about access to diagnostic testing using radiopharmaceutical products for certain services. While CMS did not propose a specific change in its policy, it is soliciting comments on the following potential approaches that could enhance beneficiary access, while also maintaining the principles of the OPPS. The approaches include: (1) paying separately for diagnostic radiopharmaceuticals with per-day costs above the OPPS drug packaging threshold of $140; (2) establishing a specific per-day cost threshold that may be greater or less than the OPPS drug packaging threshold; (3) restructuring APCs, including by adding nuclear medicine APCs for services that utilize high-cost diagnostic radiopharmaceuticals; (4) creating specific payment policies for diagnostic radiopharmaceuticals used in clinical trials; and (5) adopting codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals.

The FAH has not heard concerns from members about access challenges in using diagnostic radiopharmaceuticals in the OPPS. However, CMS' alternative to adopt codes that incorporate the disease state being diagnosed or the diagnostic indication of a particular class of diagnostic radiopharmaceuticals may help provide more information on the need to address access to testing for certain types of diseases. **The FAH generally supports CMS' OPPS packaging policy and is concerned that excluding diagnostic radiopharmaceuticals from the packaging policy could lead to unnecessary price increases and redistribution in the OPPS. If CMS were to change the packaging policy status of diagnostic radiopharmaceuticals, the FAH believes that the packaging threshold should match that of other separately paid drugs and biologics with a packaging threshold of $140.**

VIII. Payment for Partial Hospitalization and Intensive Outpatient Services

The OPPS CY 2024 includes a number of changes related to mental and behavioral health services and reimbursement. Section 4124 of the *Consolidated Appropriations Act (CAA), 2023* created a new benefit category for intensive outpatient services which was added to the scope of benefits that may be provided by community mental health centers (CMHCs). Effective for items and services furnished on or after January 1, 2024, intensive outpatient services are also added as an "incident to" service under section 1861(s)(2)(B) of the Act and may also be furnished by hospital outpatient departments, CMHCs, FQHCs, and RHCs. These services are furnished under an intensive outpatient program (IOP). An IOP is similar to a PHP; it is a distinct and organized outpatient program of psychiatric services provided for individuals who have an acute mental illness, including depression, schizophrenia, or substance use disorders. However, it is considered to be less intensive than a partial hospitalization program (PHP).

CMS proposes a scope of benefits, a list of covered intensive services, and distinctions between IOP and PHP services. CMS also proposes to establish patient eligibility criteria for IOP services – which are largely consistent with PHP services. **The FAH supports these proposals establishing the IOP program.**

CMS proposes a number of changes to its payment methodology for PHP services for 2024 – including changes to reimburse IOP services. CMS proposes to establish four separate PHP APC per diem payment rates and four separate IOP per diem payment rates as follows:

Provider Type	# of Services per Day	IOP APC	PHP APC
CMHC	3	5851	5853
CMHC	4 or more	5852	5854
Hospital-based	3	5861	5863
Hospital-based	4 or more	5862	5864

Additionally, for hospital-based PHPs, CMS proposes to calculate payment rates using the broader OPPS data set instead of hospital-based PHP data only. The broader OPPS data set would permit the agency to capture data from claims not identified as PHP, but that include the service codes and intensity required for a PHP day. Because the goal is to establish consistent coding and payment between the PHP and IOP benefits, CMS proposes to consider all OPPS data for PHP days and non-PHP days that include 3 or more of the same service codes.

CMS initially notes that because IOPs furnish the same types of services as PHPs, but at a lower intensity, it is appropriate to use the same data and methodology for calculating payment rates for both PHP and IOP for 2024 and to set the same rates for both PHP and IOP services. This is because the IOP is a newly established benefit, and CMS lacks definitive data on utilization.

Hospital-based PHP payment rates for 3 services per day and 4 services per day would be calculated based on cost per day using the broader OPPS data set. This would be a change from the current methodology of using only PHP data, and CMS believes it would result in more precise calculations. CMS would calculate the PHP rates for CMHCs and hospital-based programs separately and proposes to use the latest available 2022 claims data and 2021 cost data.

IX.C. Solicitation of Public Comments on the Services Described by CPT Codes 43775, 43644, 43645, and 44204

CMS is not proposing to remove any codes from the IPO list. However, CMS is requesting public comment on and considering whether to remove the following CPT codes, which represent gastric restrictive procedures, from the IPO list for CY 2024:

- CPT code 43775 (Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy)
- CPT code 43644 (Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and roux-en-y gastroenterostomy)
- CPT code 43645 (Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction)
- CPT code 44204 (Laparoscopy, surgical; colectomy, partial, with anastomosis).

Given the intricacies and comorbidities involved with patients undergoing these procedures, the FAH emphasizes the need for careful review before deciding on their safety for Medicare beneficiaries in outpatient settings. It's essential for CMS to evaluate the most recent

clinical evidence from surgeons and other experts, and maintain its rigorous criteria before considering changes to remove these procedures from the IPO list.

Specifically, concerning CPT 44204, executing this procedure in outpatient facilities could substantially elevate morbidity and mortality risks for the Medicare demographic. Even among younger, healthier individuals, the procedure typically necessitates a three-day hospital stay. Considering the increased medical complexities of the Medicare group, a 3-5 day hospitalization seems likely. We do not believe that allowing such procedures in outpatient settings, with patients discharged the same day, would be safe or prudent given the way the procedure is performed today. Such a move could put patients at a much greater risk of complications like ileus and anastomotic leak, potentially culminating in sepsis or death. The FAH strongly advises CMS to retain CPT 44204 on the IPO list.

X.A. Supervision by Nurse Practitioners, Physician Assistants, and Clinical Nurse Specialists of Cardiac Rehabilitation, Intensive Cardiac Rehabilitation, and Pulmonary Rehabilitation Services Furnished to Hospital Outpatient

To maintain similar policies for direct supervision of cardiac rehabilitation (CR), intensive cardiac rehabilitation (ICR) and pulmonary rehabilitation (PR) services under the OPPS and physician fee schedule, CMS proposes to allow direct supervision for CR, ICR, and PR to include the virtual presence of the physician through audio-video real-time communications technology (excluding audio-only) through December 31, 2024. In addition, for CY 2024, CMS proposes to expand the practitioners who may supervise CR, ICR, PR services to include nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs). These nonphysician practitioners also would be permitted to supervise these services in CY 2024 through audio-video real-time communications technology. **The FAH appreciates and supports these CMS proposals as this would permit greater access to these services, especially amid ongoing workforce shortages.**

In addition, the FAH urges that the flexibility to provide direct supervision through real-time audio/video technology be made permanent. In the experience of our member hospitals, physicians and other professionals have been able to provide clinically appropriate supervision for impacted services such as diagnostic tests and incident-to services through synchronous audio-visual telehealth. Further, requiring the physician or other supervising professional to be physically present in the same building has negligible patient-safety benefits. The reality is that a physician office, clinic, or hospital outpatient department typically has many other practitioners on site who can assist if a physical presence is required. Moreover, in an emergency, the most appropriate course of action is to transfer the patient to an emergency department, not wait for the supervising physician or other practitioner to arrive. A virtually available supervisor may even facilitate a faster transfer of the patient to the emergency department when necessary.

Moreover, under a permanent policy, there should not be a requirement for a service-level modifier to identify when direct supervision is provided via appropriate telehealth technology. Physicians and other supervising practitioners benefit from the flexibility to supervise in person, via telehealth, or through a combination of modalities depending on clinical need and circumstances. In some cases, services may even be supervised in part through an in-person presence and in part through a telehealth modality. Requiring practitioners to track

whether and to what extent they supervised through telehealth would significantly increase administrative burdens associated with these flexibilities, undermining their ability to improve physician care delivery. Because there is no obvious benefit to collecting data on how supervision is facilitated, the burdens associated with a modifier requirement cannot be justified. **Thus, the FAH requests that the definition of direct supervision of CR, ICR, and PR services be permanently amended to allow supervision to be provided via audio-visual technology, and without the requirement for a new modifier.**

X.C. OPPS Payment for Specimen Collection for COVID–19 Tests

In the May 8, 2020, COVID-19 interim final rule with comment, CMS created a new evaluation and management (E/M) code (C9803) for a hospital outpatient clinic visit with specimen collection to test for COVID-19. **Although CMS had initially expected to retire the code at the end of COVID–19 PHE, we appreciate that the code remains in effect for 2023.** CMS, however, proposes to delete the code effective January 1, 2024.

The FAH notes that many hospitals still provide services for specimen collection via a nasopharyngeal swab – whether to diagnose COVID-19 or another illness – yet there is not a code to report specimen collection via a nasopharyngeal swab. **If CMS deletes the current COVID-19 specimen collection code, we urge the agency to implement a similar code for ongoing specimen collection via a nasopharyngeal swab rather than to only allow blood specimen collection.**

X.D. Remote Services

<u>Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes; and Periodic In-Person Visits</u>

In the 2023 OPPS final rule, CMS created three HCPCS C-codes for mental health services furnished by hospital staff to beneficiaries in their homes through communications technology. CMS did not specify whether the codes should be used for individual or group services, preferring to keep the coding more general until CMS has experience with these codes. CMS now proposes to create a new, untimed, HCPCS C-code describing group therapy. Also, CMS proposes to modify the individual psychotherapy codes to remove the word "initial" from the descriptor to make clear that the codes can be used for an initial or subsequent encounter. **The FAH supports these proposals and believes the group therapy code will minimize any confusion and ensure appropriate patient access to these services.**

In addition, in the 2023 OPPS final rule, CMS adopted a policy to allow OPPS payment for remote mental health services when a hospital outpatient is receiving these services in their home. Consistent with analogous statutory requirements that apply to the Medicare telehealth benefit under the physician fee schedule, CMS requires an in-person visit within six months prior to or after the remote mental health service. The visit after the first encounter must occur within 12 months. The *CAA, 2022* delayed the application of these requirements under the PFS for 151 days after the end of the COVID-19 PHE. CAA, 2023 delayed the application of these

requirements through December 31, 2024. CMS is proposing the same delay for remote outpatient mental health services provided by hospitals and CAHs.

As the FAH has previously commented, we support permitting the provision of mental health services furnished remotely by hospital staff to beneficiaries in their homes. The FAH also supports extending this policy to PHP and IOP services. In addition, we support delaying the requirement of an in-person visit within six months prior to the initial mental health telehealth service through December 31, 2024.

FAH member hospitals have extensively provided these services to patients at home during the PHE and believe that mental health services are well-suited for remote delivery via communication technology, while providing important clinical benefits for patients. In addition, patients across the United States suffer from the serious shortage of qualified mental health providers in this country. This compromises the ability of patients to get timely access to care, and sometimes requires patients to travel long distances for necessary services. The delays associated with provider scarcity have significant negative consequences on health. For example, individuals are likely to develop more acute mental illness when they do not receive needed and timely interventions, ultimately leading to increased suffering for patients and their families, as well as higher burdens on the health care system. The use of communications technology offers an opportunity to interrupt a cascade of negative outcomes by ensuring that care is available promptly.

Multiple studies support the need for ongoing flexibility and expanded coverage of telehealth for mental health services. For example, previous epidemics have shown that the impact on mental health and substance use will continue for years to come.[12] Further studies demonstrate that telehealth is particularly effective in mental healthcare delivery.[13] This is true for PHP services delivered via telehealth as well. A comparative effectiveness study demonstrated that the only significant differences between those who participated in PHPs via telehealth technologies and those who attended in person was that those who participated via telehealth had greater lengths of stay and were more likely to stay in treatment until completed.[14]

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[12] Hawryluck L, Gold WL, Susan, S: SARS Control and Psychological Effects of Quarantine, Toronto, Canada. Emerg Infect Dis. 10;7: 1206–1212 (July 2004); Reardon S: Ebola's mental-health wounds linger in Africa: healthcare workers struggle to help people who have been traumatized by the epidemic. Nature, 519; 7541:13 (2015); Goldmann E, Galea S: Mental health consequences of disasters. Ann Rev Public Health, 35:169–83 (2014). Available online at https://www.annualreviews.org/doi/full/10.1146/annurev-publhealth-032013-182435?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub%3Dpubmed.

[13] Mace S, Boccanelli A, Dormond M: The Use of Telehealth within Behavioral Health Settings: Utilization, Opportunities, and Challenges. Behavioral Health Workforce Research Center, University of Michigan, (March 2018) Available at https://behavioralhealthworkforce.org/wp-content/uploads/2018/05/Telehealth-FullPaper_5.17.18-clean.pdf ; Bashshur RL, Shannon GW, Bashshur N, Yellowlees PM: The empirical evidence for telemedicine interventions in mental disorders. Telemed J E Health, 22(2): 7-113 (Jan. 2016).

[14] Zimmerman M, Terrill D, D'Avanzato C, et al.: Telehealth Treatment of Patients in an Intensive Acute Care Psychiatric Setting During the COVID-19 Pandemic: Comparative Safety and Effectiveness to In-Person Treatment. J Clin Psychiatry. 82(2) (2021). Available at https://www.psychiatrist.com/jcp/covid-19/telehealth-treatmentpatients-intensive-acute-care-psychiatric-setting-during-covid-19/

Other studies have shown that various types of mental health services (and often delivered through PHPs) can be provided effectively via telehealth including depression screening, follow up care after hospitalization, behavioral counseling for substance use disorders (SUD), medication management, and psychotherapy for mood disorders.[15] Telehealth has been found to increase retention for SUD treatment, including medication treatment, especially when treatment is not otherwise available or requires lengthy travel.[16] In addition, there is evidence of reduced utilization of higher-cost services associated with providing access to mental healthcare services via telehealth technologies.[17]

The experience of our members in delivering mental healthcare services during the PHE is consistent with these research studies. They were able to continue providing mental health and addiction treatment services during the PHE and experienced significantly reduced missed appointments by patients. In addition, telehealth enabled patients and family members who do not have PHPs in their communities to access these services remotely which significantly improved access to a level of care that is simply not otherwise available in most communities, especially in rural areas.

Outpatient Therapy, Diabetes Self-Management Training (DSMT), and Medical Nutrition Therapy (MNT)

During the COVID-19 PHE, CMS allowed outpatient therapy services, DSMT and MNT to be furnished by hospital employed staff to patients in their homes through the use of real-time interactive telecommunications technology. At the expiration of the COVID-19 waivers, CMS used sub-regulatory guidance to allow these services to continue to be provided and paid under the OPPS when provided by hospital employees to patients in their homes through the end of 2023.

Another COVID-19 waiver allowed CMS to add outpatient therapy, DSMT and MNT to the list of telehealth services that could be paid under the physician fee schedule when provided by an eligible practitioner or supplier. Physical, occupational and speech language pathologists were temporarily designated as "eligible telehealth distant site practitioners" and able to bill for these services under the physician fee schedule when furnished via telehealth.

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[15] National Quality Forum and AHA Center for Health Innovation: Redesigning Care: a How-To Guide for Hospitals
and Health Systems Seeking to Implement, Strengthen and Sustain Telebehavioral Health. (2019). Available at https://www.aha.org/system/files/media/file/2020/03/Telebehavioral-Health-Guide-FINAL-031919.pdf.

[16] Lin L, Casteel D, Shigekawa E, et al.: Telemedicine-delivered treatment interventions for substance use disorders: A systematic review. Journal of Substance Abuse Treatment, 101: 38-49 (June 2019).

[17] Shigekawa E, Fix M, Corbett G, et al.: The current state of telehealth evidence: A rapid review. Health Affairs, 37(12): 1975-1982 (2018).

The CAA, 2023 extended most flexibilities for Medicare telehealth services, including retention of physical and occupational therapists and speech-language pathologists as eligible telehealth distant site practitioners through the end of 2024. In the 2024 PFS proposed rule, CMS is extending these telehealth waivers consistent with the CAA, 2023. CMS indicates that its proposal includes outpatient therapy, DSMT, and MNT services furnished via telehealth by staff of hospital outpatient departments.

We commend CMS for recognizing the value of telehealth beyond the PHE in these proposed provisions and appreciate CMS' proposals to continue to advance the use of telehealth in Medicare. This extension will provide the flexibility needed to offer these outpatient therapy services to patients, especially those who have difficulty traveling to a hospital and otherwise would not have access to these critical services.

X.E. OPPS Payment for Dental Services

Policies adopted in the 2023 physician fee schedule final rule allow payment for certain dental services performed in outpatient settings. For 2024, CMS proposes to assign 229 additional dental codes to clinical APCs and allow payment for them under the OPPS when payment and coverage requirements are met. **The FAH supports the addition of these dental codes for coverage and payment under the OPPS and believes that coverage for these dental services is critical since they are inextricably linked and substantially related to the clinical success of other covered medical services.** This will assist in ensuring that poor oral health in these circumstances does not further complicate the treatment of other covered medical conditions to which these dental services are inextricably linked – and will promote higher quality care for patients.

XIV. Hospital Outpatient Quality Reporting (OQR) Program Requirements, Proposals, and Requests for Comment

1. Retention, Removal, Replacement, or Suspension of Quality Measures from the Hospital Outpatient Quality Reporting (OQR) Program Measure Set

A. Proposed Removal of the Left Without Being Seen Measure (LWBS)

CMS proposes to remove the LWBS measure from the program beginning with the CY 2024 reporting period/CY 2026 payment determination. The FAH supports the removal of this measure from the OQR program.

2. Modifications to Previously Adopted Measures

A. Proposed Modification of the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure

CMS proposes to modify the previously adopted COVID–19 HCP measure beginning with CY 2024 reporting period/CY 2026 payment determination. The FAH supports the intent of this measure, but we remain concerned that the current specifications are flawed given the lack of a stable definition of "up to date" and the numerator, which refers the end user to a document with varying definitions of "up to date," could negatively impact the reliability and validity of the measure. A standardized way to collect this information must be made available. The FAH continues to believe that it is too soon to include a measure on COVID-19 vaccinations since the underlying evidence for this measure is still emerging and methods to address measure collection challenges related to anticipated "booster" shots will likely be required.

Should CMS choose to move forward with this measure, we recommend that it be aligned with the requirements of the Hospital Conditions of Participation (COPs) and allow not only medical contraindications but also capture when individuals decline vaccination. We also recommend CMS revise the measure specifications to require data to be submitted in monthly or quarterly periods instead of one week a month for each quarter, in line with other Quality Reporting Program measures. The updated specifications and testing results must also be endorsed by the Consensus-Based Entity (CBE) prior to implementation in the Hospital OQR Program.

B. Proposed Modification of Survey Instrument Use for the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure

CMS proposes to modify the previously adopted Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure beginning with CY 2024 reporting period / CY 2026 payment determination. Specifically, the allowable survey instruments that an HOPD may use to assess changes in patient's visual function will be limited to three specific tools.

The FAH supports the standardization of the instruments used to evaluate changes in visual function, but it is not clear whether these revisions have been tested to ensure that the performance scores are reliable and valid. This measure was not originally developed for use at the facility level and, to our knowledge, testing at this level has never been completed. While further refinement of these specifications should improve the reliability and validity, testing to confirm that assumption should be completed and endorsement by the CBE received prior to implementation in the Hospital OQR program.

C. Proposed Modification of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure Denominator Change to Align with Current Clinical Guidelines

CMS proposes to modify the denominator for the previously adopted Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure beginning with CY 2024 reporting period/CY 2026 payment determination. These changes will align the measure with the recent revisions to the United States Preventive Services Task Force (USPSTF) recommendations on colorectal cancer screening. The FAH supports changing the age to 45 years to align with the recent USPSTF updates.

3. Proposed Adoption of New Measures for the Hospital OQR Program Measure Set

A. Proposed Re-adoption with Modification of the Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures Measure

CMS proposes to re-adopt the HOPD Procedure Volume measure with modification, with voluntary reporting beginning with the CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. The FAH supports the adoption of this measure in the OQR program once endorsement by the CBE is received.

B. Proposed Adoption of the Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO–PM)

CMS proposes to adopt the THA/TKA PRO–PM into the Hospital OQR Program using the same specifications as finalized for the hospital-level measure adopted into the Hospital IQR Program with modifications to include procedures performed in the HOPD setting. Voluntary reporting would occur in CYs 2025 and 2026 reporting periods followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination.

We support the development and implementation of PRO-PMs but we also believe that additional questions and work remain before their widespread use such as the degree to which multiple PRO-PMs could lead to survey fatigue for patients, the potential impact that additional PRO-PMs may have on the reporting of well-established measures such as HCAHPs, and what level of data collection burden for an individual PRO-PM is acceptable for a hospital or other healthcare provider. Hospitals are already encountering challenges with the implementation of this measure in the Hospital Inpatient Quality Reporting (IQR) program given the significant lead time (at least 15 months) required to begin data collection for this measure (this does not even factor in the time required to design and implement the data collection processes and tools and educate clinicians and staff) and due to delays by CMS in releasing detailed information on the measure requirements. The degree of implementation burden for this measure must not be minimized, particularly for hospitals who provide care in small, rural under-served communities. CMS should allow hospitals to gain experience and provide feedback on this measure through its use in HIQR before its inclusion in any other quality program.

Furthermore, we are very concerned to see that this measure has not yet been fully tested nor has it been endorsed by the CBE. This measure must be fully tested for feasibility, reliability, and validity and informed by the Hospital IQR implementation before it is implemented in any other program. The FAH cannot support the inclusion of this measure in the Hospital OQR program until testing demonstrates that the results are reliable and valid and endorsement is achieved.

C. Proposed Adoption of the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Outpatient) Measure

CMS proposes to adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography in Adults (Hospital Level – Outpatient) Measure, beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.

While the FAH appreciates that reporting on this measure will be voluntary for the first year of reporting, we believe additional time for hospitals to integrate and gain experience with the required software is needed before widespread implementation and reporting begins. We suggest that measure adoption be delayed for at least an additional year.

XIV.C. Hospital OQR Program Quality Measure Topics for Potential Future Consideration

CMS seeks public comment to address: (1) quality measurement gaps in the HOPD setting, including the ED; (2) changes in outpatient care (such as shifts in volume, technology use, and case complexity); (3) growth of concerns around workforce and patient safety; (4) the transition to digital quality measurement; and (5) interest in patient-reported outcomes. Comment on quality measure topics for the Hospital OQR program include promoting safety (patient and workforce), behavioral health, and telehealth.

The FAH appreciates CMS' efforts to continue to evolve and expand the measures that are included in the Hospital OQR program. We support a focus on promoting safety both for patients and the workforce but urge CMS to consider targeted solutions that address today's patient safety challenges, including those that were exposed during the recent public health emergency. Adoption of existing measures such as the Severe Sepsis and Septic Shock: Management Bundle measure may be convenient but it may not necessarily address the specific issues encountered by facilities at this time.

Hospitals and health systems face many challenges in meeting their commitments to advancing patient safety and we encourage CMS to support the research that is needed to better understand the impact of the pandemic on patients and the health care system.[18] We believe that those learnings can be applied to forging a new era in patient safety that detects and addresses patient harm at every point in the care-giving process including:

- identifying and testing new team-based models that address longstanding workforce issues;
- optimizing the use of Patient Safety Organizations;
- distinguishing between non-preventable and preventable harms; and

[18] Sands KE, Blanchard EJ, Fraker S, Korwek K, Cuffe M. Health Care–Associated Infections Among Hospitalized Patients With COVID-19, March 2020-March 2022. *JAMA Netw Open*. 2023;6(4):e238059. doi:10.1001/jamanetworkopen.2023.8059.

- remove barriers to innovation.

While many of these efforts are focused on building or reinforcing infrastructures, we believe that these actions would result in a strong foundation on which future patient safety focused measures could be implemented.

The FAH supports exploration of potential measures addressing behavioral health and telehealth but again encourages CMS to complete the necessary analyses and evidence reviews to determine what clinical areas or concerns are ripe for measure development and testing. While measure alignment across settings and providers should be considered, adoption of existing measures should only occur when the topic is directly relevant to the settings and patient populations of interest and not just serve as a "check the box" activity.

CMS must also ensure that each produces results that are reliable and valid for the relevant setting and be endorsed by the CBE prior to consideration of any quality program. Furthermore, no additional measures should be considered for inclusion in this program until we collectively have a better understanding on how care delivery has changed and what levers and metrics would be most effective in facilitating the highest quality and safest care possible.

XVIII. Proposed Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges

The FAH continues to be supportive of price transparency initiatives that provide patients with access to clear, accurate, and actionable information. We appreciate that a number of the hospital price transparency elements of the Proposed Rule reflect experience gained working with hospitals in the course of CMS' education, monitoring, and enforcement activities. But other elements of the proposed changes to 45 C.F.R. Part 180 raise significant concerns, particularly with respect to the effective date for formatting new data elements, the proposed requirement to add an "expected allowed amount" data element, and the proposed attestation and certification requirements.

Effective Date for Formatting and New Data Elements. The Proposed Rule includes a number of significant proposed changes to hospital price transparency requirements under 45 C.F.R. 180.50(b) and (c), including new data elements and formatting requirements. If finalized, these requirements would become effective a mere two months after the final rule is released, providing an exceedingly narrow window within which each hospital would be required to digest the requirements of the final rule, gather necessary data and information, incorporate the new data elements into its machine-readable file, and re-format its machine-readable file using a CMS template. ***The FAH has significant concerns that this proposed timeframe is unduly burdensome and inadequate to provide hospitals with a reasonable and realistic opportunity to comply with these new requirements. Rather, the FAH strongly urges CMS to delay the effective date to January 1, 2025, ensuring that the new requirements are effective no earlier than one year after publication of the final rule and finalization of any required machine-readable file template(s).***

The FAH appreciates CMS' recognition of the significant burdens associated with the adoption and conformation to the new CMS template layout and encoding of standard charge information of the newly proposed data elements with the proposed 60-day enforcement grace period. An enforcement grace period, however, is insufficient compared to an effective date that is designed to provide a reasonable and appropriate window for achieving compliance. Notably, a number of hospitals are subject to state law requirements that incorporate the requirements of 45 C.F.R. § 180.50 (*e.g.*, Va. Code § 32.1-137.05(A)), such that the effective date of amendments to § 180.50 triggers obligations and enforcement risks under state law, notwithstanding any Federal enforcement grace period. For these hospitals, an enforcement grace period from CMS is particularly inadequate, and it is critical that the effective date of any amendments to § 180.50 be set in a manner that reasonably permits compliance with the amended requirements prior to the effective date.

In light of the significant nature of the proposed changes to § 180.50, the FAH believes that a January 1, 2025, effective date is appropriate. Providing a delayed effective date will allow hospitals to time their adoption of the finalized template and inclusion of new data elements with their annual updates to their machine-readable files over the coming year, reducing unnecessary burdens on hospitals. In addition, such a delay in the effective date will ensure that those hospitals that are not currently using a CMS machine-readable file template are reasonably able to achieve compliance by the effective date. These hospitals include those that invested in compliance early on, developing their own machine-readable file formats to comply in good faith with hospital price transparency requirements in 2021 before CMS released its first templates in late 2022. In structuring the effective date for new requirements, the FAH believes it is most appropriate to evaluate the burdens on these hospitals that pursued compliance before voluntary templates were available and incurred more significant expenses doing so. For these hospitals, a January 1, 2024, effective date (even with a 60-day enforcement grace period) does not provide a reasonable timeframe within which to completely restructure their machine-readable files to comply with any finalized template.

Additional Data Elements. The Proposed Rule includes a number of amendments to § 180.50(b) that would require the inclusion of additional data elements in the machine-readable file. The FAH appreciates that some of these additions—for example, the explicit statement in proposed § 180.50(b)(2)(i) that "plan(s) may be indicated as categories (such as 'all PPO plans')" in appropriate cases—are pragmatic reflections of experience gained in the course of reviewing hospital compliance with current hospital price transparency laws. The FAH, however, is concerned that other proposed data elements may be unnecessarily burdensome or have unintended consequences.

In particular, the Proposed Rule significantly underestimates the burden associated with calculating and displaying a "consumer-friendly expected allowed amount" for each payer-specific negotiated charge that is expressed as a percentage or algorithm under proposed § 180.50(b)(2)(iii). It appears that this proposal is made based on the "understanding that hospitals often have such information already calculated and available as part of their revenue cycle management systems." 88 Fed. Reg. at 49,854. But the expected allowed amount information that is likely to be available to the hospital is different from the proposed "consumer-friendly expected allowed amount" in a couple critical ways. First, the FAH

understands that existing expected allowed amount data generally reflects estimates at the consolidated claim level and that hospitals do not typically have expected allowed amount data for individual items and services. Second, the definition of "consumer-friendly expected allowed amount" under proposed § 180.20 would necessitate modeling an average amount for the average patient. The Proposed Rule does not provide guidance for how a hospital might model the expected allowed amount to obtain such an average and whether hospital-specific case mix and acuity would be reflected in the expected allowed amount. As such, the proposed requirement to include an expected allowed amount would not leverage existing data and would instead necessitate the creation of new processes to calculate appropriate estimates of expected allowed amounts modeled based on an unspecified average patient. The FAH, therefore, requests that CMS forego finalization of the consumer-friendly expected allowed requirement at this time in order to further engage with hospitals on ways that available data can be efficiently leveraged to provide consumers with more context for payer-specific negotiated charges expressed as an algorithm without creating excessive and unanticipated burdens for hospitals.

The FAH is also concerned that proposed § 180.50(b)(1)(i) might be read as imposing a new, burdensome, and unexplained requirement to list every address at which the hospital furnishes items or services, including each hospital outpatient department that uses the same standard charges. The Proposed Rule indicates that proposed § 180.50(b)(1)(i) is designed to address the fact that "hospital information sometimes becomes disassociated from the file as it is further processed," which suggests that the intent is to move current hospital location information under subsection (d)(2) into the data encoded in the machine-readable file but not to require the addition of new name and address information for every hospital outpatient department. The FAH, therefore, requests that CMS clarify that the locations that must be listed under proposed § 180.50(b)(1)(i) are limited to the hospital's inpatient location(s) when standard charges do not differ amongst the hospital outpatient departments.

Attestation (§ 180.50(a)(3)) and Certification (§ 180.70(a)(2)(iv)). The Proposed Rule includes a requirement that each hospital include in the machine-readable file an attestation that the information displayed is true, accurate, and complete to the best of the hospital's knowledge and belief and new regulatory authority permitting CMS to require an authorized official to certify the accuracy and completeness of the data. As a threshold issue, the FAH opposes unnecessary provider attestations and certifications because they create significant burdens for providers. With respect to the proposed attestation requirement, the preamble to the Proposed Rule indicates that the attestation is designed to address potential public confusion with respect to blank cells that are intentional and appropriate. The inclusion of the proposed hospital attestation in the machine-readable file, however, is unlikely to address confusion involving blank cells. Moreover, to the extent that there is material confusion regarding blank cells in machine-readable files, that issue can be effectively and efficiently addressed through the insertion of null values (*e.g.*, "N/A").

The Proposed Rule also would permit CMS to require "submission of certification by an authorized hospital official as to the accuracy and completeness of the data in the machine-readable file" (proposed § 180.70(a)(2)(iv)). This is explained as a requirement that might be necessary to resolve allegations of *specific* inaccuracies or omissions, but this limitation is not present in the draft regulation, creating the possibility that this authority could be used to obtain

an authorized hospital official's certification as to the accuracy and completeness of the data in the entirety of the machine-readable file. It would simply be unreasonable to require a hospital official to certify the accuracy and completeness of the many thousands of lines of data that are included in the machine-readable file. To the extent that a certification is ever required, it should be limited to cases where there is credible information indicating a problem with a targeted and narrow subset of data (*e.g.*, a small handful of specified cells or a particular item or service that is not listed) that can reasonably by reviewed by the authorized hospital official and the certification should be confined to that identified subset of data. These guardrails would ensure that any certification authority is appropriately reserved for extraordinary circumstances and that the certification demands are not wholly infeasible.

Accessibility (§ 180.50(d)(6)(ii)). Proposed § 180.50(d)(6)(ii) would refine the existing requirement that the machine-readable file be displayed in a prominent manner by requiring that the hospital use a link in the footer on its website labeled "Hospital Price Transparency" that links directly to the page that hosts the link to the machine-readable file. The FAH requests that CMS refocus these standards on ensuring that the machine-readable file is accessible and transparent rather than setting out technical web design requirements. For example, hospitals need the flexibility to allow the link to be placed either in the header or footer on its website. At least one state requires that this link or button be "immediately viewable upon accessing the home page of the hospital's publicly accessible website without having to scroll," such that placement of the link in the footer would not satisfy state law requirements. 25 Tex. Admin. Code § 133.53(b). The goals of prominent display and accessibility can be adequately achieved while providing hospitals with the flexibility to place the link in either the header or the footer so that hospitals are better able to place the link in a manner that complies with both Federal and state law. In addition, the FAH supports limiting the required text for the link in the header or footer to "Price Transparency" to address technical limitations that may necessitate a shorter string of text in a header. Finally, insofar as the Proposed Rule suggests that the linked page must host the link to the machine-readable file, the FAH believes that such a requirement is unnecessarily technical and burdensome. This is particularly evident in situations where the hospital website hosts information for more than one hospital location such that an additional page is required. In such a case, the header or footer link might bring the user to a price transparency page that includes a link to a standard charges page that hosts the machine-readable files for multiple hospital locations.

Enforcement and Additional Documentation (§ 180.70(a)(2)(v)). Under proposed § 180.70(a)(2)(v), a hospital might be required to submit additional documentation to validate standard charges, including contracting documentation. The FAH is concerned that this provision contemplates a far more burdensome audit and review process compared to the processes that have been established over the past few years. At present, CMS' monitoring and assessment activities properly focus on ensuring compliance with the machine-readable file requirements without validating the specific methodologies reasonably deployed to translate the data and algorithms in third-party payer's rates sheets into machine-readable files, and the FAH supports retaining this focus on compliance monitoring and assessment rather than data validation. Although the FAH does not believe that requiring the submission of payer contracts under proposed § 180.70(a)(2)(v) is necessary for the efficient and appropriate enforcement of 45 C.F.R. Part 180, if such a provision is finalized, the FAH strongly urges CMS to expressly

designate the contracts as confidential commercial information that is exempt from disclosure under the Freedom of Information Act. Facility participation agreements between hospitals and payers contain a range of competitively sensitive terms and conditions beyond the negotiated rates and should not be collected in a manner that risks disclosure under FOIA.

Enforcement and Compliance within Hospital Systems (§ 180.70(c)). Proposed § 180.70(c) would provide explicit regulatory authority for CMS to work with health system leadership to address deficiencies for hospitals across the health system when CMS takes action to address noncompliance in one of the health system's members. The FAH supports the educational engagement and collaboration encompassed by this proposal, but urges CMS to recognize that a health system may be unable to promptly extend a hospital-level corrective action plan into a system-wide change despite a commitment to compliance. For example, even where a health system might centralize oversight of price transparency activities, a corrective action plan for a particular hospital might necessitate a manual override for that hospital's machine-readable file that cannot be readily adopted on a system-wide basis.

Publicizing Compliance Actions and Outcomes (§ 180.70(d)). Lastly, in connection with the discussion of proposed § 180.70(d), the FAH appreciates CMS' recognition of the extraordinarily high level of hospital engagement on price transparency compliance with over 99.5 percent of hospitals identified by CMS as noncompliant having corrected their deficiencies or working toward correcting deficiencies in cooperation with CMS. Public discourse and complaints around price transparency are often inconsistent with this experience and fail to reflect critical successes in expanding hospital compliance with these complex requirements in a relatively brief period of time. The Proposed Rule suggests that increased transparency around CMS' enforcement processes and assessments might help bridge this divide, but the FAH is concerned that proposed § 180.70(d) is overly broad and might produce unintended consequences. For example, this provision would permit publicizing information before compliance activities have come to a close, either through a closure notice or civil monetary penalty. While compliance activities are ongoing, disclosure of CMS' assessment of a hospital's compliance may give an imprimatur of finality when, in fact, further exchanges of information might prompt reconsideration. The FAH strongly supports the collaborative processes that have been built between CMS and hospitals with the implementation of the hospital price transparency requirements and recommends narrowing any publicization of enforcement activities to focus on outcomes in order to preserve and support collaborative enforcement.

XVIII.D. Consumer-Friendly Displays and Alignment with Transparency in Coverage and No Surprises Act

The FAH appreciates CMS' attention to the intersections between current and pending consumer-friendly price transparency requirements and the request for comments on how the standard charges disclosure requirements might best support and complement the consumer-friendly requirements found in other transparency initiatives. With both the Transparency in Coverage final rules and the No Surprises Act, consumers increasingly have access to individualized and actionable pricing information to inform their choices with respect to shoppable services furnished by hospitals and other health care providers. This access has already significantly expanded and deepened for uninsured and self-pay patients, who receive

good faith estimates for scheduled services and upon request. In light of this evolution, the FAH believes that the consumer-friendly display requirements at 45 C.F.R. § 180.60 are diminishing in importance and that it would be appropriate to reduce hospital burdens by sunsetting these requirements. Of course, if and when these requirements sunset, many hospitals would likely voluntarily continue to maintain their online price estimator tools insofar as they provide an opportunity to engage with patients and the costs of maintaining these tools is small compared to the investment that was required to create them.

The Proposed Rule requests comments on the elements of health pricing information that consumers find most valuable in advance of receiving care. The FAH's members report that consumers seeking out health pricing information are most interested in their estimated out-of-pocket costs for scheduled services, often for purposes of financial planning over comparison shopping. At present, consumers can receive the most individualized information by meeting with a financial counselor or, if they are proceeding on a self-pay basis, by obtaining a good faith estimate. Among the diverse range of consumers served by hospitals, some prefer using online price estimator tools in order to access information in real-time, but others have a strong preference for meeting with a financial counselor so that pricing information can be provided in a personalized manner along with actionable financial assistance and charity care program information.

Finally, with respect to the minimum amount of personalized information that a consumer must provide for a price estimator tool to produce a personalized out-of-pocket estimate, FAH members report needing the following data points: (1) plan, (2) patient name, (3) date of birth, (4) member identification number, and (5) relationship to subscriber. Additional data would be needed to create a good faith estimate under the *No Surprises Act* or to screen the consumer for a financial assistances or charity care program, but we understand that these five data points are sufficient for purposes of an online price estimator tool.

XIX. Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor

CMS has made available the FY 2023 ICD-10 Medicare Code Editor (MCE) Version 40 manual file. The MCE manual is currently comprised of two chapters:

- Chapter 1: Edit code lists provides a listing of each edit, an explanation of each edit, and as applicable, the diagnosis and/or procedure codes for each edit; and
- Chapter 2: Code list changes summarize the changes in the edit code lists (for example, additions and deletions) from the prior release of the MCE software.

CMS seeks comments on a proposal to remove discussion of the MCE from the annual IPPS rulemakings, beginning with the FY 2025 rulemaking, and to address future changes or updates to the MCE through instruction to the Medicare Administrative Contractor (MACs). **The FAH urges CMS to maintain discussion of the MCE in the IPPS rulemakings.** The annual rulemaking process provides a more formal and publicly visible opportunity to provide comments to CMS on MCE manual changes, including any concerns with current edits, including specific edits or language recommended for removal or revision, edits that could be

combined, or new edits to be added. Discussion of the MCE through multiple MACs would be a more de-centralized and fragmented process, particularly with multiple MACs involved, each of which may have varying processes for interpreting and implementing the MCE manual edits. Hospital systems would then have to provide multiple submissions across various MACs and any responses from the MACs may not be in sync, leading to further fragmentation and confusion across hospitals and other providers. We believe that the more systematic, rigorous, and annual regulatory process, with opportunity for notice and public comment, will assist in promoting a more seamless process for seeking and responding to public comment while minimizing confusion about MCE edits.

XXII. Request for Public Comments on Potential Payment under the IPPS and OPPS for Establishing and Maintaining Access to Essential Medicines

CMS is seeking comment on an approach for giving hospitals a financial incentive under the IPPS, and possibly the OPPS in future years, for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply of these medicines. Based on the public comments, CMS would consider adopting a policy that would be effective as soon as cost reporting periods, beginning on or after January 1, 2024.

A report from the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) prioritized 86 essential medicines as either critical for minimum patient care in acute settings or important for acute care or acute care of respiratory illnesses/conditions, with no comparable alternative available. CMS believes that this prioritized list of medicines could be used as a starting point for the list of medicines that CMS would encourage hospitals to create a buffer stock of supplies. CMS expects that the resources required to establish and maintain access to a minimal "buffer stock" of essential medicines, such as a 3-month supply, will generally be greater than the resources required to establish and maintain access to these medicines through alternative means that are more susceptible to supply chain disruptions (for example, through so-called "just-in-time" inventory practices).

CMS believes it may be appropriate to pay separately for the additional resource costs associated with establishing and maintaining access, including through contractual arrangement, to a buffer stock of essential medicines. These potential separate payments would be in addition to payment for the essential medicines themselves, whether that payment is bundled with other items or services or the essential medicines are separately paid. CMS requests information on a number of questions related to this possible adjustment and its impact on addressing shortages of essential medicines.

The FAH appreciates CMS' and the Administration's efforts to address drug shortages and the opportunity to provide feedback on this RFI. Drug shortages – especially for commonly used generic drugs in hospitals – can cause delays in patient care and force pharmacy and clinical staff to use less optimal alternatives. Hospitals and health systems, along with their group purchasing organizations, employ numerous tactics to prevent and manage care through drug shortages. **And while we appreciate the Administration's suggestion that offering an additional inpatient adjustment for maintaining a buffer supply of essential medicines**

could be a possible tool to address shortages, the policy raises a number of questions and concerns about potential unintended consequences.

We are concerned that a policy that gives more than 5,000 hospitals an incentive to create their own 3-month buffer of essential drugs could actually cause certain drug shortages as hospitals work to stockpile essential medicines beyond patient needs and potentially lead to inequitable distribution of drugs across the health system. While we fully understand and recognize the need for a better supply of drugs and ways to address shortages, other strategies to develop a buffer stock that can be more equitably distributed might be more effective at reducing shortages.

The FAH also is concerned that the approach outlined in the OPPS rule may create significant burdens for hospitals trying to maintain and account for a buffer stock. Drugs used by hospitals are not solely used for inpatient purposes and the challenge of working with a distributor or internal processes to maintain extra stock of more than 80 different drugs, ensure that those drugs are used prior to their expiration, and account for the systems and storage costs would create significant challenges and costs. If CMS moves forward with this type of proposal, we urge CMS to allow an adjustment of all essential drugs and not try to apportion the drugs solely to Medicare's portion or the Medicare inpatient portion of the costs. Additionally, while the non-drug costs of maintaining a stockpile would be extensive, the additional funds needed simply to buy the additional drugs that would not be used would likely be cost prohibitive for many hospitals.

The alternative to link an incentive for building a stock of essential medicines to whether those medicines were manufactured and sourced in the United States – similar to the additional reimbursement that CMS created for domestically manufactured N-95 masks – might be an approach to consider, however given the dearth of domestically manufactured and sourced drugs, CMS' proposal would need to be more expansive and allow some international sourcing for source materials.

We believe these questions need to be addressed prior to the implementation of a new inpatient adjustment for maintaining a buffer stock and we would urge CMS and the Administration to take more time to thoughtfully consider both the expected and unexpected outcomes of such a proposal. We also would urge CMS to consider forming an expert panel to help advise on this issue with representation from hospitals, GPOs, distributors, manufacturers, patients, and federal agencies to help advise and provide recommendations on efforts that could address both short-term and long-term drug shortages and a resilient manufacturing environment for essential medicines.

Marriage and Family Therapist (MFT) and Mental Health (MHC) Counselor Services

The CAA, 2023 provides for a new benefit category under part B of Medicare to cover and pay for marriage and family therapist (MFT) services and mental health counselor (MHC) services. While CMS provides proposals on its implementation of this new benefit in several

contexts,[19] CMS does not include any proposals that indicate how MFT and MHC services will be paid when provided to hospital outpatients beginning January 1, 2024. The FAH requests that CMS address this gap in the regulations in the OPPS final rule.

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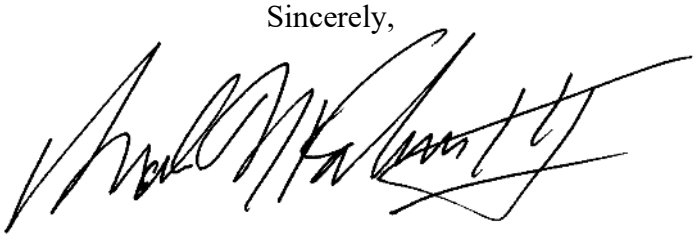
The FAH appreciates the opportunity to submit these comments on these important issues. If you have any questions, please contact me or any member of my staff at (202) 624-1534.

Sincerely,



[19] In the CY 2024 physician fee schedule proposed rule (88 FR 52361), CMS explains how it plans to make payment for these services under the PFS. In the OPPS proposed rule (88 FR 49552), CMS proposes revisions and/or additions to the personnel qualifications of MFTs or MHCs in the CMHC CoPs and implementation of this new benefit for Rural Health Clinics and Federal Qualified Health Centers.