Federation of American Hospitals®

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

RE: CMS-1771-P, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation: Proposed Rule (Vol. 87, No. 90), May 10, 2022.

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, D.C 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 comment to the Centers for Medicare & Medicaid Services (CMS) about the above referenced Proposed Rule on Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation**.**

EXECUTIVE SUMMARY

Hospital Market Basket Update

CMS proposes a market basket update of only 3.1 percent for FY 2023, which, like the FY 2022 market basket update of 2.7 percent, seriously understates the unprecedented inflationary environment hospitals and health systems are experiencing. This woefully inadequate market basket update is a product of CMS' reliance on historical data to forecast FY 2023 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. In addition, CMS proposed reducing the inadequate proposed market basket update with a 0.4 percentage point productivity adjustment to calculate the applicable percentage increase. This productivity adjustment is inappropriate in that it contemplates improbable and overstated gains in productivity. In fact, the latest data actually indicates *productivity losses* rather than gains.[1]

The FAH urges CMS to adjust its market basket update methodology to adjust for more recent data and trends that are not captured in the proposal and would not even be fully captured is IHS Global Insight, Inc.'s (IGI) updated market basket forecast in the second quarter of 2022. In addition, in the context of inflationary and other economic pressures that are simply unprecedented since the implementation of the IPPS, the FAH urges CMS to use its "exceptions and adjustments" authority under subsection (d)(5)(I) to 1) adopt a further one-time adjustment that reflects the extent to which the FY 2022 market basket update understated the rapidly rising costs of goods and services and 2) adopt a further 0.4 percentage point adjustment that fully offsets the FY 2023 productivity adjustment, reflecting the inappropriateness of a negative productivity adjustment at a time when hospitals are facing productivity losses during a pandemic that has created exceptional financial pressures that jeopardize our health care delivery system generally and hospitals in particular.

The FAH also urges CMS to address the inadequacy of the proposed LTCH PPS Standard Federal Rate for FY 2023. Relying on historical data without methodological adjustments to account for profound inflationary forces will produce in an inadequate LTCH market basket update, compounding the erosion of rates due to inadequate market basket updates in FY 2021 and FY 2022.

Uncompensated Care Disproportionate Share Hospital Payments

The FAH is concerned that the calculation of Factor 2 significantly underestimates expected contractions in Medicaid and Marketplace enrollment that will precipitate a growing uninsured rate over FY 2023 and urges CMS to adjust estimates to fully capture the impact of the anticipated conclusion of the PHE and expiration of expanded Marketplace subsidies on the uninsured rate**.** The FAH strongly urges OACT to broaden its data sources to more fully reflect current estimates of the uninsured rate in FY 2023 in light of the profound impact of the unwinding of the PHE and the expiration of the enhanced subsidies under ARPA. These

[1] U.S. Bureau of Labor Statistics. (May 5, 2022). Productivity and Costs, First Quarter 2022, Preliminary - 2022 Q01 Results. https://www.bls.gov/news.release/pdf/prod2.pdf.

estimates have significant impacts on the UC DSH funding available to support critical hospital services to the uninsured and underinsured. For example, even acknowledging an additional 1.0 percentage point of additional growth in the uninsured rate in CY 2023 (approximately 3.3 additional uninsured individuals, which would reflect a conservative projection), would increase the proposed UC DSH pool by approximately $569 million above CMS' proposal.

Outlier Payments

Overall, the proposed fixed loss threshold for FY 2023 would be a roughly $12,000 and 40 percent increase over FY 2022. And looking back just six years, CMS' proposed threshold is nearly $20,000—or more than 80 percent—higher than what it was in FY 2017. We support CMS' proposal to use the pre-PHE data—we believe the charge inflation recorded during the PHE is aberrant and, thus, is unlikely to provide a reasonably accurate forecast of charge inflation. We also believe that CMS' decision to move to publicly available data sets continues to be a thoughtful choice for the Proposed Rule. Yet, these dramatic and accelerating increases in the threshold suggest that the data used to set the proposed threshold is abnormal and CMS needs to modify its process further to calculate the adjustment factors for charge inflation and cost to charge ratios, so that the threshold will be set at a level that is not only likely to produce total outlier payments at CMS' 5.1 percent target, but helps ensure that rural hospitals, whose DRG payments are offset 5.1 percent, can access outlier payments.

Quality Measure Suppression Policies in Value Based Quality Programs

The FAH appreciates the extensive efforts made by CMS during recent rulemaking to apply policy and process flexibility in response to COVID-19 PHE impacts, such as the cross-measure suppression policy for the agency's value-based programs including the Hospital Value Based Purchasing (HVBP) program, Hospital Acquired Conditions (HAC) reduction program, and Hospital Readmissions Reduction Program (HRRP). We fully agree with CMS on the need to suppress certain measures or COVID cases within measures. Further, the FAH wholly supports CMS' proposals to adopt a special scoring policy that results in payment net-neutrality for hospitals in HVBP and to eliminate all HAC payment penalties for affected hospitals in FY 2023. CMS has struck the right balance by ensuring transparency of quality performance data, while at the same time, not penalizing hospitals when their performance scores are highly related to COVID experience.

The FAH notes that in providing rationales for special scoring and eliminating payment adjustments for the HVBP and HAC Reduction programs, CMS has cited COVID-19 PHE impacts including rapid changes in hospital care delivery protocols, shifts in procedural volumes, and unprecedented health care personnel staffing shortages. The FAH notes that these factors also apply to the hospitals affected by HRRP penalties and we urge CMS to also apply a suppression policy for FY 2023 that would eliminate all HRRP payment penalties.

I.F. Proposed Use of FY 2021 Data and Proposed Methodology Modifications for the FY 2023 IPPS and LTCH PPS Ratesetting

For the reasons CMS describe – to mitigate the effect of COVID-19 cases in FY 2023 under the assumption that there will be fewer cases compared to FY 2021 - the FAH supports CMS' proposal "to calculate the relative weights for FY 2023 by first calculating two sets of weights, one including and one excluding COVID-19 claims, and then averaging the two sets of relative weights to determine the proposed FY 2023 relative weights value." We agree that this proposed methodology is likely to "provide a more accurate estimate of relative resource use for FY 2023" than relying solely on all applicable FY 2021 cases.

On a related point, CMS's analyses of the IPPS and LTCH PPS data for FY 2022 and FY 2023 ratesetting confirm that it would be improper for CMS to proceed with the development of a post-acute care ("PAC") PPS prototype using data collected during the COVID-19 pandemic. The Improving Medicare Post-Acute Care Transformation Act of 2014, (Pub. L. 113-185) (IMPACT Act), mandates that the Secretary submit a report to Congress with recommendations and a technical prototype on a PAC PPS that could replace the existing Medicare payment systems for LTCHs, inpatient rehabilitation facilities (IRFs), skilled nursing facilities (SNFs), and home health agencies (HHAs). The IMPACT Act requires that the Secretary submit this report no later than two years after the Secretary collects two years of data on the quality measures required by section 1899B(c) of the Social Security Act. Although LTCHs and other PAC providers have not started reporting quality data for all of the measures required by section 1899B(c), we understand that the Secretary may be planning this year to submit a report to Congress with a PAC PPS prototype. This means that the report and the technical prototype would be based on data collected during the COVID-19 pandemic.

We believe CMS should delay development of a technical prototype for a possible PAC PPS until it has at least two years of data required by the IMPACT Act that are not distorted by the COVID-19 pandemic. CMS's analyses of the best available data for ratesetting now confirms that there are meaningful distortions to the data that would be used for developing a PAC PPS prototype. Specifically, CMS states in the FY 2023 IPPS/LTCH PPS Proposed Rule that the FY 2020 and FY 2021 claims data in the MedPAR file were "significantly impacted" by COVID-19. According to CMS, utilization of LTCH services was "markedly different" than the utilization that would have been expected if the pandemic had not occurred. CMS made similar findings in the FY 2023 IRF PPS Proposed Rule.

The COVID-19 pandemic has caused significant changes in the utilization of PAC services. As part of CMS's response to COVID-19, CMS wisely waived or modified several Medicare rules and regulations for PAC providers. The CARES Act also directed the agency to waive other requirements, including the site neutral payment rate for LTCH patients treated in response to the pandemic. As a result of the changes during the PHE, LTCHs and other PAC providers are treating patient populations that are not representative of the patients they typically treat. Accordingly, LTCH data will be distorted while COVID-19 PHE waivers are in effect, and for some time after the PHE as well. CMS will not have data needed for a technical prototype (e.g., utilization data, resource use data, quality measure data, etc.) that are representative of PAC providers' typical patients during this time period. Thus, a technical prototype would be

seriously flawed if it was developed with this unrepresentative data. Accordingly, CMS should delay the development of a technical prototype for a possible PAC PPS until data from PAC providers are no longer distorted by the unprecedented COVID-19 pandemic.

II. Proposed Changes to Medicare Severity Diagnosis-Related Groups (MS-DRG) Classifications and Related Weights

II. D. Proposed Changes to Specific MS-DRG Classifications

The FAH acknowledges that CMS considered the impact of COVID-19 and the public health emergency (PHE) on the claims data submitted for rule making and the implications for MS-DRG classifications and rate setting for FY 2023. As noted in the FY 2023 IPPS/LTCH PPS Proposed Rule, CMS MS-DRG analysis was based on ICD-10 claims data from the September 2021 update of the FY 2021 MedPAR file, which contains discharges received from October 1, 2020 through September 30, 2021 which will be referred to throughout these comments as the "September 2021 update of the FY 2021 MedPAR file."

Based on the review of the Proposed Rule, the FAH generally supports the proposed changes recommended for MS-DRG and/or ICD-10 code classification changes for FY 2023 except for the items to follow.

II.D.1.b Proposed Changes to Specific MS-DRG Classifications

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58448), CMS finalized a proposal to expand the existing criteria to create a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS-DRG. Specifically, this rule finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split. In the FY 2022 IPPS/LTCH PPS final rule (86FR44798), CMS delayed applying this technical criterion to existing MS-DRGs until FY 2023 or future rulemaking in light of the PHE.

Additionally, CMS also noted in the FY 2021 rule that the application of the NonCC subgroup criteria going forward may result in modifications to certain MS-DRGs that are currently split into three severity levels and result in MS-DRGs that are split into two severity levels. And any proposed modifications to the MS-DRGs would be addressed in future rulemaking consistent with CMS' annual process and reflected in Table 5 – Proposed List of Medicare Severity Diagnosis Related Groups (MS-DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay for the applicable fiscal year.

In the FY 2022 rule, findings from CMS' analysis indicated that approximately 32 MS-DRGs would be subject to change based on the three-way severity level split criterion finalized in FY 2021 which would result in the deletion of 96 MS-DRGs and creation of 58 new MS-DRGs.

For this FY 2023 rule, using the September 2021 update of the FY 2021 MedPAR file, CMS' analysis indicated that the numbers have now been revised with approximately 41 MS-DRGs being subject to change based on the three-way severity level split criteria finalized FY 2021. Specifically, they found that applying the NonCC subgroup criteria to all MS-DRGs

currently split into three severity levels would result in the deletion of 123 MS-DRGs (41 MS-DRGs x 3 severity levels = 123) and the creation of 75 new MS-DRGs. These updates would also involve a redistribution of cases, which would impact the relative weights, as well as the payment rates proposed for particular types of cases.

In light of the ongoing PHE, CMS noted concerns about the impact of implementing this volume of MS-DRG changes at this time. As a result, CMS is proposing to delay the application of the NonCC subgroup criteria to existing MS-DRGs with a three-way severity level split until future rule making, and proposing for FY 2023 to maintain the current structure of the 41 MS-DRGs that currently have a three-way severity level split (total of 123 MS-DRGs) that would otherwise be subject to these criteria.

The FAH appreciates and strongly agrees with CMS to delay the application of the NonCC subgroup criteria to existing 41 MS-DRGs with a three-way level split and to maintain that current structure of these 123 MS-DRGs. In preparing for future consideration on this topic – the FAH respectfully requests:

- CMS provide detail explanation and impact files including volumes by MS-DRG that support the proposal to reduce the 123 MS-DRGs, especially in light of the dynamic data. Examples of the shifts and/or questions are noted below for illustrative purposes.
    - MS-DRGs that were proposed in FY2022 to be removed are not present on the FY2023 listing.
        - MS-DRGs 146-8 ENT Malignancies
        - MS-DRGs 283-5 Acute MI, Expired
        - MS-DRGs 722-4 Malignancy Male Reproductive
    - MS-DRGs that were proposed in FY2022 to become either a single tier MS-DRG now meet the criteria for three tier MS-DRG in FY2023 (e.g. MS-DRG 283-5 Acute Myocardial Infarction, expired).
    - MS-DRGs within table 6P.1b includes a list of deleted MS-DRGs and list of created MS-DRGs with XX for the numbers. Many of these have the same narrative but appear they would obtain a new MS-DRG number. For example, MS-DRG 180 is Respiratory Neoplasms with MCC in both lists of MS-DRGs. The same is true for MS-DRGs 20, 77, 94, 97, 146, 196, 239, 255, 288, 368, 408, 420, 423, 432, 435, 548, 573, 597, 616, 622, 628, 665, 754, 757, 802, 834, 843, 846, 853, 867, 957, 974. For continuity with reporting, why would MS-DRGs with the same narrative have new MS-DRG numbers assigned?
    - MS-DRGs that were proposed in FY2022 to maintain their three tiers, now seemingly meet the criteria for reduction to double or single tier MS-DRG.
        - MS-DRGs 77-79 Hypertensive Encephalopathy
        - MS-DRGs 97-99 Non-bacterial Infection of Nervous System except viral meningitis
        - MS-DRGs 180-2 Respiratory Neoplasms
        - MS-DRGs 196-8 Interstitial Lung Disease
        - MS-DRGs 239-241 Amputation for Circulatory Disorders Except Upper Limb and Toe
        - MS-DRGs 368-370 Major Esophageal Disorders
        - MS-DRGs 432-4 Cirrhosis and Alcoholic Hepatitis

        - MS-DRGs 435-7 Malignancy of Hepatobiliary System or Pancreas
        - MS-DRGs 799-801Splenectomy
        - MS-DRGs 802-4 Other OR Px of Blood & Blood Forming Organs
        - MS-DRGs 831-3 Other Antepartum Dx without OR
        - MS-DRGs with proposed revisions have had some impact by recent or future rule making. For example, MS-DRGs 408, 409, 410, 411, 412, 413 all involve cholecystectomy and CMS is requesting additional information for future rule making for cholecystectomy within FY2023 rule
- CMS provide volumes to support data transparency for the new MS-DRGs proposed so that the weight impact is available for review for these reduced tiers.
- CMS re-review and consider patient mix in terms of volumes, especially since the Medicare population would not have the volume/patient mix for some of the MS-DRGs such as Obstetrics, as noted in below examples. The FAH requests that CMS consider the impact that initiatives such as maternal health quality initiatives and maternity hospital designation, as well as the FY 2023 CMS solicitation for comments for conditions represented by low volumes within the MS-DRG Structure.
    - MS-DRGs with C-section without sterilization (MS-DRGs 786-788) will maintain the three tiers; however, MS-DRGs with C-section with sterilization (MS-DRGs 783-785) will not maintain three tiers.
    - This is repeated with vaginal delivery as well (with sterilization MS-DRGS 796-798 vs. without MS-DRGs 805-807).
    - The majority of the obstetrical MS-DRGs that are proposed to be deleted are proposed to result in single tier MS-DRGs (e.g., MS-DRG 783-785 (C section with Sterilization), 796-8 (Vaginal Delivery with Sterilization), MS-DRGs 817-819 (Other Antepartum Dx with O.R. Procedure), and MS-DRGs 831-3 (Other Antepartum Dx without O.R. Procedure).
- CMS (re)evaluate the distribution of the 123 (prior year 96) revised MS-DRGs, which has risen from 54 to 63 surgical and 42 to 60 medical MS-DRGs to ensure the assigned weights are representative of resource consumption. The proposed impact of the redistribution appears to be higher in the surgical cases.
- CMS use good data to determine proposed changes to specific MS-DRG Classifications. Typically, CMS has required two years of good data to reassign MS-DRGs for new codes. The FAH recommends that CMS consider two years of good data be available for analysis prior to implementing a change of this degree. For example, consider a run out period through the end of FY 2024 for the MedPAR file to use for a FY 2026 rule.

II-D-13.b Proposed Changes to the MS-DRG Diagnosis Codes for FY 2022 – Overview of Comprehensive CC/MCC Analysis

The FAH appreciates the careful consideration of public comments that CMS received in response to the severity designation proposals in FY 2020 IPPS rulemaking. The FAH acknowledges that as a result, CMS did not finalize the proposed changes to the severity designations for the 1,492 ICD-10-CM diagnosis codes at that time.

Since the FY 2020 IPPS rulemaking on this topic, CMS has provided additional background related to the methodology utilized and clinical rationale applied across diagnostic categories that drove the FY 2020 IPPS proposals. In addition, CMS has provided opportunity for comment regarding the introduction of 9 new guiding principles for which continued feedback is solicited, as well as other possible ways to incorporate meaningful indicators of clinical severity which were finalized in FY 2021. CMS plans to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data, and the application of the 9 guiding principles, and plans to present the findings and proposals in future rulemaking.

In the FY 2022 IPPS/LTCH PPS Proposed Rule (86 FR 25175 through 25180), CMS requested comments on a potential change to the severity level designations for "unspecified" ICD-10-CM diagnosis codes. Specifically, CMS considered changing the severity level designation of "unspecified" diagnosis codes to a NonCC where there are other codes available in the code subcategory that further specify the anatomic site. In the FY 2022 final rule CMS maintained the severity level designation of the "unspecified" diagnosis codes currently designated as a CC or MCC where there are other codes available in the code subcategory that further specify the anatomic site. Instead for FY 2022, CMS finalized a new Medicare Code Editor (MCE) code edit for "unspecified" codes effective with discharges on and after April 1, 2022.

CMS believes it is not appropriate in FY2023 to propose any change to the designation of any ICD-10-CM codes, including the "unspecified" codes that are subject to the MCE code edit for "unspecified. The FAH supports CMS' decision to not move forward with any changes for severity related to "unspecified" diagnosis codes to allow time to gather data on this new edit.

The FAH urges CMS to allow one to two full years of data availability before proposing any additional changes. Having one to two full years of data will allow for meaningful analysis in future rule making. Prior to moving forward, the FAH requests that CMS provide data via Proposed Rule to promote data transparency and public comment related to the information collected as a result of the 4/1/22 MCE code edit for "unspecified". The information should contain by diagnosis code, the reason codes submitted on the claim (i.e., "UNABLE TO DET LAT 1" or "UNABLE TO DET LAT 2").

II-D-13.d Proposed Changes to the MS-DRG Diagnosis Codes for FY 2022 – Request for Information on Social Determinants of Health Diagnosis Codes

The FAH acknowledges that CMS' request for public comments on how the reporting of diagnosis codes in categories Z55-Z65 may improve our ability to recognize severity of illness, complexity of illness, and/or utilization of resources under the MS-DRGs. CMS requests comments on the following questions:

- How the reporting of certain Z codes – and if so, which Z codes – may improve CMS ability to recognize severity of illness, complexity of illness and utilization of resources under MS-DRGs?
- Whether CMS should require the reporting of certain Z codes – and if so, which ones – to be reported on hospital inpatient claims to strengthen data analysis?

- The additional provider burden and potential benefits of documenting and reporting of certain Z codes, including potential benefits to beneficiaries.
- Whether codes in the Z59 (Homelessness) have been underreported and if so, why".

The FAH believes that the answers to each of these questions have overlapping themes and highlight the need for transparent collaboration with stakeholders prior to any Z code requirement to address the ability to capture the data. CMS will need to address the lack of definitions, conflicting priorities with reporting due to insufficient data fields for reporting, lack of key designations to demonstrate the impact to the patient's health, as well as the need to provide time for education to providers and coders along with the burden of updating electronic health record/billing systems to facilitate the codes for consistent reporting.

CMS noted that social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality of life outcomes and risks. While SDOH do not describe current illnesses or injuries at the individual level, they are widely recognized as important potential predictors for risk for developing medical conditions. These subset of 96 diagnosis codes that describe SDOH are included with CMS table 6P.5a of the FY2023 Proposed Rule.

CMS noted that they have heard from stakeholders about a number of reasons for why there may be less routine documentation and reporting of SDOH in the inpatient setting. They included the Z codes are not required, do not affect MS-DRG assignment, consistent protocols may not be in place for documenting/reporting, patient's willingness to discuss personal social/economic/environmental conditions, reliability of documentation in medical records, and potential bias in screening as well as pressures on provider's time.

The FAH is committed to working with CMS on what must be a continuous and sustained effort to ensure health care equity nationwide. We commend CMS for reaching out to stakeholders and concur with CMS that the questions about determining impact of Z codes on the patient's health, severity, or complexity of illness as well as resource utilization should be explored. The FAH encourages CMS to continue considering an approach to improve health equity data that encompasses a combination of modes for intake (e.g., abstracted measure, ICD-10-CM SDOH Z code, assessment, quality measure, etc.) in a manner in which the most meaningful data may be effectively obtained.

We agree with CMS that there is uncertainty in the current data and that there are multiple contributing factors. CMS indicated they were uncertain if the data was impacted because of the public health emergency, reduced hospitalizations of certain conditions or if the conditions are underreported. The FAH recommends that CMS continue to work with key industry stakeholders to establish SDOH diagnosis consistency with identification, documentation, definitions, guidelines, as well as infrastructure to allow the data to be reported.

It is important to note that the SDOH coding guidelines which allowed documentation from non-providers, including other clinical providers as well as self-reported patient information, went into effect 10/1/21. Thus, this new coding guideline was not implemented nor

would be reflected in the table 6P.5a SDOH data. It is unlikely this new guideline would have substantially changed the code volumes but there could be some shift.

CMS seeks public comment on whether they should consider requiring a more robust documentation and claims data reporting. CMS also seeks public comment on developing protocols to standardize the screening for SDOH for all patients while recognizing the varied perspectives from different sized hospitals in both urban and rural settings. CMS is seeking comment on which SDOH codes are mostly likely to influence hospital care resource utilization related to inpatient care and believed homelessness was potential starting point for discussion. CMS provided data for Z59.0 (Homelessness) and acknowledged this subcategory was further expanded in FY 2022 and now includes {as of 10/1/22} Z59.00 (Homelessness, Unspecified), Z59.01 (Sheltered homelessness), and code Z59.02 (Unsheltered homelessness). In FY 2020 the Z59.0 diagnosis was proposed to change severity from NonCC to CC and received mostly supportive comments; however, it was maintained by CMS as NonCC.

The FAH encourages CMS to methodically approach the requirement for reporting SDOH codes. If the decision is to move forward with mandatory reporting, FAH recommends using homelessness as the required condition. Based on an incremental approach, the industry and CMS can further evaluate the challenges associated with reporting ICD-10 codes representing SDOH.

The FAH recognizes that there are some states that require reporting of homelessness with varied definitions. CMS must provide clear definition for homelessness and should work, where possible, to ensure the state reporting requirements align with the Medicare definition.

The FAH supports CMS' previous consideration that homelessness (Z59.00, Z59.01, and Z59.02) impacts the use of hospital resources and thus should be designated as a CC. The FAH agrees with CMS that homelessness involves a level of care more in line with diagnoses designated as CC. The diagnosis of homelessness does appear to have impact on patient's health and would impact hospital resource utilization. CMS provided data in FY 2020 and FY 2023 that mathematically support promoting this diagnosis to a CC. The FAH reviewed the total number of cases with any of the three homeless codes to determine the percent of cases within MS-DRGs in various tiers of MS-DRGs (i.e. MS-DRGs that recognize MCC or CC, MS-DRGs that are not impacted by MCC or CC, MS-DRGs that would be impacted with presence of MCC or CC). These data also seemed to support CMS' data that homelessness should be a CC.

The FAH strongly recommends that for consistent reporting of homelessness as well as other SDOH that clear definitions and documentation requirements be defined as well as infrastructure to support the new reporting requirement. The FAH has outlined key considerations that CMS will need to provide and/or address:

- Provide consistent definitions for those reporting the homelessness diagnoses to ensure consistency. For example, how should one consider someone that lives in a nomadic life in a van, such as that depicted in the film Nomadland? Would this be unsheltered homelessness (Z5902) or Inadequate housing (Z591), Housing Instability, housed with risk of homelessness (Z59.811)). CMS should work with other stakeholders to publish FAQs **PRIOR** to implementation of this requirement.

- Recognize that the requirement of the SDOH diagnosis codes would likely require changes to the institutional diagnosis code data fields with the electronic and paper billing forms. There would be a need to expand and/or prioritize the diagnoses that are reported within UB/5010 Claims Form as well as the MedPAR Data. Often, complex care requires reporting a significant number of diagnosis codes on the claim and it is not uncommon to use all the available fields. Currently only 25 diagnoses are captured on the 837i claim (UB04 electronic claim form) and 19 diagnoses on the paper bill.
- It would be necessary for providers to prioritize which codes will make it to the claim to ensure diagnoses needed for multiple programs are included (e.g. code designations such as Major Comorbidity or Complication (MCC), Comorbidity/Complication (CC) or Hospital Acquired Condition (HAC) with MS-DRGs or Risk Model versions of MS-DRG Risk Models code designations such as Hierarchical Condition Category (HCC), Risk of Mortality (ROM), Severity of Illness (SOI), or other quality programs such as ICR, HRRP, VBP, PSI, Maternity Designation, etc.).
- Provide guidance on handling discrepancies in the provided information. It is not uncommon for responses to differ based on who captured the information or the timeframe. This can be impacted by the patient's willingness to discuss and provide private information related to their personal living conditions. For example, the patient or family may provide different information to social worker versus a nurse or treating physician which results in conflicting documentation. Responses may also be collected with various intake forms that ask about homelessness in last twelve months and the patient may answer "yes" as they were homeless the first six months but not the most recent six months.
- Consider multiple intake options for SDOH in addition to ICD-10-CM SDOH Z codes such as abstracted measure, or some other reporting measure especially when there are broad definitions to consider within the documentation.
- Provide instructions to MACs that there will be certain circumstances when a claim that includes a homelessness diagnosis code may also include a patient "address" and that these claims should not be rejected nor denied. There have been instances reported where payers are denying claims with homelessness included as a diagnosis on the claim form when an address has been provided. Homeless patients often provided an address that may be from a shelter, may be for mail only, a family member's address, or even a false address.
- CMS should reinforce the Official Coding Guidelines that allow source documentation for SDOH code to be based on non-provider documentation such as nursing staff or self-reported by the patient. The guidelines may require further revision for required reporting. Currently the Official Coding Guidelines indicate "Codes describing social determinants of health (SDOH) <u>should be assigned</u> when this information is documented. For social determinants of health, such as information found in categories Z55-Z65, persons with potential health hazards related to socioeconomic and psychosocial circumstances, code assignment <u>may be</u> based on medical record documentation from clinicians involved in the care of the patient who are not the patient's provider since this information represents social information, rather than medical diagnoses".
    - If homelessness was a required code for reporting, electronic medical record systems would need to be updated to capture this information. For example, nursing intake forms would need to be updated once clear definitions are

available, such as the difference between sheltered and unsheltered. In addition, computerized coding systems may have to be re-programed to look at documentation beyond physician documentation to capture the homeless diagnosis and the associated specificity. Providers and coders would need to be educated on the required additional documentation that would be necessary to support the diagnosis of the various types of homelessness.

We again urge CMS to start with an incremental approach to reporting SDOH Z-codes. A requirement to report one code category, e.g., homelessness, could assist in determining provider burden, system impact and unintended consequences. If CMS were to require the reporting of all SDOH Z codes, there would be tremendous operational and technology impacts. The requirement of these additional SDOH diagnoses will impact the operating systems with electronic health record, computer assisted coding for facilities, providers and payers. The requirement also impacts hospital staff with additional resources for training, documentation, productivity, and consistent reporting. It is common that patients have more than one SDOH. For example, if a patient is homeless, it is logical they may have other SDOH diagnoses such as food instability, unemployment, and/or social isolation.

The FAH suggests CMS evaluate the impact to items such as core measures or HAC with the use of SDOH codes. For example, when there is a diagnosis of homelessness along with HAC diagnosis such as decubitus, should the patient be excluded from the HAC or other PSI program? The FAH recommends that CMS consider a study to determine potential impact to cases when there is an ICD-10-CM diagnosis code for homelessness captured along with HAC diagnosis. The insight from such an assessment would assist in determining if homelessness would meet an exclusion or inclusion criteria for measures.

In conclusion, the FAH appreciates CMS request for comments on reporting of SDOH ICD-10 codes. As mentioned previously, we urge CMS to be methodical and thoughtful as they consider this reporting. For example, determine what items need to be proactively addressed prior to making any of the reporting of SDOH codes a requirement. Additionally, this should be an incremental approach by starting with only one select category, specifically homelessness. In conjunction with the requirement, CMS should designate homelessness as a CC which will appropriately reimburse providers and capitalize on the MS-DRG logic that the condition will be captured on the claim form to gain the incremental benefit of furthering data collection on health equity and disparities.

Also, FAH reiterates that required reporting of SDOH beyond homelessness to other SDOH codes should not be contemplated at this time. This should be considered only after making data available for review and comment. There are many items that require further definition and clarification before CMS' vision for improved reporting of SDOH for use by CMS can move forward. For future consideration, each of the 96 SDOH diagnosis codes should be considered on the merit of the individual diagnosis as opposed to grouping all SDOH codes together for consideration.

II-D-19.an Other Policy Issues – Comment Solicitation on Possible Mechanisms to Address Rare Disease and Conditions Represented by Low Volumes within MS-DRG Structure

CMS is requesting information on mechanisms in which rare diseases and conditions with low patient volumes in the claims data may be addressed. CMS provided examples and acknowledged that the MS-DRG system is a system of averages. The examples demonstrated situations that looked at best care setting, best reimbursement, high cost of medication with rare diseases and low maternity volume within Medicare population. CMS noted that obstetrics and newborn patients are not high volume in the Medicare data and CMS generally advises that other payers should develop DRGs to address the needs of their patients. CMS explained that MS-DRGs are intended to group together diseases and procedures with similar clinical characteristics and/or resources. The rare diseases and conditions with low volumes are a unique challenge to this methodology with the small subsets of population. CMS acknowledged it has been difficult for MS-DRG determination noting concern that basing MS-DRG reclassification decisions on small numbers of cases can lead to complexities in determining relative weights due to the impact several expensive cases could have. Higher volumes within a MS-DRG provides greater stability and predictability for annual updates. CMS also requested comments on meaningful ways to potentially improve access to treatment for postpartum depression in certain populations.

The FAH acknowledges the impact rare and low volume data can have on the MS-DRG classification system. In general, there is potential to capture the rare disease or treatment with a coding classification system (e.g., ICD-10-CM, ICD-10-PCS, HCPCS, etc.) for data analysis. The FAH requests that CMS provide data analysis within the rule making process that outlines data transparency on any specific proposals within future rule making. It is probable that there is not one solution that works with all rare disease or low volume conditions. The FAH believes there are multiple options that can be considered to capture appropriate reimbursement for rare disease and low volume mimicking current infrastructure within MS-DRGs (e.g., outlier, NTAP, MS-DRG structure change, etc.) or consideration of other publicly available databases to supplement the MedPAR data with low volume. Examples of MS-DRG structure to reflect with and without rare disease/low volume could be similar to how MS-DRGs currently recognize with or without a diagnosis or procedure that may not necessarily have a designation as MCC, CC, or Recognized OR. (e.g., MS-DRG 64-5 impacted by TPA use, MS-DRGs 280-5 impacted by discharge disposition, MS-DRGs 463-5 or 570-2 or 622-4 or 901-3 impacted by site of debridement or diagnosis, etc.)

II.E. Recalibration of the FY 2023 MS-DRG Relative Weights

II.E.2.d. Proposed Cap for Relative Weight Reductions

In past years, CMS has selectively limited reductions in the relative weight for specific MS-DRGs in order to facilitate payment stability. These policies were adopted as one-time measures in response to concerns raised in the public comments about large reductions in specific MS-DRGs. For FY 2022, CMS considered the comments on prior rulemaking as part of proposing a broader policy to limit reductions in relative weights.

CMS cites its statutory authority under sections 1886(d)(4)(B) and (C) and 1886(d)(5)(I)(i) of the Act to propose a permanent 10 percent annual cap on the reduction in a MS-DRG's relative weight beginning with FY 2023. CMS proposes to adopt this policy budget neutral consistent with section 1886(d)(4)(C)(iii) of the Act, which requires changes to the relative weights not increase or decrease aggregate payments.

While CMS considered reduction limits of 20 percent and 5 percent, it proposed the 10 percent cap to mitigate the financial impact resulting from significant fluctuations in the relative weights, particularly for low volume MS-DRGs, without the larger budget neutrality adjustment associated with a smaller cap. The proposed policy would affect 27 MS-DRGs, based on the FY 2021 claims data used for this Proposed Rule.

The Federation appreciates CMS' interest in payment stability. However, we believe it is premature for CMS to adopt a permanent cap annually on the reduction in any MS-DRG's relative weight. **The Federation supports a limitation of a 10 percent drop in an MS-DRG's relative weight only for FY 2023 and urges CMS to apply this policy without a budget neutral offset**. There are special circumstances with the calculation of the FY 2023 MS-DRG relative weights that support having a 10 percent cap on reductions in an MS-DRG's relative weight for one year only.

First, CMS used FY 2019 utilization to set the MS-DRG relative weights for FY 2022 when it normally would have used FY 2020 utilization. CMS adopted this Federation supported policy because of concerns that the FY 2020 utilization was atypical as a result of COVID-19 and using FY 2020 utilization would have a material effect on the MS-DRG relative weights. Now that CMS proposes using FY 2021 utilization to set the FY 2023 relative weights, CMS is skipping overuse of FY 2020 utilization and moving ahead two years instead of a single year as it would normally to set the MS-DRG relative weights. Moving ahead two years to set the MS-DRG relative weights is creating more instability in the relative weights than would normally be expected. Evidence of this instability can be found in the large change to the normalization factor between the FY 2022 final rule and the FY 2023 Proposed Rule—1.82029 to 1.947540—a much larger increase than is typical (for instance, the change from FY 2019 to FY 2020 was 1.761195 to 1.789031).

Second, CMS itself acknowledges the special circumstance of transitioning from using utilization where COVID-19 is more common in FY 2021 than it expects will be the case in FY 2023. As CMS believes there will be fewer COVID-19 cases in FY 2023 than FY 2021, CMS is proposing to determine the relative weight for the MS-DRGs where COVID cases are grouped by averaging the relative weights calculated with and without COVID-19 cases. By averaging the relative weights, CMS believes the result will reflect a more accurate estimate of the relative resource use for the cases treated in FY 2023 than if no special adjustment were made. The same argument would apply to the limitation on reductions to the MS-DRG relative weight. As COVID-19 is more common in the FY 2021 utilization than we expect it will be in the FY 2023, we support applying the special one-time limitation on reductions to an MS-DRG relative weight. However, as COVID-19 becomes more endemic in the population and less severe and common in hospitals over time, Medicare utilization can be expected to return to its former level

of annually stability negating the need for any permanent cap on reductions to MS-DRG relative weights.

F. Add-On Payments for New Services and Technologies for FY2023

8. Proposed Use of National Drug Codes (NDCs) to Identify Cases Involving Use of Therapeutic Agents approved for New Technology Add On Payment

In the FY 2016 IPPS/LTCH final rule (80 FR 49434 through 49435), as part of the transition to the ICD-10-CM and ICD-10-PCS coding system from ICD-9-CM, CMS established the use of "Section "X" New Technology codes. These ICD-10-PCS classifications were to identify new technologies or procedures that have historically not been captured through ICD-9-CM codes to more precisely describe information on a specific procedure or technology found within other sections of ICD-10-PCS. CMS noted they continued to receive comments in opposition to the continued creation of the new ICD-10-PCS (e.g., Section X) procedure codes for the purpose of administering the new technology add-on payment for drugs and biologics. Within the ICD-10 Coordination & Maintenance Committee Meetings the public comments stated that the ICD-10-PCS classification system was not intended to represent unique drugs/therapeutic agents and is not appropriate code section for this purpose.

This proposal creates an inconsistent approach to add-on payment for new technology. Currently, add-on payment for new technology is determined based on the presence of ICD-10-PCS code on the inpatient claim. This proposal bifurcates and un-necessarily requires two standards for devices and drugs. The FAH recommends that the current reporting of ICD-10-PCS code remain the current approach until further evaluation is conducted.

The FAH recommends that CMS convene a technical expert panel (TEP) consisting of various industry experts, including but not limited to pharmacy, revenue cycle, coding, to evaluate the issue, explore potential options, and submit a recommendation to be included in an upcoming IPPS Proposed Rule.

CMS noted that the majority of stakeholders that have commented with alternative suggestions supported the use of National Drug Codes (NDCs), because it would avoid creating duplicate codes within the ICD-10-PCS and NDC to identify the same technology/product and allow for predictive and efficient coding. Other suggestions noted by CMS included 3EO Administration Table within ICD-10-PCS code set and RxNorm. All of these, plus other options such as the HCPCS code set or a revision to the process that allows the ICD-10-PCS code to be pending assignment until the finalization of the add on payment determination, should be explored by the TEP and presented in an upcoming Proposed Rule.

Should CMS move forward with requiring NDC codes for drug add on payments, the following items must be considered and addressed prior to implementation:

- Reporting Location on the UB – There is not a unique field on the UB for only the NDC number(s). The current Medicare Claims Processing Manual indicates that box 43 may be used; however, this is a shared field. This field includes the following: Revenue code description, investigational device exemption (IDE) number, or NDC Number.

- Sustainability for the NDC Number – The FDA will run out of NDC numbers within the next 15 years. The FDA may need to adjust the NDC number format or expand the field length.
- Multiple NDC Numbers for One Drug Product Dose – The drug manufacturer and the NDC assign NDC numbers with one being a 10 digit code and the other being an 11 digit code. Additionally, if the drug has different strengths, there would be a separate NDC for each. Each NDC number would have to be reported on a separate line with the same date of service.
- Complexity of Information Transfer – The drug manufacturer put the 10 digit NDC numbers format on the drug product package and/or in the bar code. The 5010 Standard requires the 11 digit NDC number format be used for billing on the claim. The conversion process from 10 to 11 digits can be complex depending on the level of information that is shared. NDC numbers have three segments. Converting the NDCs from a 10 digit to an 11 digit form requires placing the zero in the correct location based on the 10 digit format. For a 10 digit NDC in the 4-4-2 format, add a 0 in the 1st position. For a 10 digit NDC in the 5-3-2 format, add a 0 in the 6th position. For a 10 digit NDC in the 5-4-1 format, add a 0 in the 10th position. Complexities in converting the 10 to 11 digit NDCs could lead to confusion when trying to reconstitute the NDC back to its FDA standard (e.g. 12345-0678-09 (11 digits) could be 12345-678-09 or 12345-0678-9 depending on the firm's configuration).
- If at any time, the code for the drug would be considered with the MS-DRG, such as we see with CAR-T-Cell, the NDC currently does not have an option for use within the MS-DRG grouping process. It is possible for conditions, such as these, the ICD-10-PCS code may still be necessary for the drug.

WAGE INDEX

III.G.4 Continuation of the Low Wage Index Hospital Policy

The FAH supports CMS' proposal to continue its low wage index hospital policy. Under this policy, which was first adopted in FY 2020, CMS has temporarily increased the hospital wage index values below the 25th percentile by half of the difference between the hospital's wage index value and the 25th percentile wage index value. CMS has indicated its intent for these policies to remain in place for four years to account for the minimum four-year lag between the hospital cost reporting year (FY 2020) where wages are paid and the federal fiscal year (FY 2024) that is used to determine the wage index.[2] Consistent with this intent, in the Proposed Rule, CMS proposes to continue these policies for FY 2023.

The FAH applauds CMS' continued efforts to resolve the negative feedback loop the wage index creates for low wage hospitals and strongly supports CMS addressing this critical problem that disproportionately impacts rural hospitals by continuing its policy to increase the wage index values of low wage index hospitals.

[2] 87 Fed. Reg. at 28,369.

As CMS observed when first adopting the low wage index hospital policy, the wage index has created a "downward spiral" whereby low wage index hospitals receive lower reimbursement, which decreases their ability to invest in recruiting and retaining employees, which then further depresses reimbursement. This negative feedback loop has a particularly detrimental effect on rural hospitals, and a disproportionate number of low wage index hospitals have traditionally been rural hospitals.

Rural hospitals play a critical role in ensuring access to care for the approximately 60 million Americans that live in rural areas across the United States.[3] Dependence on rural hospitals is particularly acute for Medicare beneficiaries—approximately one out of every four Medicare beneficiaries live in rural areas and depend on rural hospitals for care.[4] Because Medicare beneficiaries disproportionately rely on rural providers to access care, Medicare reimbursement tends to have a greater influence on rural hospitals' revenue as compared to non-rural hospitals.

The wage index, however, has only aggravated the financial problems for many rural hospitals, impeding their ability to invest in recruiting and retaining employees. As a result, Medicare beneficiaries continue to encounter in rural areas what CMS has described as "a stretched and diminishing rural workforce,"[5] a problem which has only been exacerbated as rural hospitals continue to face workforce shortages and facility closures due to the impact of COVID-19.[6]

The FAH appreciates CMS' much needed efforts to continue addressing the acute problems that rural hospitals face. CMS policy must ultimately ensure that Medicare reimbursement formulas do not operate to magnify the stress on the rural health delivery system and contribute to access issues for Medicare beneficiaries living in rural areas. Thus, the FAH supports CMS' proposal to continue its policy of increasing the wage index values for hospitals with a wage index value in the lowest quartile of the wage index values across all hospitals. Continuation of this policy would help those hospitals that have been most severely impacted by the wage index's negative feedback loop to make much needed investments in their labor forces.

The FAH urges CMS to remove the FY 2023 Proposed Rule's continuation of a budget neutrality adjustment to the IPPS standardized amounts, as we believe such budget neutral adjustments are neither required nor authorized by Congress.

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[3] *See* U.S. Census Bureau, "One in Five Americans Live in Rural Areas" (last rev. Oct. 8, 2021). Available at: https://www.census.gov/library/stories/2017/08/rural-america.html.

[4] CMS, Improving Health in Rural Communities: FY 2021 Year in Review, 9 (Nov. 2021).

[5] CMS, Rural Health Strategy, 2 (May 8, 2018); *See* CMS, Improving Health in Rural Communities: FY 2021 Year in Review, 1 (Nov. 2021).

[6] *See* CMS, Improving Health in Rural Communities: FY 2021 Year in Review, 1 (Nov. 2021) (noting that rural hospitals with thin operating margins have been particularly vulnerable to the impacts of COVID-19, resulting from practitioner shortages and facility closures).

In the FY 2020 IPPS final rule, CMS invokes 42 U.S.C. § 1395ww(d)(3)(E) and its exceptions and adjustments authority under § 1395ww(d)(5)(I)(i) as the basis for raising low wage index values.[7] CMS made this policy budget neutral for FY 2020 through 2022 and proposes to continue budget neutral implementation in FY 2023 through a 0.1795 precent budget neutrality adjustment.

If CMS could adopt this policy under 42 U.S.C. § 1395ww(d)(3)(E), budget neutrality would be required. However, subsection (d)(3)(E) requires the wage index to reflect "the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level."[8] Although CMS has and is proposing to intervene to override the result produced by 42 U.S.C. § 1395ww(d)(3)(E) for sound policy reasons, it can only do so to the extent that another provision of the Medicare Act provides the necessary statutory authority. For this reason, CMS originally cited the exceptions and adjustments authority under 42 U.S.C. § 1395ww(d)(5)(I)(i) as an alternative statutory basis for its low wage index hospital policy.[9]

Subsection (d)(5)(I), however, restricts the Secretary's authority to adopt budget neutrality adjustments to only adjustments for transfer cases, and budget neutrality is neither required nor authorized in other circumstances. Clause (i) of § 1395ww(d)(5)(I) authorizes the Secretary to "provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate." No budget neutrality authority is included under this clause. Rather, Congress adopted clause (ii) at CMS' express request in order to provide limited authority for a budget neutrality adjustment only when CMS makes an adjustment under clause (i) for transfer cases. This clause states:

> In making adjustments under clause (i) for transfer cases . . . the Secretary may make adjustments...to assure that the aggregate payments made under this subsection for such fiscal year are not greater or lesser than those that would have otherwise been made in such fiscal year.

Because the statute explicitly restricts the Secretary's authority to adopt budget neutrality adjustments in connection with adjustments for transfer cases, budget neutrality is neither required nor authorized in other circumstances. Moreover, it is also worth noting that where Congress has amended § 1395ww(d)(3)(E) to mitigate the impact of the wage index on certain low wage index hospitals (clause (ii)) and hospitals in frontier states (clause (iii)), it has expressly done so in a non-budget neutral manner, instructing CMS to disregard the impact of clauses (ii) and (iii) in developing any budget neutrality adjustment under subsection (d)(3)(E)(i). This legislative history indicates that, contrary to CMS' assertion in the FY 2020 IPPS final rule,[10] it is inappropriate to mitigate the wage index's impact on low wage index hospitals in a budget neutral manner. For this reason, CMS' low wage index hospital policy may properly be

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[7] 84 Fed. Reg. 42,044, 42,329 (Aug. 16, 2019).

[8] *See Bridgeport Hospital, et. al. v. Becerra*, No. 1:20-cv-01574, at *9 (D.D.C. Mar. 2, 2022).

[9] 84 Fed. Reg. 19,158, 19,396 (May 3, 2019)

[10] 84 Fed. Reg. 42,331 (Aug. 16, 2019) ("[W]e would consider it inappropriate to use the wage index to increase or decrease overall IPPS spending.").

adopted as an adjustment under 42 U.S.C. § 1395ww(d)(5)(I)(i), but may not be implemented in a budget neutral manner. Accordingly, the FAH urges CMS to remove the Proposed Rule's budget neutrality adjustment to the IPPS standardized amounts for the low wage index hospital policy.

Beyond the CMS low-wage policy to assist rural hospitals, the FAH supports the Save Rural Hospitals Act of 2021, which would establish a wage index floor of 0.85 in a non-budget neutral manner, and urges CMS' support. This legislation would provide stability to low wage index hospitals, fostering long-term planning and investing in recruiting and retaining staff in low wage index markets without eroding Medicare to other hospitals.

III.N. and Addendum V.B.5 Permanent Cap on Wage Index Decreases (42 C.F.R. § 412.64(h)(7) and 42 C.F.R. § 412.525(c)(1))

The FAH strongly supports the proposal to permanently cap wage index decreases for subsection (d) hospitals and LTCHs at 5 percent as set forth in proposed 42 C.F.R. § 412.64(h)(7) and § 412.525(c)(1), but urges CMS to apply the permanent cap in a non-budget neutral manner. Like other commenters, the FAH has urged CMS to make a permanent 5 percent maximum reduction policy to protect hospitals from large year-to-year variations in wage index values, and the FAH appreciates CMS' response to this recommendation in the Proposed Rule. A policy that ensures each hospital's wage index will not be less than 95 percent of its final wage index for the prior fiscal year appropriately promotes predictability for hospitals as they budget and plan their operations and mitigates instability in IPPS and LTCH PPS payments that might otherwise result from significant wage index decreases. As noted in the Proposed Rule, recent years have demonstrated factors beyond a hospital's control—from changes in wage index policies and the COVID-19 PHE—may result in unpredictable fluctuations in wage index values in the absence of a cap. Rather than adopting transition policies each year when policies or circumstances make such fluctuations more likely, it is sensible and appropriate to simply make the cap permanent so that hospitals can more accurately plan their operations and budgeting.

This policy is particularly important as hospitals continue to budget for an uncertain future amidst the ongoing volatility of the COVID-19 PHE, including the PHE's extraordinarily variable impact on hospital wage levels between hospitals and over time. In addition, once the PHE ends, hospitals expect that the ramifications of the PHE will continue to be felt for some time as PHE-impacted data is used to set the wage index in future fiscal years, making it appropriate to insulate hospitals from significant wage index reductions indefinitely. For example, hospitals that are now incurring extraordinary labor costs due to record inflation, wage increases, and increased reliance on expensive contract and traveling agency nurses[11] due to

[11] At the same time that market conditions and the PHE increased hospital reliance on traveling agency nurses, the rates charged by staffing companies have drastically increased. Between 2019 and 2022, the hourly rate charged to hospitals for travel nurses increased by 213 percent, and expenses for contract travel nurses went from 4.7 percent to 38.6 percent of the median hospital's total nurse labor expenses. *See* American Hospital Association, Massive Growth in Expenses and Rising Inflation Fuel Continued Financial Challenges for America's Hospitals and Health Systems, p.3 (Apr. 2022). These rate hikes have fueled exorbitant growth in the revenues of staffing firms, some tripling their revenues and net incomes in just one year. *Id.* at 4.

workforce departures and COVID-19 surges may have previously seen depressed labor costs due to layoffs and pay reductions due to the significant drop in inpatient and outpatient volumes at other points in the PHE. The FAH continues to support robust stakeholder engagement in preparing for the data challenges that the pandemic will pose in post-pandemic years, but at this time, the proposed permanent cap would provide needed assurance that wage index reductions will be avoided or limited.

For similar reasons, the FAH urges CMS to adopt the proposed permanent cap on wage index decreases in a non-budget neutral manner. Although CMS has previously used its exceptions and adjustments authority under 42 U.S.C. § 1395ww(d)(5)(I)(i) to budget neutralize transition wage index policies, the statute neither authorizes nor requires budget neutrality, as explained further above in the context of the low wage index hospital policy.[12] Moreover, even if CMS' adjustment authority authorizes budget neutrality adjustments, such an adjustment is not appropriate to fund a policy that is designed to address factors beyond hospitals' control, including the extraordinary nationwide impact of a PHE on subsection (d) hospitals and LTCHs. A budget neutrality adjustment, on the other hand, would put undue financial pressure on hospitals that do not benefit from the permanent cap in a given year (including hospitals that have been and continue to experience wage index increases due to record inflation and the extraordinary impact of the pandemic on hospital and LTCH wage levels in their labor markets). The FAH strongly recommends, therefore, that CMS not apply budget neutrality to offset the costs of a permanent 5-percent cap on any reductions to their wage index values in FY 2023 and thereafter.

Finally, we note that CMS is not proposing to apply the stop-loss for a new hospital in an area where the stop-loss would otherwise apply. Although we understand the rationale for this approach, we are concerned that this will create an unnecessary inequity in Medicare payments for hospitals in the same market and we would encourage CMS to apply the same area wage index value for new and existing hospitals under this policy.

DISPROPORTIONATE SHARE HOSPITAL PAYMENTS

IV.D.2. Calculation of Factor 2 for FY 2023

The FAH is concerned that the calculation of Factor 2 significantly underestimates expected contractions in Medicaid and Marketplace enrollment that will precipitate a growing uninsured rate over FY 2023 and urges CMS to adjust estimates to fully capture the impact of the anticipated conclusion of the PHE and expiration of expanded Marketplace subsidies on the uninsured rate. Factor 2 of the UC DSH calculation adjusts Factor 1 for the change in the number of uninsured individuals in the United States since 2013, the last year before the ACA's coverage expansion. The higher the uninsured rate, the larger the aggregate dollar amount of UC DSH payments that are distributed to IPPS hospitals under Factor

[12] Likewise, CMS' authority to adopt appropriate adjustments to the LTCH PPS under section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. 106-554, does not require budget neutral implementation of the proposed cap on wage index decreases for LTCHs.

3. Because Factor 2 turns exclusively on the uninsured rate, it is critical that CMS' estimate accurately accounts for significant factors that are expected to fuel the uninsured rate. For FY 2023, OACT estimates the uninsured rate as 9.2 percent, a 1.1% increase over the projections of the uninsured rate CMS used for FY 2022. The 2013 uninsured rate is calculated at 14 percent. Based on this difference, OACT estimates that Factor 2 is equal to 0.6571. When multiplied by Factor 1 ($9.949 billion), proposed Factor 2 produces a UC DSH pool of only $6.583 billion. This amount would mark the smallest UC DSH pool over the past six years. The proposed reduction to aggregate UC DSH payments fails to adequately account for the anticipated significant loss of coverage with the scheduled expiration of the public health emergency, producing a depressed uninsured rate that does not capture the projected outlook for 2023.

Factor 2 is determined using estimates of the uninsured from the National Health Expenditure Accounts (NHEA). NHEA projections "are constructed using a current-law framework" and do not "attempt to speculate on possible deviations from current law."[13] Importantly, NHEA's analysis assumes that the PHE ends in 2022 and does not continue into 2023.[14] The PHE due to COVID was most recently renewed effective April 16, 2022, and will expire on July 15, 2022 if not renewed. By the time rulemaking is complete for FY 2023, it is expected that the PHE will have been renewed for another 90 days and will be set to expire on October 13, 2022.[15] Consistent with NHEA's approach, these comments do not attempt to address the impact of any further extensions of the PHE that might postdate the final rule.

The NHEA projects that the insurance rate writ large will "peak in 2022 at 91.1%" mainly due to the growth in Medicaid enrollment before the conclusion of the PHE. As NHEA acknowledges, the significant growth in Medicaid enrollment in recent years has been significantly fueled by the maintenance of eligibility requirements that states must satisfy through the end of the month in which the PHE ends in order to receive increased Federal medical assistance percentage (FMAP) under the Families First Coronavirus Response Act.[16] In light of this requirement, NHEA projects "rising expected growth in [Medicaid] enrollment of

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[13]NHEA, Projections of National Health Expenditures and Health Insurance Enrollment: Methodology and Model Specifications, p.1 (Mar. 28, 2022), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf.

[14] National Health Expenditure Projections 2021–30: Growth to Moderate as COVID-19 Impacts Wane, p.2 (Mar. 28, 2022), https://www.cms.gov/files/document/national-health-expenditure-projections-2021-30-growth-moderate-covid-19-impacts-wane.pdf.

[15] The Secretary has committed to providing "60 days' notice prior to termination" of the PHE. Sec'y, Ltr. to Governors on the COVID-19 Response (Jan., 21, 2021), *at* https://aspr.hhs.gov/legal/PHE/Pages/Letter-to-Governors-on-the-COVID-19-Response.aspx. Because no notice has been provided to date, it is anticipated that the PHE will be renewed rather than being allowed to expire on July 15, 2022.

[16] Families First Coronavirus Response Act § 6008(b)(3), Pub. L. 117-127, 134 Stat. 177, 208-09 (2020).

8.2 percent" in 2021,[17] followed by a 0.9 percent reduction in enrollment in 2022.[18] "In 2023, Medicaid enrollment is projected to drop significantly (by 2.6 million, or 3.2 percent) as states are expected to continue to proactively trim their enrollments."[19] Ultimately, this projection indicates Medicaid enrollment of 78.9 million in 2023, an increase in 6.6 million compared to Medicaid enrollment prior to the PHE in 2019 (72.3 million).[20]

The FAH is concerned that the NHEA's projections vastly understate the impact of the maintenance of eligibility requirements on Medicaid enrollment and the expected decline in late 2022 and 2023 following the end of the PHE. A recent analysis by Kaiser Family Foundation (KFF) estimates that baseline growth in Medicaid enrollment accounts for approximately 3.5 million enrollees, while 18.7 million enrollees are attributable to the maintenance of effort requirements.[21] These estimates are based in part on modeling actual 2018 data under a maintenance-of-effort scenario to distinguish between baseline growth and growth due to the maintenance of effort requirement.[22] Based on these observations, the KFF analysis projects an enrollment decline of between 5 and 13 percent in 2023 (5.3 million to 14.2 million enrollees).[23] This significantly exceeds the relatively modest 3.2 percent contraction projected by NHEA. Consistent with the KFF projections, last year the Urban Institute analyzed the anticipated impact

[17] National Health Expenditure Projections 2021-2030: Forecast Summary, p.3, https://www.cms.gov/files/document/nhe-projections-forecast-summary.pdf; National Health Expenditure Projections 2021–30: Growth to Moderate as COVID-19 Impacts Wane, p.9 (Mar. 28, 2022), https://www.cms.gov/files/document/national-health-expenditure-projections-2021-30-growth-moderate-covid-19-impacts-wane.pdf.

[18] National Health Expenditure Projections 2021-2030: Forecast Summary, p.3, https://www.cms.gov/files/document/nhe-projections-forecast-summary.pdf; National Health Expenditure Projections 2021–30: Growth to Moderate as COVID-19 Impacts Wane, p.9 (Mar. 28, 2022), https://www.cms.gov/files/document/national-health-expenditure-projections-2021-30-growth-moderate-covid-19-impacts-wane.pdf.

[19] National Health Expenditure Projections 2021-2030: Forecast Summary, https://www.cms.gov/files/document/nhe-projections-forecast-summary.pdf.

[20] NHE Projections, Table 17, Health Insurance Enrollment and Enrollment Growth Rates, https://www.cms.gov/files/zip/nhe-projections-tables.zip.

[21] Elizabeth Williams, Robin Rudowitz, Bradley Corallo, Fiscal and Enrollment Implications of Medicaid Continuous Coverage Requirement During and After the PHE Ends (May 10, 2022), https://www.kff.org/medicaid/issue-brief/fiscal-and-enrollment-implications-of-medicaid-continuous-coverage-requirement-during-and-after-the-phe-ends/.

[22] Bradley Corallo, Robin Rudowitz, and Jennifer Tolbert, Unwinding the PHE: What We Can Learn From Pre-Pandemic Enrollment Patterns (May 10, 2022), https://www.kff.org/medicaid/issue-brief/unwinding-the-phe-what-we-can-learn-from-pre-pandemic-enrollment-patterns/.

[23] Elizabeth Williams, Robin Rudowitz, Bradley Corallo, Fiscal and Enrollment Implications of Medicaid Continuous Coverage Requirement During and After the PHE Ends (May 10, 2022), https://www.kff.org/medicaid/issue-brief/fiscal-and-enrollment-implications-of-medicaid-continuous-coverage-requirement-during-and-after-the-phe-ends/.

of a late-2021 end to the PHE, concluding a significant loss of coverage (15 million) in the year following the end of the PHE.[24]

At the same time that Medicaid enrollment is expected to markedly shrink, the premiums for coverage on the individual market are expected to significantly increase. The American Rescue Plan Act (ARPA) temporarily expanded premium assistance for eligible individuals purchasing Marketplace coverage in 2021 and 2022.[25] A recent analysis of by the Assistant Secretary for Planning and Evaluation (ASPE) projects that 3 million people would become uninsured if the ARPA subsidies expire pursuant to current law.[26] This loss of insurance will include both those who lose access to the expanded subsidies under ARPA and those unsubsidized enrollees that will lose coverage due to the resulting increase in Marketplace premiums.[27] In contrast, NHEA only projects a 0.6 million reduction in direct purchase private health insurance, which includes Marketplace and non-Marketplace coverage.[28] The expiration of ARPA premium assistance and resulting increases in Marketplace premiums of approximately 53 percent[29] also complicates the viability of Marketplace coverage for the subset of individuals that lose their Medicaid benefits following the end of the PHE and seek to take advantage of other coverage options.

All of these factors make significant increases in the uninsured rate well beyond OACT's estimates in the Proposed Rule a certainty that must be accounted for by OACT in Factor 2 of the UC DSH determination. The FAH strongly urges OACT to broaden its data sources to more fully reflect current estimates of the uninsured rate in FY 2023 in light of the profound impact of the unwinding of the PHE and the expiration of the enhanced subsidies under ARPA. These estimates have significant impacts on the UC DSH funding available to support critical hospital services to the uninsured and underinsured. For example, even acknowledging an additional 1.0 percentage point of additional growth in the uninsured rate in CY 2023 (approximately 3.3 additional uninsured individuals, which would reflect a conservative projection considering the

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[24] Matthew Buettgens, Andrew Green, What Will Happen to Unprecedented High Medicaid Enrollment after the Public Health Emergency? (Sep. 2021), https://www.urban.org/sites/default/files/publication/104785/what-will-happen-to-unprecedented-high-medicaid-enrollment-after-the-public-health-emergency_0.pdf.

[25] American Rescue Plan Act of 2021 § 9661, Pub. L. 117-2, 135 Stat. 4 (amending IRC §36B(b)(3)(A)).

[26] ASPE, Projected Coverage and Subsidy Impacts If the American Rescue Plan's Marketplace Provisions Sunset in 2023 (Mar. 23, 2022), https://aspe.hhs.gov/sites/default/files/documents/1647ad29528ee85a48d6ffa9e7bfbc8f/arp-ptc-sunset-impacts-03-22-22%20Final.pdf.

[27] *Id.* at 4.

[28] NHE Projections, Table 17, Health Insurance Enrollment and Enrollment Growth Rates, https://www.cms.gov/files/zip/nhe-projections-tables.zip.

[29] Cynthia Cox and Krutika Amin, For ACA Enrollees, How Much Premiums Rise Next Year is Mostly up to Congress (May 18, 2022), https://www.kff.org/policy-watch/for-aca-enrollees-how-much-premiums-rise-next-year-is-mostly-up-to-congress/.

studies described above), would increase the proposed UC DSH pool by approximately $569 million above CMS' proposal.

IV.D.3(e) Methodology for Calculating Factor 3 for FY 2023 and Subsequent Fiscal Years (42 C.F.R. § 412.106(g)(1)(iii)(C)(10))

The FAH commends CMS for its efforts over the past several years to: 1) better define the costs of uncompensated care, in particular by including the cost of uninsured discounts into the definition of charity care for Worksheet S-10 ("WS S-10") purposes to be consistent with ACA section 3133's mandate; 2) better define the terms of its instructions to providers for the preparation of Worksheet S-10 so that costs are more accurately and consistently reported by hospitals; 3) allow providers to amend their Worksheet S-10s to comply with CMS's revised instructions; and 4) develop, engage in, and improve an audit process aimed at more accurately allocating and disbursing UC-DSH payments to providers. Given the relative weights Factor 3 assigns to hospitals, the FAH appreciates CMS' efforts over recent fiscal years to rigorously audit all hospitals' reported data to ensure hospitals are reporting costs consistently and accurately so that the audited Worksheet S-10 data better captures reliable, relative differences in hospitals' uncompensated care levels, and eligible hospitals receive their fair share of the UC-DSH pool.

The FAH also supports CMS' proposal to use the average of the audited FY 2018 and audited FY 2019 Worksheet S-10 data for purposes of calculating Factor 3 in FY 2023 and to use, in subsequent fiscal years, a three-year average spanning the three most recent fiscal years for which audited data are available. Following the extensive FY 2018 audits, Worksheet S-10 audits are becoming more uniform, allowing CMS to again blend multiple years of data in allocating UC-DSH funds. Doing so promotes predictability and minimizes volatility in UC-DSH payments.

Finally, the FAH notes with approval that CMS appears to be using the latest available data in determining UC-DSH eligibility. The Proposed Rule uses the December 2021 HCRIS extract and indicates CMS' intent to use the March 2022 update of HCRIS to calculate Factor 3 for the final rule. The use of the latest available data is critical to the proper allocation of UC-DSH payments, and the FAH encourages CMS to use the latest available data that becomes available prior to the development of the final rule.

IV.D.3(d) Per Discharge Amount of Interim Uncompensated Care Payments

The FAH urges CMS to reconsider its exclusion of FY 2020 data from the calculation of the per-discharge amount used to make interim UC-DSH payments and to instead use an average of the two most recent years of discharge data. Hospitals generally receive interim UC-DSH payments on a per-discharge basis, and the amount of these payments is calculated by dividing the hospital's total UC-DSH payments by the historical 3-year average

of discharges.[30] For FY 2022, CMS modified this calculation to be based on an average of FY 2018 and FY 2019 based on the "belief that computing a 3-year average with the FY 2020 discharge would underestimate discharges, due to the decrease in discharges during the COVID-19 pandemic."[31] Since that time, CMS and stakeholders have had additional time to assess actual discharge trends. With more recent data and experience, it appears that the FY 2022 methodology *significantly overstated* hospital discharges in FY 2022. This can be seen by comparing the ratios in the discharges column used for Factor 1 in the Proposed Rule against the corresponding discharge ratios in the FY 2022 Final Rule—more current data produces a discharge ratio of 0.947 rather than 1.013 for FY 2021 and 1.007 rather than 1.059 for FY 2022.[32] Based on current data, it appears that the FY 2022 discharge methodology overstates discharges nationally by approximately 18%, and this overestimation depresses interim UC-DSH payments, producing cash flow issues for hospitals. Inadequate interim payments compromise the UC DSH program's effectiveness in supporting hospital care for uninsured and underinsured patients, particularly in the midst of the PHE due to COVID and record inflation, labor shortages, and supply chain shortages that have severely disrupted hospital budgeting and operations.

The FAH is concerned that CMS' proposal to use discharge data from FY 2018, FY 2019, and FY 2021 for purposes of determining hospitals' per-discharge amounts in FY 2023 will likewise significantly overstate expected discharges and depress interim UC-DSH payments. Starting with total IPPS claims for FY 2019 based on the FY 2022 Final Rule impact file data (8,938,506 cases) and using the Factor 1 discharge ratios in the Proposed Rule and the FY 2019 data from the FY 2022 Final Rule and the Proposed Rule's Factor 1 discharge ratios for FY 2020, FY 2021, FY 2022, and FY 2023, the projected IPPS cases in FY 2023 would be 7,421,181. Similarly, starting from FY 2021 cases (7,203,511) as reported in the FY 2023 impact file and using the Proposed Rule's Factor 1 discharge ratios for FY 2022 and FY 2023 would produce a projected 7,326,475 cases in FY 2023. Both of these numbers are significantly lower than the average of FY 2018, FY 2019, and FY 2021 data (8,360,937 cases). In fact, it appears that the proposed methodology would likely overstate discharges by 11.2 to 12.4 percent for FY 2023. Using the average of the three most recent years of data (FY 2019, FY 2020, and FY 2021) would similarly overstate discharges by 6.5 to 7.7% based on this methodology to approximate projected FY 2023 discharges.[33] **Rather, based on our efforts to validate the reliability of different discharge data, it appears that using the average of the two most recent years of**

[30] Some hospitals may receive a lower amount through a voluntary process where documentation demonstrates that there would likely be a significant recoupment at cost report settlement if the per-discharge amount is not lowered. 87 Fed. Reg. at 28,395.

[31] 87 Fed. Reg. at 28,395.

[32] *Compare* 87 Fed. Reg. at 28,384 (discharge ratios for FY 2021 and FY 2022 in the Proposed Rule) *with* 86 Fed. Reg. at 45,228 (discharge ratios for FY 2021 and FY 2022 in the FY 2023 Final Rule).

[33] We also modeled using a two-year average of FY 2019 and FY 2021, but this overstated projected discharges by 8.1 to 9.2 percent under these methodologies.

data (FY 2020 and FY 2021) produces the most plausible and verifiable projection of FY 2023 discharges (only overstating discharges by between 0.3 and 1.6 percent).[34]

IV.F. Counting Days Associated With Section 1115 Demonstrations in the Medicare DSH Medicaid Fraction

The FAH again opposes CMS' proposal to limit section 1115 patient days that hospitals may include in the Medicaid fraction of their Medicare DSH calculations. As the commenters explained in response to a similar proposal in the FY 2022 IPPS Proposed Rule,[35] CMS lacks the statutory authority to exclude section 1115 demonstration days from the DSH calculation once CMS has approved the applicable section 1115 demonstration. Limiting section 1115 waiver days in the DSH calculation as proposed conflicts with the Medicare Act, the congressionally ratified existing regulations, and recent court decisions. Moreover, the Proposed Rule fails to adequately consider the burden of the proposal on hospitals or its financial impacts.

In this Proposed Rule, despite having reviewed the significant comments of the FAH and other stakeholders strongly opposing CMS' FY 2022 proposal, CMS proposes a largely similar and equally problematic regulatory change. The Proposed Rule again proposes to amend 42 C.F.R. § 412.106(b)(4) to pick and choose amongst the range of section 1115 demonstration projects under which patients will be "regarded as" eligible for medical assistance. In particular, the proposal would exclude from the numerator of the Medicaid fraction (i) patients whose care was provided through an uncompensated care pool demonstration approved under section 1115, (ii) patients who are provided—through a 1115 demonstration—health insurance that fails to provide for essential health benefits ("EHBs"), and (iii) patients who received premium assistance under a section 1115 demonstration that accounted for less than 90 percent of the cost of the patient's health insurance or was used to purchase health insurance that does not provide EHBs.[36] This proposal, like the FY 2022 proposal, continues to advance a false interpretation that only section 1115 days where patients received inpatient care through health insurance can be included in the Medicaid fraction.

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[34] We note that, to the extent that a hospital documents that this methodology would understate their projected FY 2023 discharges, they could make use of CMS' process to request a lower per discharge interim UC-DSH payment.

[35] In the FY 2022 IPPS Proposed Rule, CMS proposed to amend 42 C.F.R. § 412.106(b)(4) so that a patient day associated with a section 1115 demonstration may only be included in the Medicaid fraction of the DSH adjustment if the patient "*directly receives inpatient hospital insurance coverage on that day under a waiver authorized under section 1115(a)(2) of the Act*, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver." 86 Fed. Reg. 25,070, 25,695 (May 10, 2021), proposing revision to 42 C.F.R. § 412.106(b)(4)(i) and deletion of 42 C.F.R. § 412.106(b)(4)(ii)(emphasis added). In the FY 2022 IPPS Final Rule, CMS stated it would not move forward with its FY 2022 IPPS Proposed Rule amending 42 C.F.R. § 412.106(b)(4) and would revisit the issue of section 1115 demonstration days in future rulemaking. 86 Fed. Reg. 73,416, 73,418 (Dec. 27, 2021).

[36] 87 Fed. Reg. at 28,400-02, 28,645-46, proposing revisions to 42 C.F.R. § 412.106(b)(4).

These minor alterations show that the FY 2023 IPPS Proposed Rule fails to respond to the vast majority of the comments the FAH and others presented in their comments to the FY 2022 IPPS Proposed Rule. **In particular, CMS fails to address the fact that once CMS approves a section 1115 demonstration, CMS cannot thereafter change course and exclude patient days under that section 1115 demonstration from the DSH calculation.** CMS does not acknowledge or address these important reliance interests, despite commenters bringing them to CMS' attention during the FFY 2022 IPPS rulemaking.

Furthermore, CMS' rationale for including days of patients who receive premium assistance through certain section 1115 demonstrations but not others appear arbitrary. Among patients who receive premium assistance through an approved demonstration, CMS proposes to only include those whose premium assistance accounted for 90 percent or more of the cost of the patient's health insurance and was used to purchase health insurance that provides EHBs. CMS continues to wrongly contend that "regarded as eligible" for Medicaid only "includes patients who receive health insurance through a section 1115 demonstration where state expenditures to provide the insurance may be matched with funds from Title XIX."[37] However, if the issue is whether the section 1115 demonstration provides health insurance or not, *then it should not matter whether the section 1115 demonstration covers at least 90 percent of the premium costs*. Likewise, it should not matter whether the health insurance purchased with premium assistances provides EHBs. Instead, under CMS' logic, it should only matter that the section 1115 demonstration provides inpatient coverage to patients. But what CMS is asking for is more—the section 1115 premium assistance demonstration not only has to provide health insurance, but it also must be used to fund at least 90 percent of EHB-level coverage. This logical inconsistency shows that CMS is cherry picking section 1115 demonstrations and arbitrarily tacking on requirements where there should be none.

Neither the plain language of the Medicare DSH statute nor the plain language of the applicable regulations permit CMS to limit the section 1115 patient days that may be counted in the Medicaid fraction of Medicare DSH payment adjustment to waiver days where patients are provided with health insurance. Courts that have considered CMS' recent attempts to limit the section 1115 waiver days counted in the Medicaid fraction in this manner have found CMS' limitations unlawful.[38] In addition, CMS' proposal to limit section 1115 waiver days that may be counted to days where the section 1115 demonstration directly provides EHB coverage or, in certain cases, provides premium assistance runs afoul of the purpose of both the Medicare DSH payment statute (where the counting of Medicaid days serves only as a proxy for capturing the relatively higher costs associated with providing services to low-income patients), and the section 1115 demonstration waivers, which by their very nature are experimental and differ from traditional Medicaid insurance. Finally, the proposed 42 C.F.R. § 412.106(b)(4) would inappropriately reduce hospitals' capacity to provide needed care to low-income populations, after hospitals have legitimately relied on CMS' section 1115 waiver approval. **Therefore, the**

[37] 87 Fed. Reg. at 28,400.

[38] *Bethesda Health, Inc. v. Azar*, 389 F. Supp. 3d 32 (D.D.C. 2019), *aff'd*, 980 F.3d 121 (D.C. Cir. 2020); *Forrest Gen. Hosp. v. Azar*, 926 F.3d 221 (5th Cir. 2019); *HealthAlliance Hosps., Inc. v. Azar,* 346 F. Supp. 3d 43 (D.D.C. 2018).

FAH once again urges CMS to abandon the proposed amendment to 42 C.F.R. § 412.106(b)(4).

(1) CMS' proposed amendment to 42 C.F.R. § 412.106(b)(4) conflicts with the plain language of the Medicare DSH statute.

CMS' proposed amendment to 42 C.F.R. § 412.106(b)(4) conflicts with the plain text the Medicare DSH statute. The Medicare DSH statute provides for "an additional payment amount for each subsection (d) hospital which serves a significantly disproportionate number of low-income patients."[39] Congress enacted the Medicare DSH adjustment in recognition of the relatively higher costs associated with providing inpatient services to low-income patients, who are disproportionately sicker than other hospital patients. In establishing the statutory calculation methodology for Medicare DSH, Congress used entitlement to Supplemental Security Income ("SSI") and eligibility for Medicaid programs as proxies for capturing the low-income patients a hospital serves on an inpatient basis.

In order to compute the Medicaid fraction of the Medicare DSH calculation, the calculation *must* include in the numerator patients who are "eligible for medical assistance under [the Medicaid] State plan." 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II). But the Secretary may also include "patients *not so eligible* but who are *regarded as such* because they receive benefits under" a section 1115 waiver. *Id.* (emphasis added). In other words, Congress authorizes CMS to "regard[]" patients as Medicaid eligible for purposes of the Medicare DSH calculation as long as they "receive benefits under" an approved section 1115 waiver program.[40] The statutory text does not require patients covered under section 1115 waivers to enroll in a health insurance plan in order to be "regarded as such" under the Medicare DSH statute's Medicaid fraction computation.

CMS states it does not believe the statute gives the Secretary "blanket authority to count in the Medicaid fraction any patients who is any way related to a section 1115 demonstration."[41] In particular, CMS believes that the Medicare Act *does not permit* the agency to include in the Medicaid fraction patient days under a section 1115 waiver that is an uncompensated care pool. This interpretation of the statute has already been rejected by two Federal courts. In the *Bethesda Health* case, which rejected CMS' exclusion of uncompensated care pool patient days from the Medicare DSH calculation, the D.C. District Court concluded: "The government's proposed interpretation would informally add new and limiting phrases to a statute that is already clear when unadorned."[42] Likewise, the Fifth Circuit in *Forrest General Hospital* interpreted the Medicare DSH statute to expressly authorize 1115 waiver uncompensated care pool patients as being eligible for Medicaid for Medicare DSH purposes: "[T]he statute means that patients who

[39] 42 U.S.C. § 1395ww(d)(5)(F)(i)(I).

[40] *See Forrest Gen*. *Hosp.*, 926 F.3d at 228–29.

[41] 87 Fed. Reg. at 28,400.

[42] *Bethesda Health*, 389 F. Supp. 3d at 47 (citing *Forrest Gen. Hosp.,* 926 F.3d at 229, and *Benefit,* Black's Law Dictionary (11th ed. 2019) (defining "benefit" as the "the helpful or useful effect something has")).

aren't actually Medicaid-eligible still count towards the Medicaid fraction's numerator if they're considered or accounted to be capable of receiving a demonstration project's helpful or useful effects by reason of a demonstration project's authority. There's only one plausible way to read this."[43]

Despite this clear judicial precedent, the Proposed Rule advances statutory interpretations that the D.C. Circuit and 5th Circuit have rejected. For example, the Proposed Rule asserts:

> our authority under section 1886(d)(5)(F)(vi) of the Act *remains limited to including the days of expansion groups*—those for whom a state seeks Federal Medicaid matching funds in order to provide health insurance to individuals through a demonstration that is comparable to Medicaid state plan benefits—that is, patients who 'are regarded as' 'eligible for medical assistance under a State plan approved under title XIX.'[44]

No such limitation is found in the statute, and the courts interpreting section 1886(d)(5)(F)(vi) have concluded that CMS cannot "add new and limiting phrases to a statute that is already clear when unadorned."[45] Moreover, despite the fact that both *Forrest General Hospital* and *Bethesda Health* concluded that uncompensated care pool patient days under an approved 1115 demonstration cannot properly be excluded from the numerator of the Medicaid fraction, the Proposed Rule states that "it cannot reasonably be argued that patients associated with uncompensated care for which hospitals are reimbursed through section 1115 demonstration-authorized funding pools may be 'regarded as' eligible for Medicaid."[46] The Proposed Rule goes on to contend that CMS is statutorily prohibited from doing what the courts have said is statutorily required, saying: "Accordingly, we do not interpret the statute as *authorizing* the Secretary to 'regard as' Medicaid eligible patients with uncompensated care costs for which a hospital is reimbursed by a section 1115 demonstration-authorized uncompensated care funding pool."[47]

The Proposed Rule also repeatedly invokes secretarial discretion that the courts have held that he plainly lacks. For example, as an alternative ground for his proposal to exclude section 1115 demonstration days associated with uncompensated care pools, the Proposed Rule asserts as follows:

> "Even if the statute could be read to permit patient groups whose uncompensated care is paid for from a section 1115 demonstration-authorized funding pool to be 'regarded as' eligible for Medicaid (which the Secretary does not agree the statute

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[43] *Forrest Gen. Hosp.*, 926 F.3d at 229.

[44] 87 Fed. Reg. at 28,400 (emphasis added). In a similar vein, CMS expresses its continued belief that, "in order for days associated with section 1115 demonstrations to be counted in the numerator of the Medicaid fraction, the statute requires those days to be of patients who can be 'regarded as' eligible for Medicaid." *Id.*

[45] *Bethesda Health*, 389 F. Supp. 3d at 47; *Forrest Gen. Hosp.,* 926 F.3d at 229.

[46] 87 Fed. Reg. at 28,401.

[47] *Id*. at 28,402 (emphasis added).

> permits) . . . we are proposing to use our discretion under section 1886(d)(5)(F)(vi) of the Act to exclude from the Medicaid fraction the days of patients whose care costs may be reimbursed to the hospitals through uncompensated/undercompensated care pools.[48]

The Proposed Rule likewise claims that the Secretary has the discretion to "include only the days of patients . . . who receive health insurance through a section 1115 demonstration that provides" EHBs and to include "only those days of patients who have bought health insurance that provides EHB using premium assistance obtained through a section 1115 demonstration that is equal to at least 90 percent of the cost of the health insurance."[49] These assertions of discretion run directly contrary to the only plausible reading of the statute as identified in *Forrest General Hospital* and *Bethesda Health*: the numerator of the Medicaid fraction reflects inpatient days for patients not eligible for Medicaid "if they're considered or accounted to be capable of receiving a demonstration project's helpful or useful effects by reason of a demonstration project's authority."[50]

The proposed amendment to 42 C.F.R. § 412.106(b)(4) is also contrary to law insofar as it would permit the exclusion of section 1115 days *after* CMS has already approved a section 1115 waiver. **Notably, CMS does not provide any explanation as to why it could be appropriate to apply such an exclusion to demonstration projects previously approved by CMS, despite court decisions and stakeholder comments indicating that such a reversal in policy is inappropriate and unlawful.** The Medicare DSH statute allows the Secretary to include in the Medicaid fraction "patient days of patients not so eligible [for medical assistance under a State plan] but who are regarded as such because they receive benefits under a demonstration project approved under subchapter XI."[51] Once the Secretary approves a section 1115 waiver, the Secretary cannot thereafter change course and exclude those section 1115 demonstration days from the DSH calculation. Courts reviewing the statutory provision and CMS' existing implementing regulation have held similarly. In *Forrest General Hospital*, 926 F.3d at 233, the Fifth Circuit held that once "the Secretary authorizes a demonstration project, no take-backs. The statutory discretion isn't discretion to exclude populations that the Secretary has already authorized and approved for a given period; it's discretion to authorize the inclusion of those populations in the first place." Similarly, in *Bethesda Health*, 389 F. Supp. 3d at 52,[52] the D.C. District Court held that the Secretary must exercise his discretion *prospectively*, not "after a demonstration project has already been fully approved and implemented and the bill comes due." The statute and case law make it clear that CMS cannot exclude section 1115 patient days under existing, CMS-approved demonstration projects from the Medicare DSH calculation. Therefore, CMS should decline to finalize the proposed amendment to 42 C.F.R. § 412.106(b)(4), but at a

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[48] *Id*. at 28,401.

[49] *Id*. at 28,400, 28,401.

[50] *Forrest Gen. Hosp.,* 926 F.3d at 229; *Bethesda Health*, 389 F. Supp. 3d at 47 (quoting *Forrest Gen. Hosp.,* 926 F.3d at 229).

[51] 42 U.S.C. § 1395ww(d)(5)(F)(i)(I).

[52] The D.C. Circuit adopted the D.C. District Court's opinion as the "law of this circuit." *Bethesda Health, Inc. v. Azar*, 980 F.3d 121, 123 (D.C. Cir. 2020).

minimum must confine any such amendment to patient days under section 1115 waivers approved on or after the effective date of such an amendment.

In its Proposed Rule, CMS fails to acknowledge this statutory authority and proceeds under the mistaken assertion that the courts found CMS' exclusion of section 1115 waiver days unlawful *only* under the plain language of CMS' currently applicable *regulations*.[53] CMS highlights three recent cases, including the above-referenced *Forrest General Hospital* and *Bethesda Health*, and states only that courts have decided cases "interpreting the current language of the *regulation* at § 412.106(b)(4) . . .."[54] According to CMS, "these courts have concluded that if a hospital received payment for otherwise uncompensated inpatient hospital treatment of a patient, that patient is 'eligible for inpatient hospital services' within the meaning of the current regulation."[55] **However, as explained above, the courts in both *Forrest General Hospital* and *Bethesda Health* also held that the Medicare Act itself bars the Secretary from excluding section 1115 days for inpatient hospital services once the Secretary approves the section 1115 waiver.** Not only does the Proposed Rule ignore this precedent, but CMS asserts in the Proposed Rule that the statute actually *requires* many key aspects of the agency's proposal, despite clear and final judgments confirming that the plain text of the statute plainly does not so require. Therefore, simply amending the regulation at 42 C.F.R. § 412.106(b)(4) will not allow CMS to exclude section 1115 demonstration days from the DSH calculation once the Secretary approves a section 1115 waiver, and CMS' proposal to do so violates the plain language of the Medicare Act.

(2) CMS' proposed amendment is inconsistent with the purpose of the Medicare DSH statute and the purposes of section 1115 waiver programs

The proposed regulatory amendment would reduce hospitals' ability to serve indigent populations, directly contravening the purpose of the Medicare DSH statute. As discussed, Congress enacted the DSH adjustment to provide additional Medicare reimbursement to hospitals for the increased cost of providing services to their low-income patients. *See* 42 U.S.C. § 1395ww(d)(5)(F)(i)(I). The statutory mandate setting forth the Medicaid fraction computation similarly focuses on including days of patients eligible for medical assistance under a State plan or regarded as eligible for medical assistance under a State plan "because they receive benefits under a demonstration [waiver]." 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II). CMS, however, proposes excluding inpatient days under approved 1115 waivers for uncompensated care pool patients and certain premium assistance patients. The former assertion is divorced from the Medicare DSH statute's language and purpose, and the latter is unsupported by evidence or the terms of any approved demonstration program.

Instead of supporting the purpose of the DSH payment adjustment, CMS states in the Proposed Rule that "[w]hile these [uncompensated care] pools may result in hospitals receiving some payment for inpatient hospital services they provide to uninsured or underinsured individuals, such payments are not a form of health insurance and do not entitle any particular

[53] 87 Fed. Reg. at 28,400.

[54] *Id*. (emphasis added).

[55] *Id.*

individual to any specific benefit."[56] But distinguishing whether a section 1115 waiver directly provides for hospital *insurance coverage* is not the purpose of the DSH payment or the Medicaid fraction. The purpose of the DSH payment is to provide "an additional payment amount for each subsection (d) hospital which serves a significantly disproportionate number of low-income patients," 42 U.S.C. § 1395ww(d)(5)(F)(i)(I), and the statute uses Medicaid or section 1115 waiver days as a readily available proxy for low-income patient days, 42 U.S.C. § 1395ww(d)(5)(F)(vi). The statute, in plain terms, defines when a patient is "regarded" as eligible for medical assistance—the patient is "regarded as such" if he or she receives benefits under a section 1115 waiver, and nothing in 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II) requires medical assistance through health insurance. Moreover, the Medicaid Act sets forth precisely the categories that qualify as "medical assistance," and enrollment in a health insurance plan is not one of them. Inpatient care—which can be provided through an uncompensated care pool, premium assistance, or health insurance—is one of those categories, and each of the remaining thirty categories of medical assistance is a type of medical care. 42 U.S.C. § 1396d(a).

CMS argues that populations eligible for care under the uncompensated care pools may be "quite distinct" from groups who are eligible for Medicaid.[57] But CMS provides no support for that improbable statement, and in fact it appears far more likely that uncompensated care pools in non-expansion states serve a patient population that would be covered as part of the Medicaid expansion population in another state. Moreover, the Proposed Rule does not even provide an explanation as to the ways in which these groups may be distinct (*e.g.*, household income, health status) or the relevance of those potential distinctions to the Medicare DSH calculation. In the end, any differences between those receiving benefits under a CMS-approved demonstration project and those eligible for Medicaid is irrelevant to the question of whether a patient is "regarded as" eligible for Medicaid in the statutory framework, and the Proposed Rule provides no explanation as to why any potential distinctions could be relevant to the purposes of the DSH statute.

(3) The Proposed Rule fails to account for the significant financial impacts and burdens of CMS' proposed policy.

Finally, the Proposed Rule does not account for – let alone consider – any of the potential financial implications and burdens on hospitals by excluding these section 1115 days. CMS claims that the proposed change is "not estimable" because the agency lacks "information on the number of section 1115 days by hospital, which would be required to make an estimate."[58] Yet, in conjunction with appealing this issue, many of the adversely affected hospitals have submitted to the Secretary's Provider Reimbursement Review Board estimates of the financial impact of excluding section 1115 days for numerous cost reporting periods, along with numerous hospitals who have estimated the financial impact in protesting the issue on their cost reports submitted to the agency. Critical data elements regarding the financial impacts of this proposal are thus within the agency's possession but unavailable to commenters. In addition, the D.C. Circuit and the Fifth Circuit both noted that the exclusion of uncompensated care pool patient days from the

[56] 87 Fed. Reg. at 28,401.

[57] *See id*.

[58] 87 Fed. Reg. at 28,713.

Medicaid fraction would significantly reduce hospitals' DSH payments and thus have an adverse financial impact on hospitals across the United States, a point that was echoed and in the significant objections raised by hospitals in response to CMS' proposed amendment for FY 2022. The significant financial impact of CMS' proposal on hospitals is a critical policy consideration, and the agency cannot merely disclaim the ability to estimate the impacts and proceed to adopt such a policy. If CMS needs additional time to meet its legal obligations to consider this important aspect of its proposed policy, it should at a minimum withdraw this proposal until such analysis can be completed and provided to stakeholders for comment.

The proposed policy would also place the burden on hospitals to determine 1) which patients receive health insurance through a section 1115 demonstration, 2) whether a section 1115 demonstration patient's coverage provides EHBs, and, 3) whether a patient receiving premium assistance under a section 1115 demonstration has sufficient assistance to fund at least 90 percent of the premium cost. It is unclear how hospitals would obtain this data, and the Proposed Rule provides no guidance or discussion of the operational feasibility of doing so. Adding to this burden, because the proposal would change the rules for counting patient days at the start of the FY, hospitals would be faced with the even more complicated task of counting patient days differently for those portions of their cost reporting period that fall within FY 2022 and those that fall within FY 2023. Pursuant to section 3506(c)(1)(A)(iv) of the Paperwork Reduction Act ("PRA"), CMS is required to review "a specific, objectively supported estimate of burden" associated with proposed collections of information. But the burden estimates set forth in the Proposed Rule do not address the burden associated with this proposed 1115 demonstration days proposal.[59] Here, CMS has neither asked for comments on the additional collection burden on hospitals, nor offered any burden estimate as required under the PRA.

In light of the foregoing concerns, the FAH urges CMS to abandon the proposed amendment to 42 C.F.R. § 412.106(b)(4), retaining the existing regulation that properly uses CMS' approval of a section 1115 demonstration as a sufficient basis for inclusion of the associated patient days in the numerator of the Medicaid fraction.

V.A.1 Proposed FY 2023 Inpatient Hospital Update and VIII.C.2 Proposed FY 2023 LTCH PPS Standard Federal Payment Rate

CMS proposes a market basket update of only 3.1 percent for FY 2023, which, like the FY 2022 market basket update of 2.7 percent, seriously understates the unprecedented inflationary environment hospitals and health systems are experiencing. This woefully inadequate market basket update is a product of CMS's reliance on historical data to forecast FY 2023 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, recent data suggests that the market basket for FY 2022 is trending toward a 4.0 percent increase over FY 2021 (well in excess of the 2.7 percent market basket update for FY 2022) and that the FY 2021 market basket update also failed to capture inflationary trends.

[59] 87 Fed. Reg. at 28,627-44.

In addition, CMS proposed reducing the inadequate proposed market basket update with a 0.4 percentage point productivity adjustment to calculate the applicable percentage increase. This productivity adjustment is inappropriate in that it contemplates improbable and overstated gains in productivity. In fact, the latest data actually indicates *productivity losses* rather than gains.[60]

In light of the foregoing, the FAH urges CMS to adjust its market basket update methodology to adjust for more recent data and trends that are not captured in the proposal and would not even be fully captured in IHS Global Insight, Inc.'s (IGI) updated market basket forecast in the second quarter of 2022. In addition, in the context of inflationary and other economic pressures that are simply unprecedented since the implementation of the IPPS, the FAH urges CMS to use its "exceptions and adjustments" authority under subsection (d)(5)(I) to 1) adopt a further adjustment that reflects the extent to which the FY 2022 market basket update understated the rapidly rising costs of goods and services and 2) adopt a further 0.4 percentage point adjustment that fully offsets the FY 2023 productivity adjustment, reflecting the inappropriateness of a negative productivity adjustment at a time when hospitals are facing productivity losses during a pandemic that has created exceptional financial pressures that jeopardize our health care delivery system generally and hospitals in particular.

The FAH also urges CMS to address the inadequacy of the proposed LTCH PPS Standard Federal Rate for FY 2023. Relying on historical data without methodological adjustments to account for profound inflationary forces, as we have recommended for the IPPS update, will produce in an inadequate LTCH market basket update, compounding the erosion of rates due to inadequate market basket updates in FY 2021 and FY 2022.

Background

Under section 1886 of the Act, CMS is required to update hospital rates based on the based on the estimated percentage "by which the cost of the mix of goods and services . . . comprising routine, ancillary, and special care unit inpatient hospital services" for the FY "will exceed the cost of such mix of goods and services for the preceding" FY,[61] subject to the productivity adjustment and further adjustments for hospitals that fail to submit quality information and/or are not meaningful EHR users.[62] CMS is proposing to use a hospital market basket of 3.1 percent to update inpatient hospital rates for FY 2023. This market basket is based on the forecast of CMS' contractor, IHS Global Insight, Inc. (IGI). IGI's fourth quarter 2021 forecast (with historical data through the third quarter of 2021) for the hospital market basket is 3.1 percent. IGI's fourth quarter 2021 forecast of total factor productivity is 0.4 percent.

The Proposed Rule indicates that CMS' forecast of the FY 2023 hospital market basket and the offset for productivity will be updated if more recent data becomes available before the

[60] U.S. Bureau of Labor Statistics. (May 5, 2022). Productivity and Costs, First Quarter 2022, Preliminary - 2022 Q01 Results. https://www.bls.gov/news.release/pdf/prod2.pdf.

[61] Social Security Act § 1886(b)(3)(B)(iii).

[62] *Id.* at § 1886(b)(3)(B)(i)(XX), (vii), (ix), (xi).

final rule. If CMS follows past practice, this will mean that the FY 2023 final rule update will be based IGI's second quarter 2022 forecast of the FY 2023 hospital market basket with historical data through the first quarter of 2022. **The FAH strongly urges CMS to use later data on the market basket increase for FY 2023 as it has in past years and to further adjust its estimate to appropriately capture significant inflationary trends that will further fuel rising hospital operating costs but may not yet be fully captured in IGI's second quarter 2022 forecast.** Upward pressure on hospitals costs that has been occurring throughout the pandemic and other global economic developments is not well represented using third quarter 2021 historical data. Later data will be far more likely to capture the accelerating rate of increase in costs that hospitals have experienced in recent months and are expected to continue in the upcoming year, particularly if CMS further adjusts its market basket estimate to better represent anticipated economic trends. Even the recent Congressional Budget Office (CBO) May 2022 Baseline Projections estimate a market basket increase that is 1.1 percentage points higher than proposed by CMS.[63] Later data will also recognize the most recent trends in economy-wide, private nonfarm business multifactor productivity.

The Projected Inflation Undergirding CMS' Proposed Market Basket Fail to Capture Actual Hospitals' Experience of Record Inflation

The FAH is concerned that the historical data upon which the proposed FY 2023 forecast of the market basket is based is less than the rate of increase that hospitals are experiencing. For instance, the National Hospital Flash Report shows that hospitals' total expenses and labor expenses per adjusted discharge increased 19 percent in calendar year (CY) 2020.[64] These increases far exceed the Office of the Actuary's (OACT) modest April 18, 2022, market basket figures of 2.0 percent (total expenses) and 2.4 percent (hospital compensation) for the same period. We recognize that National Hospital Flash Report figures are discharge-adjusted and may not be completely comparable to the fixed weight index and the proxy figures from Bureau of Labor Statistics' (BLS) Employment Cost Index (ECI) that CMS uses to determine the hospital market basket. Nevertheless, these figures also remain significantly lower than comparable projections reported by PINC AI™.[65] According to the PINC AI™ analysis, hospital labor rates alone increased 6.5 percent per hour for FY 2021 (these expenses account for 67.2 percent of the index), which was not captured by the mere 2.4 percent market basket update adopted for FY 2021. This PINC AI™ data on hourly hospital labor rates is directly comparable to the ECI data that CMS uses as proxies for the labor-related items in the hospital market basket. PINC AI's historical figures are also higher than those included in OACT's April 18, 2022, release. PINC AI's 6.5 percent figure compares to OACT's 2.7 percent for wages and salaries for all civilian workers in hospitals (53 percent of the market basket) and 3.0 percent for all other labor-related services (14.7 percent of the index).

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[63] CBO Baseline Projections, Medicare (May 2022), available at: https://www.cbo.gov/system/files/2022-05/51302-2022-05-medicare.pdf.

[64] KaufmanHall, National Hospital Flash Report, p.4 (Jan. 2021), https://www.kaufmanhall.com/sites/default/files/2021-01/nationalhospitalflashreport_jan.-2021_final.pdf.

[65] Premier, Inc. (PINC) AI™ Data: CMS Data Underestimates Hospital Labor Spending (Apr. 12, 2022), https://premierinc.com/newsroom/blog/pinc-ai-data-cms-data-underestimates-hospital-labor-spending.

PINC AI™'s figures further show rapidly accelerating labor costs increasing by approximately 4.6 percent between the third and fourth quarters of 2021 and an additional in 7.7 percent between the fourth quarter of 2021 and the first quarter of 2022 alone. These figures are reported directly from hospital payroll records and significantly exceed CMS' FY 2022 projection of a 3.6 percent increase in labor costs for the four quarters ending September 30, 2022.

Along similar lines, CMS' own data are now showing that the hospital updates for both FY 2021 and FY 2022 were less than the overall market basket figures that are included in CMS' April 18, 2022, data release. For FY 2021, CMS updated hospital rates by 2.4 percent, yet CMS' historical data indicate the market basket rate of increase was actually 0.6 percentage points higher than the market basket update. While FY 2022 data remains incomplete, current CMS projections show that the market basket increased at least 1.3 percentage points more than the FY 2022 market basket update (a current projection of 4.0 percent compared to the2.7 percent market basket update adopted by CMS). In sum, the actual market basket update hospitals received while they responded on the front lines to the COVID-19 pandemic, faced labor and supply shortages, and navigated record inflation was at least 1.9 percentage points below the actual rate of increase in these years.

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 pandemic, necessitating an outsized reliance on contract staff – particularly travel nurses – to meet patient demand. 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.[66] **We understand that the BLS' ECI only captures the salary increases associated with employed staff, and thus whole 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 PINC AI™, and 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.

In the attached analysis (Attachment A) for the FAH and the American Hospital Association, FTI Consulting likewise recognizes 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

[66] Massive Growth in Expenses and Rising Inflation Fuel Continued Financial Challenges for America's Hospitals and Health Systems, American Hospital Association, April 2022.

> 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.[67]

Given the discrepancy between external data sources on the increase in hospital labor costs and the BLS ECI historical data that IGI uses to forecast the FY 2023 market basket, **the FAH requests that CMS use external data sources in order to improve the accuracy of its estimate of the FY 2023 hospital market basket.** We believe the use of such external data (along with the use of the most recent data available at the time of final rulemaking) would result in a more accurate projection of the hospital market basket for FY 2023 and appropriately lessen the likelihood that the final FY 2023 IPPS market basket update will, for the third consecutive year, fall short of the actual hospital market basket for hospital goods and services.

Accounting for Understatement of Pandemic Market Baskets

Given the unprecedented nature of the pandemic and its extraordinary impact on hospital costs alongside record inflation, the FAH urges CMS to consider a one-time adjustment to ensure that the FY 2023 rate increase is applied to a base rate that more accurately incorporates actual inflation during the pandemic. This use of CMS' exceptions and adjustment authority under section 1886(d)(5)(I)(i) of the Social Security Act is appropriate to help mitigate the risk that the pandemic and global economic instability will jeopardize the viability of America's hospitals. Without such an adjustment, IPPS rates will fail to meet hospital costs, compounding the instability already produced by the COVID-19 pandemic. As we have noted above, the projected market basket used to update IPPS rates for FY 2021 and FY 2022 is a combined 1.9 percentage points below later information available on the actual rate of hospital cost inflation for these two years. The nature of the market basket update calculation precludes correcting for past understatements of market basket updates consistent with the IPPS being a prospective payment system. Nonetheless, section 1886(d)(5)(I)(i) authorizes the Secretary to "provide by regulation for such other exceptions and adjustments to such payment amounts under [subsection (d)] as the Secretary deems appropriate." The unique and unprecedented circumstances confronted by IPPS hospitals today warrant CMS' exercise of its exceptions and adjustments authority in the form of a one-time positive adjustment of no less than the amount by which the FY 2022 market basket update was understated.

Why Hospital Cost Inflation Can be Expected to Continue into FY 2023

The hospital market basket data OACT released on April 18, 2022, suggest that forecasted increases in the cost of hospital labor will be temporary during FY 2022 then decline for FY 2023. CMS shows the compensation portion of the market basket that accounts for 53.0 percent of the total as increasing from 2.7 percent for the four quarters ending with the third

[67] FTI Consulting, Report: Assessing the Adequacy of Proposed Updates to the Hospital Inpatient Prospective Payment System, page 4.

quarter of 2021 to a high of 3.9 percent for the four quarters ending with the second quarter of 2023 before beginning to decline again in subsequent quarters.

These projections, however, are inconsistent with a hospital-focused analysis of inflationary trends. Rather, the forecast should recognize that hospital inflation will lag general economy-wide inflation represented by the Consumer Price Index (CPI) as stated in the attached analysis by FTI Consulting:

> …significant changes in the CPI, which measures changes in prices paid by consumers, and the Producer Price Index (PPI), which tracks changes in price experienced by producers, can have a major impact on wage and salary expectations that can feed into future changes to the ECI. Higher inflation can create upward pressure on wage expectations as workers seek an increase in wages to better meet the increasing cost of living. This can be exacerbated when labor is in short supply, as is currently the case in the hospital sector.[68]

As FTI notes, the CPI was 8.6 percent for the 12-month period ending in May 2022.[69] This is a significantly higher rate of growth than is reflected in the market basket for inpatient services. FTI states that these more recent inflation pressures are likely to work their way into industry sectors where labor is short supply further driving up wages in future years.

FAH agrees with this analysis and further notes that economy-wide general inflation is expected to continue into the future. In a recent Senate Finance Committee hearing, U.S. Secretary of the Treasury Janet Yellen said she expected inflation to remain high and the Biden administration would likely increase the 4.7% inflation forecast for this year in its budget proposal. During this hearing, Secretary Yellen indicated that inflation was being fueled by high energy and food prices causes by Russia's war in Ukraine, a shift to goods purchases during the pandemic and by new COVID-19 variants and persistent supply chain disruptions[70] –factors that can be expected to continue to plague world-wide economies in the months to come.

The FAH requests that CMS recognize that hospital inflation will generally lag economy-wide inflation and that the expectations for sustained inflation should be recognized in the projection of the hospital market basket for FY 2023.

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[68] FTI Consulting, Report: Assessing the Adequacy of Proposed Updates to the Hospital Inpatient Prospective Payment System, page 5.

[69] *Id.* at 5, citing U.S. Bureau of Labor Statistics, Consumer Price Index Summary - 2022 M05 Results (June 10, 2022), https://www.bls.gov/news.release/cpi.nr0.htm.

[70] David Lawder & Anrea Shalal, Yellen says inflation to stay high, Biden likely to up forecast (June 8, 2022), https://www.reuters.com/markets/us/us-faces-unacceptable-levels-inflation-yellen-tells-senators-2022-06-07/.

Total Factor Productivity

Pursuant to section 1886(b)(3)(B)(xi)(II) of the Act, the Secretary to 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 offsets for economy wide total productivity is that the hospital sector should be able to realize the same productivity gains as the general economy. Even before the pandemic, however, OACT questioned the wisdom underlying this assumption. An OACT analysis from 2016 indicated:

> The most recent 10-year moving average growth of hospital MFP, ending in 2013, ranges from 0.1 percent to 0.5 percent, compared to 0.8 percent growth in private nonfarm business MFP. In addition, more recently published estimates of hospital productivity by other researchers seem to indicate that hospitals are unable to achieve the productivity gains of the general economy over the long run. In the 2015 Trustees Report, it was assumed that hospitals could achieve productivity gains of 0.4 percent per year over the long range; this growth rate is relative to the assumed growth in private nonfarm business MFP of 1.1 percent.[71]

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**.**

Another factor to consider during recent years is instability in the level of productivity improvements both economy-wide and specifically for hospitals resulting from the COVID-19 pandemic. While use of a 10-year moving average may be designed to improve stability of the offset when there in instability in the year-to-year productivity changes, it also has the effect minimizing the impact of lower productivity growth during a pandemic that is unprecedented in modern medicine. As noted by FTI, two of the periods of decreased productivity occurred during the COVID-19 pandemic – a 0.4 percent decline in July 2021 and a 0.6 percent decline in January 2022.[72] Yet these substantial declines that disproportionately impact hospitals are significantly discounted in a 10-year moving average**.**

It is possible that later data on productivity may result in a lower offset to the market basket making the offset less of an issue. As noted by FTI, hospital inpatient services have

[71] Paul Spitalnic, Steve Heffler, Bridget Dickensheets and Mollie Knight, Hospital Multifactor Productivity, An Updated Presentation of Two Methodologies, page 2 (Hospital Multifactor Productivity: An Updated Presentation of Two Methodologies (cms.gov))

[72] FTI Consulting, Report: Assessing the Adequacy of Proposed Updates to the Hospital Inpatient Prospective Payment System, page 8.

not recovered to pre-pandemic levels,[73] and it is highly unlikely that hospitals have achieved the significant productivity gains incorporated into the FY 2023 IPPS prospective rate adjustments. However, the same may be true of general economy-wide productivity. According to BLS, nonfarm business sector labor productivity decreased 7.3 percent in the first quarter of 2022.[74] The FAH requests that CMS use this later figure on economy-wide non-farm total factor productivity when determining the offset to the IPPS market basket for FY 2023. It is our hope that this later data on total factor productivity results in no offset needed to the IPPS market basket.

In the event that does not happen, the FAH believes that the highly unusual circumstances of the COVID-19 pandemic are sufficient reason for the Secretary to again invoke his section 1886(d)(5)(I)(i) "exceptions and adjustments" authority to provide a one-time adjustment that offsets application of the otherwise applicable productivity adjustment for FY 2023.

V.C. Low Volume Hospitals

The FAH urges CMS to update its analysis of the additional incremental costs per discharge for low volume hospitals and expand eligibility for the low-volume hospital adjustment to include hospitals with between 201 and 800 discharges in a fiscal year. Section 1886(d)(12) of the Act provides a payment in addition to a hospital's IPPS payment for each qualifying low-volume hospital beginning in FY 2005. To qualify as a low-volume hospital, the hospital must be more than a distance specified in the statute from another IPPS hospital and have fewer than a statutory specified number of discharges. With respect to the discharge criterion, the FAH notes that section 1886(d)(12)(C)(i)(IV) defines a low-volume hospital as a hospital with less than 800 total discharges (Medicare and non-Medicare) during the fiscal year for each fiscal year beginning with FY 2023. However, under 42 CFR §412.101(b)(2)(i), CMS limits the payment adjustment to hospitals with fewer than 200 total discharges.

CMS' limitation of the low-volume hospital adjustment to hospitals with fewer than 200 total discharges is based on regression analyses described in both the FY 2005 and FY 2006 IPPS rules. Based on these regression analyses, CMS determined that only hospitals with fewer than 200 total discharges should receive a low-volume adjustment at all and that these hospitals should receive the maximum adjustment of 25 percent.[75] Although CMS acknowledged that it "is important to regularly investigate the relationship between hospitals' standardized costs per discharge for purposes of the low-volume adjustment" and indicated it would reevaluate the low-

[73] Swanson, Erik. "National Hospital Flash Report: March 2022." Kaufman Hall, March 28, 2022. https://www.kaufmanhall.com/insights/research-report/national-hospital-flash-report-march-2022

[74] Productivity and Costs, First Quarter 2022, Preliminary - 2022 Q01 Results." U.S. Bureau of Labor Statistics. U.S. Bureau of Labor Statistics, May 5, 2022. (Productivity and Costs, First Quarter 2022, Revised (PDF) (bls.gov))

[75] 69 Fed. Reg. at 49102, 70 Fed. Reg. at 47434.

volume adjustment in the FY 2007 Proposed Rule,[76] the Proposed Rule provides no rationale supporting the ongoing validity in FY 2023 of its previous analyses that used two-decade old data modeled against FY 2005 and FY 2006 IPPS projections.

The FAH requests that CMS consider updating its regression analysis to determine whether this provision should be assisting more hospitals. The IPPS has significantly evolved since CMS originally developed its empirical justification for limiting the low-volume hospital payment adjustment to exclude hospitals with between 200 and 800 discharges in a fiscal year such that the continued application of this dated empirical justification is inappropriate. In addition, irrespective of any regression analysis, it makes intuitive sense that any hospital with fewer than 800 total discharges is likely to face higher costs per discharge as they will have a fewer number of discharges upon which divide a fixed pool of costs. In combination with the distance criterion, the low-volume hospital provision is designed to maintain access to care where there is an insufficient volume of discharges to support a full-service IPPS hospital.

Absent data on how many hospitals will meet the distance criterion of being at least 25 miles away from another IPPS hospital versus 15 miles, a recent analysis of Medicare cost reports and the provider-specific file indicates that there are only 24 hospitals with less than 200 discharges and 136 hospitals with between 200 and 799 discharges currently receiving the low-volume hospital adjustment. Therefore, the universe of potential hospitals that could potentially receive a low-volume adjustment up to 799 discharges remains exceedingly small. Even if CMS is unable to complete an update to its regression analysis for low-volume hospitals, **the FAH requests CMS expand hospital eligibility for the maximum low-volume hospital adjustment of 25 percent to any hospital with less than 800 discharges that also meets the distance criterion, consistent with the statutory requirements.**

V.D. Medicare-Dependent Small Rural Hospitals

As noted in the Proposed Rule, the Medicare-dependent, small rural hospital (MDH) program is currently set to expire at the end of FY 2022. The FAH appreciates CMS' reminder of the regulatory process facilitating a seamless transition from MDH status to sole community hospital (SCH) status upon expiration of the MDH program under 42 C.F.R. § 412.92(b)(2)(v). The Proposed Rule, however, does not provide further details as to how CMS will handle situations where a hospital's MDH status expires on September 30, 2022, but Congress later extends the MDH program retroactive to the day after the expiration date as has occurred in the past. **The FAH requests that CMS provide further details in the FY 2023 IPPS final rule as to how it will handle hospitals returning to MDH status if Congress extends the MDH program after its expiration date and retroactive to October 1, 2022.**

In particular, the FAH urges CMS to retroactively reinstate the MDH status of hospitals that participated in the MDH program in FY 2022 but reclassified as SCHs pursuant to the process under 42 C.F.R. § 412.92(b)(2)(v) or cancelled their rural status. With prior extensions of the MDH program by Congress, CMS automatically reinstated MDS status to qualifying hospitals without the need for the hospital to apply for MDH classification. However, this

[76] 70 Fed. Reg. at 47,434.

reinstatement did not apply to hospitals that transitioned to becoming SCHs or cancelled rural status before the MDH program was extended. These hospitals have had to take on the burden of reapplying for MDH status when Congress retroactively reinstated the MDH program. This process creates an unnecessary break in MDH participation, partially defeating Congress's goals in retroactively reinstating the MDH program. In addition, it leaves MDHs to choose between maintaining eligibility for MDH reinstatement upon retroactive extension of the program and making use of the regulatory process to transition to SCH status upon the MDH program's expiration. **The FAH requests that CMS automatically reinstate MDH status to all previously qualifying hospitals if the MDH program is extended after October 1, 2022, including hospitals that became SCHs and hospitals that cancelled rural status.**

The FAH notes that the MDH program and the expanded low-volume hospital program, both of which are set to expire at the conclusion of FY 2022, serve as critical lifelines to many rural hospitals that have been maintaining vital hospital services in their communities during the COVID PHE but are seeing shrinking or negative margins and record inflation. The FAH supports the Rural Hospital Support Act (S.4009), which would extend these programs and provide other relief to these critical community hospitals.

GRADUATE MEDICAL EDUCATION PAYMENTS

V.F.2 *Milton S. Hershey Medical Center, et al. v. Becerra* Litigation (42 C.F.R. § 413.79(c)(2)(iii))

The FAH supports CMS' proposed change to the DGME calculation in response to the decision in *Milton S. Hershey Medical Center, et al. v. Becerra*.[77] Critically, the Proposed Rule accurately reflects Congress' explicit instruction in 42 U.S.C. § 1395ww(h)(4)(C) by ensuring the total weighted allopathic and osteopathic FTE count is equal to the FTE cap where the weighted allopathic and osteopathic FTE count exceeds the FTE cap. As the *Hershey* Court explained, the text of 42 U.S.C. § 1395ww(h)(4)(C) "is clear" and that it "does not give the Secretary the latitude to decide . . . to change the weights that Congress assigned to residents and fellows when he calculates the FTE residents for each hospital." 2021 WL 1966572, at *8. **The proposed amendment to § 413.79(c)(2)(iii) appropriately acknowledges the law as enacted by Congress and should be finalized.**

The FAH, however, does not support the proposal to carry out the statutory requirements and the *Hershey* decision through retroactive rulemaking when it could appropriately apply existing statutory law and remedy past underpayments without resorting to retroactive rulemaking. **The proposal at issue simply does not fit within CMS' "limited authority to make retroactive 'substantive change[s]'" in policy under section 1871(e)(1)(A) of the Social Security Act[78] because the policy itself was already adopted by Congress.** The *Hershey* Court made clear that the statutory scheme left "no gaps for the Secretary to fill" on this

[77] No. 19-2680, 2021 WL 1966572, (D.D.C. May 17, 2021), *appeal dismissed*, No. 21-5169, 2021 WL 4057675 (D.C. Cir. Aug. 23, 2021).

[78] *Azar v. Allina Health Svcs.* (*Allina II*), 139 S. Ct. 1804, 1812 (2019)

issue.[79] In other words, the proposed policy is already dictated by the statute as explained in *Hershey*, and there is no room for CMS to substantively change the policy enacted by Congress.

The FAH instead urges CMS to forego retroactive rulemaking that exceeds its authority and to recognize that the existing regulation is a legal nullity in light of *Hershey* and apply the required policy to all hospitals. The statutory payment requirement requires no substantive change in policy and can be properly effectuated without rulemaking by, for example, instructing the MACs on correcting GME payments to conform to the statute. CMS recently took this approach when recalculating Part C GME and NAHE payments going back to 2002. CMS' Transmittal A-03-043 "provide[d] MACs with instructions on how to" recompute payments "for CYs 2002 through 2018."[80] In doing so, CMS set out the methodology for calculating payments and instructed the MACs 1) to report the corrected payment amounts on the cost report for then-unsettled cost reports and 2) to issue corrected payments for cost reports already settled within the three-year reopening period and cost reports appealed to the PRRB.

CMS should undertake a similar approach alongside finalization of the Proposed Rule on a prospective basis, thereby addressing the Secretary's obligation to establish certain rules under section 1886(h)(4). Notably, section 1886(h)(4) sets no deadline by which the Secretary must promulgate regulations, and thus a prospective regulation may fulfill the Secretary's obligation.[81] Indeed, because retroactive rulemaking is unnecessary to comply with section 1886(h)(4), the limited exception for retroactive rulemaking "necessary to comply with statutory requirements" under 1871(e)(1)(A)(i) does not apply.

Further, there are no grounds to invoke the exception for retroactive rulemaking that is in the public interest. There is no public interest in promulgating a retroactive regulation that could, at most, mirror the statutory mandate, which the *Hershey* Court's determination left "no gaps for the Secretary to fill."[82]

The FAH is also concerned that CMS, on the one hand, proposes a retroactive rule but, on the other, states that this retroactive rulemaking would not be the basis to reopen final settled cost reports under 42 C.F.R. § 405.1885(c)(2). Section 405.1885(c)(2) is not applicable because it does not cover retroactive rules adopted pursuant to section 1871(e)(1)(A), as CMS has proposed. The Proposed Rule presents no explanation as to why retroactive rulemaking with no real retroactive effect is appropriate where doing so will only serve to prevent hospitals from receiving proper payments mandated by the statute.

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[79] 2021 WL 1966572, at *8.

[80] CMS Pub. 100-20, Transmittal No. 10520 (Dec. 14, 2020), https://www.cms.gov/files/document/r10520otn.pdf.

[81] By way of comparison, the Supreme Court has opined that, if "a statute prescribes a deadline by which particular rules must be in effect, and if the agency misses that deadline, the statute may be interpreted to authorize a reasonable retroactive rule despite the limitation of the APA." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 224-25 (1988). In the absence of a deadline, however, section 1886(h)(4) cannot properly be read to require retroactive rulemaking.

[82] 2021 WL 1966572, at *8.

In conclusion, the FAH appreciates and supports CMS' thoughtful proposed amendment to 42 C.F.R. § 413.79(c)(2)(iii) and to the relevant cost report instructions, as these proposed changes memorialize existing statutory requirements. Nonetheless, the FAH strongly disputes CMS' assertion that it has authority to adopt this regulation retroactively, and urges CMS instead to 1) finalize the Proposed Rule prospectively, 2) acknowledge that the existing regulation is set aside, and 3) ensure that providers are made whole for past underpayments under the unlawful regulation by, for example, providing appropriate instructions to the MACs on recomputing payments.

H. Hospital Readmissions Reduction Program (HRRP): Proposed Updates and Changes

Measure Changes in Response to the COVID-19 PHE: Newly Proposed Changes

Technical Measure Specification Update to Include Covariate Adjustment for COVID-19 beginning with FY 2023

CMS announces modifications of the measure specifications for each of the HRRP's six condition/procedure specific risk-standardized readmission measures to include a covariate adjustment for patient history of COVID-19 in the 12 months prior to the admission, beginning with the FY 2023 program year. The FAH supports this modification and requests that CMS continue to monitor whether any further specification changes are appropriate to account for other impacts of the PHE on these measures.

Proposed Resumption of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for the FY 2024 Program Year

CMS proposes that beginning in FY 2024, the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure will no longer be suppressed under the HRRP. CMS concomitantly announces technical specification changes to this measure such that cases with COVID-19 primary or secondary diagnoses will be excluded from the numerator and denominator of that measure, aligning its specifications with those previously announced for the Program's five other readmission measures.

The FAH supports the resumption of this measure for the FY 2024 program year, but only if the measure is finalized with the exclusions of primary or secondary diagnosis of COVID-19 and the covariate adjustment for a history of a COVID-19 diagnosis in the 12 months prior to an admission. We assume that CMS will be conducting interim data analyses prior to FY 2024 rulemaking and would not proceed with measure resumption at that time if the analyses exposed unexpected or increasing COVID-19 PHE impacts on hospitals. We agree with extending the technical specification modification to exclude COVID-19 cases from the pneumonia readmission measure, as already done for other Program measures.

Measure Changes for FY 2023 in Response to the COVID-19 PHE: Prior Changes

The FAH notes that suppression of the pneumonia readmission measure for FY 2023 HRRP payment determinations was finalized in the IPPS FY 2022 final rule. As a suppressed

measure, hospital-specific pneumonia measure ERRs will be calculated but not be used for payment reduction calculations, effectively weighting this measure at zero percent for the FY 2023 payment year. Also announced in that rule were updates to the technical specifications for the Program's remaining five readmission measures, such that cases with COVID-19 primary or secondary diagnoses during index admissions and readmissions will be excluded from the numerators and denominators of those measures, beginning with FY 2023. CMS does not propose changes to its previously finalized suppression decision, and the FAH reiterates our prior support for suppression. We also continue to support exclusion of cases with COVID-19 diagnoses from other measure calculations.

HRRP Changes in Response to the COVID-19 PHE: Combined Effects

As described above, CMS has made a series of changes to the HRRP in response to effects of the COVID-19 PHE on the Program. The rationale for the changes as described in the FY 2022 IPPS Proposed and Final Rules and the current FY 2023 IPPS Proposed Rule rests heavily on the impact of COVID-19 pneumonia on the Program's pneumonia readmission measure. In adopting suppression of that measure, CMS cited Measure Suppression Factor 2: clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the COVID-19 PHE. The proposal made in the FY 2023 IPPS Proposed Rule to resume use of the pneumonia readmission measure (i.e., stop measure suppression) for the FY 2024 payment determination year is justified by CMS with data showing substantial declines of COVID-19 pneumonia rates from peak months of the pandemic and by expanded ICD-10-CM diagnostic coding specific for pneumonia due to coronavirus disease (J12.82).

The FAH appreciates the extensive efforts made by CMS during recent rulemaking to apply policy and process flexibility in response to COVID-19 PHE impacts, such as the cross-measure suppression policy for the agency's value-based programs including the HRRP. We fully agree with CMS that the HRRP pneumonia readmission measure is clearly compromised for use in making FY 2023 HRRP payment adjustments and have supported this measure's suppression. We also agree with CMS that COVID infections when present have added substantial comorbidity for the other five conditions for which there are HRRP measures (e.g., heart failure, complications of lower extremity total joint arthroplasty), and we acknowledge the agency's technical measure specifications to exclude COVID-19 cases from HRRP calculations. We also note further adjustments made to the FY 2022 calculations, such as adjusting the neutrality modifier year and the measure lookback period.

Considered together, a substantial package of COVID-related adjustments has been implemented and/or proposed for the FY 2023 HRRP payment year. However, stepping back to consider the HRRP as part of the IPPS pay-for-performance (P4P) program group, the FAH believes CMS should take steps to further mitigate the financial implications with HRRP, similar to what it has done for the HAC and VBP programs. We note the measure specification changes to exclude COVID-19 cases have been made to all three hospital P4P programs. For FY 2022, CMS suppressed multiple Hospital Value-Based Purchasing (HVBP) Program measures and adopted a special scoring policy that resulted in payment net-neutrality for hospitals, and CMS is proposing to do so again for FY 2023. For FY 2022, CMS suppressed data from the entirety of

CY 2020 and suppressed multiple measures, and for FY 2023 is proposing scoring changes that would eliminate all HAC RP penalties, creating HAC RP payment net-neutrality for hospitals. Yet for the HRRP, COVID-19 changes are limited to FY 2023 and involve only the pneumonia readmission measure.

The FAH notes that in providing rationales for the more extensive changes and special scoring being applied to the HVBP and HAC Reduction programs, CMS has cited COVID-19 PHE impacts including cited rapid changes in hospital care delivery protocols (Measure Suppression Factor 3), shifts in procedural volumes (Measure Suppression Factor 4), and unprecedented healthcare personnel staffing shortages (also Measure Suppression Factor 4). The FAH notes that these factors also apply to the hospitals in the HRRP and potentially merit special scoring changes, if not for FY 2022, at least for FY 2023. We further note that CMS had the same opportunity to focus on a pneumonia measure in the HVBP (pneumonia mortality measure) whose patient profile likely overlapped heavily with that of the HRRP pneumonia readmission measure, yet CMS did not confine its COVID-19 changes to simply suppressing the pneumonia mortality measure but instead cited suppression factor 2 as one of the several factors leading to special scoring.

The FAH also observes that CMS has voiced concerns for all of its P4P programs about measure comparability over time, given the evolution of SARS-CoV-2 transmission rates and disease severity over time. The agency also has repeatedly expressed concerns that the substantial temporal and geographic variations in COVID-19 rates and acuity have caused sufficiently different hospital impacts across the county, such that fair hospital performance assessments and equitable payment adjustments cannot be made. We agree wholeheartedly with these concerns and believe they also apply to the HRRP, as well. We believe that the same concerns that led to CMS proposing net-neutral payment adjustments under the HVBP and HAC Reduction programs also should apply to the HRRP. We note the agency's statement that its data analyses to date project only "minimal" impacts of COVID-19 on readmission measure results for the FY 2023 program year, but we wonder if additional or deeper data dives are needed. For example, at least some of the minimal impacts are the result of shifting care patterns, such as increased patient avoidance of hospitals (and of readmissions), particularly as hospital-at-home care delivery options have expanded. We find it difficult to accept that hospital performance across the range of quality measures of both the HVBP and HAC Reduction programs could be profoundly affected and somehow the measures of the HRRP show minimal impacts. We also recall that virtually half of the HRRP FY 2023 applicable period (July 1, 2018, through June 30, 2021) falls within declared dates for the COVID-19 PHE.

The FAH respectfully asks CMS to consider whether special scoring and payment adjustments might also be needed for the HRRP to ensure sufficient and equitable response to the COVID-19 PHE. At a minimum, we request that CMS share more of its analyses that led to its estimate of minimal impact on HRRP hospital participants by COVID-19.

Request for Public Comment on Possible Future Inclusion of Health Equity Performance in the Hospital Readmissions Reduction Program

CMS notes that the Hospital Readmissions Reduction Program (HRRP) currently uses beneficiaries' dual eligibility for Medicare and Medicaid as a proxy for a beneficiary's social risk and uses dual eligibility, as required by the statute, to divide hospitals into peer groups for comparison under the program. In keeping with the agency's enterprise-wide focus of health equity and disparities, CMS is seeking comment on variables associated with or measures of social risk and beneficiary demographics as well as on broader definitions of dual eligibility for potential future incorporation into the Program. The comment request is divided into three topics.

Incorporating Hospital Performance For Beneficiaries With Social Risk Factors In The HRRP

The FAH finds the balance of benefits, risk, and unintended consequences of incorporating hospital performance for beneficiaries with social risk factors into the HRRP to be unfavorable at this time and in the manner inferred through the questions posed by CMS for multiple reasons. The HRRP and its companion hospital pay-for-performance (P4P) programs (i.e., Hospital Value-Based Purchasing Program and Hospital-Acquired Condition Reduction Program) are designed by statute to focus on reducing Medicare payments for high-profile, high-cost, and partially avoidable events. CMS appears to be redirecting the focus of the HRRP to reducing payments for observed disparities that may be associated with some of the readmissions captured through the Program. While we fully support CMS in its overarching goal to identify and resolve disparities, we do not support the HRRP as an appropriate vehicle to reach that goal. We also question whether such redirection is consistent with the letter or intent of the applicable statute. The Program's statutory requirement for peer grouping is designed to facilitate equitable payments to hospitals not patient-level equity in clinical outcomes.

Further, the FAH notes that hospital readmission is the far downstream result of many interlocking factors that are often outside of hospitals' control. These include the nature and trajectory of the specific disease processes for which there are HRRP measures; optimal care for those diseases often appropriately occurs in multiple non-hospital settings. We observe that readmission may represent best available care for a patient who develops issues post-discharge but who lacks resources to other options for those issues due to factors for which the hospital is not responsible (e.g., a pneumonia patient readmitted for parenteral antibiotic administration and supplemental oxygen but ineligible for home-based services or lacking a volunteer caregiver).

The FAH believes that the path to health equity would be much better defined by efforts based on measures applicable to specific, actionable, upstream factors. For example, reducing disparities in timely provision of percutaneous coronary intervention for acute coronary syndromes seems a better-focused target than readmission after acute myocardial infarction. We also believe that the path to equity should far more often reward desired behaviors than utilize penalty-only programs like the HRRP.

The FAH also notes that the HRRP formula and its associated calculations are complex and complicated. For example, problems with the computations of the Program's penalties have

been detailed by the Medicare Payment Advisory Commission (MedPAC).[83] Moreover, the HRRP already requires a 3-year applicable period for enough hospitals to reach the 25-case minimum threshold on at least one of the Program's measures to reach acceptable reliability levels. Stratification of measure results is very likely to be fraught with reliability concerns since already marginal case numbers will be fragmented. The FAH has previously described the stacking effects of the HRRP when combined with the those of the HVBP and HAC Reduction Programs.[84] These substantive impacts on hospitals continue and an unintended consequence of modifying the HRRP to address disparities could be even more serious adverse impacts.

Finally, the FAH observes that confidential reporting of hospital-specific HRRP performance results in which hospitals are stratified into quintiles based on dual eligibility as a proxy for social risk has a very short track record, a large part of which has occurred during the atypical times of a public health emergency. An early evaluation of the effects of the first three years of hospital peer grouping has recently been published.[85] The authors report that stratification by proportion of dual enrollees was associated with significant decreases in Program penalties at hospitals with the highest proportion of dual enrollees (-0.9 percentage points), rural hospitals (−0.08 percentage points), and those with a large share of Black and Hispanic or Latino patients (-0.6 percentage points). They conclude that allocation of fewer penalties to rural hospitals and hospitals caring for a high share of patients in poverty or from racial or ethnic minority backgrounds represents an improvement in equity within the HRRP.

The FAH strongly recommends that the Program's current, statute-compliant structure be left undisturbed for at least three more years to reflect readmissions rates in periods less affected by the COVID-19 PHE, to include at least one more applicable performance period, and to validate the early peer-reviewed findings of hospital stratification by dual eligibility.

Linking Performance In Caring For Socially At-Risk Populations And Payment Reductions By Calculating The Reductions Based On Readmission Outcomes For Socially At-Risk Beneficiaries

The FAH supports confidential reporting of hospital-specific HRRP performance results stratified for social risk factors. We concur that building on the current CMS Disparity Methods represents a viable strategy. Results reported should include those for the Program's individual measures and overall Program performance as well as appropriate comparative data. We believe that confidential Program results reporting could be beneficial to hospitals in meeting requirements of the Hospital Commitment to Health Equity measure proposed for addition to the Hospital Inpatient Quality Reporting Program (HIQR) beginning with FY 2023 reporting, such as equity strategic plan construction and implementation and self-directed analysis for

[83] Medicare Payment Advisory Commission. Problems with the computation of HRRP penalties. Report to the Congress: Medicare and the Health Delivery System, Online Appendix A June 2018, updated November 2019.

[84] Kahn CN, Ault T, Potetz L et al. Assessing Medicare's Hospital Pay-For-Performance Programs And Whether They Are Achieving Their Goals. Health Affairs 2015; 34:1281-1288.

[85] Shashikumar SA, Waken RJ, Aggarwal R, et al. Three-Year Impact Of Stratification In The Medicare Hospital Readmissions Reduction Program. Health Affairs 2022; 41:375-382.

performance disparities. Confidential comparative data could also serve to incent hospitals to improve their internal subgroup performances and their rankings within their peer groups without triggering costly, meaningless media campaigns. We encourage CMS to explore using HRRP raw data to detect significant disparities within the Program's current, or perhaps even more granular, dual-eligibility peer groups. Examining case mix and social risk mix within the peer groups could be informative, such as correlation with area-based indices.

The FAH opposes linking HRRP performance results for socially-at-risk beneficiaries to the Program's payment reduction calculations and outcomes. Payment reductions should be implemented only as a last resort in the pursuit of health equity and only for measures with standardized definitions, having unambiguous specifications, and for which clear, causal links to better health outcomes (i.e., not simply possible correlations) have been established by independent investigators in peer-reviewed publications.

Measures Or Indices Of Social Risk, In Addition To Dual Eligibility, That Should Be Used To Measure Hospitals' Performance In Achieving Equity In The Hospital Readmissions Reduction Program

The FAH asks CMS to clarify what is meant by "achieving equity in the Program". We believe that peer grouping based on dual eligibility so far is proving effective as a means to move the Program towards more equitable payment reductions for hospitals serving large numbers of vulnerable beneficiaries. We suggest that this should be the criterion by which interventions to increase equity within the HRRP should be judged. Reducing readmission disparities at the patient level represents a vastly different undertaking that needs its own criterion. Developing this criterion would require having comprehensive data for numerous, interlocking, upstream variables and their contributions to causality, much of which information is unavailable and/or unknown currently. It also is unclear whether this criterion would best be applied to the HRRP or as part of criteria applicable to other CMS quality measures and programs.

Essential first steps for establishing an appropriate criterion are standardizing definitions for sociodemographic variables to be collected and improved self-reported data collection methods. CMS has not yet shared standardized definitions nor conducted a systematic scan of the frequency and range of variables already being collected by hospitals. We are concerned that the current comment request seems to rush past these fundamental initial steps. The FAH calls attention to the ongoing work by MedPAC to define the patients, hospitals, and clinicians for whom policy options intended to advance health equity are most appropriate and feasible (e.g., expanded definition of low-income beneficiaries, multifactorial hospital Safety Net Index).[86]

<u>Summary</u>

- CMS is to be commended for its continued global commitment to achieving equity throughout its quality and value-based programs, including the HRRP.

[86] Medicare Payment Advisory Commission. Medicare payment policies to support safety-net providers. Leveraging Medicare policies to address social determinants of health. Meeting Presentations March 2022 and April 2022.

- Available evidence suggests that equity, as defined by a criterion appropriate to the HRRP (equitable payment reductions), is being advanced under the current structure of the Program.
- The Program should be left undisturbed for at least three additional years so that the durability of the observed increased equity can be accurately assessed.
- The HRRP and its payment reductions are not well suited to be the vehicle for reducing readmission disparities at the patient-level that are associated with upstream sociodemographic factors.
- HRRP data may be useful as part of investigating upstream factors for which causality may be established through carefully-designed analyses.
- Stratified HRRP performance data should continue as confidential-only reporting to hospitals.
- The FAH is committed to be a willing and pragmatic partner to CMS in shared initiatives to advance health equity and reduced outcome disparities.

I. HOSPITAL VALUE-BASED PURCHASING PROGRAM (HVBP)

Changes in Response to the COVID-19 PHE Measure Suppression

CMS proposes to suppress the following HVBP program measures for payment year FY 2023:

- Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (NQF #0166)
- National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)
- NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)
- American College of Surgeons- Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753)
- (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcomes Measure (NQF #1716)
- (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717)

CMS cites suppression rationales that include significant deviations in national performance compared to recent prior years; unprecedented changes in healthcare personnel staffing; rapid changes in clinical guidelines; and rapid declines in case volumes. The FAH supports all of the HVBP measure suppression proposals for the FY 2023 payment year and thanks CMS for recognizing the continuing challenges that hospitals face every day while striving to provide high-quality care during the ongoing COVID-19 PHE. We recognize that CMS has had to strike a balance in appreciating the overwhelming consequences of the COVID-19 on hospitals, providers, and patients with providing transparency of hospital performance to beneficiaries.

We believe most of the suppression policies proposed in this rule for FY 2023 is the appropriate level of accountability, while allowing for adjustments to support the system's recovery. We look forward to working with CMS to identify the right time to relax its suppression policies and resume the previous level of quality reporting, accountability, and transparency through public reporting of hospital performance.

Special Scoring Policy and Payment Adjustments

Further, CMS proposes a special scoring policy for the FY 2023 payment year for the HVBP program. CMS states that equitable value-based payment adjustments would be challenging to implement using established HVBP methodology, given the proposed suppression of all of the measures of two of the four domains of the HVBP program. Under the special scoring policy, no Total Performance Scores would be awarded to hospitals, and CMS would assign to each hospital a value-based incentive payment amount that matches the 2 percent payment reduction applied to the hospital per statute. As a result, HVBP program payments would be net-neutral for all hospitals for FY 2023.

The FAH supports the proposed special scoring policy for the HVBP FY 2023 payment year. We appreciate the support for hospitals that CMS has shown by making measure, process, and policy adjustments to its quality programs in response to the COVID-19 PHE.

Operational Changes

CMS proposes to update the baseline and performance periods for the CAHPS measure and the five NHSN Safety Domain measures for program year FY 2025. These changes would account for the downstream effects of FY 2023 measure suppression proposals, if finalized. CMS also outlines performance standard adjustments for HVBP program payment years FY 2025 through FY 2027 that would reflect the proposed baseline and performance period updates, if finalized. The FAH supports the updated baseline and performance periods and adjusted performance standards as proposed.

Technical Measure Specification Updates to Include Covariate Adjustment for COVID-19 Beginning with the FY 2023 Program Year

CMS proposes to modify the technical measure specifications for MORT-30-AMI, MORT-30-CABG, MORT-30-COPD, MORT-30-HF, and COMP-HIP-KNEE measures to include a covariate adjustment for patient history of COVID-19 in the 12 months prior to the admission beginning with the FY 2023 program year. The FAH supports this modification to these measures and encourages CMS to continue to monitor whether any additional changes to the measures due to the impact of the public health emergency may be required.

Technical Updates to the Specifications for the MORT-30-PN Measure Beginning with the FY 2024 Program Year

CMS announces technical specification updates to the MORT-30-PN measure beginning with the FY 2024 program year: 1) to exclude patients with either principal or secondary diagnoses of COVID-19 from the measure denominator, and 2) to add a covariate that adjusts for

history of COVID-19 in the 12 months prior to the admission to the measure's risk adjustment model. CMS also states a plan to resume use of the MORT-30-PN measure with the FY 2024 payment year (i.e., end measure suppression).

The FAH agrees with the two technical specification updates as announced as steps to account for COVID-19 disease effects on measure performance and to isolate potential effects of "long COVID". We also encourage CMS to continue to monitor whether any additional changes to the measure due to the impact of the public health emergency may be required. The FAH thanks CMS for sharing its plan for measure resumption starting with the FY 2024 payment year. With the technical updates described above, the measure – when considered in isolation – appears to be structured appropriately to return to use in the HVBP Program at that time. However, we urge CMS to consider the combined effects of the multiple Program adjustments being made that would affect FY 2024 payment year determinations. The FAH believes that the combined effects of data suppression and shortened applicable period, along with any lingering impacts of COVID-19 that are uncovered by CMS monitoring in the interval prior to FY 2024 proposed rulemaking, should lead to serious consideration by CMS of again applying scoring and payment adjustments for FY 2024 payment determinations.

J. HOSPITAL-ACQUIRED CONDITION (HAC) REDUCTION PROGRAM

Changes in Response to the COVID-19 PHE

Measure Suppression for FY 2023

CMS proposes to suppress for payment year FY 2023 all six of the HAC Reduction program's measures: the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) and five hospital-associated infection (HAI) measures that are reported through the CDC's National Health Safety Network (NHSN). CMS cites suppression rationales that include significant deviations in national performance compared to recent prior years; unprecedented changes in healthcare personnel staffing; rapid changes in clinical guidelines; and rapid declines in case volumes. Additionally, for the CMS PSI 90 measure CMS expresses concerns about the comparability of measure data over time, as the measure's applicable period includes data from the COVID-19 PHE, but the reference period does not.

The FAH supports all of the HAC Reduction Program measure suppression proposals for the FY 2023 payment year. We appreciate efforts being made by CMS to maintain the integrity of the program's measures during the pandemic.

Scoring and Payment Adjustments for FY 2023

As a consequence of suppressing all Program measures, no measure scores would be available for CMS to calculate FY 2023 payment year Total HAC scores. Without Total HAC scores, CMS would be unable to identify the worst-performing quartile of hospitals to whom the Program's payment reduction penalty would be applicable per statute. Therefore, CMS proposes to implement a scoring policy under which all hospital Total HAC Scores will equal zero and no HAC Reduction payment penalties will be applied for the FY 2023 HAC Reduction Program payment year.

The FAH strongly supports the proposed scoring policy for the HAC Reduction Program FY 2023 payment year. We thank CMS for appropriately modifying this penalty-only program for hospitals while the latter continue to adapt to the evolving and unpredictable COVID-19 PHE.

Public Reporting of HAC Reduction Program Results for FY 2023

CMS proposes to publicly report the CDC NHSN HAI measure results but not calculate or report measure results for the CMS PSI 90 measure for the HAC Reduction Program FY 2023 program year. The FAH supports CMS' proposal to not calculate or report measure results for the CMS PSI 90 measure. We agree with reporting the CDC NHSN HAI performance results confidentially to hospitals, as the data, despite their flaws, could help hospitals assess the strengths and weaknesses of their responses to the COVID-19 PHE. However, the FAH disagrees with public reporting of the results from all P4P programs in which measures have been suppressed, including the HAC Reduction Program. The P4P programs are complex and difficult to translate into accessible, comprehensible, and meaningful information for patients and families absent unprecedented health care system impacts by a PHE. We continue to be skeptical that easily understood descriptions of data limitations due to COVID-19 effects for FY 2023 can be crafted. At a minimum, public reporting should be delayed for the agency to obtain input from beneficiary advocates and to allow full testing of data disclaimer language through focus groups.

Measure Suppression for FY 2024

CMS has previously finalized the suppression of all CY 2020 CMS PSI 90 and NHSN HAI measure data from payment year FY 2024 performance calculations. CMS now further proposes to suppress FY 2021 data from all five Hospital-Associated Infections (HAI) measure calculations, citing significant deviation in national performance from recent prior years (Measure Suppression Factor 1) along with significant changes in case volumes (Measure Suppression Factor 4). If finalized, these changes would result in a 12-month applicable period for the NHSN HAI measures of CY 2022 for determining FY 2024 payments.

The FAH supports suppression of the CY 2021 measure data. We agree with CMS that the data are very unlikely to be representative of hospital performance absent COVID-19 PHE effects. We believe that the remaining, abbreviated applicable period for payment year FY 2024 also is unlikely to be representative and we recommend that CMS adopt scoring and payment changes for FY 2024 analogous to those proposed for FY 2023.

Technical Measure Specification Update to Risk-Adjust for COVID-19 Diagnoses in the CMS PSI 90 Measure beginning with the FY 2024 HAC Reduction Program Year

CMS announces a plan to update the measure specifications to risk-adjust for COVID-19 diagnosis in the CMS PSI 90 measure beginning with the FY 2024 HAC Reduction Program Year. The FAH supports this modification to the CMS PSI 90 measure and requests that CMS continue to monitor whether any additional changes to the measure due to the impact of the public health emergency may be required. We further ask that CMS consider whether the

modified CMS PSI 90 measure in combination with the proposed CY 2021 NHSN HAI measure data suppression will in fact allow equitable and meaningful Total HAC scores to be calculated for the FY 2024 payment year.

Changes Unrelated to the COVID-19 PHE

Technical Measure Specification Update to the Minimum Volume Threshold for the CMS PSI 90 Measure beginning with the FY 2023 Program Year

Unrelated to the COVID-19 PHE, CMS announces a technical update to this measure's specifications by raising the minimum volume threshold from 25 to 50 cases beginning with the FY 2023 program year. The FAH agrees with the increase to the minimum volume threshold as a step toward minimizing the unintended consequences of penalizing smaller or lower volume hospitals based on scores that may not demonstrate sufficient reliability. Adjunctively, we believe that CMS should examine the intraclass correlation coefficients (ICC) at the minimum threshold rather than at the median and set the minimum volume at a number that will produce an ICC of 0.6 or higher.

HAI Data Submission Requirements for Newly Opened Hospitals

Beginning with program year FY 2023, CMS proposes to update the definition of "newly opened" hospital applicable to the HAC RP. A hospital would be termed newly opened for a program year if its Medicare-Accept Date falls within the final 12 months of the 24-month performance period for HAI measures for that program year. This change would accurately reflect the current process through which HAI measure results are directly transferred from CDC to the HAC RP and is estimated to impact less than 0.25 percent of hospitals.

The FAH supports this proposal. We recommend that CMS review the current process to ensure that hospital compliance burden is not increased by this change.

HAC Reduction Program Request for Information: Digital CDC NHSN Measures

CMS requests information on the potential inclusion of two digital NHSN measures (Healthcare-associated Clostridioides difficile Infection Outcome measure and Hospital-Onset Bacteremia & Fungemia Outcome measure) in the HAC Reduction Program.

The FAH conceptually supports the shift to digital quality measurement as it will hopefully advance our ability to achieve comprehensive interoperability and the capture of meaningful, actionable information that supports and enhances patient care within and across settings. We encourage CMS to continue to test the two digital CDC NHSN, implementing them only when shown to be reliable, valid, and feasible for hospital reporting. In addition, these measures must be endorsed by the National Quality Forum prior to their adoption into the HAC Reduction Program. Please also see our response below in this letter to the RFI entitled *Continuing to Advance to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR®) in Hospital Quality Programs*.

IX. Quality Data Reporting Requirements for Specific Providers and Suppliers

A. Assessment of the Impact of Climate Change and Health Equity

The FAH is committed to advancing health equity and specifically as it relates to climate change and the environment. We recognize climate change is a significant factor impacting the health of individuals, particularly vulnerable populations, and underserved communities. The FAH notes the significant public health threat imposed by climate-related emergencies and has called for providers, hospitals, and health systems to identify patients affected by excessive heat, unsafe housing, polluted air, wildfires, extreme weather events (hurricanes, flooding, etc.), sea-level rise, water and food supply, mental health impacts of all of the above, asthma, increases in vector-borne diseases, and subpar water quality.

CMS seeks input on what hospitals can do to address climate change's impact on Medicare patients, including how to determine likely climate impacts more effectively and particularly on the most vulnerable beneficiaries; determine potential costs of these impacts; and develop plans to mitigate catastrophic and chronic impacts for these populations (that is, plans for resilience).

The FAH recommends that hospitals and health systems work with public entities, especially local officials, to create comprehensive, regionally-based emergency preparedness. In doing so, we believe it will help to reduce emissions within communities where they operate. The FAH supports engaged partnerships with local suppliers who employ local residents to reduce emissions to ensure supply distribution in extreme weather events and to support the economies in which they operate. Additionally, the FAH recommends that hospitals engage with patients through assessments to determine potential vulnerabilities. Lastly, the FAH encourages public/private partnerships to:

- Increase housing quality (heating/cooling, indoor air)
- Provide community resources (cooling centers, green spaces)
- Improve transportation to improve access to care and services
- Improve community health knowledge and behaviors

CMS is interested in learning how it can support hospitals in crafting and implementing hospital responses. Again, we support collaboration with public officials in the development of regionally-based guidance on disaster preparedness. We request CMS publish what it believes are best practices in preparedness / learnings from prior events, education on climate-related illnesses and including guidance on what to look for and how to treat / prevent specific scenarios in the future, and specific reimbursement/coding for treatment/prevention of climate-related illness.

The FAH supports the approaches hospitals are using to reduce their own greenhouse gas emissions. We've heard from our members examples of what they're doing to improve energy efficiency in facility operations, how they are investing in renewable energy, engaging with suppliers to reduce emissions in supply chain, purchasing locally to reduce transportation emissions (also improves local/regional economies and decreases transportation risk in supplies),

and changing anesthetic gases from desflurane to sevoflurane, reducing nitrous oxide use. We recognize these efforts are a first step and we look forward to working with CMS in the identification of additional ways that cut greenhouse gas emissions.

B. Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs—Request for Information

General Considerations

CMS requests input into key principles and approaches to be considered as the agency further develops its strategy for advancing health equity across its quality reporting and value-based programs.[87] This RFI focuses on consistent measurement of disparities and routine reporting of stratified measure results as strategic tools to closing equity gaps in its programs. CMS plans to employ these tools to provide actionable information about disparities to providers across the continuum of care through applications of the tools tailored to accommodate the contextual and structural variations across its quality enterprise. In this RFI, CMS defines health equity as *the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes*. CMS also adopts a definition of measure stratification as the calculation of measure results for specific groups or subpopulations of patients.

The FAH welcomes the opportunity to respond to this Equity Measurement RFI on behalf of our hospital and health system members and their associated clinicians. Our members are diverse in size, location, and mix of services provided but are united in their commitment to achieving the best possible outcomes for all of their patients through holistic care without regard to demographic or social risk factors. We support the agency's definition of health equity and fully concur with CMS that approaches to identifying and addressing disparities in its programs must balance the twin goals of establishing consistency across programs with program-specific flexibility.

Key Considerations For Cross-Setting Use Of Quality Measures And Results Stratification

Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification

The FAH agrees with CMS that hospital-specific stratified results from the Within-Provider and Across-Provider Disparity Methods can support meaningful self-directed analysis by a hospital of its care for patients with and without specific sociodemographic risk factors associated with outcomes disparities. We also agree that care must be taken to avoid the inadvertent introduction of measurement and selection biases during stratification. We recommend that results be routinely examined for internal inconsistences (e.g., highly

[87] Described at https://www.cms.gov/cms-strategic-plan.

improbable results) and for consistent directional trends for interrelated stratification variables (e.g., low income and full Medicaid eligibility). The introduction of disparity methods and stratified reporting into a specific quality program must be fully transparent to providers and should begin on a small scale (e.g., a well-established measure and a single social risk variable). Interactions of stratification with a measure's risk adjustment methodology must be proactively sought and their impacts on accuracy, validity, and reliability assessed by CMS before stratified results are reported to providers. Privacy safeguards must be embedded into every step of the measurement, stratification, and reporting processes.

Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting

The FAH strongly agrees with CMS that decisions about how to identify and prioritize measures for possible stratified reporting should be made at the individual quality program level. In some programs, decision making should even occur at the domain or other subgroup level. Principles listed by CMS as being under consideration include the use of measures that are: existing, validated, and reliable clinical measures; outcome measures for which some evidence of disparities exists among Medicare beneficiaries; measures for which adequate sample sizes are available; measures broadly representative of providers and outcomes; and measures of appropriate access and care. The FAH believes that all of these principles have merit. We also agree with CMS that modifications may be needed based on the demographic or social risk variable being examined, each quality program's structure, and the intended use of a given measure. Decisions should incorporate stakeholder input and decision making should be done transparently.

The FAH recommends that CMS also consider the following as guiding principles for selecting and prioritizing measures for disparities reporting: 1) measures for which CMS already has data sources containing potentially relevant demographic or social risk factors (e.g., zip code or dual-eligibility status); 2) measures for which self-reporting of data are inherent in the measure, such as experience-of-care surveys and patient-reported outcome performance measures (PRO-PM); 3) measures for which CMS can calculate performance results timely and provide feedback promptly to providers, as aging data quickly become irrelevant; 4) expansion beyond clinical measures to resource use measures, as providing appropriate and equitable care to at-risk patients may necessitate increased resource use (e.g., unplanned readmissions) that could cause what otherwise appears to be poor resource use performance; and 5) measures that are likely to align with collection and reporting requirements of states and other third-party payers as a means of minimizing provider burden that also will strengthen the validity and reliability of measure results. We also suggest that CMS explore mining of potentially relevant qualitative data already being generated in many of its programs as an adjunct to identifying disparities and drivers of disparities. These data include observations made by accrediting agencies and state surveyors, resident and family/caregiver complaints, ombudsmen reports, and insights gleaned during QIO interactions with facilities.

Principles for Social Risk Factor and Demographic Data Selection and Use

CMS notes the challenges of selecting from the myriad factors for which associations with disparities have been suggested and the limited availability of high-quality (i.e., self-reported) data sources for certain variables. CMS describes proxy variables (e.g., neighborhood indices) and tools (imputation for missing data) for possible use when self-reported data are scarce.

The FAH strongly recommends that CMS begin disparity analyses and stratified reporting with demographic and social risk variables for which CMS already has large data sets (e.g., Medicare enrollment and claims data) containing potentially relevant information (e.g., diagnoses, dual-eligibility status). We note that small variations may be smoothed out when data are collected and stratified for large groups and subgroups but will continue to impact reliability and utility of results for smaller populations and low-frequency variables. We further recommend strongly that all variables to be analyzed for disparities be required to have clear, standardized definitions that are used consistently across CMS quality programs. Practical barriers to the number of variables to be studied also must be taken into account, including reporting burden created for providers and optimal allocation of finite provider and CMS resources.

The FAH recognizes that patients may be reluctant to share sensitive personal information, contributing to the challenge of missing data points for the gold standard, self-reported data. When self-reported data availability is particularly limited, we support the judicious use of some of the substitute variables being considered by CMS, such as neighborhood-based variables (e.g., Area Deprivation Index, Census Bureau's Community Resilience Estimates). The FAH does not support the use of imputed data techniques to replace missing demographic data, at least until considerably more data are made publicly available by CMS about data imputation efficacy and accuracy when used in its quality programs. The assumptions of the imputation technique may introduce unanticipated biases into the original data set. We firmly believe that CMS resources are better invested into enhanced efforts for collection of self-reported data than into expanding techniques for data imputation. We also suggest CMS carefully consider the translation of such indexes into composite measures. Composite scores can be useful, but they must be carefully considered, as underlying variables may or may not be predictive of performance for a given quality program.

The FAH strongly encourages CMS to seek out alternative sources of social risk factor data in other HHS initiatives and other federal programs. Work underway by the Medicare Payment Advisory Commission could inform considerations of new sociodemographic variables (e.g., the expanded low-income category discussed at recent Commission meetings)[88], as might

[88] Medicare Payment Advisory Commission. Medicare payment policies to support safety-net providers. Leveraging Medicare policies to address social determinants of health. Meeting Presentations March 2022 and April 2022.

the work of the Health Level 7 (HL7® Gravity Project. Finally, the FAH suggests that CMS explore establishing a needs assessment process through which variables with high face validity for potential disparities -- but lacking standardized definitions, credible self-reported sources within CMS data sets, and/or suitable proxy variables -- could be identified, analyzed, and refined in a transparent manner for future use (e.g., sexual orientation/gender identity).

Identification of Meaningful Performance Differences for Use in Stratified Results Reporting

CMS briefly describes multiple potentially useful methods for identifying meaningful performance differences (i.e., disparities) and sharing them with providers through stratified results reports: confidence intervals, standard deviation-based cut points, clustering algorithm use, rank ordering, categorization using thresholds or fixed intervals, benchmarking, and peer grouping. Comments are solicited about preferred methods.

The FAH believes that the preferred method(s) will vary with the quality measure and the program in which it is being used, the sociodemographic variable being studied, the disparity method being used, provider type, care setting, and intended audience for the results. Decision making should most often rest at the program level though domain, subgroup, and measure level decisions could be appropriate in select circumstances. We advise CMS to consider first if stratified results calculation and reporting of a given measure-sociodemographic variable combination is appropriate and the likelihood that the ensuing results when presented to providers will incent them to conduct self-directed analyses that could lead to effective interventions to reduce disparities. We also note that when multiple comparisons are performed, some statistically significant associations inevitably will emerge. Not all will be causal relationships and not all will be worthy of time and resource investment by providers to explore, particularly when exploration would depend heavily on scarce or costly health IT resources and capabilities. Establishing a CMS-sponsored technical assistance program for resource-limited providers should be considered.

The FAH recommends that categorization using thresholds or fixed intervals and rank ordering methods be used with particular care. Application of these methods carries relatively high risk for creating subgroups that could be inappropriately characterized as practicing discrimination. Labeling of providers as discriminatory, even though unintentional, when based on poorly chosen statistical methods and/or inappropriate application of stratified reporting results could cause long-term and nearly irreparable harm to beneficiaries, providers, and the Medicare program. The same risk appears even higher for the method of regression decomposition, not included in this RFI but described in some detail by CMS in recent rulemaking for other Medicare sectors (e.g., Inpatient Rehabilitation Facility Prospective Payment System FY 2023 Proposed Rule).

The FAH opposes the use of decompensation techniques in Medicare quality reporting and value-based programs at this time. Should CMS wish to adopt this analytic tool for use

across its quality enterprise as something other than a research tool for internal agency use only, the FAH believes that CMS must first come to stakeholders with a body of evidence that credibly, transparently, and explicitly addresses the application of Blinder-Oaxaca decomposition to Medicare disparities data analysis. The evidence must include readily understood – but not oversimplified -- simulation and modeling examples and results using actual deidentified Medicare data from several quality programs. A plan that details how results would be used internally by CMS and perhaps someday shared publicly must also be presented with special attention to how misrepresentation of providers as discriminatory would be avoided.

Guiding Principles for Reporting Disparity Results

CMS observes that the agency typically begins with confidential reports to providers before transitioning to public reporting of results from its quality reporting and value-based programs. CMS believes that initial confidential reporting is especially beneficial when new programs, measures and/or measurement methodologies are being introduced. The agency also believes that public results reporting enables market forces to incent improvement by providers in order to remain competitive. CMS states that statute requires public reporting of results from all its quality programs and strongly implies that stratified results would be similarly subject to mandatory public reporting.

The FAH strongly believes that confidential reporting to providers is entirely appropriate for measures and initiatives involving stratification for demographic and social risk factors. Results reporting should be accompanied by a review and correction process and be subject to data validation. Properly structured provider-only reporting should create an environment that facilitates the detection of unintended consequences or confusing results before any public reporting of these sensitive data is considered. Transition to public reporting should be planned and implemented in a deliberate and unhurried manner, and only after the data collected have demonstrated a high degree of reproducibility and after a period of confidential reporting that is sufficient to identify unintended consequences. We note that statute provides the Secretary with considerable discretion and flexibility regarding public reporting.

The FAH believes it to be essential for CMS to structure any public reporting of disparities comparison results in a way that avoids the risk of further disadvantaging providers who serve populations and areas with limited resources (e.g., located in low-income and rural communities). Also prior to public reporting, we strongly encourage CMS to undertake focus groups to test messaging and understanding of disparities data, so that the results reported are clear for patients, families, and caregivers. Finally, the FAH recommends that privacy protection be the foundational principle on which CMS bases decisions about disparities reporting. The importance of privacy safeguards for patients and facilities cannot be overemphasized.

Conclusion

The FAH remains supportive of the essential work being done by CMS related to healthcare disparities and inequities as represented by this Equity Measurement RFI. Application

of methods for identifying and reporting disparities within CMS programs remains a worthy goal to which the FAH recommends a deliberative, consistent, coordinated approach be taken by the agency. Some of the tools and methods described in this RFI appear promising for use in CMS programs. The FAH remains fully committed to working with CMS, HHS, and others on additional principles, tools, and methods for disparities reporting that seem likely to be feasible, practicable, and lead to improved health outcomes.

C. Continuing to Advance to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs–Request for Information

Background

In this RFI, CMS seeks feedback as it continues to articulate its vision and associated strategies for moving its entire quality enterprise to fully digital quality measurement by 2025. Special attention is given to refining the definition of digital quality measure (dQM), data standardization strategies and opportunities, and incorporating Fast Healthcare Interoperability Resources (FHIR®) into reporting existing electronic clinical quality measures (eCQM) to create dQMs. CMS builds on a predecessor RFI that was included as part of FY 2022 IPPS rulemaking, in which attention was directed to three key topics: definition of a digital quality measure, using FHIR® for existing eCQM reporting, and changes under consideration to advance dQM development (e.g., requiring dQMs to be self-contained tools).

The FAH congratulates CMS for continuing to think strategically and aspirationally about its quality enterprise, moving forward to what will inevitably be a world in which health information exchange is digital. We have long supported efforts to achieve comprehensive interoperability and data liquidity – the free flow of meaningful, actionable information that supports and enhances patient care within and across settings. We also have regularly supported proposals to improve electronic health information exchange whenever advances in health information technology (health IT) can improve quality and access to care while being cost-effective and without adding provider burden.

Refined Potential Future Definition of Digital Quality Measures (dQMs)

Based on feedback received to the predecessor RFI, CMS offers a refined definition of digital quality measure: a quality measure, organized as self-contained measure specifications and code packages, which uses one or more sources of health information that is captured and can be transmitted electronically via interoperable systems. The term “software” from the predecessor definition is eliminated in favor of “organized as self-contained measure specifications and code packages” but the remainder of the definition is unchanged. CMS continues to take a broad view of dQM data sources, including but not limited to electronic health records (EHRs), medical devices, patient-reported data, registries, and health information exchanges. CMS asks for input on the refined definition and on potential consideration or challenges related to non-EHR data sources.

The FAH supports the refined definition. We agree with CMS that standardized and clear definitions for all terms in all phases of the dQM transformation initiative will be necessary. We continue to support considering a broad range of potential data sources for use in dQMs, but we concomitantly recommend that the range should be tailored to reflect the focus of each quality program and the purpose and structure of its included dQMs. Incorporation data from non-EHR sources will add to the challenges of data standardization and interoperability for most stakeholders and will impose added burden on providers. Tailoring of data sources at the program and measure levels should reduce the frequency of the challenge. The FAH strongly recommends the use of pilot testing or other real-world trials before dQMs reliant on non-EHR data sources are proposed for addition to any CMS quality program. Only in that way can data-driven decisions be made as to whether the value added by data from non-EHR sources outweighs the consequences for a given program or dQM.

Data Standardization Activities to Leverage and Advance Standards for Digital Data

CMS reiterates its plan to design and operationalize its digital quality reporting enterprise using FHIR-based standards. CMS believes that data standardization, including requirements for interoperability of data elements, is essential to implement its digital quality measurement vision. The agency also views data standardization as foundational to alignment of CMS and other federal healthcare program data requirements. Further, data standardization is seen as necessary to enable use of a single set of provider-submitted data to subsequently satisfy multiple use cases, avoiding repetitive submissions of the same data (e.g., across quality programs, public health reporting, clinical decision support). CMS seeks comment on implementation guides (IGs) that would support its data standardization plan (e.g., Health Level 7 – HL7® – FHIR US Core Implementation Guide). CMS also requests comment on other data and reporting components for which standardization should be considered.

The FAH reiterates our prior support for data standardization including interoperability as long as standardization is not allowed to outweigh the value and utility of the data for its intended CMS quality program use. We recommend adopting standards and their related IGs that can be tailored for application at the program and measure levels and that minimize provider reporting burden. We further recommend that when potential conflicts emerge, considerations of quality program utility and provider burden should take precedence over modifying standards to accommodate use cases beyond the CMS quality enterprise.

The FAH has no objection to the specific IGs catalogued in the RFI for future use by CMS. However, we reserve explicit support for these and other IGs to be adopted systemwide until more concrete information is provided on which to base our comments, such as one or more specific examples of fully developed dQMs for use in an actual CMS quality program. In terms of other components to be standardized, we note that effective quality measurement requires smooth interplay between measures and data collection, data reporting, data submission, results calculations and feedback, data validation processes, data display, and payment adjustment policies and processes.

Finally, the FAH emphasizes the importance of timeline considerations for achieving standardization and advancing the transition of the CMS quality enterprise to fully digital. CMS states that the transition will be incremental and will begin with the uptake of FHIR Application Programming Interface (API) technology and shifting eCQM reporting using FHIR® standards. We fully support an incremental transition process. However, we note -- despite several years of experience and considerable investment of monetary and human capital – that our members continue to encounter substantial obstacles with trying to successfully report the current eCQMs of the Hospital Inpatient Quality Reporting (HIQR) Program and the Promoting Interoperability Program (PIP) for acute care and critical access hospitals.

They report needing an average of 18-24 months to roll out a single eCQM that is ready for reliable clinical reporting in their systems, often due to factors outside of their control (e.g., delayed health IT product delivery from vendors, unexpected conflicts between the eCQM software and the hospital's primary EHR). Further, despite awareness of these challenges, CMS continues to propose the addition of new eCQMs and to increase the number of measures required to satisfy PIP reporting requirements. The FAH firmly believes that our members cannot be expected to begin to participate in the CMS transformation to digital measurement until real progress is made in addressing the existing, longstanding, eCQM operational issues. We also believe that continued addition of eCQMs and increasing required reporting is not appropriate; such actions worsen current problems faced by hospitals and do little if anything to contribute to a successful transition to dQMs.

Additionally, transitioning to digital data collection and submission will be even more challenging for long-term care hospitals (LTCH), who were not part of the significant investment that was made for acute, hospital EHR systems. The FAH request that CMS take this into account when requiring any new dQM requirements for LTCHs, as additional investments will be necessary in order to successfully submit digital data that we hope would be cost-neutral to LTCHs.

Approaches to Achieve FHIR® Electronic Clinical Quality Measures (eCQM) Reporting

CMS emphasizes the key role played by eCQMs as part of its strategic plan to transition to a fully digital quality measurement enterprise, describing FHIR-based eCQM reporting as a model for how future digital reporting can occur. CMS also describes actively working on refining or repackaging current eCQMs to fit within the dQM umbrella. Further, CMS catalogues in detail its activities, ongoing and envisioned, that are intended to advance reporting of FHIR-based eCQMs and future dQMs, such as participation in HL7® Connectathons, engagement with standards development organizations, and collaboration with vendors. CMS requests input about additional venues to engage with implementers while transitioning to digital quality measurement, data flow options to be considered for FHIR-based eCQM reporting, and other critical considerations during the transition.

The FAH finds several aspects of this RFI worrisome. First, having provided numerous examples, CMS requests input about additional venues to engage with implementers. We applaud CMS for its extensive outreach, but we are disturbed by a prominent absence: hospitals

are nowhere mentioned in this section of the RFI. Given that hospitals are the entities who will be required to collect, report, and submit eCQM performance data and bear the expense of increased eCQM adoption, where and how are they being engaged by CMS other than through rulemaking? This apparent oversight is even more troubling in the context of the ongoing, substantial challenges hospitals face in reporting the current set of eCQMs. Perhaps CMS perceives that hospitals are included in "implementers" with whom it cites intended engagement, but since hospital participation underpins eCQM reporting, their future role in the digital transformation as envisioned by CMS clearly deserves specific attention.

Furthermore, the FAH firmly believes that engagement by CMS with the hospital community must involve more venues devoted to dialogue about the agency's digital quality initiatives than notice-and-comment rulemaking. Our concern is heightened even further by the agency's statement that "We also anticipate that prior to the implementation of any mandatory FHIR-based eCQM reporting requirements within our quality programs, it would be necessary to undertake voluntary reporting of FHIR-based eCQMs to allow time to learn and enhance systems and processes, both internally and among providers and vendors". While the FAH absolutely believes that voluntary reporting must precede required reporting of FHIR-based eCQMs, there also should be robust hospital-agency dialogue before reaching the point that even voluntary reporting is proposed. The agency seems to be espousing a view that real-world reporting by hospitals as provided for through rulemaking is the appropriate initial venue for finding out how well – or not -- the FHIR-based eCQM measures and processes work. This timepoint is far too late for learning and enhancing by CMS, vendors, and providers about successes and failures that could have been discovered through pilot, demonstration, or other trial mechanisms.

In this RFI section, CMS also asks about data flow options to be considered for FHIR-based eCQM reporting and states a desire for data flows that support using the same data for measurement and provider feedback as are used for patient care and other use cases such as public reporting. The FAH fully supports utilization of data for multiple use cases when the primary use case, efficient and accurate data reporting by hospitals, will not be compromised. The first data flow that should be considered is the interface between the clinical workflow and the eCQM, which our members report is extremely poor for current eCQMs. Determining optimal data flows is another area that demands robust communication and collaboration between hospitals and CMS. Next most important is the are the data flows required for data retrieval from EHRs via FHIR® APIs. Hospital personnel should not be needed to do anything than initialize data retrieval and authorize data submission once the data have been processed. Making a business case to justify the costs of eCQM adoption by a hospital requires that hospital personnel should not be required for routine measure management.

Conclusion

The FAH encourages CMS to continue its important work in charting a strategic plan for development and implementation of digital quality measurement agency-wide, as represented by the current RFI and its FY 2022 predecessor. The task ahead is large, commensurate with the potential promise of better care for Medicare beneficiaries that could be realized through a thoughtful, comprehensive, practicable, digital approach to quality measurement across the CMS

enterprise. The FAH perceives that CMS has accomplished much in the way of articulating a vision and identifying concepts. However, we also perceive that the time has arrived to move beyond RFIs and HL7 Connectathons to more concrete steps.

Some of the questions posed both this year and last are largely technical questions that might better be considered through one or more Technical Expert Panels (TEPs) hosted by CMS with support as needed from the Office of the National Coordinator for Health IT (ONC) rather than through more RFIs or proposed rulemaking. The output of the TEPs could be used to inform stakeholder meetings, convened by CMS. Each meeting should have a clear focus and at a minimum include those who will be tasked to implement digital quality measurement in the trenches (i.e., hospitals and other providers). CMS should use the TEP and stakeholder meeting feedback to complete development of a parsimonious but meaningful set of FHIR-based eCQMs and to design one or more trial opportunities for those measures by relevant providers (e.g., pilot testing by a volunteer group of acute care and critical access hospitals). The trial design should be transparent and announced publicly with an opportunity for stakeholder comment before participant recruitment. Participants should be incented to participate through grants to offset expenses of operationalizing the eCQMs, free technical assistance, and reduced required eCQM reporting plus PIP bonus points. Results of the trials must be shared transparently with participants and should also be made public as long as data privacy safeguards can be put in place.

CMS should engage its in-house laboratory, Center for Medicare and Medicaid Innovation (CMMI), in trial design and rollout rather than collectively using IPPS hospitals as a test bed through HIQR Program and PIP eCQM requirements. CMS also needs to ascertain from hospitals their actual state of readiness to incorporate FHIR-based API use as part of their quality measurement efforts in the very near term. While the steps outlined above are underway, other related health IT initiatives should mature and their potential roles in a digital CMS quality enterprise can be assimilated.

The FAH stands ready to partner with CMS in the important but pragmatic work that must be done.

D. Advancing the Trusted Exchange Framework and Common Agreement–Request for Information

The FAH believes that cohesiveness in health information technology (HIT) management can improve the quality and efficiency of care provided to patients, reduce provider burden, and advance population health management and breakthroughs in health care research. The FAH appreciates ONC's leadership efforts to further the exchange and use of health information and offers the below comments in response to the Trusted Exchange Framework and Common Agreement (TEFCA) Request for Information (RFI).

The FAH and its members are committed to furthering TEFCA's goals in establishing a universal policy for interoperability, simplifying connectivity for organizations to securely exchange health information to improve patient care and access to information. As TEFCA is

still in early implementation stages, it needs to be tried and tested before being widely adapted to all CMS programs. It is premature to consider expansion of TEFCA into CMS programs and without specific proposals, our comments cannot thoroughly address such potential expansion. In the event of any future expansion of TEFCA, we urge CMS to provide hospitals and all stakeholders an opportunity for regulatory notice and comment.

In the meantime, the FAH urges CMS to consider the following principles regarding further advancement of TEFCA:

- TEFCA should support a variety of use cases in the health care community, as well as a variety of health care payment purposes, such as streamlined prior authorization, utilization management, and other provider-to-payer communications.
- As discussed above, we believe it is premature to consider expanding the use of TEFCA across CMS programs. In the future, if such consideration becomes appropriate, CMS would need to ensure that TEFCA creates a floor for interoperability across CMS programs, with standardized clinical content and methods of delivery for all data sets – this would promote transparency, provide minimum necessary guardrails for data exchange, and ease burden for use cases.
- CMS also should evolve these data sets in alignment with the ONC Standards Version Advancement Process (SVAP) so that the health care community exchanges data in a more structured way.
- With any CMS-sponsored use of TEFCA, a uniform approach would "right-size" the clinical content needed for a particular service or purpose, increasing health care efficiencies and targeted care.
- CMS also should consider establishing a public health Qualified Health Information Network (QHIN) to participate in TEFCA, which could support public health reporting required by CMS programs and ease the significant burden and expense on providers of working with state public health agencies.

The FAH applauds TEFCA's potential to accelerate interoperability across the country but there are significant concerns that need to be addressed in doing so at such scale. For example, a key obstacle to data exchange is patient matching. A standard patient matching approach across the TEFCA model is critical to ensure participants do not miss or mismatch patients. This will be vital to its maturity while ensuring confidence in patient identity resolution overall. Also, there is a lack of consistency in the availability and use of mapping terminologies and CPT codes. These inconsistencies are a barrier to true interoperability, so advancing the standardization of semantic terminologies and licensing public use of highly adopted terminologies would advantage all participants. We are also concerned about potential bad actors participating in TEFCA –interoperable health data exchange increases efficiency but also creates the possibility that some may misuse this information, which could undermine the strides taken to promote interoperability. As TEFCA continues to mature, we urge CMS and ONC to work with stakeholders to address these significant challenges.

E. Hospital Inpatient Quality Reporting (IQR) Program

New Measures Being Proposed for the Hospital IQR Program Measure Set

Hospital Commitment to Health Equity beginning with the CY 2023 reporting period/FY 2025 payment determination

The FAH has several concerns about this measure. We note that during pre-rulemaking, the Measures Application Partnership's (MAP) Hospital Workgroup observed that evidence for a linkage between the measure and improved health outcomes had not been established. Similarly, the MAP also noted that a performance gap among hospitals for the measure's five structural elements (i.e., to which attestation would be required) had not been demonstrated.

We believe that many of the priorities included in this structural measure are currently addressed by hospitals and health systems. Many already have in place language and communication access plans woven into their frameworks for ongoing provision of culturally competent care to patients with limited English proficiency and hearing or vision disabilities. These plans typically form part of the curricula for onboarding and refresher training of patient-facing staff. Hospitals also maintain certified electronic health record technology (CEHRT) capabilities as required under the CMS Promoting Interoperability Program for hospitals.

These activities also overlap with accreditation requirements of hospitals generally or of special hospital programs (e.g., accreditation of bariatric surgery programs that mandates culturally competent care of morbidly obese patients). Discharge processes are already set up to evaluate a patient's access to their medication, transportation needs to downstream physicians and services and hospitals' interventions help patients return to the community in the most successful way they can. Healthcare providers already work to mitigate risk factors, such as certain social determinants which could negatively affect our patients' outcomes. A measure that assesses hospitals' commitment to equity could disadvantage certain providers, as every community differs in their available resources. Providers should not be penalized for resources, or lack thereof, outside the scope of their care.

The FAH urges CMS to first catalogue what hospitals are already doing before establishing new measures or requirements to preclude burden caused by overlap and redundancy. A complete environmental scan, listening sessions, focus groups, and/or a Technical Expert Panel would be helpful. We also believe that the measure development process will also ensure that the measure is closely linked to clinical outcomes and that there is a clear gap in hospital performance on these specific structural elements. CMS should not pursue measures which increase burden on healthcare providers and do not have a direct, peer-reviewed link to the quality of care they provide.

In addition, the FAH believes that CMS has the opportunity to address inequities in care through existing measurement efforts. For example, the collection of race/ethnicity, payer, and gender have always been included in the electronic clinical quality measure (eCQM) specifications as supplemental data elements. CMS could choose to make the collection and reporting of these data required. This change would allow hospitals to collect the data, use it for

improvement purposes, and receive automatic credit through reporting of these data rather than require them to attest to it through a structural measure. Further specificity regarding what would specifically satisfy each of the statements is also needed to ensure that every hospital interprets and attests to them consistently. For example, what constitutes a majority of patients under question 2b and what are the minimum requirements for participation in a local, regional, or national quality improvement activity under question 4a?

Requiring the reporting of a potentially flawed measure to which revisions may soon be needed creates unnecessary burden for CMS and for providers and squanders finite resources that could be invested by CMS and providers into more effective equity initiatives. While we do not support this measure at this time, we are prepared to partner with CMS to refine this measure or develop alternative measure concepts.

Screening for Social Drivers of Health beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination

The FAH supports the development and implementation of measures that seek to address inequities in care and those factors that may directly or indirectly impact an individual's ability to achieve positive health outcomes. Regrettably, the FAH is unable to support the inclusion of this measure in the Hospital Inpatient Quality Reporting (IQR) Program for several reasons.

While the FAH supports the overall intent, we do not believe that the measure as specified provides evidence to demonstrate that screening of these specific factors in the inpatient setting is linked to improvements in health outcomes nor is it clear on the degree to which the selected factors are aligned with the work of the Health Level 7 (HL7) Gravity Project. It also assesses the rate of screens completed by a hospital in the absence of any information on the degree to which a facility has been equipped with the necessary resources and tools to address the individual's needs for any one of the selected factors. Any implementation of this measure is premature until these resources and tools are widely available, and the measure currently does not exclude patients whose length of stay is only one or two days, which makes it far more difficult for a hospital to administer this screening in addition to all of the other important clinical activities that may take place during an admission.

We also believe that by allowing hospitals to screen on one or all of the five factors using any tool negatively impacts the validity of the resulting performance scores as there is increased potential for hospitals who opt to focus on one risk factor will be compared against another that attempts to screen all patients on all five items. CMS should consider putting forward a measure that leverages social determinants of health that are standardized through the HL7 Gravity project, provides the necessary denominator exclusions, and is fully tested for feasibility, reliability, and validity.

The FAH believes that these questions and concerns must be addressed and endorsement by the NQF should be achieved prior to implementation of this measure in the Hospital IQR Program.

Screen Positive Rate for Social Drivers of Health beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination

The FAH supports the development and implementation of measures that seek to address inequities in care and those factors that may directly or indirectly impact an individual's ability to achieve positive health outcomes. Regrettably, the FAH is unable to support the inclusion of this measure in the Hospital Inpatient Quality Reporting (IQR) Program for several reasons.

While the FAH supports the overall intent, we do not believe that the measure as specified provides evidence to demonstrate that reporting of the positivity rate for one or more of these factors in the inpatient setting is linked to improvements in health outcomes. It also assesses the rate of positive screens in the absence of any information on the degree to which a facility has been equipped with the necessary resources and tools to address the individual's needs for any one of the selected factors. Any implementation of this measure is premature until these resources and tools are widely available, and the measure currently does not exclude patients whose length of stay is only one or two days, which makes it far more difficult for a hospital to administer the required screening in addition to all of the other important clinical activities that may take place during an admission.

We also believe that the current proposed measure calculation is flawed since it will report five separate rates based on the total number of patients 18 years and older on the date of admission screened for all five factors. The first measure on screening allows hospitals to select whether they will report on one or all of the five items using any tool, but this subsequent measure assumes that hospitals will screen on all five. As a result, it remains unclear whether there will be sufficient denominator sizes to enable reliable and valid comparisons. It also demonstrates that neither of these measures are adequately tested; otherwise, these types of inconsistencies would have been addressed and the specifications modified. CMS should only implement a measure that leverages social determinants of health that are standardized through the HL7 Gravity project, provides the necessary denominator exclusions, and is fully tested for feasibility, reliability, and validity.

The FAH believes that these questions and concerns must be addressed and endorsement by the NQF should be achieved prior to implementation of this measure in the Hospital IQR Program.

Cesarean Birth electronic clinical quality measure (eCQM) with inclusion in the measure set beginning with the CY 2023 reporting period/FY 2025 payment determination, and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination

The FAH supports the inclusion of this measure but only if its endorsement status by the NQF is maintained and further testing is completed across a broader set of hospitals and electronic health record systems (EHRs). The FAH identified that measure testing was only completed across seven hospitals and two EHRs. The FAH strongly encourages CMS to assess the feasibility and validity of collecting the required data elements from additional hospitals and EHRs. Thorough assessments of each data element and the required calculations and logic must

be vetted across more hospitals and vendor systems to truly understand whether this measure is ready for implementation. If the measure is not determined to be feasible and valid in the majority of vendor systems currently used, then it would be prudent for CMS to delay implementation until these gaps can be addressed.

Severe Obstetric Complications eCQM with inclusion in the measure set beginning with the CY 2023 reporting period/FY 2025 payment determination, and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination

The FAH strongly supports efforts to address pregnancy-related morbidity and mortality and we appreciate the CMS developing an outcome measure that specifically addresses this issue. While we encourage CMS to further test this eCQM to assess the feasibility of collecting the required data elements from electronic health record systems (EHRs) and determine if the measure is reliable and valid across a broader set of EHRs vendors and hospitals, we are encouraged to see the number of hospitals and vendor systems used. We also ask that the measure be endorsed by the NQF prior to its implementation in the Hospital IQR Program.

Hospital-Harm—Opioid-Related Adverse Events eCQM (NQF #3501e) beginning with the CY 2024 reporting period/FY 2026 payment determination

The FAH is concerned with the lack of an adequate performance gap for this measure since the recent submission to the NQF reported performance scores across six hospitals that ranged between 0.11 to 0.45%. eCQMs require significant resources and time for hospitals to implement and only those eCQMs with demonstrated gaps in care should be used for accountability purposes. We recommend that CMS continue to test this measure across a broad range of hospitals and vendor systems to determine the extent to which there is sufficient variation in performance scores to warrant the measure's use in the Hospital IQR Program.

Global Malnutrition Composite Score eCQM (NQF #3592e) beginning with the CY 2024 reporting period/FY 2026 payment determination

The FAH was unable to determine the extent to which this composite has been adequately evaluated for feasibility and tested for reliability and validity across a broad range of hospitals and vendor systems. eCQMs require significant resources and time for hospitals to implement and only those eCQMs with robust testing should be used for accountability purposes. We recommend that CMS continue to test this measure across a broad range of hospitals and vendor systems prior to its use in the Hospital IQR Program.

Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #3559) beginning with two voluntary periods, followed by mandatory reporting for the reporting period which runs from July 1, 2025, through June 30, 2026, impacting the FY 2028 payment determination

The FAH continues to have the same concerns expressed in our response to the FY 2022 IPPS Proposed Rule and we do not believe that CMS adequately addressed this issue. We believe that additional questions and work remain before this or any other PRO-PM are implemented in

the Hospital IQR program. These analyses should include the degree to which multiple PRO-PMs could lead to survey fatigue for patients, the potential impact 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 health care provider.

The proposed data submission approach for voluntary and mandatory reporting, particularly for those hospitals that elect to submit data to CMS for measure aggregation and calculation, does not provide sufficient time for hospitals to gain experience and use the resulting data to improve their data collection processes. For example, hospitals who are able to start reporting in CY 2023 will have just received their first year of results and those facilities who begin in CY 2024 will not have received any feedback reports prior to the start of mandatory reporting. In addition, it is still not known whether response rates will be sufficient across the 425 days of data collection to enable reliable and valid comparisons of hospital performance. We encourage CMS to extend the voluntary reporting period to allow more hospitals to gain experience with the measure requirements, particularly due to its complexity.

Medicare Spending Per Beneficiary (MSPB) Hospital (NQF #2158) beginning with the FY 2024 payment determination

The FAH appreciates CMS' ongoing efforts to further refine and improve this measure. However, we continue to question the scientific acceptability of the measure based on the risk model's fit with the unadjusted and adjusted R-squared ranging from 0.11 to 0.67 across the Major Diagnostic Categories. The FAH does not believe that the reasons for this result were adequately addressed, and risk adjustment must be improved. In addition, we remain concerned with the risk adjustment approach to determine whether inclusion of social risk factors. The FAH believes that this approach should not consider the identification and testing of social risk factors as supplementary to clinical risk factors. Even with testing of the social risk factors after the clinical risk factors, analyses showed that hospitals' measure scores shift when some or all of the social risk factors are applied within the risk model and particularly just over 15% of safety-net hospitals moved above or below the delta. This shift should lead CMS to reconsider inclusion of some or all of the variables in the risk model.

CMS must address the concerns with the risk model prior to implementation of this updated measure in the Hospital IQR Program. We also believe that public reporting of duplicate but differing measure results across the Hospital IQR and Hospital VBP Programs should not be allowed. The potential for misleading and/or inaccurate information must be avoided at all costs and this measure should be suppressed in the Hospital VBP Program once data from the updated version are made publicly available.

Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA/TKA (NQF #1550) beginning with the FY 2024 payment determination.

The FAH appreciates the inclusion of the additional ICD-10 codes for mechanical complications in response to feedback from subject matter experts. While we agree that these changes will likely not significantly impact the reliability and validity of the measure, we

encourage CMS to update the testing and achieve endorsement of these changes the National Quality Forum before implementation in the Hospital IQR Program.

We also believe that public reporting of duplicate but differing measure results across the Hospital IQR and Hospital VBP Programs should not be allowed. The potential for misleading and/or inaccurate information must be avoided at all costs and this measure should be suppressed in the Hospital VBP Program once data from the updated version are made publicly available.

Proposed Refinements to Current Measures in the Hospital IQR Program Measure Set

Proposed Refinement of the Hospital-Level, Risk-Standardized Payment Associated with an Episode of Care for Primary Elective Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Measure (NQF #3474) Beginning with the FY 2024 Payment Determination and for Subsequent Years

CMS proposes a refinement to this measure that expands the measure outcome to include 26 clinically vetted mechanism complication ICD-10 codes, for the FY 2024 payment determination and subsequent years.

The FAH appreciates the inclusion of the additional ICD-10 codes for mechanical complications in response to feedback from subject matter experts. While we agree that these changes will likely not significantly impact the reliability and validity of the measure, we encourage CMS to update the testing and achieve endorsement of these changes the National Quality Forum before implementation in the Hospital IQR Program.

Proposed Refinement of the Excess Days in Acute Care (EDAC) After Hospitalization for Acute Myocardial Infarction (AMI) Measure (NQF #2881) Beginning with the FY 2024 Payment Determination and for Subsequent Years

CMS proposes to refine this measure by increasing the minimum case count for reporting.

The FAH appreciates that CMS was responsive to the concerns of the NQF's Scientific Methods Panel and increased the case minimum to 50 patients to improve the intraclass correlation coefficients (ICC) result. The FAH believes that measures must meet a minimum ICC reliability threshold of 0.6 or higher. Based on the information submitted to NQF, it would require at least 300 patients before this threshold could be achieved and therefore would limit the number of hospitals on which the measure could be reported. As a result, the FAH does not believe that this measure is appropriate for use in the Hospital IQR Program.

Potential Future Inclusion of Two Digital National Healthcare Safety Network (NHSN) Measures

CMS seeks public comment on the application of one or both of the NHSN measures ((Healthcare-associated Clostridioides difficile Infection (CDI) Outcome measure and Hospital-Onset Bacteremia & Fungemia Outcome measure)) in the Hospital IQR Program.

The FAH supports the shift to digital quality measurement as it will hopefully advance our ability to achieve comprehensive interoperability and the capture of meaningful, actionable information that supports and enhances patient care within and across settings. We also support the changes to the numerator to add the clinical component of qualifying antimicrobial therapy and believes that it will improve the validity and accuracy of the CDI measure. The FAH encourages CMS to continue to test and implement the two digital CDC NHSN measures and ensure that they are feasible to implement by hospitals and produce reliable and valid results. In addition, these measures must be endorsed by the National Quality Forum prior to implementation in the Hospital IQR Program.

Form, Manner, and Timing of Quality Data Submission

Reporting and Submission Requirements for eCQMs

CMS proposes to modify the eCQM reporting and submission requirements to increase the number of eCQMs to be reported beginning with the CY 2024 reporting period/FY 2026 payment determination. The FAH supports this change as it enables hospitals to leverage electronic data collection and reporting to the greatest extent possible.

Data Submission and Reporting Requirements for Hybrid Measures

Proposed Modification of the Zero Denominator Declarations Policy and Case Threshold Exemptions Policy for Hybrid Measures

CMS proposes to remove zero denominator declarations and case threshold exemptions as an option for the reporting of hybrid measures beginning with the FY 2026 payment determination. The FAH support this change.

Proposed Data Submission and Reporting Requirements for Patient-Reported Outcome-Based Performance Measures (PRO-PMs)

CMS proposes to allow hospitals to choose from two options for data submission and outlines the requirements for voluntary and mandatory reporting for patient-reported outcome-based performance measures (PRO-PMs) beginning with the FY 2026 payment determination.

The FAH cautions CMS on moving too quickly to mandatory reporting of the THA/TKA PRO-PM. Given the complexity of the measure, we believe that hospitals will need additional time and experience to ensure successful and sufficient reporting of the data required for this measure. We ask that CMS reconsider the proposed 50% submission requirement for pre-operative and matching post-operative PRO data. While this response rate would likely be optimal for establishing adequate sample sizes for reliability, it is not clear whether hospitals will be able to produce this degree of completeness initially. It remains unclear on the degree to which response rates could be negatively affected due to the lengthy data collection period of over one year. There is significant potential for hospitals to be unable to meet the 50% requirement and we encourage CMS to reduce this requirement. We also urge CMS to extend the

voluntary reporting period beyond two years to allow hospitals to gain more experience with the measure.

Validation of Hospital IQR Program Data

Proposed Modifications to the Existing Processes for Validation of Hospital IQR Program eCQM Data

CMS proposes to modify the eCQM validation policy to increase the requirement from 75 percent to 100 percent of requested medical records, beginning with the FY 2025 payment determination. The FAH supports this change, particularly since the vast majority of hospitals already provide 100 percent of all requested medical records.

H. Proposed Changes to the Medicare Promoting Interoperability Program

e-Prescribing Objective: Mandatory Reporting Query of Prescription Drug Monitoring Program

CMS proposes to change the Query of Prescription Drug Monitoring Program (PDMP) measure from optional to mandatory reporting beginning with the CY 2023 EHR reporting period. Two exclusions would be available for hospitals lacking access to a pharmacy that can accept electronic prescriptions for controlled substances and those who cannot report on this measure in accordance with applicable law. CMS further proposes at the same time to expand the measure to include Schedule III and IV controlled substances instead of only Schedule II. The measure would require a "Yes/No" response and 10 points would be awarded for a Yes response; as a result, the measures under e-Prescribing Objective of the PIP would be worth a total of 20 points.

The FAH supports changing the Query of Prescription Drug Monitoring Program (PDMP) measure to mandatory reporting as proposed with the associated exclusions and the expansion to Schedule III and IV controlled substances. We also support the proposed value of 10 points. We recommend that CMS verify vendor readiness for making these changes timely before finalizing them beginning with FY 2023.

Public Health and Clinical Data Exchange Objective: Mandatory Measure Addition, Active Engagement Revisions, and Scoring Modifications

CMS proposes a number of changes to the Public Health and Clinical Data Exchange Objective, all to begin with the CY 2023 EHR reporting period. First, a new mandatory measure, Antimicrobial Use and Resistance (AUR) Surveillance would be added, resulting in a total of five mandatory measures and two optional measures under this objective. Hospitals reporting a "Yes" response or meeting an exclusion criterion would receive credit for the measure. The FAH recognizes the critical importance of data exchange between hospitals and public health agencies and registries, as has been repeatedly demonstrated during the COVID-19 PHE. We also acknowledge the necessity for responsible antibiotic stewardship.

However, the FAH cannot support adoption of the AUR Surveillance measure as proposed by CMS at this time. Our members continue to report challenges at the state and EHR vendor levels with fully implementing three of the four existing required measures under this

objective, namely Immunization Registry Reporting, Electronic Reportable Laboratory Results Reporting, and Electronic Case Reporting. Bi-directional HIE between hospitals and public health agencies is far from the smooth flow described by CMS, particularly when state lines are crossed (e.g., multistate health systems) or when EHR products from other than the few market-dominant vendors are used by hospitals. To add a fifth public health mandatory reporting measure for CY 2023 reporting will push our hospitals far beyond their capacity to comply in terms of time, personnel, and cost. If CMS elects to push forward with the AUR Surveillance measure, the FAH strongly recommends delay until at least the CY 2024 EHR reporting period and making the measure optional for at least a two-year period during which 10 bonus points would be awarded for its reporting. In parallel, CMS should exert its leverage on states to enable bi-directional information exchange by all of their agencies with all of the hospitals within their states. All actors involved in this vital exchange of information should be held accountable, not solely hospitals.

CMS also is proposing to push hospitals to reach a higher level of active engagement more quickly in reporting public health measures by revising the option levels for engagement and the timeline for advancing to a higher level. Hospitals would only be allowed to remain at the Pre-production and Validation level (Option 1 Level) before moving to Validated Data Production (Option 2 Level) for each measure they report whether mandatory or optional. The FAH supports the level of engagement changes proposed by CMS but recommends that an exclusion be available to a hospital when its state agency is unable to complete bi-directional exchange with the hospital.

Finally, CMS seeks to further emphasize the significance of public health data exchange by hospitals with clinical registries and public health agencies by adjustments to the scoring for the Public Health and Clinical Data Exchange Objective. The points available for reporting all of the mandatory measures under this objective would increase from 10 points currently to 25 points; the added 15 points would come from reducing the points associated with the Provide Patients Electronic Access to Their Healthcare Information measure under the Provider to Patient Exchange Objective from the current 40 points to 25 points. When combined with the scoring changes proposed under the e-Prescribing and HIE Objectives, the PIP point distribution would be: 20 points for the e-Prescribing Objective, 30 points for the HIE Objective, 25 points for the Provider to Patient Exchange Objective, and 25 points for the Public Health and Clinical Data Exchange Objective. The FAH fully supports these scoring adjustments to recognize the absolute necessity of smooth and timely information exchange between state agencies and hospitals.

Public Reporting of Medicare Promoting Interoperability Data

CMS proposes to begin reporting of individual hospital overall PIP scores and the hospital's CMS EHR certification ID, starting with the CY 2023 EHR reporting period. Hospitals would have a 30-day preview period before their data would be publicly posted to the Care Compare website. The FAH generally supports making performance data accessible and transparent to consumers when feasible and meaningful. In that spirit, we support this proposal, though we question how meaningful and useful these particular data will be to beneficiaries and other consumers.

Promoting Interoperability Program eCQM Requirement Changes

New Measures for Mandatory Reporting

To maintain eCQM alignment, CMS proposes to add the same two eCQMs to the PIP that are being proposed for addition to the HIQR Program: Cesarean Birth eCQM and Severe Obstetric Complications eCQM. Both measures would be available for voluntary, self-selected reporting in the CY 2023 EHR reporting period followed by mandatory reporting starting with CY 2024. The FAH has several concerns about these two measures as noted previously in this letter. Feasibility and validity testing for the measures was conducted at a limited number of hospitals and using only two EHR products. The measures as currently specified are not yet NQF endorsed.

The FAH recognizes that these measures are designed to address the maternal health measure gap in CMS programs, and we support addressing that very important gap in a timely manner. However, we strongly recommend that measure adoption be deferred until further testing results are available for public review and the measures receive NQF endorsement. Maternal health improvements will not be achieved through the use of inadequately tested measures. We also note the frequent use in hospitals' Labor and Delivery units of specialized software that often does not fully integrate with the hospitals' primary EHR products. The incomplete interface impedes transfer of clinical information from the specialty software to the primary EHR in a format that would allow eCQM reporting.

Mandatory reporting of both the Cesarean Birth eCQM and Severe Obstetric Complications eCQM starting with CY 2024 reporting as proposed would increase the total number of required eCQMs from four to six. Regardless of the merits of these two measures, the FAH strongly objects to the proposal for a 50 percent increase in the number of mandatory eCQMs in a two-year period. Adding eCQM reporting capacity entails substantial time and expenses for a hospital; our members estimate a typical time of two years per measure. This includes time to validate that the vendor's solution has in fact accurately captured all of the data necessary for reporting the new eCQM, plus time to troubleshoot the problems identified, as trouble-free functionality is the exception, not the norm. Until vendors are required to provide a high-reliability product, the time for hospitals to rollout new eCQMs cannot be streamlined. The hospital clock for required reporting should not begin ticking until the vendor has delivered a complete and reliable product. Further, we note that the costs required for implementing new eCQMs is additive to the high annual costs of upgrading eCQM mapping tools each year. Should CMS choose to proceed with adopting one or both of the proposed new eCQMs, the FAH strongly recommends one or more of: delaying adoption for at least one year, adopting them separately (i.e., one per year), lengthening the period of their voluntary self-selected reporting status, awarding bonus points for their reporting, and permanent adoption only as optional, self-selected rather than mandatory measures.

New Measures for Optional, Self-Selected Reporting

CMS proposes to adopt two new eCQMs for optional, self-selected reporting by hospitals beginning with the CY 2024 EHR reporting period: Hospital Harm-Opioid-Related Adverse

Event eCQM (NQF #3501e) and Global Malnutrition Composite Score eCQM (NQF #3592e). The FAH has concerns about these measures as already stated above with our comments on the HIQR Program. In relation specifically to the PIP, we believe that translating the rather complex, multi-step Global Malnutrition Composite Score eCQM into a practicable eCQM for hospital use will be challenging for vendors and hospitals and suggest that measure adoption be delayed for an additional year. Regarding the Hospital Harm-Opioid-Related Adverse Event eCQM (NQF #3501e), we are skeptical about the volume of these incidents in the inpatient setting and suggest that the measure be respecified for outpatient settings.

X. Changes for Hospitals and Other Providers and Suppliers

B. Condition of Participation (CoP) Requirements for Hospitals and CAHs To Report Data Elements To Address Any Future Pandemics and Epidemics as Determined by the Secretary

CMS is proposing revisions to the hospital and critical access hospital (CAH) infection prevention and control condition of participation (COP) requirements that would require hospitals and CAHs to continue COVID-19 and seasonal influenza reporting. The proposed revisions would apply upon conclusion of the COVID-19 public health emergency (PHE) and continue until April 30, 2024, unless the Secretary establishes an earlier ending date.

In addition, the Proposed Rule would establish reporting requirements for future PHEs related to epidemics and pandemics by requiring hospitals and CAHs to electronically report daily information on acute respiratory illness (including, but not limited to seasonal influenza virus, influenza-like illness, and severe acute respiratory infection), SARS-CoV-2/COVID-19, and other viral and bacterial pathogens or infectious diseases of pandemic or epidemic potential only when the Secretary has declared a PHE directly related to such specific pathogens and infectious diseases. Specifically, when the Secretary has declared a PHE, CMS proposes to require hospitals and CAHs to report specific data elements to the CDC's National Health Safety Network (NHSN), or other CDC-supported surveillance systems, as determined by the Secretary. These proposed requirements would allow reduced frequency of reporting and modified or limited data elements at the discretion of the Secretary.

The FAH appreciates CMS' leadership role in engaging stakeholders and seeking their input for gathering appropriate hospital data to address the ongoing COVID-19 PHE as well as ensure systems and processes are established, appropriate, and ready to activate for future PHEs. We welcome the opportunity to partner with CMS in providing FAH members' experience in reporting COVID-19 hospital data. In being on the front lines of this unprecedented and ongoing PHE, our members have a first-hand view of the data that is most important to track and report to best address and optimize infection control. To this end, we offer the following recommendations regarding CMS' proposals for hospital data reporting:

- *Simplify data reporting:* If CMS were to finalize the proposal to continue hospital data reporting through April 30, 2024, it is critical to simplify the data elements that need to

be reported, along with reduced frequency of the reporting requirements. This would allow hospital staff more time to focus on treating patients and reduce the time hospital staff must expend in tracking down data, especially in rural facilities where in some cases the data needs to be gathered manually from multiple departments. Reducing any over-reporting of data is especially important as we face widespread health care workforce shortages across the nation, as multiple staff are required in the effort to report hospital data.

- *Early stakeholder engagement:* For purposes of future PHEs, although planning for the unknown presents significant challenges, nevertheless, it is critically important to build into the planning structure a process to efficiently and regularly communicate with, and receive feedback from, all stakeholders involved in the reporting effort. This effort should focus on the data elements, including frequency, that make that meet the appropriate objectives for the specific PHE at hand. In addition, careful review of reporting program requirements should occur at the outset of development of the reporting program and prior to program implementation, with early stakeholder engagement and communication, to ensure that the reported data meets its intended objective. This will allow hospitals to treat and protect their patients and communities.

- *Consistency with CDC Requirements:* To streamline efforts and minimize confusion about data reporting, CMS should ensure that COP reporting requirements are consistent with CDC requirements.

- *Standardization of reporting program:* At the outset of the COVID-19 PHE, when data reporting was initiated, many reporting requirements changed often, were confusing and inconsistent with some state programs and requirements, and many were not related to an appropriate objective in terms of maximizing infection control and consistency with hospital workflows. Thus, the lesson learned from the early days of the current PHE, is that a standardized, consistent, and familiar reporting plan is vital, along with a standardized reporting frequency.

X.C. RFI: Payment Adjustments for Domestically Made N95 Respirator

CMS requests public comment on potential ways to use payment adjustments under the IPPS and OPPS to facilitate access to wholly domestically manufactured surgical N95 respirators regulated by the National Institute for Occupational Safety and Health (NIOSH). The FAH supports the Administration's policy goal of ensuring that quality personal protective equipment (PPE) is available to health care personnel when needed by maintaining production levels of wholly domestically made PPE. In particular, NIOSH-approved surgical N95 respirators are critical to controlling the spread of respiratory diseases like COVID-19 and preparing for future pandemics, and because domestic production is less vulnerable to supply chain interruptions, sustaining an appropriate level of wholly domestic production of PPE is an important component of pandemic preparedness. The FAH commends the Federal government's commitment to purchase wholly domestically made PPE in line with the requirements of section 70953 of the

Infrastructure Investment and Jobs Act, and CMS for its forward thinking on strategies to ensure the availability of high quality and reliable PPE.

CMS requests comment on two potential options:

1. Biweekly interim lump-sum payments to hospitals that would be reconciled at cost report settlement that account for the marginal difference in costs between NIOSH-approved surgical N95 respirators that are wholly domestically made and those that are not; or
2. A claims-based approach where Medicare could establish a MS-DRG add-on payment when hospitals meet or exceed a threshold of purchasing 50 percent or more wholly domestically sourced surgical N95 respirators.

Of these two options presented in the Proposed Rule, the FAH supports using the cost report to subsidize the purchase of domestically produced N95 respirator masks but urges modification of the proposal to simplify administration of the adjustment and minimize provider burdens. In developing any payment adjustment program to support hospitals' purchase of wholly domestically made NIOSH-approved surgical N95 respirators, CMS should maintain a primary focus on minimizing the burden of the program in order to ensure that hospitals can participate in the program without unnecessarily diverting resources to operational overhead and record keeping.

A cost report approach would be more amenable to burden reduction than a claims-based approach that might necessitate real-time decisions regarding eligibility for the payment adjustment. For example, CMS could use a targeted survey to determine an appropriate amount for the payment adjustment in light of typical market price differentials between wholly domestically produced and other N95 respirators and then make use of a simple cost report attestation to determine whether a hospital has met the threshold for the payment adjustment.

In addition, the FAH urges CMS to implement any payment adjustment in a non-budget neutral manner. Budget neutral implementation of a payment adjustment would be challenging to determine prospectively and would inappropriately depress Medicare payments for purposes of pandemic preparedness during an ongoing PHE while creating new compliance burdens for hospitals.

Additionally, to reduce provider burden and to assure CMS that hospitals are purchasing and using wholly domestically made NIOSH-approved surgical N95 respirators, CMS or FDA should maintain and make available a list of N95 unique device identifier codes or bar codes that meet CMS' requirements for being wholly domestically made NIOSH-approved surgical N95 respirators. Hospitals would then be able to more easy track purchases of acceptable products and maintain appropriate records for documentation and compliance purposes.

Further, while we agree that in an ideal world that products would be produced and sourced 100% domestically, including raw materials, CMS may want to consider allowing some level of foreign sourcing with domestic production. Given challenges in manufacturing, sourcing, and efforts to build resiliency and redundancy, a manufacturer may need to replace source inputs with other imported products at different points in time. CMS may want to

consider allowing some small portion of the product (for example, the wire nosepiece) to be imported.

As for other domestically sourced products, and to ensure that the volume of products included in this program would warrant the administrative complexity, CMS may want to consider additional procedural and surgical masks.

OUTLIER PAYMENTS FY 2023

Addendum II.A.4.j. Proposed Outlier Payments

For FY 2023, CMS has proposed that a case will be eligible for a high-cost outlier payment when the cost of the case exceeds the sum of the prospective payment rate for the MS-DRG plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus the proposed fixed loss threshold of $43,214. The current fixed loss threshold, which has been in effect since October 1, 2021, is $30,988. The proposed fixed loss threshold would thus be an increase of more than $12,000, on top of increases in the threshold between FYs 2017 to 2022 totaling more than $7,000. CMS states that it has used the same basic methodology to calculate the fixed loss threshold as it has since FY 2014, with limited exceptions in prior years (including, beginning in FY 2020, modifying its methodology to account for the estimated impact of outlier reconciliation and using public, FY data to calculate the charge inflation factor). For FY 2023, however, CMS has proposed several modifications to its method, essentially using a blend of data predating the period of the COVID-19 public health emergency (PHE) and more recent data from during the PHE to establish the fixed-loss threshold. Alternatively, using only more recent data exclusively from the period of the PHE, CMS has calculated an alternative fixed loss threshold of $58,904.

Overall, the proposed fixed loss threshold for FY 2023 would be a roughly $12,000 and 40 percent increase over FY 2022. And looking back just six years, CMS' proposed threshold is nearly $20,000—or more than 80 percent—higher than what it was in FY 2017. These dramatic and accelerating increases in the threshold suggest that the data used to set the proposed threshold is abnormal and CMS needs to modify its process further to adjust the data so that the threshold will be set at a level that is not only likely to produce total outlier payments at CMS' 5.1 percent target, but helps ensure that rural hospitals, whose DRG payments are offset 5.1 percent, can access outlier payments.

With all indications that the claims and other data from the PHE are not likely to be representative of the claims and payment variables in FY 2023, the FAH supports CMS' proposal to use as much data as possible that predates the PHE for purposes of key outlier calculations. This includes CMS' proposal to use data from periods before the PHE to calculate the adjustment factors for charge inflation and cost to charge ratios (CCRs). Likewise, with respect to the LTCH PPS, the FAH supports the use of pre-PHE data where appropriate, including CMS' proposal to use claims data from the FY 2021 MedPAR file and LTCH cost report data from the FY 2020 HCRIS file for FY 2023 LTCH PPS ratesetting, with appropriate modifications to the methodology for the high-cost outlier fixed loss threshold.

However, despite these helpful adjustments to CMS' method, we are concerned that CMS is proposing to use unadjusted FY 2021 claims data. This data reflects circumstances at a time when the impact of the PHE on inpatient care was most intensive and widespread and is not representative of claims expected during the remaining phase of the PHE, or after it is scheduled to conclude, in FY 2023. Specifically, more recent data indicates that there should be far fewer high-cost COVID-19 cases in FY 2023 than there were in FY 2021. In addition, recent acceleration of the fixed loss threshold's growth reflects the failure of the FY 2021 and FY 2022 market basket updates to capture real and profound increases in costs. The woefully inadequate proposed market basket update of just 3.1 percent in a time of record inflation simply leaves IPPS payments too low, pushing the costs of too many claims above the MS-DRG payment amount and driving untenable growth in the fixed loss threshold. Further, especially because the PHE will likely last through some portion of FY 2023, the NCTAP payments and COVID-19 add-on payments for the COVID-19 cases in the FY 2021 claims data must be accounted for in the FY 2023 outlier methodology.

Thus, the FAH strongly urges CMS to apply several additional adjustments when calculating the fixed loss threshold to account for 1) the expected significant decrease in high-cost COVID-19 cases, 2) an increased market basket percentage, and 3) add-on COVID-19 and NCTAP payments. Each of these adjustments alone materially reduces the calculation of the fixed loss threshold and making all of them should reduce the fixed loss threshold by approximately $6,000 (or significantly more, depending on the adequacy of the market basket update and the impact of more recent data at the time of the final rule-making).

Notably, even if CMS makes all of these recommended additional adjustments, the fixed loss threshold would still be at a level that is approximately 20 percent higher than in FY 2022 and 58 percent higher than FY 2017. The remainder of the increase may be due in whole or in part to very high charge cases, which, as we have noted with the past several year's rule-makings, continue to drive the threshold to a large extent. We remain concerned that Proposed Rule fails to appropriately address the impact of these high charge cases.

The FAH is also concerned about the proposed increase to the LTCH PPS high-cost outlier fixed loss threshold, which would compound the already significant increase to the fixed loss threshold for FY 2022, and urges CMS to make appropriate methodological adjustments like those recommended herein with respect to the IPPS fixed-loss threshold in order to ensure appropriate outlier payments to LTCHs in FY 2023.

A. Continuation of Methodological Changes Adopted for FY 2020, With Changes in the Data Sets Used Due to the PHE

CMS proposes to again apply key methodological refinements that were first applied in the FY 2020 IPPS rulemaking, with some changes in the data sets that CMS used. First, CMS proposes to again account for outlier reconciliation in the FY 2023 outlier threshold calculation. The FAH has repeatedly requested that CMS release information on the outlier reconciliation process and data showing the amounts recovered so that it can evaluate the impact of the reconciliation process on the outlier threshold, and we again commend CMS for proposing to continue addressing the impact of outlier reconciliation in setting the FY 2023 fixed-loss threshold. Watson Policy Analysis (WPA) (Attachment B) matched CMS' calculation of a -0.01 percent reconciliation factor, using the

December 2021 cost report data CMS used for the Proposed Rule; however, WPA noted that the March 2022 cost report data, which CMS is expected to use for the final rule, produced a higher reconciliation factor of -0.02 percent.

Second, the Proposed Rule charge inflation factor calculation conceptually mirrors the method CMS adopted in the FY 2020 final rule, relying on charge data from the most recent publicly available MedPAR files to compute the one-year charge inflation factor. However, for FY 2023, as it did for FY 2022, CMS proposes using the most recent MedPAR files from periods before the PHE, *i.e.*, the same FY 2018 and FY 2019 data sets that CMS used for the FY 2022 Final IPPS Rule. CMS solicited comments on an alternative approach of using the data sets from FYs 2020 and 2021. We support CMS' proposal to use the pre-PHE data—we believe the charge inflation recorded during the PHE is aberrant and, thus, is unlikely to provide a reasonably accurate forecast of charge inflation. We also believe that CMS' decision to move to publicly available data sets continues to be a thoughtful choice for the Proposed Rule. We continue to believe that CMS should disclose all aspects of its edits to the most current data used for the Proposed Rule and commit to the same process and methods when it recalculates the threshold for purposes of the final rule. Additionally, CMS should commit to make public the data files it uses for the final rule, including all edits and calculations, when it publishes the final rule.

Third, the Proposed Rule applies the same method, first adopted in the FY 2014 IPPS Rule, to project the change in CCRs. For FY 2023, however, the Proposed Rule determined that the most recent CCR data (*i.e.*, comparing the CCRs in the December 2020 update of the PSF to the CCRs in the December 2021 update of the PSF) produced anomalous results: an estimated increase in CCRs. CMS concluded that this phenomenon is "partially due to the high number of COVID-19 cases with higher charges that were treated in IPPS hospitals in FY 2021" and that it is not "reasonable to assume CCRs will continue to increase at these abnormally high rates." Thus, CMS has proposed to use a-pre PHE data set, comparing the change in CCRs from the March 2019 and March 2020 updates to the PSF. This is the same data set used in the FY 2022 IPPS Final Rule and produces a reasonable projection that CCRs will decrease. We support CMS' proposal to use the pre-PHE data, as the average CCR increase recorded during the PHE is aberrant and, thus, is unlikely to provide a reasonably accurate forecast of changes in CCRs for FY 2023. In fact, the FAH expects that CCRs will decrease on average even more than the adjustment factors set forth in the Proposed Rule.

B. High-Cost COVID-19 Cases in the FY 2021 MedPAR Data Set Significantly Skew the Fixed Loss Threshold

The FAH asks CMS also to consider whether it is appropriate to include high-cost COVID-19 cases when calculating the fixed-loss threshold and whether recent data trends suggest that the frequency of such cases will be significantly less than is present in the FY 2021 MedPAR data set. FY 2021 represents the period of the PHE with the initial nationwide surge.[89]

[89] *See, e.g.*, "CDC Laboratory Confirmed COVID-19 Hospitalizations" data, available at: https://gis.cdc.gov/grasp/covidnet/covid19_5.html. *See also* Centers for Disease Control (CDC) graph included in the Proposed Rule, at 87 Fed. Reg. at 28214.

FY 2021 also had the highest utilization of ICU beds by COVID-19 patients during the PHE.[90] Therefore, the FY 2021 MedPAR data represents a period when there was a high frequency of COVID-19 hospitalizations involving highly acute infections and complications.[91] In contrast, recent data shows that severe COVID-19 cases requiring treatment in the ICU have dropped sharply in recent months, which continues a trend of decrease in FY 2022 as compared to FY 2021.[92] Approximately one-in-four hospitalized COVID-19 patients were in an ICU bed in FY 2021, while the proportion of COVID-19 hospital patients in the ICU has declined over the second and third quarters of FY 2022, trending toward less than 15 percent ICU bed utilization. This trend is not surprising, given that at the start of FY 2021 vaccination was non-existent and, across the year, vaccination rates and COVID-19 immunity rates were much lower than they are today and will be in FY 2023. Because the United States now has a very high rate of full vaccination or previous COVID-19 infection, it is reasonable to assume that severe COVID-19 cases requiring intensive care will be far less frequent in FY 2023 than they were in FY 2021.

Based on the reasonable assumption that IPPS hospitals will face very few extremely costly COVID-19 cases during FY 2023, WPA modeled the threshold using CMS' published process for the Proposed Rule, but also trimming all COVID-19 cases from the FY 2021 MedPAR data set where the operating costs were more than three standard deviations from the geometric mean for COVID-19 cases—*i.e.*, WPA trimmed the highest and the lowest cost COVID-19 cases.[93]

As the attached report of WPA shows, trimming the extremely high-cost COVID-19 cases had the effect of reducing the threshold by over $2,100, and trimming the extremely low-

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[90] *See* "COVID-19 Reported Patient Impact and Hospital Capacity by Facility" data, available at: https://healthdata.gov/Hospital/COVID-19-Reported-Patient-Impact-and-Hospital-Capa/anag-cw7u. This data set contains reported COVID-19 admissions for IPPS hospitals "aggregated on a weekly basis." The data may be sorted to show total COVID-19 inpatient days and ICU days for weekly periods from the start of FY 2021 through May 2022, using two field names in the database: "staffed_icu_adult_patients_confirmed_covid_7_day_sum"; and "total_adult_patients_hospitalized_confirmed_covid_7_day_sum." Due to patient privacy, this data does not report patient volumes under four and, instead, reports a "-999.999" in the field. Whether or not one assigns an assumed patient volume of between one and four to the -999.999 results, however, does not materially impact the calculations of the percentages of COVID-19 patients hospitalized and those being treated in the ICU.

[91] The sort of the "COVID-19 Reported Patient Impact and Hospital Capacity by Facility" described in fn. 2, above, reveals that during FY 2021, on average, about 26 percent of COVID-19 inpatient days were days in the ICU.

[92] The sort of the "COVID-19 Reported Patient Impact and Hospital Capacity by Facility" described in fn. 2, above, reveals that, during April and May of 2022, the percentage of COVID-19 inpatient days in the ICU had dropped by more than 50% compared to FY 2021 average.

[93] See the attached WPA report *Summary of Research Modeling FY 2023 Proposed Inpatient Prospective Payment System Outlier Payments* (Attachment B) ("WPA Report") at 10. WPA trimmed the lowest cost cases because doing so mirrors the process CMS uses when trimming statistical outliers for purposes of weighting the MS-DRGs. WPA also modeled not trimming the low-cost outlier COVID-19 cases and found that it changed the impact by $1. *See* WPA report at 11.

cost cases had almost no effect.[94] The FAH urges CMS to apply this or a similar adjustment to the FY 2021 MedPAR data set to avoid factoring in high-cost COVID-19 cases that are unlikely to occur with any significant frequency in FY 2023.

C. The COVID-19 Cases in the FY 2021 MedPAR Data Should Be Modeled with NCTAP and 20 percent Add-On Payments

Based on WPA's analysis of the FY 2021 MedPAR data: 1) over 99 percent of the cases with an NCTAP procedure code also had a COVID-19 diagnosis; and 2) 40 percent of cases with an NCTAP procedure code received an NCTAP payment.[95] In addition, the COVID-19 cases in the FY 2021 MedPAR data received the 20 percent add-on payment for COVID-19 cases. Although CMS is modeling that COVID-19 cases in FY 2023 will be as frequent and as intense as they were in FY 2021, nothing in the Proposed Rule suggests that CMS also modeled that these cases will receive the same COVID-19 add-on and NCTAP payments as they did in FY 2021. The FAH believes that this inconsistent approach unreasonably skews the fixed loss threshold and is contrary to CMS' expectations that COVID-19 hospitalizations and acuity are waning and reasonable expectations of COVID-19 payment policy in FY 2023.

More specifically, there are two reasons why CMS should include in its threshold calculation the assumption that COVID-19 cases will receive a 20 percent add-on payment and, in many instances, an additional NCTAP payment. The first reason is that, conservatively, the PHE is anticipated to end no earlier than mid-October 2022,[96] which means that NCTAP payments will continue for all of FY 2023. Moreover, by using the FY 2021 MedPAR data, CMS is assuming that COVID-19 hospitalizations in FY 2023 will mirror those in FY 2021, which necessarily implies that the PHE will be further renewed, and the COVID-19 add-on payments will continue, into FY 2023. Thus, CMS' payment policies for FY 2023 will likely include COVID-19 add-on payments for at least some of the year and NCTAP payments for all of it.

In addition, the COVID-19 cases in the FY 2021 MedPAR data file received these special payments for the simple reason that *the cases were more costly*. Given that "it is reasonable to assume … that there will be fewer COVID-19 hospitalizations in FY 2023 than in FY 2021," 87 Fed. Reg. at 28111, then CMS should, at a minimum, mitigate the adverse impact of the COVID-19 claims on the fixed loss threshold by modeling them with full COVID-19-related payments.[97]

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[94] *See* WPA Report at 10: compare "Scenario D" (which includes the trim of the high-cost COVID-19 cases) with "Scenario C" (which does not); *id.* at 11 (showing that trimming the low cost COVID-19 cases changed the impact by $1).

[95] *See* WPA Report at 9.

[96] The PHE is currently set to expire on July 15, 2022. As noted previously, however, the Secretary has committed to providing "60 days' notice prior to termination" of the PHE. Sec'y, Ltr. to Governors on the COVID-19 Response (Jan., 21, 2021), at https://aspr.hhs.gov/legal/PHE/Pages/Letter-to-Governors-on-the-COVID-19-Response.aspx. Because no notice has been provided to date, it is anticipated that the PHE will be renewed rather than being allowed to expire on July 15, 2022.

[97] *See also, e.g.,* 87 Fed. at 28124 ("[I] it is reasonable to assume based on the information available at this time that there will be fewer COVID–19 hospitalizations in FY 2023 than in FY 2021

Doing so is not a perfect fix, but it will at least avoid allowing the counterfactual assumption that COVID-19 cases for FY 2023 will be the same as those in FY 2021 to grossly distort the calculations of total outlier cases when setting the threshold.

WPA has modeled the fixed loss threshold with the assumption that COVID-19 cases would receive the 20 percent add-on payment and, where it occurred in FY 2021, that they would also receive an NCTAP payment. Together, these two changes have the effect of lowering the threshold by approximately $3,200, with the NCTAP payments alone decreasing it by about $1,500.[98] The FAH urges CMS to apply these or similar adjustments to its payment assumptions for COVID-19 cases in the FY 2021 MedPAR data—otherwise, the calculations of MS-DRG payments and outlier payments for COVID-19 cases will be, respectively, inaccurately too low and too high, and thus produce an unreasonably high threshold.

D. CMS Should Model a 1.0 percent Payment Increase Because the Market Basket Needs to Be Increased By at Least That Amount

As stated above, the FAH believes that the calculation of the IPPS market basket of 3.1 percent significantly understates expected inflation and urges CMS to 1) adjust its market basket update methodology to reflect more recent data and trends and 2) use its "exceptions and adjustments" authority to adopt a further increase that reflects the extent to which the FY 2022 market basket update was understated. If CMS adopts these recommendations, there would be an increase in IPPS payments per discharge as well as in the total IPPS payments. The increase in the market basket would be at least 1.0 percent and likely much higher; and the increase would reduce the level of the fixed loss threshold, based on CMS' methodology.

WPA has modeled the fixed loss threshold with the assumption that the market basket and payment rates are increased by 1.0 percent.[99] This 1.0 percent increase to the update is consistent with the May 2022 Congressional Budget Office (CBO) Baseline Projections, which estimate a 4.2 percent market basket increase and a 0.5 percent productivity adjustment.[100] But, as explained further above in Part V.A.1 with respect to the market basket, this update would be inadequate to address the extraordinary circumstances of record inflation, an ongoing global pandemic, and two years of inadequate market basket updates. Therefore, the FAH strongly urges CMS to finalize a higher market basket update that captures ongoing inflationary pressures and one-time adjustments to appropriately address the untenable inadequacy of IPPS rates. But the impact of even a 1.0 percent change in the market basket update lowers the threshold by approximately $700.[101] If CMS adopts the recommendation to increase the market basket, the

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given the more recent trends in the CDC hospitalization data since the Omicron variant peak in January, 2022").

[98] *See* WPA Report at 9 and 10.

[99] *See* WPA Report at 10.

[100] *See* CBO Baseline Projections, Medicare (May 2022), available at: https://www.cbo.gov/system/files/2022-05/51302-2022-05-medicare.pdf.

[101] *See* WPA Report at 10.

FAH urges CMS also to factor that change into its payment assumptions for cases in the FY 2021 MedPAR data when calculating the FY 2023 fixed loss threshold.

E. Extreme Charge Cases Significantly Skew the Fixed Loss Threshold

As we have in past years, the FAH also asks CMS to consider whether it is appropriate to include extreme cases when calculating the fixed-loss threshold and whether recent volume increase in such cases points to a larger problem that CMS should investigate. WPA conducted various examinations and probing of data to understand the factors that drove CMS to increase the threshold over $7,000 between FY 2017 and FY 2022, and to propose to increase the threshold more than an additional $12,000 for FY 2023, and observed that the inclusion of extreme cases in the calculation of the threshold, the rate of which are increasing over time, significantly impacts CMS' determination of the fixed-loss threshold.[102]

In the IPPS rate-setting process for the MS-DRG relative weights, statistical outliers (*i.e.*, extreme cases) are generally removed from calculations on the basis that they improperly skew those calculations. In calculating the outlier threshold, however, those statistical outliers are not excluded from the calculation. To observe the impact of these statistical outliers on the calculation of the threshold, WPA calculated how the proposed FY 2023 threshold would differ after the removal of cases that had total charges above particular trim points. The results of WPA's analysis are included in the tables below:

FY 2023 Proposed Rule Table

Trim threshold	Total Cases	Removed cases	FLT	Percentage of cases removed
None	7,241,437	-	$43,252	0.000%
$3,000,000	7,240,787	650	$40,929	0.009%
$2,750,000	7,240,602	835	$40,612	0.012%
$2,500,000	7,240,313	1,124	$40,143	0.016%
$2,250,000	7,239,916	1,521	$39,569	0.021%
$2,000,000	7,239,328	2,109	$38,890	0.029%
$1,750,000	7,238,355	3,082	$37,986	0.043%
$1,500,000	7,236,777	4,660	$36,850	0.064%
$1,250,000	7,233,866	7,571	$35,254	0.105%
$1,000,000	7,227,965	13,472	$33,080	0.186%
$750,000	7,213,279	28,158	$29,777	0.389%
$500,000	7,165,667	75,770	$24,311	1.046%
$250,000	6,902,728	338,709	$14,841	4.677%

[102] *See* WPA Report at 8. The tables from the WPA report have been reproduced here with minor editing for formatting purposes.

The FY 2023 table illustrates that the removal of a relatively small number of extremely high cost (using total charges as a proxy for cost) cases from the calculation significantly decreases the threshold. For example, removing all cases with total charges above $2,000,000 (2,109 cases) drives the threshold down over $4,300. Removing all cases at certain other thresholds, lower than $2,000,000, but still high enough to be considered extreme high-cost cases, drives the threshold down even further. For example, removing all cases with total charges above $1,000,000 (13,472 cases) drives the threshold down over $10,000, and removing all cases with charges above $500,000 (75,770 cases) drives the threshold down almost $20,000.

Furthermore, these cases are increasing quickly over time, but still represent a very small percentage of total cases. To demonstrate this trend of an increase in extremely high charge cases, WPA created the following table illustrating the number of cases with covered charges above $1.5 million for each of the past several years:[103]

Year	Number of cases over $1.5 million	Percentage of total cases	Number of unique providers
2011	926	0.0088%	272
2012	994	0.0098%	272
2013	1,092	0.0111%	283
2014	1,329	0.0141%	306
2015	1,539	0.0161%	320
2016	1,733	0.0185%	334
2017	2,291	0.0250%	403
2018	2,650	0.0286%	398
2019	3,128	0.0348%	441
2020	3,666	0.0474%	474
2021	4,659	0.0643%	527

If this trend continues (that is, if the number (and proportion) of extreme cases continues to increase each year), the impact of this population of cases on the threshold will likewise increase. Thus, it is imperative that CMS carefully consider what is causing this trend, whether the inclusion of these cases in the calculation of the threshold is appropriate, or whether a separate outlier mechanism should apply to these cases that more closely hews outlier payments to marginal costs. A 2013 OIG Report, Medicare Hospital Outlier Payments Warrant Increased Scrutiny, https://oig.hhs.gov/oei/reports/oei-06-10-00520.asp, concurs with this view.

The FAH urges CMS to carefully study this problem as it pertains to outlier payment policy. Not only is this consistent with the calculation process used for IPPS rate setting generally, but it will also produce a threshold that more accurately reflects the universe of cases.

[103] *See* WPA Report at 9.

F. Calculation of Actual Outlier Payment Percentages Based on Actual Historical Payment Data

The FAH believes that ordinarily it is important to the process for setting the outlier threshold that CMS accurately calculate prior year actual payment comparisons to the 5.1 percent target. Without doing so, it is impossible for CMS to appropriately modify its methodology to achieve an accurate result. However, CMS established the FY 2021 fixed-loss threshold before the significant COVID-19 surges in FY 2021, which significantly changed the claims environment during FY 2021 as compared to even FY 2020 and prior years. Thus, CMS' estimate of 5.62 percent of outlier payments as a percentage of MS-DRG payments for FY 2021 likely speaks to the unusual claims patterns and costs-per-case that the PHE has occasioned rather than to an ongoing trend of any kind.

CMS' estimates of past outlier payments also routinely exceed the calculations of outlier payments based on HCRIS cost report data, as demonstrated in the below table from the WPA Report at p. 6. Furthermore, the use of more recent HCRIS data (*i.e.*, the March file versus the December file) also has a significant impact on the calculation of the actual outlier payment level.

Federal Fiscal Year (Month of HCRIS release)	Number of cost reports	IPPS Payments Net of IME, DSH and Outlier amounts	Outlier Payments	Outlier Payment Level (%)	Target Outlier Payments (5.1%)	Shortfall in Outlier Payments
FY 2013 (December)	2,875	$75,513,803,937	$3,820,292,807	4.82%	$4,058,170,707	($237,877,900)
FY 2013 (March)	3,047	$80,760,714,604	$4,270,125,578	5.02%	$4,340,143,777	($70,018,199)
FY 2014 (December)	2,388	$63,505,784,324	$3,085,415,408	4.63%	$3,412,850,369	($327,434,961)
FY 2014 (March)	3,054	$82,479,662,313	$4,343,131,876	5.00%	$4,432,521,368	($89,389,492)
FY 2015 (December)	2,850	$78,849,610,927	$3,847,264,205	4.65%	$4,238,185,938	($390,921,733)
FY 2015 (March)	3,036	$84,552,076,553	$4,283,484,754	4.82%	$4,543,853,974	($260,369,220)
FY 2016 (December)	2,852	$81,185,256,122	$4,223,366,030	4.94%	$4,362,921,000	($139,554,970)
FY 2016 (March)	3,048	$87,553,087,944	$4,689,098,313	5.08%	$4,705,190,000	($16,091,687)
FY 2017 (December)	2,989	$79,429,360,478	$3,912,972,441	4.70%	$4,268,623,000	($355,650,559)
FY 2017 (March)	3,244	$88,346,767,109	$4,686,222,555	5.04%	$4,747,820,000	($61,597,445)
FY 2018 (December)	2,790	$84,057,274,313	$4,265,424,988	4.83%	$4,517,329,000	($251,904,012)
FY 2018 (March)	2,926	$88,630,962,545	$4,661,913,364	5.00%	$4,763,126,000	($101,212,636)
FY 2018 (March 2021	2,933	$88,836,943,282	$4,674,326,383	5.00%	$4,774,210,000	($99,883,617)

HCRIS data update from before)						
FY 2019 (March)	3,129	$84,889,614,212	$4,571,900,758	5.11%	$4,562,000,000	$9,900,758
FY 2020 (March)	3,143	$82,905,093,301	$4,685,300,183	5.35%	$4,455,430,000	$229,870,183
FY 2021 (March)	444	$11,932,185,112	$615,293,614	4.90%	$641,250,000	($25,956,386)

Note: 2021 data does not have all providers' cost report yet.

The FAH emphasizes the importance of CMS using the most recent data available to more accurately assess the outlier payment level. The trend from this data indicates CMS has generally fallen short of its 5.1% outlier target virtually every FY since at least 2013 (the exceptions being hitting it in FY 2019 and overshooting the target during the PHE) and yet it is still proposing a significant increase in the threshold this year with no rationale offered by CMS to explain the prior year shortfalls in payment.

G. Using the Most Recent Data to Calculate the Threshold

We also note that with each IPPS rulemaking for more than a decade, the final fixed-loss threshold established by CMS has consistently been lower than the threshold set forth in the proposed rule, and the variance between the proposed and final thresholds has generally exceeded 4 percent. The only exception is FY 2022. The table below derived from WPA Report at p.7 shows this trend of regular, significant variances between proposed and final fixed-loss thresholds:

FY	Proposed	Final	Variance	% of Variance
2009	$ 21,025	$ 20,045	$ (980)	-4.66%
2010	$ 24,240	$ 23,140	$ (1,100)	-4.54%
2011	$ 24,165	$ 23,075	$ (1,090)	-4.51%
2012	$ 23,375	$ 22,385	$ (990)	-4.24%
2013	$ 23,630	$ 21,821	$ (1,809)	-7.66%
2014	$ 24,140	$ 21,748	$ (2,392)	-9.90%
2015	$ 25,799	$ 24,626	$ (1,173)	-4.55%
2016	$ 24,485	$ 22,544	$ (1,941)	-7.93%
2017	$ 23,681	$ 23,573	$ (108)	-0.46%
2018	$ 26,713	$ 26,537	$ (176)	-0.66%
2019	$ 27,545	$ 25,769	$ (1,776)	-6.45%
2020	$ 26,994	$ 26,552	$ (442)	-1.63%
2021	$ 30,006	$ 29,064	$ (942)	-3.31%
2022	$ 30,967	$30,988	$ 21	0.07%
2023 Proposed	$ 43,214			

Although the FAH can only speculate as to why this drop in the threshold occurs, the FAH believes the decline is most likely due to the use of updated CCRs and/or additional/other data in calculating the final threshold. This again emphasizes that CMS must ordinarily use the most recent data to appropriately calculate the outlier threshold. However, as discussed, FY 2023

is an exception because using some of the more recent data will mean using data that is likely skewed by the PHE and that will thus generate a threshold that is unlikely to produce total aggregate payments reaching CMS's 5.1% target.

With regard to the current rule-making WPA was able to replicate the threshold within $38. Thus, we have high confidence that WPA understands CMS's methodology and has accurately modeled that methodology.

The FAH is not proposing a threshold for FY 2023. While we have confidence in the work of WPA, its work is dependent on large variables in the outlier calculation. We also note that the impact of the inclusion of extreme cases in the calculation of the fixed loss threshold is significant and we urge CMS to carefully study this trend and whether outlier payment policy should be adjusted so that it is fair to all hospitals that fund outlier payments. Finally, we recognize that with the release of the MedPAR final data with additional claims, which will lead to new weights being calculated, and with updated cost to charge ratios, it is appropriate to recalculate the fixed loss threshold from the data that will be released with the final rule.

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The FAH appreciates the opportunity to submit these comments. If you have any questions, please contact me or any member of my staff at (202) 624-1500.

Sincerely,

REPORT

Assessing the Adequacy of Proposed Updates to the Hospital Inpatient Prospective Payment System

Overview

On April 18, 2022, the Centers for Medicare & Medicaid Services (CMS) released its annual proposed rule for the fiscal year (FY) 2023 Inpatient Prospective Payment System (IPPS), projecting a market basket update of 3.1 percent, to be reduced by a 0.4 percent productivity adjustment.[1] This year marks the third consecutive rate setting period mired in pandemic-related uncertainty. While federal relief funding sustained hospitals and health systems through the initial waves of COVID-19, providers continue to grapple with myriad financial pressures, from supply chain disruptions to labor shortages to rising inflation. FTI Consulting's analysis finds that reliance on lagging indicators of hospital costs to determine prospective market basket and productivity adjustments in this highly dynamic and uncertain health care environment would likely result in significant underpayments to acute care hospitals in FY 2023.

[1] FY 2023 Hospital Inpatient Prospective Payment System (IPPS) and Long Term Care Hospitals (LTCH PPS) Proposed Rule - CMS-1771-P." CMS, April 18, 2022. https://www.cms.gov/newsroom/fact-sheets/fy-2023-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care-hospitals-ltch-pps.

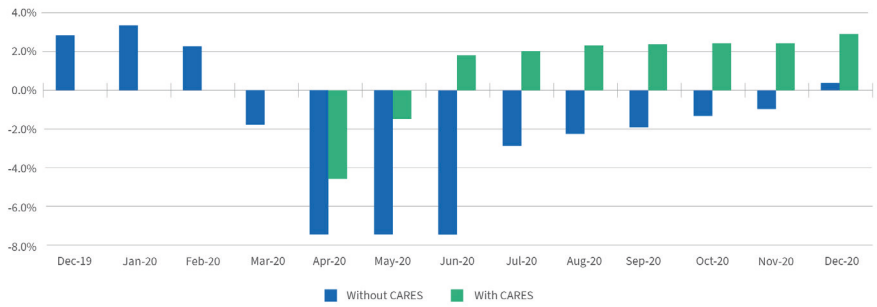
Background: Financial Condition of U.S. Hospitals

Impacts of COVID-19 Continue to Reverberate

The U.S. health care system has undergone a period of severe disruption in recent years driven by the COVID-19 pandemic and record-high inflation. In the early stages of the pandemic, hospitals curtailed elective procedures to free up capacity to care for COVID-19 patients while demand for emergency services dropped as a result of lockdowns.[2,3] Coupled with a rise in the number of uninsured patients, this dramatic decline in patient volume cut off many hospitals' most essential revenue streams,[4] just as the cost of providing care began to rise. Although Congress and the Biden Administration implemented numerous policies to lessen the adverse impact of the pandemic, including the creation of the Provider Relief Fund (PRF), which allocated over $170 billion to heath care providers,[5] financial challenges persist for many hospitals.

Though many hospitals have long struggled to stay afloat on narrow margins, the COVID-19 pandemic put additional, unforeseen strains on hospitals and health systems, particularly in rural and underserved areas. Skyrocketing expenses – driven by the rising cost of supplies, supply chain issues, and labor shortages – led to a 14.4 percent increase in labor expenses per adjusted discharge in 2020 compared to pre-pandemic levels.[6] As a result of this and other pandemic-related challenges, hospitals' median operating margins fell 55.6 percent in 2020 and have yet to fully recover (Figure 1).[7] More recently, during the peak of the Omicron surge in early 2022, government assistance to hospitals was insufficient to fully offset inflationary pressures, alongside continuing supply chain challenges, and widespread labor shortages that caused wage escalation, leaving many hospitals in the red.[8] In April 2022, total expenses and total labor expenses were 25.2 and 26.2 percent higher than 2020 levels, respectively.[9] As federal COVID-19 funds are depleted and inflationary pressures continue to escalate, hospitals are likely to remain embroiled in a precarious financial position throughout the remainder of 2022 and into FY 2023.

Figure 1: Kaufman Hall Operating Margin Index YTD by Month



Source: "National Hospital Flash Report: January 2021." Kaufman Hall, January 25, 2021.

[2] Mattingly, Aviva S., Liam Rose, Hyrum S. Eddington, Amber W. Trickey, Mark R. Cullen, Arden M. Morris, and Shery M. Wren. "Trends in US Surgical Procedures and Health Care System Response to Policies Curtailing Elective Surgical Operations During the COVID-19 Pandemic." JAMA Network Open. JAMA Network, December 8, 2021. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2786935.

[3] Hartnett, Kathleen P., Aaron Kite-Powell, Jourdan DeVies, Michael A. Coletta, Tegan K. Boehmer, Jennifer Adjemian, and Adi V. Gundlapalli. "Impact of the COVID-19 Pandemic on Emergency Department Visits - United States, January 1, 2019–May 30, 2020." Centers for Disease Control and Prevention. Centers for Disease Control and Prevention, June 11, 2020. https://www.cdc.gov/mmwr/volumes/69/wr/mm6923e1.htm.

[4] Boserup, Brad, Mark McKenney, and Adel Elkbuli. "The Financial Strain Placed on America's Hospitals in the Wake of the COVID-19 Pandemic." The American Journal of Emergency Medicine. Elsevier Inc., July 2021. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7347328/#:~:text=The%20financial%20strain%20created%20by,the%20current%20surge%20in%20unemployment.

[5] Biniek, Jeannie Fuglesten, Nancy Ochieng, MaryBeth Musumeci, and Tricia Neuman. "Funding for Health Care Providers during the Pandemic: An Update." KFF, January 27, 2022. https://www.kff.org/coronavirus-covid-19/issue-brief/funding-for-health-care-providers-during-the-pandemic-an-update/.

[6] "National Hospital Flash Report: January 2021." Kaufman Hall, January 25, 2021. https://www.kaufmanhall.com/insights/research-report/national-hospital-flash-report-january-2021.

[7] "High Hospitalization Rates, Consumer Fears Hit Hospitals, Physician Groups Hard." Kaufman Hall, January 25, 2021. https://www.kaufmanhall.com/news/high-hospitalization-rates-consumer-fears-hit-hospitals-physician-groups-hard.

[8] Swanson, Erik. "National Hospital Flash Report: May 2022." Kaufman Hall, May 31, 2022. https://www.kaufmanhall.com/insights/research-report/national-hospital-flash-report-may-2022.

[9] Ibid.

Even setting aside pandemic-related pressures, Medicare has historically under-reimbursed hospitals for their services, putting them in a deficit position. Hospitals' aggregate Medicare margins have ranged from -5.4 percent to as low as -9.9 percent over the last decade according to the Medicare Payment Advisory Commission (MedPAC).[10,11] In its most recent report to Congress, MedPAC predicted that IPPS hospitals' Medicare margins will be around -9 percent in 2022 even after COVID-19 relief funds are factored in, and nearly -10 percent without COVID-19 relief.[12] These persistent negative margins in uncertain economic times demonstrate the importance of ensuring that adjustments to IPPS payment rates reflect the current financial reality faced by hospitals and health systems.

Macroeconomic-Level Factors

IPPS, which determines payments for acute care hospital inpatient stays under Medicare Part A, relies on lagging indicators of hospital costs to set reimbursements prospectively.[13] For example, the FY 2023 proposed payment adjustments incorporate FY 2021 Medicare Provider Analysis and Review (MedPAR) data, as well as FY 2020 Medicare Cost Reports, while relying upon a 2018-based market basket to determine cost and expenditure weights and the third quarter 2021 Employment Cost Index (ECI) to predict changes in the price proxies.[14] This results in a projected market basket update of 3.1 percent, which is then reduced by 0.4 percentage points to account for a productivity adjustment.[15] To the extent that historical data are good predictors of future changes in market basket components, it is reasonable from an economic perspective to use such historical data to calculate prospective Medicare rate changes. However, it is highly unlikely that the COVID-19 pandemic and the ensuing recovery period would in any sense be considered indicative of a steady-state economic environment. To that end, these lagging indicators and outdated data do not adequately capture and thereby cannot predict the significant disruptions created by the COVID-19 pandemic for hospitals, health systems, and other providers.

"To the extent that historical data are good predictors of future changes in market basket components, it is reasonable from an economic perspective to use such historical data to calculate prospective Medicare rate changes. However, it is highly unlikely that the COVID-19 pandemic and the ensuing recovery period would in any sense be considered indicative of a steady-state economic environment."

The demand and supply shocks experienced during the early years of the pandemic and continuing well into this year strongly indicate that great caution and consideration must be factored into calculating the market basket and productivity adjustments in setting prospective payment rates. In the FY 2023 IPPS proposed rule, price proxies in the market basket reflect IHS Global Inc.'s (IGI's) fourth quarter 2021 forecast, which is based on a four-quarter percentage change in the moving average. Although these adjustments are based on forecasts using the most recent data available at the time of the proposed rate setting, the results are released on a lagged basis, usually three to four months after preparation of the forecast. As such, they do not adequately account for recent economic trends that have significantly increased costs to hospitals, including labor and inflation.

Hospital Labor Costs and Workforce Shortages

Hospitals and health systems have been especially hard hit by the workforce shortages associated with the pandemic. The pandemic exacerbated existing shortages of physicians, nurses, and other hospital personnel by increasing competition for workers, as well as driving up the burnout rate among clinicians.[16] With hospital workers stretched to the limit due to the demand for hospital services and the burden of caring for severely ill patients in record numbers, widespread burnout placed enormous pressure on health

[10] "March 2021 Report to the Congress: Medicare Payment Policy." MedPAC, March 15, 2021. https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/.

[11] "March 2022 Report to the Congress: Medicare Payment Policy." MedPAC, March 15, 2022. https://www.medpac.gov/document/march-2022-report-to-the-congress-medicare-payment-policy/.

[12] Ibid.

[13] "FY 2023 Hospital Inpatient Prospective Payment System (IPPS) and Long Term Care Hospitals (LTCH PPS) Proposed Rule - CMS-1771-P." CMS, April 18, 2022. https://www.cms.gov/newsroom/fact-sheets/fy-2023-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care-hospitals-ltch-pps.

[14] Ibid.

[15] Ibid.

[16] "Impact of the COVID-19 Pandemic on the Hospital and Outpatient Clinician Workforce." The Office of the Assistant Secretary for Planning and Evaluation (ASPE). Department of Health and Human Services, May 3, 2022. https://aspe.hhs.gov/sites/default/files/documents/9cc72124abd9ea25d58a22c7692dccb6/aspe-covid-workforce-report.pdf.

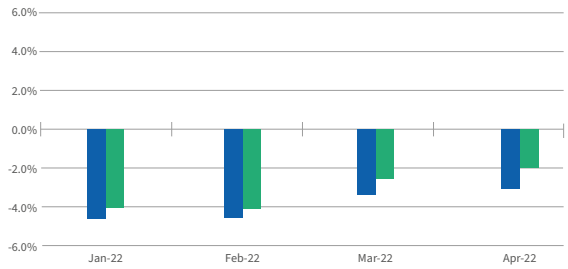
systems to pay more to attract and retain workers. That trend has yet to abate: a March 2022 report from Elsevier Health found that 47 percent of U.S. clinicians plan to leave their jobs in the next two to three years.[17]

Moreover, hospitals 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.[18] 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.[19] Median wages for contract nurses reached triple the median wages of employed nurses in March 2022.[20] Due to rising labor expenses coupled with only small increases in volume and revenue, hospitals saw large declines in operating margins in January through March 2022.[21]

Although the inflated wages and benefits offered by traveling and temporary staffing nursing agencies have somewhat moderated in recent months,[22] it is unlikely that the upward pressures on labor costs for hospitals will be mitigated anytime soon. An October 2021 survey by Kaufman Hall indicated that 92 percent of hospitals have experienced challenges in attracting and retaining support staff.[23]

Significant increases in hospitals' labor costs, coupled with workforce shortages, continue to place immense strain on the health care system. All told, as of March 2022, hospital labor expenses had increased by more than one-third relative to pre-pandemic levels.[24] Hospital financials for the first quarter of 2022 returned to worrisome levels due to the Omicron surge in early 2022 (Figure 2).[25] Inflationary pressures within the economy and fierce competition for health care workers will continue to put upward pressure on wages and benefits through 2022 and likely into 2023. Using data that typically lags two to four years to project labor costs in this uncertain economic environment will fail to account for the ongoing staffing challenges faced by acute care hospitals. CMS should recognize in its market basket adjustments how the understated market basket forecasts for 2021 and 2022 due to COVID-19 and inflation are embedded in payments, as well as how upward pressure on wages and benefits, and costs of supplies and pharmaceuticals, will likely be a mid- to long-term factor adversely affecting hospital operating costs and margins.

Figure 2: Kaufman Hall Operating Margin Index YTD by Month



Source: Swanson, Erik. "National Hospital Flash Report: May 2022." Kaufman Hall, May 31, 2022.

[17] "Clinician of the Future Report 2022." Elsevier, March 15, 2022. https://www.elsevier.com/__data/assets/pdf_file/0004/1242490/Clinician-of-the-future-report-online.pdf.

[18] Yang, Y. Tony, and Diana J. Mason. "Covid-19's Impact on Nursing Shortages, The Rise of Travel Nurses, And Price Gouging." Health Affairs, January 28, 2022. https://www.healthaffairs.org/do/10.1377/forefront.20220125.695159/.

[19] "The Financial Effects of Hospital Workforce Dislocation: A Special Workforce Edition of the National Hospital Flash Report." Kaufman Hall, May 11, 2022. https://www.kaufmanhall.com/insights/research-report/special-workforce-edition-national-hospital-flash-report.

[20] Ibid.

[21] Ibid.

[22] Norman, Hannah. "Travel Nurses Raced to Help during Covid. Now They're Facing Abrupt Cuts." NBCNews.com. NBCUniversal News Group, May 8, 2022. https://www.nbcnews.com/health/health-news/travel-nurses-raced-help-covid-now-facing-abrupt-cuts-rcna27716.

[23] "2021 State of Healthcare Performance Improvement Report: COVID Creates a Challenging Environment." Kaufman Hall, October 18, 2021. https://www.kaufmanhall.com/insights/research-report/2021-state-healthcare-performance-improvement-report-covid creates#:~:text=2021%20State%20of%20Healthcare%20Performance%20Improvement%20Report%3A%20COVID%20Creates%20a%20Challenging%20Environment,-October%2018%2C%202021&text=The%20COVID%2D19%20pandemic%20continues,health%20systems%20across%20the%20country.

[24] "The Financial Effects of Hospital Workforce Dislocation: A Special Workforce Edition of the National Hospital Flash Report." Kaufman Hall, May 11, 2022. https://www.kaufmanhall.com/insights/research-report/special-workforce-edition-national-hospital-flash-report.

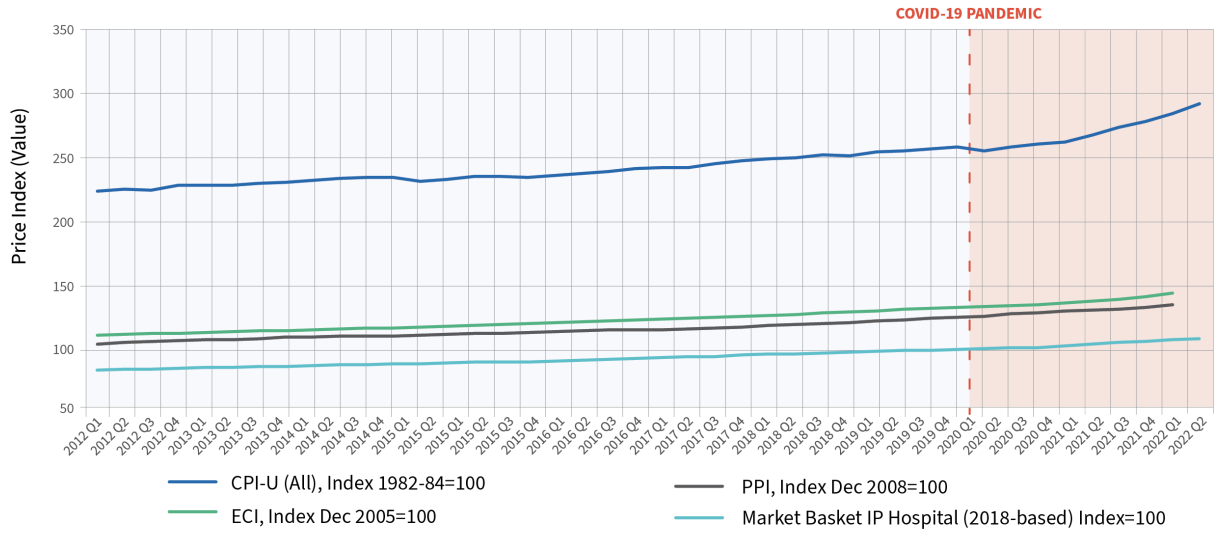
[25] Swanson, Erik. "National Hospital Flash Report: May 2022." Kaufman Hall, May 31, 2022. https://www.kaufmanhall.com/insights/research-report/national-hospital-flash-report-may-2022.

Current and Projected Inflation

In an era of historic inflation across the broader economy, the Altarum Institute notes that health care inflation hovers close to its historic average of two percent as a result of prospective rate-setting.[26] This contrasts sharply with the Consumer Price Index (CPI), a measure of general inflation, which hit 8.6 percent over the 12-month period ending in May 2022.[27] The differential exists because health care costs paid by consumers typically reflect rates negotiated in the year prior, rather than the actual cost of inputs borne by hospitals and health systems at the time of care delivery.[28]

In a steady state economy with small and stable changes in inflation and costs, it is possible to predict with some accuracy the anticipated rate of increase in the cost of goods and services to determine provider reimbursements. That is the rationale for using historical data and adjusting IPPS price proxies using the ECI, a measure of compensation costs, despite its reliance on lagging indicators. However, significant changes in the CPI, which measures changes in prices paid by consumers, and the Producer Price Index (PPI), which tracks changes in price experienced by producers, can have a major impact on wage and salary expectations that can feed into future changes to the ECI. Higher inflation can create upward pressure on wage expectations as workers seek an increase in wages to better meet the increasing cost of living. This can be exacerbated when labor is in short supply, as is currently the case in the hospital sector. Figure 3, below shows the major price indices relevant to understanding these inflationary pressures for hospital workers. These data reveal that – despite shocks in price indices over time – the market basket captures these in a muted way that is in stark contrast to what hospitals and health systems actually experience.

Figure 3: Price Index, Cost Index, and CMS Market Basket IP Hospital, Quarterly, Seasonally Adjusted (2012-2022)

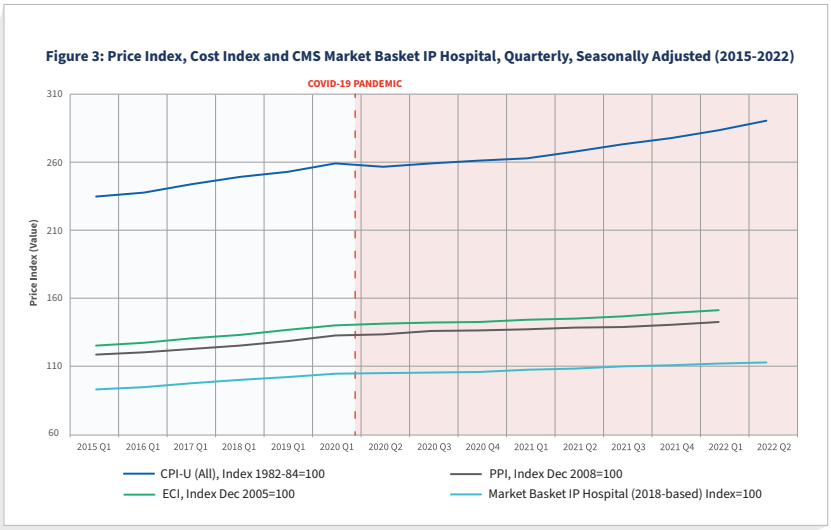


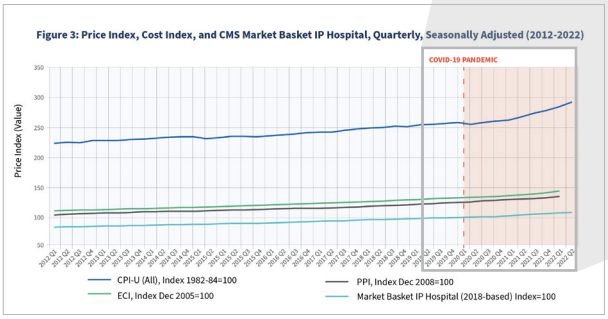
Source: Consumer Price Index (CPI) Databases, U.S. Bureau of Labor Statistics; Employment Cost Index (ECI), FRED, Federal Reserve Bank of St. Louis; Producer Price Index (PPI), FRED, Federal Reserve Bank of St. Louis; CMS Market Basket Index Levels, IHS Global Inc. (IGI) 2021q4 Forecast by CMS, OACT, National Health Statistics Group

[26] "Inflation Is Booming. Why Hasn't It Hit Health Care?" Advisory Board. Advisory Board, April 15, 2022. https://www.advisory.com/daily-briefing/2022/04/15/inflation-us.

[27] "Consumer Price Index Summary - 2022 M05 Results." U.S. Bureau of Labor Statistics. U.S. Bureau of Labor Statistics, June 10, 2022. https://www.bls.gov/news.release/cpi.nr0.htm.

[28] "Inflation Is Booming. Why Hasn't It Hit Health Care?" Advisory Board. Advisory Board, April 15, 2022. https://www.advisory.com/daily-briefing/2022/04/15/inflation-us.





Source: Consumer Price Index (CPI) Databases, U.S. Bureau of Labor Statistics; Employment Cost Index (ECI), FRED, Federal Reserve Bank of St. Louis; Producer Price Index (PPI), FRED, Federal Reserve Bank of St. Louis; CMS Market Basket Index Levels, IHS Global Inc. (IGI) 2021q4 Forecast by CMS, OACT, National Health Statistics Group

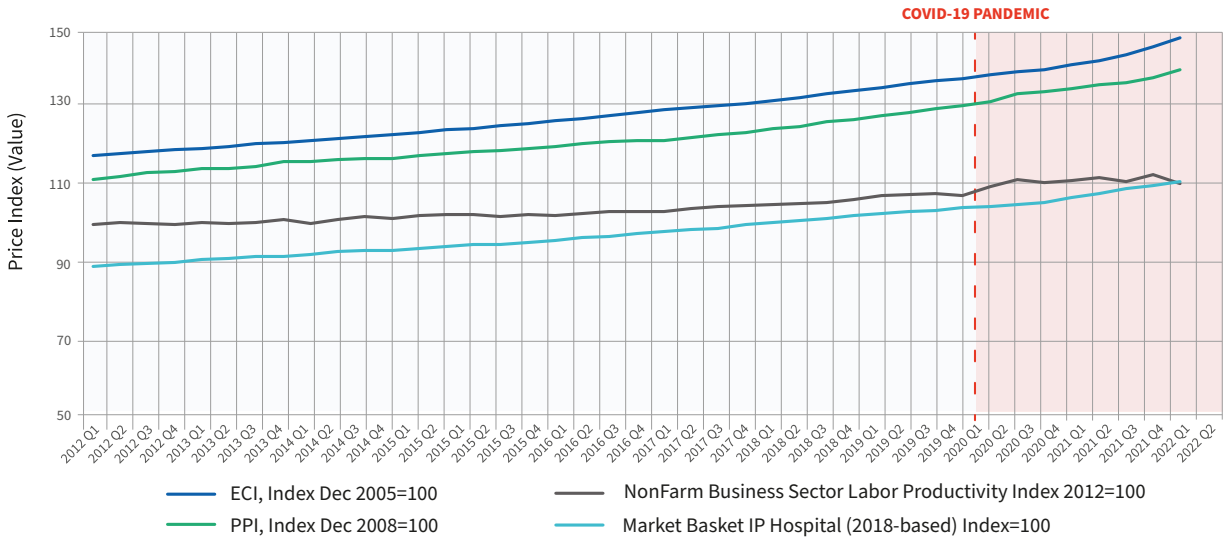
The CPI for All Urban Consumers (CPI-U) for all services shows a significantly steeper upward trend than is reflected in the market basket for inpatient hospital services. Since the start of the pandemic, this growth has exceeded growth in the Market Basket for Inpatient Hospital Services (Figure 3).[29] These more recent inflationary pressures are likely to work their way into wage expectations, particularly in industry sectors where labor is in short supply, thus driving up labor costs even further.

Using the third quarter 2021 data for market basket forecasting, as the FY 2023 IPPS Proposed Rule would do, risks capturing only the very beginning of this upward pressure on prices and wages in the economy (Figure 4).[30] Although the ECI has historically been fairly stable with annual growth rates ranging from a low of about 1.6 percent to a high of 2.8 percent just prior to the beginning of the pandemic, compensation costs have increased rapidly over the past year. From 2.6 percent in April 2021 to the most current estimate of 5.0 percent in January 2022, workers are commanding significantly higher wages. Historical data from the fourth quarter of 2021 misses this continuing upward trend in early 2022.

[29] Consumer Price Index (CPI) Databases, U.S. Bureau of Labor Statistics; Employment Cost Index (ECI), FRED, Federal Reserve Bank of St. Louis; Producer Price Index (PPI), FRED, Federal Reserve Bank of St. Louis; CMS Market Basket Index Levels, IHS Global Inc. (IGI) 2021q4 Forecast by CMS, OACT, National Health Statistics Group

[30] Employment Cost Index (ECI), FRED, Federal Reserve Bank of St. Louis; Producer Price Index (PPI), FRED, Federal Reserve Bank of St. Louis; NonFarm Business Sector Labor Productivity, FRED, Federal Reserve Bank of St. Louis; CMS Market Basket Index Levels, IHS Global Inc. (IGI) 2021q4 Forecast by CMS, OACT, National Health Statistics Group

Figure 4: Cost Index and CMS Market Basket IP Hospital, Quarterly, Seasonally Adjusted (2012-2022)



Source: Employment Cost Index (ECI), FRED, Federal Reserve Bank of St. Louis; Producer Price Index (PPI), FRED, Federal Reserve Bank of St. Louis; NonFarm Business Sector Labor Productivity, FRED, Federal Reserve Bank of St. Louis; CMS Market Basket Index Levels, IHS Global Inc. (IGI) 2021q4 Forecast by CMS, OACT, National Health Statistics Group

Although it may reach its peak in 2022, the high rate of inflation the U.S. economy is experiencing is not projected to abate in the near term, furthering the critical need to consider the likelihood that these inflationary pressures will factor into costs and wage expectations. Fannie Mae projects that inflation, as measured by the CPI, peaked in March 2022 at an annual rate of 8.5 percent, although month-to-month changes may continue.[31] Nonetheless, Fannie Mae forecasts inflation to remain elevated, averaging 5.5 percent in the fourth quarter of 2022.[32] With respect to ECI, the Congressional Budget Office (CBO) projects a 5.4 percent increase for 2022 and a 4.1 percent increase for 2023.[33] The CBO estimates the ECI increased 5.0 percent in 2021. The CBO's projections typically fall in the middle range of the likely outcomes under current law, suggesting the possibility that the actual increase in compensation costs could be even higher.[34]

Accounting for recent and future trends in inflationary pressures and cost increases in the Hospital Market Basket will be essential to ensuring that Medicare payments for acute care services in FY 2023 more accurately reflect the cost of providing hospital care.

[31] "Inflation Rate Signals Tighter Monetary Policy and Threatens 'Soft Landing'." Fannie Mae, April 19, 2022. https://www.fanniemae.com/research-and-insights/forecast/inflation-rate-signals-tighter-monetary-policy-and-threatens-soft-landing#:~:text=Inflation%2C%20as%20measured%20by%20the,and%20declines%20in%20auto%20and.

[32] Ibid.

[33] "The Budget and Economic Outlook: 2022 to 2032." Congressional Budget Office, May 25, 2022. https://www.cbo.gov/publication/58147.

[34] Ibid.

Productivity

Under the Affordable Care Act (ACA), CMS is required to annually adjust hospital payments under the IPPS to reflect anticipated gains in productivity over time.[35] The productivity adjustment is equal to the 10-year moving average of changes in the annual economy-wide, private nonfarm business total factor productivity (TFP).[36] The measure is intended to contain health care spending by ensuring payments more accurately reflect the true cost of providing hospital care. In the FY 2023 IPPS Proposed Rule, CMS proposes using IHS Global, Inc.'s (IGI's) fourth-quarter 2021 forecast of the IPPS market basket rate of increase, which uses data through third-quarter 2021.[37] This produces a projected productivity adjustment of 0.4 percentage points to the proposed FY 2023 market basket adjustment of 3.1 percent, reducing the update to 2.7 percent.[38,39]

The use of nonfarm business TFP by CMS in its productivity adjustment formula is meant to capture gains from new technologies, economies of scale, business acumen, managerial skills, and changes in production.[40] Using private nonfarm business TFP effectively assumes the hospital sector should be able to mirror productivity gains across the broad private nonfarm business sector. However, in an economy marked by great uncertainty in performance due to the demand and supply shocks of dealing with a public health crisis such as COVID-19, this assumption may generate significant departures from economic reality.

Basing the adjustment on a 10-year moving average of the change in TFP also mitigates large year-to-year fluctuations that might occur. Over the last decade, there have been only four periods of productivity decreases. Notably, two of the periods of decreased productivity occurred during the COVID-19 pandemic – a 0.4 percent decline in July 2021 and a 0.6 percent decline in January 2022.[41] Two productivity declines in the last 12-month period is a material disruptor of the relatively steady-state increases in private, nonfarm productivity gains. Although the productivity adjustment uses a 10-year moving average for private nonfarm business productivity gains, two declines in this productivity metric should be noteworthy when considering the appropriate payment updates in the FY 2023 IPPS.

CMS has acknowledged the disconnect between Medicare productivity and the 10-year moving average private nonfarm business TFP. A 2016 analysis by the CMS Office of the Actuary (OACT) found that the average growth rate of hospital multi-factor productivity (now referred to as TFP) ranged from 0.1 percent to 0.6 percent compared with the average growth of private nonfarm business multifactor productivity (MFP) of 1.0 percent.[42] More recent research cited in the CMS OACT analysis indicates that hospitals could achieve productivity gains of 0.4 percent per year over the long run compared with an assumed growth in private nonfarm business MFP of 1.1 percent, representing just over one-third (36.3 percent) of the gains in the private nonfarm business sector.[43] Particularly in a period of record inflation and unprecedented public health challenges, using the 10-year moving average nonfarm business sector TFP to adjust the market basket percentage increase could exacerbate Medicare underpayments to hospitals.

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[35] "Methodology for Projecting Total Factor Productivity for the Private Nonfarm Business Sector." CMS, March 2022. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/TFP_Methodology.pdf.

[36] "Compilation Of The Social Security Laws." Social Security Administration. Accessed June 1, 2022. https://www.ssa.gov/OP_Home/ssact/title18/1886.htm.

[37] "Methodology for Projecting Total Factor Productivity for the Private Nonfarm Business Sector." CMS, March 2022. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/TFP_Methodology.pdf.

[38] Total factor productivity is calculated as follows: *TFP growth = Output growth - [(labor input growth * labor share) + (capital input growth * capital share)].* This is a measure of changes in efficiency that cannot be accounted for by the change in total combined inputs (i.e., hours worked, capital and intermediate purchases).

[39] "FY 2023 Hospital Inpatient Prospective Payment System (IPPS) and Long Term Care Hospitals (LTCH PPS) Proposed Rule - CMS-1771-P." CMS, April 18, 2022. https://www.cms.gov/newsroom/fact-sheets/fy-2023-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care-hospitals-ltch-pps.

[40] Methodology for Projecting Total Factor Productivity for the Private Nonfarm Business Sector." CMS, March 2022. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/TFP_Methodology.pdf.

[41] "Methodology for Projecting Total Factor Productivity for the Private Nonfarm Business Sector." CMS, March 2022. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/TFP_Methodology.pdf.

[42] Spitalnic, Paul, Stephen Heffler, Bridget Dickensheets, and Mollie Knight. "Hospital Multifactor Productivity: An Updated Presentation of Two Methodologies." CMS, February 22, 2016. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/ProductivityMemo2016.pdf.

[43] Ibid.

The COVID-19 pandemic continues to negatively affect hospital services, unlike other areas of private nonfarm business economy. Whereas the private nonfarm business economy experienced a rapid increase in output and productivity gains when communities began emerging from COVID-19 lockdowns in late 2021, the same has not been true for hospital services.[44] Generally, hospital services have been slower to return to pre-pandemic levels,[45] and it is highly unlikely that hospitals have achieved the significant productivity gains incorporated into the FY 2023 IPPS prospective rate adjustments. An October 2021 survey conducted by Kaufman Hall found that many hospitals and health system leaders feel the COVID-19 pandemic made it significantly more difficult for them to improve their performance.[46]

CMS currently relies on the most recent TFP forecast available even when economic trends, such as employment and labor productivity, are uncertain or highly variable. Recently, the COVID-19 pandemic, along with the trillions of dollars in relief funds appropriated in response, injected significant volatility into the U.S. economy. This in turn exacerbated the disconnect between projections used in the proposed rules and the most recent data available prior to finalizing the IPPS productivity adjustment. For example, in FY 2021, CMS initially proposed a negative productivity adjustment of .4 percent to the IPPS market basket,[47] which was ultimately set to zero in the final rule.[48]

According to the Bureau of Labor and Statics' (BLS) most recent release on TFP, nonfarm business sector labor productivity decreased 7.3 percent in the first quarter of 2022 as output decreased 2.3 percent and hours worked increased 5.4 percent.[49] This represents the largest decline in quarterly productivity since the third quarter of 1947.[50] This decrease in TFP is more akin to FY 2021 productivity adjustments where a decrease in productivity of 0.1 percent points resulted in a zero productivity adjustment.[51] Here, if the decrease in productivity continues into the second quarter, we should expect to see a significant reduction in the productivity adjustment, possibly even a zero productivity adjustment. It is important to note that the FY 2021 zero adjustment is based on a forecast of a 0.1 percentage point decline in TFP that pales in comparison to the most recent productivity declines.

Significant uncertainty will persist into the first half of 2023, and likely beyond, regarding the direction and magnitude of U.S. economic performance as inflationary pressures caused by multiple factors (such as fiscal and monetary policy, supply chain disruptions, and the war in Ukraine) have affected productivity. This uncertainty, as well as the likely greater divergence of hospital services productivity from overall private nonfarm business sector productivity, should be considered in settling on a productivity adjustment for FY 2023.

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[44] "Employment Recovery Continues In 2021, With Some Industries Reaching or Exceeding Their Prepandemic Employment Levels." U.S. Bureau of Labor Statistics, May 2022. https://www.bls.gov/opub/mlr/2022/article/employment-recovery-continues-in-2021.htm.

[45] Swanson, Erik. "National Hospital Flash Report: May 2022." Kaufman Hall, May 31, 2022. https://www.kaufmanhall.com/insights/research-report/national-hospital-flash-report-may-2022.

[46] "2021 State of Healthcare Performance Improvement Report: COVID Creates a Challenging Environment." Kaufman Hall, October 18, 2021. https://www.kaufmanhall.com/insights/research-report/2021-state-healthcare-performance-improvement-report-covid-creates#:~:text=2021%20State%20of%20Healthcare%20Performance%20Improvement%20Report%3A%20COVID%20Creates%20a%20Challenging%20Environment,-October%2018%2C%202021&text=The%20COVID%2D19%20pandemic%20continues,health%20systems%20across%20the%20country.

[47] "Fiscal Year (FY) 2021 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Acute Care Hospital (LTCH) Proposed Rule (CMS-1735-P), CMS, May 11, 2020. https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2021-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-acute.

[48] "Fiscal Year (FY) 2021 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Acute Care Hospital (LTCH) Final Rule (CMS-1735-F)." CMS, September 2, 2020. https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2021-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-acute-0.

[49] "Productivity and Costs, First Quarter 2022, Revised." U.S. Bureau of Labor Statistics. U.S. Bureau of Labor Statistics, May 5, 2022. https://www.bls.gov/news.release/pdf/prod2.pdf.

[50] Ibid.

[51] FY 2022 IPPS productivity adjustment was proposed at 0.2 percentage points based on IGI's fourth quarter 2021 forecast of TFP but IGI's second quarter 2021 forecast reflected a significant change in the estimate to 0.4 percentage points for FY 2022. The FY 2021 productivity adjustment proposed was 0.4 percentage points using IGI's fourth quarter 2019 forecast. More recent data based on IGI's June 2020 forecast indicated a -0.1 percentage point growth for FY 2021. As section 1886(b)(3)(B)(xi)(I) of the Act requires a reduction not an increase for the productivity adjustment, the adjustment was set to zero.

Conclusion: Current Economic Realities Are Not Reflected in Proposed IPPS Update, Put Hospitals' Financial Viability at Risk

As CMS prepares to finalize the FY 2023 IPPS and LTCH PPS Rule – as well as Fiscal Year 2023 Inpatient Rehabilitation Facility (IRF), Inpatient Psychiatric Facility (IPF), and Medicare Hospital Outpatient Prospective Payment System (PPS) Final Rules – considering the ongoing impacts of COVID-19 and recent inflationary pressures will be essential to ensuring the stability and resiliency of the health care system as it emerges from a global pandemic. Hospital operating margins in 2022 reveal the adverse impact of higher costs and a change in the mix of resources needed to respond to new surges and new COVID-19 variants. The proposed FY 2023 IPPS rate adjustment effectively attempts to return to the steady-state lagged adjustment methodology used prior to the pandemic without fully accounting for dynamics like the continuing effects of wage and inflationary pressures. Given the long history of Medicare underpayments, the failure to account for these pressures in the latest IPPS rule will likely exacerbate the deficit in Medicare funding that hospitals already experience and create further challenges for our hospitals and health system, at a time when they remain vulnerable to financial distress.

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Attachment B

Summary of research modeling

FY 2023 Proposed Inpatient Prospective Payment System

Outlier Payments

Date: June 16, 2022

Introduction

Watson Policy Analysis (WPA) was asked to analyze issues and replicate outlier payments from the Centers for Medicare & Medicaid Services (CMS) Fiscal Year (FY) 2023 Inpatient Prospective Payment System (IPPS) proposed rule. In short, this outlier policy sets forth a set of rules whereby CMS provides payment to inpatient hospitals for a portion of their high cost inpatient cases once particular thresholds are met. CMS describes its methodology and logic starting on page 28663 of the Federal Register.[1] We attempted to replicate the CMS logic and then compared our results and made a variety of adjustments to assess the impact of using different parameters. This report summarizes our findings.

Note: Due to the Covid-19 Public Health Emergency (PHE), CMS is proposing a change in policy this year in terms of how weights are computed. CMS is proposing to create the weights based on a blend of two weights – one set of weights based on all cases, and one set of weights based on cases excluding COVID cases. They also ask for comments on the alternative of using just one set of weights – including all cases. For all analyses, CMS is proposing to use FY2021 MedPAR data.

Summary

A summary of findings is as follows:

- WPA was able to come close to the CMS calculation of the Fixed Loss Threshold (FLT).
    - For the proposed blended weights, CMS published $43,214 while WPA calculated $43,252.
    - For the alternative weights, CMS published $58,798 while WPA calculated $58,904.
- WPA replicated other factors that went into the payment calculation.
- WPA was able to replicate the CMS calculation of the necessary adjustment for the target percentage based on the outlier reconciliations reported in the cost reports.
- WPA was able to come close to the estimate of charge inflation. The proposed rate is effectively the same as before because the value is being reused, and was replicated previously. For the proposed alternative, CMS reported a charge inflation of 20.1589% over two years while WPA has calculated 19.8868%.

[1] "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation". Published in Federal Register, Vol 87, No. 90., Tuesday, May 10, 2022

- It is possible to generate different Fixed Loss Thresholds depending on different assumptions about the future. This year is atypical still because of the uncertainty due to COVID. Making different assumptions about the future due to COVID can lead to alternative fixed loss threshold.

Background on outlier payments

In the IPPS program, CMS has established the concept of "outliers" to be high cost cases which are paid an additional amount so that providers' potential losses are limited. When the estimated costs of a case exceed the payment for the case, plus a threshold, CMS will generally pay 80% of the costs that exceed the payment plus the threshold. CMS pays 90% for discharges assigned to one of the "burn" diagnosis related groups (DRGs).

This threshold is known as the "fixed loss threshold" (FLT) and is set prospectively with each rule based on a target that operating outlier payments will be 5.1% of total operating payments, including outliers. This target is determined by simulations of expected payments.

Background from CMS on outlier payments can be found at:
http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.html

Additional detail is provided by CMS each year in the IPPS rule.

Analysis 1: Replication of the CMS estimated FY 2023 outlier payment from the FY 2023 IPPS proposed rule

WPA estimated payments, including outlier payments from the FY 2021 Proposed Medicare Provider Analysis and Review (MedPAR) Proposed File, following the methodology set forth in various IPPS rules. In modeling payments, WPA used information from the following data sources:

- MedPAR FY 2023 proposed file: contains inpatient hospital claims from FY 2021 that were used by CMS to model proposed FY 2023 payments,
- Table 5 – Weight file: contains the proposed weights for FY 2023,
- Impact file: contains hospital specific characteristics and payment factors,
- DSH Supplemental File: contains uncompensated care per claim payment amounts for providers,
- The FY2023 Proposed IPPS rule, in particular information on cost and charge inflation factors, and
- Inpatient Provider of Services File: contains provider specific information.
- Hospital Cost Reporting Information System (HCRIS) data containing cost reports from providers. This information was used to calculate the adjustment to the outlier target based on the historical outlier reconciliation.

All of these analyses were then repeated using the "alternative" weights as opposed to the proposed "blended" weights.

In addition, other factors such as charge inflation, CCR adjustment factors, and standardized payment amounts from the proposed rule were used.

Complete payments were calculated including operating, capital, disproportionate share hospital (DSH), indirect medical education (IME), uncompensated care, etc. for each case, following the CMS methodology. The CMS methodology excludes sole community hospitals, hospitals that have become Critical Access Hospitals (CAHs), and Maryland hospitals.

Using the proposed blended weights, WPA calculated a fixed loss threshold of: $43,252 versus the published number of $43,214, a difference of $38 or about 0.09%.

Using the alternative weights and factors, WPA calculated a fixed loss threshold of: $58,904 versus the published number of $58,798, a difference of $106 or about 0.18%.

Please note that the FLT will adjust with the release of the final rule and associated files, in addition to the recalculated weights.

Analysis 2: Comparison of Cost-to-Charge ratios from the FY 2022 proposed rule Impact file and the Inpatient Provider Specific File

As part of the analysis, we compared the CCRs included in the impact file (used in modeling the FLT) with the CCRs from the Provider Specific File (PSF). CMS used the same CCRs both in the proposed blended methodology and in the alternative methodology.

For the modeling using the FY 2021 data, used the December 2021 release of the PSF file. Comparing the 3,214 providers listed in the impact file and the December 2021 PSF file, we had a match rate of 75.23% (2,418 providers).

Using this data, the average difference in operating CCRs between the impact file and the PSF file (weighted by discharges) was 0.119% when all providers were used, and -0.445% when just providers with differences were used.

For the modeling using the FY 2021 data, used the March 2022 release of the PSF file. Comparing the 3,214 providers listed in the impact file and the March 2022 PSF file, we had a match rate of 78.59% (2,573 providers).

Using this data, the average difference in operating CCRs between the impact file and the PSF file (weighted by discharges) was 0.001% when all providers were used, and -0.431% when just providers with differences were used.

The table of matching statistics reported four years ago in a report from The Moran Company – “Modeling Fiscal Year 2015 Inpatient Prospective Payment System Outlier Payments” dated June 23, 2014, and then updated with WPA calculated data is as follows:

IPPS Rule for FY	Matching Rate Between Impact file and Most recent PSF CCRs	Average Percent Difference Between the Impact File and Most Recent PSF Operating CCR of the Same Hospital (weighted By Discharges)
Final 2010*	93.2%	0.4%
Final 2011*	96.4%	0.1%
Final 2012 - Dec 2010 Update	96.9%	0.2%
Final 2012 - March 2011 Update	65.3%	1.6%
Final 2013	92.1%	0.0%
Final 2014	97.2%	-0.1%
Proposed 2015 - Dec 2015 Update	98.8%	-2.7%
Proposed 2015 - March 2015 Update	64.8%	1.0%
Proposed 2016 - Dec 2015 Update	89.6%	-0.02%
Proposed 2016 - March 2015 Update	61.6%	0.19%
Proposed 2017 - Dec 2016 Update	94.16%	-0.014%
Proposed 2017 - March 2017 Update	65.70%	0.236%
Proposed 2018 – December 2017 update	94.33%	-0.017%
Proposed 2018 – March 2018 update	67.33%	-0.342%
Proposed 2019 – December 2018 update	97.33%	-0.002%
Proposed 2019 – March 2018 update	67.69%	0.240%
Proposed 2020 – December 2018 update	97.49%	-0.027%
Proposed 2020 – March 2019 update	70.12%	0.209%
Proposed 2021 – December 2020 update	97.49%	-0.027%
Proposed 2021 – March 2020 update	70.12%	0.209%
Proposed 2022 – December 2019 update	96.35%	-0.648%
Proposed 2022 – March 2020 update	68.49%	-0.208%

* Vaida Health Data Consulting, Modeling FY 2013 IPPS Outlier Payment. June 11, 2012

Note that WPA developed new programs to analyze the data, so there may be differences with the previous analyses by The Moran Company and Vaida Health Consulting. However, the matching percentage calculated by WPA is within a similar matching percentage as that calculated by the Moran Company. In addition, the average difference in operating CCR is much smaller.

Analysis 3: FY 2021 Outlier payment using FY 2021 MedPAR data

In order to examine the actual outlier payments, WPA modeled payments and combined outlier payment information to estimate the actual payments. But it must be recognized that FY 2021 was a very strange year due to the Covid-19 Public Health Emergency. The chart below shows operating payments and the outlier payments that we calculated. The operating payments and the total payments are based on the modeling simulation. The outlier payment amount is modeled from the FY 2021 Proposed data. In the simulation using the CMS FLT we estimate that outlier payments are 5.76%.

Note: The 20% add-on COVID payment is also included here. This add-on applies only to operating payments.

Data Source	Operating IPPS Payments Net of IME, DSH and Outlier Amounts ($) (Does not include Capital)	Outlier Payments ($)	Outlier Payment Level (%)	Total Medicare Payment ($) for context
MedPAR 2020 Actual Outlier Payments, FY 2020 Final Rule Impact File Adjustment Factors. Correction Notice version	$ 78,542,433,967	$ 4,797,293,692	5.76%	$ 106,325,461,671

Analysis 4: Outlier payments from Medicare cost reports

For the past several years, WPA has calculated estimated outlier payments based on the HCRIS cost report data. This analysis has been conducted each year as a part of the IPPS proposed rule analysis.

Federal Fiscal Year (Month of HCRIS release)	Number of cost reports	IPPS Payments Net of IME, DSH and Outlier amounts	Outlier Payments	Outlier Payment Level (%)	Target Outlier Payments (5.1%)	Shortfall in Outlier Payments
FY 2013 (December)	2,875	$75,513,803,937	$3,820,292,807	4.82%	$4,058,170,707	($237,877,900)
FY 2013 (March)	3,047	$80,760,714,604	$4,270,125,578	5.02%	$4,340,143,777	($70,018,199)
FY 2014 (December)	2,388	$63,505,784,324	$3,085,415,408	4.63%	$3,412,850,369	($327,434,961)
FY 2014 (March)	3,054	$82,479,662,313	$4,343,131,876	5.00%	$4,432,521,368	($89,389,492)
FY 2015 (December)	2,850	$78,849,610,927	$3,847,264,205	4.65%	$4,238,185,938	($390,921,733)
FY 2015 (March)	3,036	$84,552,076,553	$4,283,484,754	4.82%	$4,543,853,974	($260,369,220)
FY 2016 (December)	2,852	$81,185,256,122	$4,223,366,030	4.94%	$4,362,921,000	($139,554,970)
FY 2016 (March)	3,048	$87,553,087,944	$4,689,098,313	5.08%	$4,705,190,000	($16,091,687)
FY 2017 (December)	2,989	$79,429,360,478	$3,912,972,441	4.70%	$4,268,623,000	($355,650,559)
FY 2017 (March)	3,244	$88,346,767,109	$4,686,222,555	5.04%	$4,747,820,000	($61,597,445)
FY 2018 (December)	2,790	$84,057,274,313	$4,265,424,988	4.83%	$4,517,329,000	($251,904,012)
FY 2018 (March)	2,926	$88,630,962,545	$4,661,913,364	5.00%	$4,763,126,000	($101,212,636)
FY 2018 (March 2021 HCRIS data update from before)	2,933	$88,836,943,282	$4,674,326,383	5.00%	$4,774,210,000	($99,883,617)
FY 2019 (March)	3,129	$84,889,614,212	$4,571,900,758	5.11%	$4,562,000,000	$9,900,758
FY 2020 (March)	3,143	$82,905,093,301	$4,685,300,183	5.35%	$4,455,430,000	$229,870,183
FY 2021 (March)	444	$11,932,185,112	$615,293,614	4.90%	$641,250,000	($25,956,386)

Note: 2021 data does not have all providers' cost report yet.

The FY2013 analysis was conducted in the Spring of 2015 during the proposed rule comment period, and each Fiscal year was done in the successive calendar years following that. The month refers to the data release month of the HCRIS data.

Note: We are reporting an updated version of the 2018 data and still showing the earlier one due to the update for the FY 2022 Proposed Rule.

Note that these numbers are subject to change as more hospitals submit cost reports and also cost reports are reviewed and revised.

Analysis 5: Fixed Loss Threshold over time

From examining the fixed loss threshold in proposed rules and final rules, there is a pattern of the fixed loss threshold declining. The following table shows the fixed loss thresholds for recent years.

FY	Final	Proposed	Variance	% of Variance
2009	$ 20,045	$ 21,025	$ (980)	-4.66%
2010	$ 23,140	$ 24,240	$ (1,100)	-4.54%
2011	$ 23,075	$ 24,165	$ (1,090)	-4.51%
2012	$ 22,385	$ 23,375	$ (990)	-4.24%
2013	$ 21,821	$ 23,630	$ (1,809)	-7.66%
2014	$ 21,748	$ 24,140	$ (2,392)	-9.90%
2015	$ 24,626	$ 25,799	$ (1,173)	-4.55%
2016	$ 22,544	$ 24,485	$ (1,941)	-7.93%
2017	$ 23,573	$ 23,681	$ (108)	-0.46%
2018	$ 26,537	$ 26,713	$ (176)	-0.66%
2019	$ 25,769	$ 27,545	$ (1,776)	-6.45%
2020	$ 26,552	$ 26,994	$ (521)	-1.93%
2021	$ 29,064	$ 30,006	$ (942)	-3.31%
2022	$ 30,988	$ 30,967	$ 21	0.07%
2023		$ 43,214		

Note: FY 2023 is based on the proposed blended weight.

Analysis 6: Outlier Reconciliation

In the FY2020 IPPS rule, CMS finalized a new methodology to adjust the outlier target percentage to account for outlier reconciliation. WPA was successful in replicating the CMS calculations exactly given the logic described. WPA matched their calculation of -0.01% when using the December 2021 data. However, using the March 2022 data, WPA found a slightly different reconciliation factor of: -0.02%. The change from -0.01% to -0.02% for the Final Rule may be immaterial, given CMS currently rounds to the nearest 3rd decimal place. The outlier target will stay at .949 (5.1%) regardless if the reconciliation factor is -0.01% or -0.02% (.9491 or .9492, respectively).

Analysis 7: Explorations on high charge cases

As evidenced in Analysis 5, the Fixed Loss Threshold has been adjusting over time, generally increasing. In response to this, WPA conducted various examinations and probing of the data and other issues that may relate to the Fixed Loss Threshold.

No single, definitive, cause for the increase was identified. However, one intriguing finding of this research was:

a) The impact of "extreme" cases on the Fixed Loss Threshold; and
b) The increase in the rate of "extreme" cases.

In the IPPS rate-setting process, statistical outliers – extreme cases – generally are removed from the calculations during the normal methodology. However, these cases are left in during the calculation of the Fixed Loss Threshold.

To examine this issue, WPA tested trimming out cases with covered charges greater than particular thresholds. This removed the case if the *covered charges* were greater than a threshold.

The following table shows the results at different trim points when using the proposed blended weights data.

Scenario	Cases	Removed cases	FLT	Percentage of cases removed
Base	7,241,437	-	$ 43,252	0.000%
Trim at: 3,000,000	7,240,787	650	$ 40,929	0.009%
Trim at: 2,750,000	7,240,602	835	$ 40,612	0.012%
Trim at: 2,500,000	7,240,313	1,124	$ 40,143	0.016%
Trim at: 2,250,000	7,239,916	1,521	$ 39,569	0.021%
Trim at: 2,000,000	7,239,328	2,109	$ 38,890	0.029%
Trim at: 1,750,000	7,238,355	3,082	$ 37,986	0.043%
Trim at: 1,500,000	7,236,777	4,660	$ 36,850	0.064%
Trim at: 1,250,000	7,233,866	7,571	$ 35,254	0.105%
Trim at: 1,000,000	7,227,965	13,472	$ 33,080	0.186%
Trim at: 750,000	7,213,279	28,158	$ 29,777	0.389%
Trim at: 500,000	7,165,667	75,770	$ 24,311	1.046%
Trim at: 250,000	6,902,728	338,709	$ 14,841	4.677%

Removing a relatively small number of cases can have the impact of shifting the Fixed Loss Threshold potentially thousands of dollars.

As was noted in previous years, the number and proportion of very high charge cases (defined here as having *covered charges* greater than $1.5 million) have been increasing over time. In the FY2021 data, this trend continued. There is an increase at a much faster rate than previous years for this 2021 data. (Note: 2020 data has also been updated to the final rule.)

Year	Number of cases over $1.5 million	Percentage of total cases	Number of unique providers
2011	926	0.0088%	272
2012	994	0.0098%	272
2013	1,092	0.0111%	283
2014	1,329	0.0141%	306
2015	1,539	0.0161%	320
2016	1,733	0.0185%	334
2017	2,291	0.0250%	403
2018	2,650	0.0286%	398
2019	3,128	0.0348%	441
2020	3,666	0.0474%	474
2021	4,659	0.0643%	527

Analysis 8: Different assumptions for the future

FY 2021 was still during the COVID Public Health Emergency (PHE), and it is still unknown if COVID will be of the same volume and severity of cases in FY 2023. However, these cases are used for modeling the payments and Fixed Loss Threshold for the IPPS system for FY 2023. If certain PHE policies are maintained, and depending on distribution of cases in the future, a different Fixed Loss Threshold would be a more appropriate in order to maintain the 5.1% outlier payment target. Setting the FLT too high while there is a reasonable expectation of changes in FY 2023 may lead to CMS dramatically underpaying high cost outlier cases.

To this end, WPA was asked to model different FLTs depending on different assumptions. For all of these cases, WPA used the blended weights and factors proposed by CMS in the FY 2023 IPPS Proposed Rule.

Scenario A: New COVID-19 Treatments Add-On Payment (NCTAP) is maintained

If the New COVID-19 Treatment Add-On Payment (NCTAP) providing additional payment for certain costly treatments for COVID, is maintained for FY 2023, WPA estimates that this would shift the FLT down to approximately $41,746.

From analysis of the FY2021 MedPAR data used in rate-setting, over 99% of the NCTAP cases had a COVID diagnosis. Of the cases with an NCTAP procedure code, only 40% of them

actually received an NCTAP payment. Even so, the NCTAP payment was not always sufficient, in that 15% of those cases also still received a high cost outlier payment.

Policies here:

- NCTAP continued

Scenario B: Scenario A, plus 20% COVID add-on

If, in addition to Scenario A, COVID cases continued to receive the 20% increase in operating payments, this would shift the FLT down to approximately $40,033

Policies here:

- NCTAP continued
- 20% COVID add-on continued

Scenario C: Scenario B, plus 1% increase in payment rates

If, in addition to Scenario B, there was an increase in the proposed payment rates by 1% to account for the expected increase due to inflation that has not yet been captured by the data collection, the new FLT would be approximately $39,300.

Policies here:

- NCTAP continued
- 20% COVID add-on continued
- Additional 1% on all payment rates

Scenario D: Scenario C, plus a trim on statistical outliers that were COVID cases

Extending Scenario C by trimming out COVID cases where the cost was more than three standard deviations from the geometric mean would shift the FLT down to $37,194. Note that this trim of outliers occurs just for the COVID cases, based on the mean cost of COVID cases, and the trim occurs both above and below.

Policies here:

- NCTAP continued
- 20% COVID add-on continued
- Additional 1% on all payment rates
- Trim of statistical outliers of cost – COVID cases only

Scenario E: Scenario D, but removing the 20% COVID add-on

Recognizing that the 20% COVID add-on may not be continued, the next scenario removed that policy. This led to a modeled FLT of $38,490.

Policies here:

- NCTAP continued
- Additional 1% on all payment rates
- Trim of statistical outliers of cost – COVID cases only

Scenario F: Scenario E, but refined to only remove outliers on the "top" end

Expecting that, given treatments, more severe COVID cases would be fewer, WPA also modeled the FLT should the trim of statistical outliers only be on the "top end" – where the costs of the case exceed the geometric mean by three standard deviations. This also continued to limit to COVID cases. The new FLT modeled here, was different only by $1, of $38,489.

Policies here:

- NCTAP continued
- Additional 1% on all payment rates
- Trim of statistical outliers of cost – COVID cases only, only removing cases from the "top end".