



Charles N. Kahn III
President and CEO

June 10, 2024

Via electronic submission at <http://www.regulations.gov>

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System (LTCH-PPS) and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes (CMS-1808-P; CMS-1808-CN)

Dear Administrator Brooks-LaSure:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, childrens', and cancer services.

The FAH appreciates the opportunity to submit comments to Centers for Medicare & Medicaid Services (CMS) about the above-referenced Proposed Rule for the IPPS and LTCH-PPS, published in the Federal Register (89 Fed. Reg. 35934) on May 2, 2024. This letter will detail FAH's comments on the IPPS, LTCH-PPS, and quality reporting and value-based payment programs. The FAH will submit a separate letter on the Transforming Episode Accountability Model (TEAM) proposal.

EXECUTIVE SUMMARY

Market Basket Update

The FAH requests CMS adopt a one-time forecast error adjustment to the FY 2025 IPPS operating update based on the forecast shortfalls in the hospital market basket in FY 2021 through FY 2023. We also note that CMS itself acknowledges that the total factor productivity adjustment applied to the update is more than hospitals can realize.

The market basket is intended to capture changes in labor and other costs that a hospital will encounter on a year-by-year basis when updating payment rates. As has been clear from the FY 2021 through FY 2023 data, the market basket update significantly understated the actual increase in hospital costs by a combined 4.3 percentage points due to an unprecedented confluence of circumstances during the COVID-19 PHE. The FAH requests that, in recognition of this unique and extraordinary situation, CMS apply an adjustment of +4.3 percentage points to the IPPS update taking into account the combined forecast error previously not adjusted for the years FY 2021 through FY 2023. If CMS were to adopt the FAH's recommendation, the update would be the market basket of 3.0 percent plus 4.3 percentage points for forecast error correction less 0.4 percentage points for productivity or a net 6.9 percent.

In addition, the FAH maintains that the standardized amount improperly continues the adjustments adopted under section 7(b)(1)(B) of Pub. L. No. 110-90, as amended by section 631(b) Pub. L. No. 112-240, section 414 of Pub. L. 114-10, and section 15005 of Pub. L. No. 114-255 (collectively, the TMA) into FY 2024. Pursuant to section 7(b)(2) and (4) of the TMA, no adjustment made under section 7(b)(1)(B) may continue beyond FY 2023, but CMS erroneously continued these adjustments in FY 2024. The FAH strongly urges CMS to eliminate this error for FY 2025 with a positive 0.9657% adjustment (representing the 0.9412% cumulative adjustments made under section 7(b)(1)(B) of the TMA, inflated by the 2.6% proposed FY 2025 applicable percentage increase to the standardized amount).

The FAH further notes that adopting our suggestion would have the benefit of lowering the outlier fixed loss threshold.

Outlier Payments

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 total PPS payment, plus the proposed fixed loss threshold of \$49,237. This proposed threshold is more than a fifteen percent and a \$6,487 jump from the current fixed loss threshold of \$42,750, which has been in effect since October 1, 2023, and remains significantly elevated over the level at which CMS set the threshold before the COVID-19 PHE.

The FAH notes that, in the past, CMS has deviated from its general methodology for calculating the outlier threshold when necessary to address data aberrations or otherwise produce a more accurate estimate of anticipated outlier cases. The cost-to-charge ratio (CCR) adjustment

factor for FY 2025 is markedly anomalous from the historical annual change in CCR – a proposed positive one-year national operating CCR adjustment factor of 1.03331 when all years since 2013 have had a negative CCR adjustment. We believe this calculation of an anomalous, first-time, year-over-year increase in CCRs is not consistent with reasonable expectations for CCRs in FY 2025, and is instead the product of skewed data, particularly from the peak inflationary period of the COVID-19 PHE in 2022 and early 2023. The FAH therefore urges CMS to modify its outlier methodology for FY 2025 to develop a fixed loss threshold that reflects reasonable expectations for FY 2025, including through the use of a CCR adjustment factor that is consistent with the most recent CCR data and the established trend of declining rather than increasing CCRs.

New Medical Residency Training Programs

CMS is using the FY 2025 IPPS proposed rule to further develop policy on the meaning of “new medical residency training program.” However, the language in the rule is unclear whether CMS intends to propose new policy or merely engaging in a request for information (RFI) on these issues in preparation for proposing future policy. The FAH urges CMS to clarify whether the policy being proposed with respect to a numerical standard of 90 percent constituting an “overwhelming majority” of residents is intended to be a regulatory change in policy (and, if so, how and when that change is intended to be applied) or a discussion item where CMS plans to propose future changes to regulation. Either way, CMS cannot construe a substantive change in policy be applied retroactively.

Further we urge CMS to clarify in the final rule that its policy is intended to allow a residency program to be considered new as long as 90 percent or more of the residents entering the program are in their first year of training in that specialty or subspecialty—not necessarily as a PGY-1. With this clarification, residents with prior training towards an initial specialty board certification as a prerequisite subspecialty training or a transitional year program accredited by the ACGME as a prerequisite for training in an advanced categorical program would not disqualify a program from being considered new.

In addition, given accrediting requirements and the goal of turning out highly trained physicians, **the FAH does not believe CMS should have any requirement that would preclude a program from being considered new merely because it hired more than 50 percent of its faculty and a program director with prior experience in these roles.** It should be sufficient that 90 percent or more of the residents are new to that specialty or subspecialty program for a residency or fellowship program to be considered “new.”

Long-Term Care Hospitals

Similar to the IPPS market basket, data for LTCHs show that CMS has understated the LTCH market basket by a combined 4.3 percentage points for FY 2021 – FY 2023. **The FAH requests that CMS also provide for a forecast error adjustment for the combined understatement of the FY 2021 through FY 2023 LTCH market baskets when updating the FY 2025 LTCH rates. Adopting this one-time forecast error adjustment to address the exception and unprecedented circumstances surrounding the COVID-19 PHE would make**

the LTCH PPS update equal to 2.8 percent plus 4.3 percentage points for forecast error less 0.4 percentage points for total factor productivity or a net 6.7 percent.

For FY 2025, CMS proposes to increase the HCO fixed-loss amount for LTCH PPS standard federal rate cases, from \$59,873 in FY 2024 to \$90,921 in FY 2025. This staggering \$52,403 increase would significantly cut Medicare payments to LTCHs for patients with the greatest resource needs. The FAH is concerned that the data used to project the fixed-loss threshold is not representative of what LTCHs will experience in FY 2025 because of the unique circumstances LTCHs and short-term acute hospitals faced throughout the pandemic. The FAH offers two alternative proposals for setting the outlier threshold, each of which would produce more appropriate outlier projections for FY 2025.

Quality Reporting

CMS proposes to modify and permanently require hospitals and critical access hospitals (CAHs) to report data on acute respiratory illnesses, such as COVID-19, influenza, and respiratory syncytial virus (RSV). This data would include confirmed infections, hospital capacity, and limited patient demographics. The FAH does not support the proposed CoP and urges CMS to consider alternative approaches, such as voluntary reporting and investment in infrastructure for efficient data sharing. We also recommend modifications to the proposed CoP if it is adopted, including allowing for weekly data snapshots, providing more specific data requirements, and removing the provision for increased reporting during potential PHEs.

Finally, in CY 2022, CMS outlined 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 previously cautioned CMS on moving too quickly to mandatory reporting of the THA/TKA PRO-PM. Several unforeseen issues and challenges have made reporting difficult for hospitals and CMS' responses have often been conflicting and unclear. Yet CMS is still holding hospitals accountable. This measure is very expensive to implement, there hasn't been enough time to get processes in place and CMS continues to move the guardrails. The methodology also fails to account for low-volume sites. **We urge CMS to delay the mandatory reporting of this measure in IQR from July 1, 2024, to January 1, 2025, at the earliest, to give hospitals more time to prevent the payment penalties that potentially hundreds of hospitals will incur because CMS failed to properly specify, and field test this measure. We also urge CMS to lower the 50% response rate requirement and include a minimum threshold.**

* * *

The FAH appreciates the opportunity to offer comments on the FY 2025 IPPS and LTCH-PPS Proposed Rule. Our detailed comments are included in the following pages in Appendix A of our letter and further supported by the WPA Report attached as Appendix B. If you have any questions or would like to discuss further, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

Sincerely,

A handwritten signature in black ink, appearing to be "Andrew M. ...". The signature is fluid and cursive, with a large initial 'A' and a long horizontal stroke at the end.

APPENDIX A:
FAH Detailed Comments on FY 2025 IPPS/LTCH PPS Proposed Rule (CMS-1808-P)

MS-DRG CLASSIFICATIONS AND RELATIVE WEIGHTS

II.C Proposed Changes to Specific MS-DRG Classifications

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 2025 except for the items to follow.

II.C.1.b Basis for Proposed FY 2025 MS-DRG Updates

Grouper

For FY 2025, CMS is providing a test version of ICD-10 MS-DRG Grouper Software Version 42 along with conversion files to assist with analysis.

The FAH appreciates the public availability of V42 draft grouper. While this grouper appears to allow for a case-by-case analysis and a minimal batch analysis, it does not allow providers the opportunity to assess a large batch analysis. It would be more beneficial to have a Batch z/OS version of the test grouper so that it could be better utilized for broader and more meaningful analysis purposes. The FAH requests the public availability of a Batch z/OS version of the test grouper for all future rulemaking

Proposed Changes to the Medicare Code Editor (MCE)

In the FY 2024 IPPS/LTCH PPS final rule (85 FR 58764), as noted in CY 2024 Outpatient Prospective Payment System and Ambulatory Surgical Center (OPPS/ASC) proposed rule (88 FR 49552, July 31, 2023), consistent with the process used for updates to “Integrated” Outpatient Code Editor (I/OCE), CMS finalized the proposal to address any future revisions to the IPPS Medicare Code Editor (MCE) including any additions or deletions of ICD-10 diagnosis and procedure codes to the applicable MCE edit code lists, outside the annual IPPS rulemakings. Thus, beginning with the FY 2025 rulemaking, IPPS MCE revisions are removed from the annual IPPS rulemaking and future changes or updates to the MCE will generally be addressed through instruction to the Medicare administrative contractors (MACs).

The FAH recognizes the importance of the MCE and is concerned with the removal of MCE proposals from IPPS formal rulemaking. Identifying key considerations and mitigating unintended consequences are a key benefit of public review and consideration of stakeholder comments. The FAH believes the proposed process is not transparent on key areas such as when the manual will be updated, effective dates, or ability to provide feedback with timely responses. The FAH requests that CMS reconsider including updates to the MCE as part of the rulemaking process.

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The FAH acknowledges CMS' intent to deactivate the MCE edit for Diagnosis and Age/Sex Conflict Edit for inpatient admissions as of October 1, 2014. Consistent with our comments to continue inclusion of MCE proposals within IPPS rulemaking, we encourage CMS to delay deactivation of this edit until CMS evaluates the effectiveness of condition code 45 ("gender incongruence"), and provides an opportunity for public comment on the change.

FY 2025 MS-DRG Updates

The FAH acknowledges that 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, FY 2023, and FY 2024 IPPS/LTCH PPS final rules, CMS delayed applying this technical criterion to existing MS-DRGs and acknowledged the impact of PHE on the data. In FY 2024, an alternative grouper and alternative table 5 of MS-DRGs with weights was provided that reflected the application of the NonCC subgroup.

The finalized criteria included NonCC Subgroup includes parameters for three-way split for MCC, CC, and NonCC; two-way split for MCC vs CC/NonCC; as well as a two-way split for MCC/CC vs NonCC. Criteria include 5 items such as 500 cases in each group, percent of patients, percent cost, etc. The application of the NonCC Subgroup criteria that requires 500 cases in each subgroup is the most common parameter when applied to existing MS-DRGs that impacts the severity levels created with the base MS-DRG.

For FY 2025, CMS has proposed to delay the application of the NonCC Group; however, the details of the application of the data that provides the specifics on the volume of MS-DRGs impacted was not included in the Proposed Rule. With review of this Proposed Rule and prior rules dating back to FY 2021 since the initial proposal, CMS has provided specific numbers on the specific MS-DRGs that would change annually based on the three-way severity level split criterion finalized in FY 2021. This information has been included annually within table 6P.1b or 6P.1c with a listing of the MS-DRGs that would be subjected to deletion and/or creation with the application of the NonCC Subgroup. In FY 2024, for the first time, table 6p.10a through 6P.10f and the alternative table 5 provided weight information for the potential revisions to the MS-DRGs.

The volume of cases that CMS concluded would have been impacted by the application of the criterion in recent years has been as follows:

- FY 2022: 32 MS-DRGs would have been subject to change, which would result in the deletion of 96 MS-DRGs and the creation of 58 new MS-DRGs.
- FY 2023: 41 MS-DRGs would have been subject to change, which would result in the deletion of 123 MS-DRGs and the creation of 75 new MS-DRGs.
- FY 2024: 45 base MS-DRGs would have been subject to change which would result in the deletion of 135 MS-DRGs and the creation of 86 new MS-DRGs. CMS also proposed to exclude 12 obstetrical MS-DRGs from application of the policy.

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In the FY 2025 Proposed Rule, however, CMS did not provide any new information from or analysis of the FY 2023 MedPAR file as it related to base, deleted, or new MS-DRGs related to the application of the NonCC subgroup criteria. CMS proposed to continue to delay application of the NonCC subgroup criteria to existing MS-DRGs with a three-way severity split for FY 2025. CMS notes they continue to consider public comments received in FY 2024 rulemaking and welcomed continued feedback for future rulemaking.

The FAH appreciates and strongly agrees with CMS proposal to delay the application of the NonCC subgroup criteria to existing MS-DRG structure. The FAH believes that the new data should have been included within the Proposed Rule to continue efforts to view the impact of the policy. This is especially true because annual reviews since the FY 2021 initial proposal have shown a different number of MS-DRGs impacted with some dropping off and reappearing on subsequent years.

The FAH appreciated the availability of V41A grouper as well as the proposed new MS-DRGs with the weights and volume shifts included within the tables last year. The FAH requests that CMS provide updated alternate test software for FY 2025 with grouper V42 (e.g. V42a) to facilitate further analysis.

After reviewing this information, the FAH respectfully continues to request that the NonCC subgroup criteria be reassessed and not applied to the existing MS-DRGs. The FAH supports this conclusion for multiple reasons outlined below involving issues with data reliability and transparency due to the annual fluctuations.

The FAH believes that the dynamic nature of the MS-DRGs that are impacted for the last three fiscal years demonstrates a need to reassess the structure of the criteria. The FAH is concerned that this information was not provided for FY 2025. Since the initial proposal in FY 2021, the MS-DRGs impacted have changed annually. This change has not been a simple addition of new MS-DRGs each year. MS-DRGs have been demonstrated to revolve year-to-year with MS-DRGs being appropriate for a three-way split one year and reduced to less tiers in subsequent years and vice versa. As mentioned, the deletions and new MS-DRGs have increased annually (e.g. MS-DRG deletions from 96 to 123 to 135 and MS-DRG additions from 58 to 75 to 86). Examples of the dynamic nature for consideration of additional explanation or revisions to the methodology as well as transparency on the frequency to review the criteria include:

- MS-DRGs that were proposed in FY 2022 to be removed, changed in FY 2023 to not be impacted and then in FY 2024 they are back on the list to be removed (e.g., MS-DRGs 283-5 Acute MI Expired, MS-DRGs 722-4 Malignancy Male Reproductive, etc.)
- MS-DRGs that had not previously been proposed to the removal list but were new for FY 2024 (e.g., MS-DRGs 11-3 Tracheostomy, MS-DRGs 539-41, etc.)
- MS-DRGs that were proposed in FY 2023 for removal, and were dropped off in FY 2024 (e.g., MS-DRGs 597-9 Malignant Breast Disease, 802-4 Other OR Blood and Blood Forming Organs, etc.)
- It appears this methodology could result in reporting challenges with exact narratives with new MS-DRGs assigned. The tables in FY 2024 demonstrated for the first time with actual MS-DRG numbers assigned instead of “XX” placeholders as in prior years.

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All of these numbers were new numbers for the three tier MS-DRGs that would become double or single tier MS-DRGs once implemented. The first tier of every one of the 45 base pairs had the same narrative. For example, MS-DRG 180 is Respiratory Neoplasms with MCC in V41 and would become MS-DRG 209 still titled Respiratory Neoplasms with MCC in V41a. From a reporting standpoint, should MS-DRGs with the same narrative have new MS-DRG numbers assigned? How would this be impacted with updates especially when a three tier MS-DRG goes to a two tier MS-DRG one year and returns to a three tier MS-DRG another year? What is the frequency for which the cases will be reviewed with the NonCC Subgroup Criteria?

The FAH believes that the application of the Non-CC sub-criteria for the new and existing MS-DRGs further demonstrates that the methodology needs to be reassessed as this resulted in the elimination of two-way splits for with and without MCC/CC. Not a single existing or new MS-DRG resulted in the two-way split of with and without MCC/CC over the three fiscal years of proposals. Since the application of the NonCC subgroup would clearly result in fewer MS-DRGs split by the presence of a CC, the impact of the presence of a CC on MS-DRG assignment is diminishing. Additionally, there are MS-DRGs that clearly demonstrate all of the cost criteria considerations but are excluded simply because of low volume.

The FAH would request that this reassessment of the case count consider revisions to the NonCC Subgroup include the following:

- Consider the dynamic coding system which is always expanding with further specificity and how that should impact individual case counts within the methodology. Providing further specificity for single codes with multiple new options does spread out the individual case counts and perhaps groups of codes should be considered with the MCC/CC counts. For example, in FY 2021, the single codes F10.188 and F10.988 which are still valid 1-10 codes for Alcohol abuse with other alcohol induced disorders were impacted with the creation of new codes to provide further specificity for the types of disorders with alcohol abuse. New codes in the range of F10.121-F10.931 were created to reflect alcohol dependence with various combinations of intoxication, withdraw, delirium. This dilution is built into the system with the constant creation of new codes which spreads what was in one code across many, making it difficult to hit the 500 count.
- What consideration is given with a triplet with weighting when a higher percentage of cases falls in the higher tier of the MS-DRG?
- What consideration is given with MS-DRG determination when the MS-DRG within CMS data doesn't even have 500 cases with all of MedPAR data total? This was the case with FY 2025 with proposed MS-DRG 850 that only has 367 cases noted for this MS-DRG total within the rule and the AOR/BOR report.
- Would guiding principles similar to those created for MCC/CC be helpful in determining weight impact to minimize the higher negative impact especially with surgical MS-DRGs?

The FAH strongly requests that FY 2025 data in regards to the MS-DRG impact be shared as this is important in order to continue to evaluate the impact. The FAH is concerned

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with what may be in the data for increases and decreases within the MS-DRGs especially since this data would include MedPAR data for FY 2023 (10/1/22-9/30/23) which would represent lowest COVID-19 impact of data available since the official end of the pandemic on May 11, 2023. The FAH strongly recommends and urges CMS to consider a technical expert panel (TEP) made up of clinical, coding and other stakeholders and experts to review criteria and methodologies. Overall, the FAH would like an opportunity to better understand the rationale for dynamic nature of the proposals since the initial proposal annually and the fact no details on the potential impact were included this fiscal year for review. The proposal's volumes have changed as well as the fluctuation of which specific MS-DRGs would be created and deleted. The methodology has resulted in the CC impact on MS-DRGs fading without transparency of CMS intent.

II.C.4. MDC 05 (Diseases and Disorders of the Circulatory System)

II.C.5.a Concomitant Left Atrial Appendage Closure (LAAC) and Cardiac Ablation

CMS received a request to create a new MS-DRG for patients with concomitant left atrial appendage closure (LAAC) and cardiac ablation for atrial fibrillation in MDC 05. The requestor, the manufacturer of the Watchman, indicated it is ideal to perform the LAAC and cardiac ablation at the same time for symptomatic atrial fibrillation.

CMS reviewed the request utilizing nine codes to identify the LAAC and 27 codes for the cardiac ablation. Analysis included total case volume, average LOS and costs for MS-DRGs 273 and 274. CMS noted that the concomitant LAAC with the ablation can improve symptoms and the data analysis did show higher than average costs and LOS. CMS also noted that the MCC/CC subgroups failed to support a two-tier MS-DRG as the costs were not >20%. Lastly, CMS noted the failure of the criteria for with and without MCC potential for the new MS-DRG as it failed to support the case count and the 20% in costs. For these reasons, CMS is proposing to create only the base MS-DRG 317 (Concomitant Left Atrial Appendage Closure and Cardiac Ablation) for FY 2025.

The FAH has reviewed the data analysis included in the rule and requests some data transparency and/or clarification on the information. CMS noted that within MS-DRG 273 and 274 there were 80 and 781 cases for a total of 861 cases. This data seems to imply that the majority of the cases would shift from MS-DRGs 273 and 274. When CMS pulled data to make the MCC/CC determinations the total was not 861 cases but 1,723 cases. The FAH analyzed the AOR/BOR File, provided by CMS, that provides volume per MS-DRG with current (V41) and proposed (V42) grouper. The AOR file showed that MS-DRG 273 and 274 had a decline of 918 cases which is higher than the number in the rule. Regardless of whether it is 861 or 918 cases, this suggests there are other MS-DRGs involved that are not discussed in the Proposed Rule. The AOR file showed declines for MS-DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC). The FAH notes that within the AOR tables, there is a decrease between version 41 and 42 of the grouper for MS-DRGs 228 of 174 cases and 229 of 662 cases. Adding the differences between 228, 229, 273 and 274 is closer to the 1723 cases included within the rule as this totals to 1,697. The FAH did use the stand alone V42 grouper and was able to confirm cases did shift from all four MS-DRGs.

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The FAH supports the creation of new MS-DRG 317 but requests data transparency on the analysis included in the proposed rule. Clarity should be provided for the MS-DRGs impacted, as well as an explanation as to why the volume is different with the 861 vs 1,723 cases. This clarity of the data is also needed with the MCC/CC determinations to ensure all the shifts were included and not just those within MS-DRG 273 and 274.

II.C.6b. Interbody Spinal Fusion Procedures

The FAH supports the need to review the spinal fusion MS-DRGs for potential changes to the logic for case assignment to the MS-DRGs with redistribution of cases among potential new, deleted and revised MS-DRGs. The FAH appreciates the granularity that the additional MS-DRGs can provide for data analysis especially in light of the fact spinal patients have multiple procedures performed during the same encounter. These procedures can involve multiple levels, single levels as well as combinations (*e.g.*, multiple with single or more than one single levels). The FAH believes the logic for all the MS-DRGs for spinal fusion should be addressed.

The FAH understands that the spinal fusion analysis began with looking at specific manufacturer devices. This led to the discovery that the levels were a factor with severity determinations with MS-DRGs. If the remaining spinal fusion MS-DRGs (*i.e.*, MS-DRGs 456, 457, 458, 471, 472, 473) were reviewed to determine areas of impact, it could lead to similar discoveries that perhaps should be addressed at the same time for the stability of reporting.

After modeling the data and reviewing the procedures with clinicians, more clarity is needed on the logic that supports the proposed 8 new MS-DRGs (402, 426, 427, 428, 429, 430, 447, 448), 3 deleted MS-DRGs (453, 454, 455), two revised MS-DRGs (459, 460) and the six MS-DRGs that remained unchanged related to spinal fusion (456, 457, 458, 471, 472, 473). The FAH is concerned as noted below that more analysis may be necessary for the logic revisions.

- After reviewing the report provided by CMS with the AOR table, the FAH reviewed the CMI calculations with V41 and V42 with the spinal fusion revisions and was surprised to see that there was no change with the CMI. A comparison of the V41 and V42 AOR tables showed a very minimal CMI shift. If the spinal fusions were more accurately reflecting the resources, it would seem logical there would be a shift when only looking at the spinal fusions with the revisions. Why is the CMI unchanged?

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V41 DRG	V41 Weight	V41 cases	V41 Wt Total (V41 wt * V41 cases)	Volume Difference Between V42-V41	Total Wt Difference	V42 DRG	V42 cases	V42 Wt Total (V42 Wt * V42 Cases)	V42 Description	V42 Weight
NEW FY25				17023	67877.5102	402	17023	67877.5102	SINGLE LEVEL COMBINED ANTERIOR AND POSTERIOR SPINAL FUSION EXCEPT CERVICAL	3.9874
NEW FY25				2833	30329.5314	426	2833	30329.5314	MULTIPLE LEVEL COMBINED ANTERIOR AND POSTERIOR SPINAL FUSION EXCEPT CERVICAL WITH MCC	10.7058
NEW FY25				13252	95917.9760	427	13252	95917.976	MULTIPLE LEVEL COMBINED ANTERIOR AND POSTERIOR SPINAL FUSION EXCEPT CERVICAL WITH CC	7.2380
NEW FY25				8323	46463.1475	428	8323	46463.1475	MULTIPLE LEVEL COMBINED ANTERIOR AND POSTERIOR SPINAL FUSION EXCEPT CERVICAL WITHOUT CC/MCC	5.5825
NEW FY25				621	5219.8776	429	621	5219.8776	COMBINED ANTERIOR AND POSTERIOR CERVICAL SPINAL FUSION WITH MCC	8.4056
NEW FY25				1871	10376.5660	430	1871	10376.566	COMBINED ANTERIOR AND POSTERIOR CERVICAL SPINAL FUSION WITHOUT MCC	5.5460
NEW FY25				2200	14818.1000	447	2200	14818.1	MULTIPLE LEVEL SPINAL FUSION EXCEPT CERVICAL WITH MCC	6.7355
NEW FY25				15489	64235.9808	448	15489	64235.9808	MULTIPLE LEVEL SPINAL FUSION EXCEPT CERVICAL WITHOUT MCC	4.1472
453	8.8614	4317	38254.6638	-4317	-38254.6638	Delete FY25			COMBINED ANTERIOR AND POSTERIOR SPINAL FUSION WITH MCC	8.8614
454	6.1163	21704	132748.1752	-21704	-132748.1752	Delete FY25			COMBINED ANTERIOR AND POSTERIOR SPINAL FUSION WITH CC	6.1163
455	4.6056	17991	82859.3496	-17991	-82859.3496	Delete FY25			COMBINED ANTERIOR AND POSTERIOR SPINAL FUSION WITHOUT CC/MCC	4.6056
456	8.4294	1553	13090.8582	10	1036.9425	456	1563	14127.8007	SPINAL FUSION EXCEPT CERVICAL WITH SPINAL CURVATURE, MALIGNANCY, INFECTION OR EXTENSIVE FUSIONS WITH MCC	9.0389
457	6.0753	3946	23973.1338	25	-399.2923	457	3971	23573.8415	SPINAL FUSION EXCEPT CERVICAL WITH SPINAL CURVATURE, MALIGNANCY, INFECTION OR EXTENSIVE FUSIONS WITH CC	5.9365
458	4.5310	1310	5935.61	8	-160.0022	458	1318	5775.6078	SPINAL FUSION EXCEPT CERVICAL WITH SPINAL CURVATURE, MALIGNANCY, INFECTION OR EXTENSIVE FUSIONS WITHOUT CC/MCC	4.3821
459	6.6323	3355	22251.3665	-2185	-16139.6375	459	1170	6111.729	SINGLE LEVEL SPINAL FUSION EXCEPT CERVICAL WITH MCC*	5.2237
460	3.6579	30272	110731.9488	-15446	-64256.8866	460	14826	46475.0622	SINGLE LEVEL SPINAL FUSION EXCEPT CERVICAL WITHOUT MCC*	3.1347
471	4.9190	3121	15352.199	0	-139.1966	471	3121	15213.0024	CERVICAL SPINAL FUSION WITH MCC	4.8744
472	2.9554	14096	41659.3184	0	-429.9280	472	14096	41229.3904	CERVICAL SPINAL FUSION WITH CC	2.9249
473	2.4606	6424	15806.8944	0	-400.8576	473	6424	15406.0368	CERVICAL SPINAL FUSION WITHOUT CC/MCC	2.3982
TOTAL		108089	502663.5177		487.6426		108101	503151.1603		
CMI			4.650459507				4.6545			

- From a clinical perspective, it is not uncommon for the same patient to have procedures included on more than one of the 6p tables provided by CMS (6p.2d through 6p.2h). The end result is the probability of duplicative data. The use of only the 6p tables will result in duplication without the creation of exclusions. For example, if working with MS-DRG 402 which uses procedures on 6p.2d, the list as it is written can provide only patients that have a single combined spinal fusion AND it can provide patients that happen to have single and multiple done in the same encounter which would route to another MS-DRG. It is interesting to note that the AOR table did have more spinal fusions with V42 than it did with V41 which seems to suggest some duplication or omission with the logic. It would be anticipated that the number of cases would be the same for spinal fusions with the same data using V41 and V42 grouper. It is not clear how the duplications were handled in the data when there was both a multiple and single on the same case to ensure it was not counted more than once.
 - CMS noted the following for each new MS-DRG within the rule which totals to 84,774 patients, however, these same MS-DRGs in V42 AOR report total of 77,643 which is a difference of 7,131 more patients included in the calculations for the rule. Is the duplication of same patients counting in multiple buckets of MS-DRG determinations?

MS-DRG	Proposed Rule Count	AOR Table Count	Difference
426/7/8	23,017	24,421 (2,833, 13,259, 8,329)	1,404
402	16,059	17,032	973
429/430	2,323	2,494 (622, 1,872)	171
447/8	28,698	17,696 (2,200, 15,496)	-11,002
459/460	14,677	16,000 (1,170, 14,830)	1,323
TOTAL	84,774	77,643	-7,131

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- It is unclear how CMS ultimately concluded that the number of levels involved became the determining cost factor for MS-DRG determination. There is no breakdown that shows the pure costs/LOS of those patients that only had single- or multiple-level with no other procedures within the data. How was the level the deciding factor when it could have been additional procedures performed or the diagnosis or the cost of the device or the number of surgeons required to insert the device, or any other factors?
 - CMS made the determination to not provide any further analysis on MS-DRGs 456, 457, 458 which are the only spinal fusion MS-DRGs that are differentiated by the principal diagnosis and defer this for future rule making. This recognizes a diagnosis can impact the LOS and charges; however, no other diagnoses are analyzed especially in relationship to the other MS-DRGs. Why was no diagnosis impact analysis performed for MS-DRG 453, 454, 455 other than trends on secondary diagnoses? If the logic is in question for the MS-DRGs shouldn't all of the spinal fusions analyzed for new logic instead of tabled for the future since it could have an impact on the structure of all based on outcome of analysis?
 - Recognizing that the weight impacts the cost analysis and this in turn impacts the hierarchy within the grouper, it seems important to note it is not all multiples that are having the highest impact on the MS-DRG but the fact they are combined approach. Note that MS-DRGs 453-55, 426-8, 402, 429-30 are the four highest and they are all the combined approaches. Multiple level not combined, MS-DRGs 447-8 falls below the single level combined and the any level for specific diagnosis MS-DRGs (402, 456-8).

Proposed Surgical Hierarchy: MDC 08	
Delete MS-DRGs 453-455	Combined Anterior and Posterior Spinal Fusion
Proposed New MS-DRGs 426-428	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical
Proposed New MS-DRG 402	Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical
Proposed New MS-DRGs 429-430	Combined Anterior and Posterior Cervical Spinal Fusion
MS-DRGs 456-458	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions
Proposed New MS-DRGs 447-448	Multiple Level Spinal Fusion Except Cervical
Proposed New Title MS-DRGs 459-460	Single Level Spinal Fusion Except Cervical
MS-DRGs 461-462	Bilateral or Multiple Major Joint Procedures of Lower Extremity
MS-DRGs 463-465	Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders
MS-DRGs 466-468	Revision of Hip or Knee Replacement
MS-DRGs 521-522	Hip Replacement with Principal Diagnosis of Hip Fracture
MS-DRGs 469-470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity
MS-DRGs 471-473	Cervical Spinal Fusion

- The proposed rule suggests that the number of levels impact the resources and reimbursement; however, where is the data to differentiate those patient that had multiple and single levels on the same patient and that impact to the resources and charges?
- If the resources and charges are unique with single and multiple levels, why were MS-DRGs 459 and 460 not deleted and new MS-DRGs created instead of creation of new MS-DRG and renaming?

The FAH supports CMS' review of logic changes and potential new MS-DRGs related to spinal fusion procedures, however we encourage CMS to consider if the current FY 2025 proposals should be postponed for future rulemaking to ensure a thorough analysis and consideration of these and other public comments can be completed. The FAH is strongly

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opposed to renaming of the MS-DRG 459 and 460 if the MS-DRGs are revised to be impacted by single vs multiple levels within other MS-DRGs.

II.C.9. MDC 17 Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms): Acute Leukemia

CMS provided analysis of MS-DRGs in MDC 17 for further refinement and noted the logic for case assignment to medical MS-DRGs 834, 835, 836 (Acute Leukemia without Major OR Procedures with MCC, with CC and without CC/MCC, respectfully) includes ICD-10-PCS procedure codes designated as O.R. procedures within these medical MS-DRGs. Information from MedPAR FY 2023 was included in the following table to differentiate cases that include a recognized O.R.

MS-DRGs 834, 835, and 836: All Cases and Cases Reporting an O.R. Procedure				
	MS-DRG	Number of Cases	Average Length of Stay	Average Costs
834	All cases	4,094	16.3	\$49,986
	Cases reporting an O.R. procedure	277	28.2	\$92,246
835	All cases	1,682	7.2	\$19,023
	Cases reporting an O.R. procedure	79	10.4	\$30,771
836	All Cases	230	4	\$11,225
	Cases reporting an O.R. procedure	7	5.9	\$17,950

CMS noted the data shows cases reporting a principal diagnosis code describing a type of acute leukemia with an ICD-10-PCS procedure code designated as O.R. procedure that isn't included in the logic for MS-DRG 820, 821, 822. The cases with O.R. procedures clearly show higher average costs and longer lengths of stay.

CMS proposes the creation of new MS-DRG 850 (Acute Leukemia with other procedures) to reflect these 367 cases that report principal diagnosis of acute leukemia and ICD-10-PCS procedure code designated as O.R. The criteria for subgroups in the base MS-DRG will fail since the overall volume is under 500. The proposal also includes the removal of reference to major O.R. procedures in the title for MS-DRGs 834, 835, 836 will change from "Acute Leukemia without Major OR Procedures with MCC, with CC, and without CC/MCC" respectively to "Acute Leukemia with MCC, with CC and without CC/MCC respectively.

The FAH supports the creation of new MS-DRG 850. The FAH requests that CMS reconsider the criteria for determining subgroups with small population MS-DRGs such as this one. The NonCC Subgroup criteria currently requires the 500-case count in each tier which is impossible to meet when the total population for the MS-DRG is under 500 cases such as this MS-DRG that has only 367 total cases. This data clearly shows higher average LOS and costs in the CC and nonCC tier that is not considered but would support subgroups for inclusion of CC/MCC.

II.C.11. Operating Room (O.R.) and Non-O.R. Procedures

CMS since the FY 2020 proposed rule has noted a multi-year project to review the process for determining when a procedure is considered an operating room procedure. CMS

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encourages the public to continue to submit comments on any factors that CMS should consider in its efforts to recognize and differentiate consumption of resources for ICD-10 MS-DRGs for consideration.

The FAH continues to support CMS' proposal for a multi-year comprehensive review on the topic. The FAH also continues to believe that thorough data analysis conducted with provider stakeholders is critical to allow for appropriate insight in providing comments. As stated in response to the FY 2020 proposed rule on this topic, the FAH recommended that CMS consider a technical expert panel (TEP) made up of industry stakeholders and experts to review methodologies for O.R. determination. The continued expertise of a TEP is critical in light of industry and technological advancements with procedures and delivery of care to encompass all patient settings. The TEP could assist in providing guiding principles for O.R. determination. **The FAH, again, strongly recommends and urges CMS to consider a technical expert panel (TEP) made up of clinical, coding and other stakeholders and experts to review methodologies for O.R. determination.**

II.C.12. Proposed Changes to the MS-DRG Diagnosis Codes for FY 2025

b. Overview of Comprehensive CC/MCC Analysis

For FY 2020 CMS proposed changes to the severity designation of 1,492 ICD-10-CM diagnosis codes and based on comments of concern expressed CMS postponed the proposal. In FY 2021, CMS' plan included a combination of mathematical analysis of claims data and application of nine guiding principles. The nine guiding principles are as follows:

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility.
- Denotes organ system instability or failure.
- Involves a chronic illness with susceptibility to exacerbations or abrupt decline.
- Serves as a marker for advanced disease states across multiple different comorbid conditions.
- Reflects systemic impact.
- Post-operative/post-procedure condition/complication impacting recovery.
- Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).
- Impedes patient cooperation or management of care or both.
- Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

CMS noted that they have not received any additional feedback or comments since FY 2021 and proposes to finalize the nine guiding principles with FY 2025.

The FAH requests that current data showing the application of the guiding principles be provided prior to the finalization of the guiding principles. The last data that showed impact on specific diagnoses was made available for FY 2020. The FAH continues to request greater

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transparency on how the nine guiding principles would be applied as well as for CMS to address the process for MCC/CC determination questions that are noted below.

- Provide definitions and criteria for applying the principles. The principles are vague, subjective and open to interpretation. There is potential to over-reach and under-reach severity designation for a specific diagnosis as some appear overly strict while others appear lax and duplicative of reporting requirements (for example, “impedes patient cooperation or management of care or both”).
- How will the guiding principles be used to differentiate between MCCs and CCs, especially since the principles seem to support more MCCs more than CCs?
- Prior to finalizing the guiding principles, what is the impact to existing codes that are determined as MCC and CC and allowing time to comment?
- Provide current examples on how the nine guiding principles have been applied, including clarification on how many principles must be met in order to obtain the MCC or CC determination.
 - Example 1: The FAH is in agreement that the social determinants of health (SDOH) homeless and housing instabilities would be CC; however, these diagnoses definitely do not meet all of the nine guidelines.
 - Example 2: The FAH acknowledges that in FY 2020 one of the proposed changes was for severe malnutrition to shift from MCC to CC. The condition definitely has potential to meet all of the guiding principles.

II.C.12.c.1 SDOH – Inadequate Housing/Housing Instability

CMS provided the data in the table below for consideration with SDOH for potential of CC determination. In considering the nine guiding principles, CMS noted inadequate housing and housing instability are circumstances that can impede patient cooperation or management of care as well as potential to require higher care by needing extended length of stay. CMS noted “inadequate housing is defined as an occupied housing unit that has moderate or severe physical problems (for example, deficiencies in plumbing, heating, electricity, hallways, and upkeep)”. CMS is proposing to assign these codes CC designation.

ICD-10-CM Code ^a	Description ^b	Total Count ^c	Cnt1 ^d	C1 ^e	Cnt2 ^f	C2 ^g	Cnt3 ^h	C3 ⁱ
Z59.10	Inadequate housing, unspecified	227	21	2.63	85	1.38	121	2.81
Z59.11	Inadequate housing environmental temperature	74	4	0.51	33	1.02	37	2.64
Z59.12	Inadequate housing utilities	162	12	0.99	80	1.65	70	2.39
Z59.19	Other inadequate housing	987	93	1.85	431	2.82	463	3.07
Z59.811	Housing instability, housed, with risk of homelessness	165	21	1.97	79	2.51	65	3.18
Z59.812	Housing instability, housed, homelessness in past 12 months	141	15	0.76	65	1.77	61	2.33
Z59.819	Housing instability, housed unspecified	1,237	96	0.92	619	2.25	522	2.88

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The FAH supports the CC designation for inadequate housing and instability codes and agrees that the impact to level of care of the diagnosis would be in line with CC designation. The FAH strongly recommends that consistent reporting for inadequate housing/instability, as well as the infrastructure to support the reporting, should be provided. Examples of key considerations include but are not limited to the following:

- Provide consistent definitions. For example, what constitutes inadequate housing environment temperature (*e.g.*, no air conditioning in hot climate vs no air conditioning in hot climate with respiratory disease vs No air conditioning regardless of climate in summer months, etc.)? Another example involves what supports inadequate housing utilities (*e.g.*, well water with odor vs well not trusted for consumption that individuals hand carry water vs well that has periods of being dry, etc.).
- Recognize that the requirement of the additional CCs with 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.).

II.C.12.e Proposed CC Exclusions List for FY 2025

CMS outlines the five principles that were established in 1987 for excluded secondary diagnoses which include the following:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another
- Specific and nonspecific (that is, not otherwise specified (NOS) diagnosis codes for the same condition should not be considered CCs for one another
- Codes for the same condition that cannot coexist such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant should not be considered CCs for on another
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another, and
- Closely related conditions should not be considered CCs for one another.

The CC Exclusion List is included as Appendix C in the ICD-10 MS-DRG Definitions Manual and includes two lists identified as Part 1 and Part 2. Part 1 lists all diagnoses defined as CC or MCC when reported as secondary diagnosis. Links exist for the collection of diagnosis

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codes when reported as principal diagnosis that would cause CC or MCC to be considered as a NonCC. Part 2 is the list of the diagnosis codes designated as an MCC only for patients that are discharged alive, otherwise, they are assigned as a NonCC. The April 1, 2024 release added a new section to Appendix C – “Part 3 Secondary Diagnosis CC/MCC Severity Exclusions in Select-MS-DRGs”. These are diagnosis codes that are designated as CC or MCC included in the definition of the logic for the listed MS-DRG. When reported as a secondary diagnosis and grouped to one of the listed MS-DRGs, the diagnosis is excluded from acting as a CC/MCC for severity in MS-DRG assignment. CMS referred to this as suppression logic and noted that in addition to excluding the secondary diagnosis CC or MCC, it also was based on the presence of other secondary diagnosis logic defined with certain base MS-DRGs which were provided in a list.

In review of MS-DRGs with suppression logic, a set of MS-DRGs containing secondary logic in the definition logic was identified to contain secondary diagnosis logic – MS-DRGs 673, 674, 675 (Other Kidney and Urinary Tract Procedures with MCC with CC and without CC/MCC, respectively). CMS noted 21 diagnosis describing conditions such as chronic kidney disease, kidney failure, and complications related to a vascular dialysis catheter or kidney transplant. The second list “or Principal Diagnosis” logic comprised four diagnosis codes describing diabetes with diabetic chronic kidney disease followed by with secondary diagnosis logic list that includes diagnosis codes N18.5 (Chronic kidney disease, stage 5) and N18.6 (End stage renal disease). CMS explained the logic lists are components of special logic in MS-DRGs 673,674, 675 with tunneled or totally implantable vascular access. The last situation involved three diagnoses describing diabetes with different kidney complications as part of logic in MS-DRG 673, 674, 675 for pancreatic islet cell transplantation. CMS indicated that both N18.5 and N18.6 were designated as MCC and felt they should be considered NonCCs with MS-DRGS 673, 674, 675 with suppression logic. Therefore, for FY 2025, CMS proposed to correct the logic so that suppression logic would apply to exclude N18.5 and N18.6 with MS-DRG 673, 674, 675.

The FAH disagrees with the application of the suppression logic within MS-DRGs 673, 674, 675 with the principal diagnoses listed above when assigned with the diagnosis N18.5 and N18.6. These two diagnoses are the highest level of severity for kidney failure with end stage and stage 5 which requires dialysis and/or transplant. The only principal diagnoses that could meet one of the five principles would be I12.0, I13.11 (as these two codes actually indicate stage 5 CKD or end stage renal disease in the principal diagnosis). The FAH believes only two diagnosis codes would be supported for suppression involving secondary diagnosis codes N18.5 and N18.6 which are included in the principal diagnosis codes I12.0 and I13.11. The FAH believes the five conditions established for exclusions were not met for the majority of the diagnoses on the principal diagnosis list and for that reason they should not be subject to suppression logic.

II.E.c Proposed Change to the Calculation of the Inpatient New Technology Add-On Payment for Gene Therapies Indicated for Sickle Cell Disease

CMS believes that it is important to balance the need to maintain an incentive for hospitals to be cost-effective and also encourage the development and use of new technologies.

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In the FY 2020 IPPS final rule, CMS adopted a general increase in the new technology add-on payment from 50 percent to 65 percent and an increase to 75 percent for Qualified Infectious Disease Products (QIDPs). In the FY 2021 IPPS final rule, CMS expanded the alternative pathway for QIDPs to include Limited Population Pathway for Antibacterial and Antifungal Drugs (LADP) and finalized the maximum new technology add-on payment percentage for LADP products to 75 percent.

CMS believes that facilitating access to gene therapies for Medicare beneficiaries with sickle cell disease (SCD) may have the potential to improve the health of impacted beneficiaries and lead to long-term Medicare savings. Consistent with its new technology add-on payment policy for products designated by the FDA as QIDP and LPAD, CMS believes the payment percent for gene therapies indicated and used for the treatment of SCD should be increased to 75 percent.

CMS proposes that, subject to its review of the new technology add-on payment eligibility criteria, for certain gene therapies approved for new technology add-on payments in the FY 2025 final rule for the treatment of SCD, effective with discharges on or after October 1, 2024, and concluding at the end of the 2- to 3-year newness period, to increase the payment percentage from 65 to 75 percent. CMS notes that if finalized, this policy would be temporary; these payment amounts would only apply to any gene therapy indicated and used specifically for the treatment of SCD that CMS approves for FY 2025 new technology add-on payments.

CMS seeks comments on the proposal and whether it should make this proposed 75 percent add-on payment percentage available only to applicants that meet certain additional criteria, such as attesting to offering and/or participating in outcome-based pricing arrangements with purchasers (without regard to whether the specific purchaser availed itself of the outcome-based arrangement) or otherwise engaging in behaviors that promote access to these therapies at lower costs.

The FAH shares CMS' concern that the normal 65 percent add-on payment for SCD gene therapy would not adequately cover the significant costs that hospitals would be asked bear when treating patients with Casgevy. While the FAH appreciates the proposed increase to 75 percent, we are concerned that this amount would still be wholly inadequate, leaving hospitals to absorb significant losses when treating SCD patients using the new and costly gene therapies. In the absence of any other evaluation or discussion of reimbursement solutions, hospitals will be left to bear enormous losses for an essential therapy where there are no alternatives with similar outcomes. These losses will directly obstruct Medicare patients' access to gene therapies based on prices that are beyond the control of the provider and hinder future treatment options for this patient population.

CMS has the statutory authority to provide for additional payment beyond the proposed 75%, and the FAH strongly urges CMS to exercise this authority. Under section 1886(d)(5)(K) of the Social Security Act, CMS is required to "establish a mechanism to recognize the costs of new medical services and technologies" in a manner that provides for "additional payment . . . in an amount that adequately reflects the estimated average cost of such service or technology." To date, CMS has implemented subparagraph (d)(5)(k) through its new technology add-on payment

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regulations at 42 C.F.R. §§ 412.87 through 412.88. In the context of SCD gene therapy, however, CMS' new technology add-on payment mechanism fails to “adequately reflect[] the estimated average cost of such service or technology” as required by the applicable statute. Payment based on a portion of charges reduced to costs under section 412.88 would result in significant financial losses for providers, as described above.

Therefore, the FAH recommends that CMS instead establish an alternative NTAP methodology that recognizes the significant costs (and extraordinary long-term value) of SCD gene therapy. In light of pricing considerations for these gene therapies, the FAH anticipates that even a 90% or 100% cost-based reimbursement methodology for SCD gene therapy would fail to adequately reflect the estimated average cost of the new therapy in FY 2025 because of the way NTAP and outlier policies use overall hospital cost-to-charge ratios to calculate the cost of the gene therapy. **Therefore, for FY 2025, the FAH urges CMS to temporarily adopt a 100% cost-based reimbursement methodology for SCD gene therapy under section 1886(d)(5)(K) and/or take other measures to ensure that the payment methodology fully recognizes the estimated average cost of the care.**

In addition to modifying the NTAP proposal to adequately reflect the estimated average cost of SCD gene therapy in the FY 2025 Final Rule, the FAH recommends that CMS:

- Issue regulatory instructions (e.g., a National Coverage Determination (NCD)) confirming that these therapies will be covered per the FDA label.
- Expand the proposal's limited focus and include transfusion-dependent beta thalassemia (TDT) patients.

Modifying CMS' NTAP proposal will enable CMS to meet its intent of fostering improved beneficiary access to care for rare diseases, consistent with Congress' instruction under section 1886(d)(5)(K) of the Act. This will also allow the agency time to develop an alternative approach to MS-DRGs and IPPS payment for product costs that significantly outweigh the patient care cost.

MARKET BASKET UPDATE

V.B Proposed FY 2025 Inpatient Hospital Update – Summary

CMS proposes a market basket update of 3.0 percent for FY 2025 which will likely understate hospital inflation for the 5th consecutive year. This market basket update is a product of CMS' reliance on historical data to forecast FY 2025 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. Beginning with FY 2021, CMS has provided for a market basket update below the actual rate of increase annually through FY 2024 as shown in the below table¹:

¹ OACT, 4th quarter 2023 release of the market basket information with historical data through the 3rd quarter of 2023 (<https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and->

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IPPS Market Basket	FY 2021	FY 2022	FY 2023	FY 2024
Forecast Used in the Update	2.4	2.7	4.1	3.3
Actual Based on Later Utilization	3.0	5.7	4.8	3.5
Difference	-0.6	-3.0	-0.7	-0.2

In addition, CMS proposed reducing the proposed market basket update with a 0.4 percentage points total factor productivity adjustment. This total productivity adjustment is inappropriate in that it contemplates improbable and overstated gains in productivity for the hospital sector as noted by the CMS Office of the Actuary (OACT) itself and detailed below.

In light of the foregoing, the FAH urges CMS to do a one-time adjustment to the market basket update methodology to account for forecast error.

Background

Under section 1886(b)(3)(B)(iii) of the Act, CMS is required to update hospital rates based on:

the percentage, estimated by the Secretary before the beginning of the...fiscal year, by which the cost [of] ... inpatient hospital services...will exceed the cost...for the preceding 12-month cost reporting period or fiscal year.

The update is subject to the productivity adjustment and further adjustments for hospitals that fail to submit quality information and/or are not meaningful EHR users.² CMS is proposing to use a hospital market basket of 3.0 percent to update inpatient hospital rates for FY 2025. This market basket is based on the forecast of CMS' contractor, IHS Global Insight, Inc. (IGI). IGI's fourth quarter 2023 forecast (with historical data through the third quarter of 2023) for the hospital market basket is 3.0 percent. IGI's fourth quarter 2023 forecast of total factor productivity is 0.4 percent.

The Proposed Rule indicates that CMS' forecast of the FY 2025 hospital market basket and the offset for productivity will be updated if more recent data become available before the final rule. If CMS follows past practice, this will mean that the FY 2025 final rule update will be based on IGI's second quarter 2024 forecast of the FY 2025 hospital market basket with historical data through the first quarter of 2024.

The FAH strongly urges CMS to use later data on the market basket increase for FY 2025 as it has in past years and to further adjust its estimate to account for forecast error in the FY 2021 through FY 2023 hospital market basket update which understated the actual rate of inflation by a combined 4.3 percentage points. In each of these years, the

[reports/medicareprogramratesstats/marketbasketdata](#)) for the actual update based on later utilization. Data for FY 2024 remains an estimate as it only reflects data through the 3rd quarter of FY 2023.

² Social Security Act § 1886(b)(3)(B)(i)(XX), (vii), (ix), (xi).

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magnitude of the difference between the market basket and the actual rate of increase exceeded 0.5 percentage points—the same threshold that the SNF PPS uses for determining when to apply a forecast error correction.³ Upward pressure on hospital costs occurring throughout the pandemic and other global economic developments is not well represented using third quarter 2023 historical data.

CMS' Understatement of Prior Year Hospital Inflation

In our public comments on the FY 2023 IPPS proposed rule, the FAH provided several sources of data that indicated that the historical data upon which the proposed FY 2023 forecast of the market basket was based was less than the rate of increase that hospitals were experiencing at that time.⁴ The evidence in these data that CMS' forecasts of the market basket during a time of high inflation and economic instability understate the actual rate of increase have been borne out by CMS' own data.

The table on the prior page shows how CMS' forecast of the market basket compares to the actual market basket based on later data since FY 2021. These data show that CMS has understated the market basket by a combined 4.3 percentage points for FY 2021 through FY 2023. Partial year data for FY 2024 shows that CMS will likely have underestimated the hospital market basket for the 4th consecutive year.

One reason that CMS' market basket data may be reflecting lower increases in staffing costs compared to what hospitals are experiencing relates to use of contract labor. Hospitals have confronted worrying shortages of hospital workers during the COVID-19 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. We understand that the Bureau of Labor Statistics' (BLS) Employment Cost Index (ECI) only captures the salary increases associated with employed staff, and thus wholly fails to capture the extraordinary growth in labor costs associated with hospitals' necessary reliance on nursing personnel that are contracted through staffing agencies during a time of labor supply shortages. This discrepancy may explain why the ECI data is so divergent from that being reported to Premier Inc (PINC) AI™. It is unreasonable to rely on the ECI data for labor expenses without appropriate adjustments that reflect the profound increase in hospital expenses for contract and travel nurses.

As we noted in our public comments on the FY 2023 IPPS proposed rule, the FAH and the American Hospital Association (AHA) provided a report from FTI Consulting that likewise

³ 89 Fed. Reg. 23428 (Apr. 3, 2024).

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

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recognized that hospital use of contracted staff has increased markedly since 2019. According to FTI:

[H]ospitals face more competition than ever from travel and temporary nurse staffing firms that are attracting a greater share of the workforce with higher pay and more generous benefits, a trend driving up hospital labor costs. The cost of contract labor relative to total labor expenses increased five-fold in 2022 compared to 2019, primarily due to the need to replace departing staff nurses with travel or agency nurses. Median wages for contract nurses reached triple the median wages of employed nurses in March 2022.⁵

In an analysis undertaken by FAH and AHA and provided to CMS in the FY 2024 IPPS proposed rule comment period, we found that the ECI is unlikely to catch up with overall level of hospital labor cost increases. Since contract labor use and general workforce composition will not likely revert to its earlier levels, growth in the ECI will continue to lag behind growth in hospital labor costs.⁶ This report relies on many of the sources we provided in our FY 2023 IPPS proposed rule comments documenting that the ECI understates the growth in hospital labor costs because it does not account for contract labor being a higher proportion of total hospital costs.

Our recommendation was that CMS consider a closely related measure to the ECI—the Employer Costs for Employee Compensation (ECEC) that may better and more timely account for growth in hospital compensation costs than the ECI. As explained in a report provided with our FY 2024 IPPS rule comments, the ECI is constructed through a multi-step process that is intended to smooth short-term fluctuations in the labor pool. However, when the underlying hospital employment structures are changing rapidly and permanently, the ECI will understate labor costs by relying on a job type that is only in the sample for two consecutive quarters, using a sampling weight for when a job first enters the sample and holding the mix of occupations fixed before there is a rebasing.⁷

The ECEC, however, is dynamic and will reflect increases in compensation and changes in the mix of labor inputs on a timelier basis. For the wages and salaries component, the ECI and the ECEC show a growth rate of 13.3 percent and 20.0 percent respectively, a 6.7 percentage point gap between the 4th quarter of 2019 and the 4th quarter of 2022. The growth in the total compensation component, which CMS uses to track benefits, is slightly lower with the ECI and the ECEC recording growth of 12.4 percent and 16.6 percent, respectively, a 4.2 percentage point gap. Combining wages and salaries and employee

⁵ FTI Consulting, Report: Assessing the Adequacy of Proposed Updates to the Hospital Inpatient Prospective Payment System, page 4, available at <https://assets.fah.org/uploads/2022/06/FY2023-IPPS-FAH-061722.pdf> (Att. A).

⁶ Federation of American Hospitals and the American Hospital Association, Hospital Employment Cost Index Undermeasures Labor Cost Growth in Recent Years, page 4 available at <https://assets.fah.org/uploads/2023/06/FAH-IPPS-2024-Comment-Final-06092023-with-Attachments.pdf> (Att. A).

⁷ See pages 6-7 of the FAH and AHA Report provided with our FY 2024 IPPS rule comments for more detail on this issue.

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benefits into a single composite measure shows the ECEC was 6 percentage points higher during this period than the ECI for items that account for 52.9 percent of the total hospital market basket. All else equal, if the hospital ECI growth had matched the hospital ECEC growth, this would have meant an additional three percentage point increase in the IPPS hospital market basket over this period. Given the parallel trends to CMS' own market basket data, these data clearly show that the ECI is too low, not that the ECEC is too high.

In the IPPS final rule, CMS rejected using the ECEC in place of the ECI stating the ECEC reflects average compensation in the economy at a point in time, including both changes in compensation and changes in employment. The wage measure in the market basket should not reflect changes in employment to be consistent with the statute that the market basket percentage increase be based on an index of appropriately weighted indicators of changes in wages and prices. The ECEC, an indicator that also includes changes in employment, is not as appropriate to use as the ECI in the IPPS market basket.⁸

The FAH respectfully disagrees with CMS' response that it is restricted by statute from using the ECEC. While it is accurate that section 1886(b)(3)(B)(iii) of the Act requires the market basket to be based on an index of "appropriately weighted indicators of changes in wages and prices which are representative of the mix of goods and services," there is no limitation that the index be fixed weight index that does not account for changes in the mix of goods and services over time.

The market basket is intended to capture changes in labor and other costs that a hospital will encounter on a year-by-year basis when updating payment rates. As has been clear from the FY 2021 through FY 2023 data, the market basket update significantly understated the actual increase in hospital costs by a combined 4.3 percentage points while the ECEC would have more accurately forecast the increase in the market basket for these years. Even if CMS does not believe that it can use the ECEC, the fact that it has more accurately measured inflation should be supportive of CMS applying a one-time adjustment for forecast error. **The FAH once again requests that CMS revisit its response and methodology related to the market basket's inability to accurately predict inflation during the volatile times presented by COVID-19 and dramatic labor shifts in 2022, and we urge CMS to address recent shortfalls using a one-time forecast error adjustment.**

Total Factor Productivity

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

⁸ 88 Fed. Reg. 59032 (Aug. 28, 2023).

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However, CMS itself takes issue with the assumption that hospitals can recognize the same kinds of productivity gains as the general economy. In a memorandum dated June 2, 2022, OACT stated: “over the period 1990-2019, the average growth rate of hospital TFP using the two methodologies ranges from 0.2 percent to 0.5 percent, compared to the average growth of private nonfarm business TFP of 0.8 percent.” The memorandum also indicates that an assumed future rate of hospital industry productivity growth of 0.4 percent per year remains reasonable compared to an assumed rate of productivity growth in the private nonfarm business sector of 1.0 percent.⁹

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

The FAH understands that CMS is required by law to adjust the IPPS market basket update for total factor productivity. However, the FAH asks CMS to consider that the adjustment for total factor productivity reduces the update below what even OACT says is reasonable for hospitals to achieve when deciding on our request to make an adjustment for forecast error as detailed below.

CMS Should Do a One-time Adjustment to the FY 2025 Update for FY 2021 through FY 2023 Forecast Error

As indicated above, the hospital update from FY 2021 through FY 2023 understated the actual rate of inflation as measured by the hospital market basket by a combined 4.3 percentage points. This significant and unprecedented understatement of the market basket results in a permanent reduction to hospital rates below the rate of inflation unless adjusted for in a future rate update. In the FY 2023 IPPS final rule, CMS indicates that “an important goal of a PPS is predictability” and that “due to the uncertainty regarding future price trends, forecast errors can be both positive and negative.”¹⁰

The FAH agrees that predictability in the future rate updates is a worthwhile goal of a prospective payment system. However, we also believe the large and anomalous understatements of past year rates must be corrected in the future to prevent what has already been chronic Medicare underpayment reported by the Medicare Payment Advisory Commission (MedPAC) from becoming even worse.¹¹

⁹ Paul Spitalnic, Stephen Heffler, Bridget Dickensheets and Mollie Knight, “Hospital Multifactor Productivity: An Update Presentation of Two Methodologies Using Data through 2019.” <https://www.cms.gov/files/document/productivity-memo.pdf>.

¹⁰ 87 Fed. Reg. 49,054 (Aug. 10, 2022).

¹¹ In its most recent report to Congress, MedPAC states that in “fiscal year (FY) 2022, the aggregate all-payer operating margin among ACHs [acute care hospitals] paid under the IPPS fell to the lowest level since 2008,

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Under the SNF PPS, CMS makes a correction for forecast error if the difference between the SNF market basket used for the update and the actual rate of increase is more than 0.5 percentage points. For the FY 2025 SNF update, CMS is proposing to increase the market basket update of 2.8 percent by 1.7 percentage points for forecast error in application of the FY 2023 update.¹² In each year between FY 2021 and FY 2023, forecast error for the hospital market basket used in the IPPS update exceeded a 0.5 percentage point difference between projected market basket and the actual increase. **The FAH requests that CMS apply an adjustment of +4.3 percentage points to the IPPS update taking into account the combined forecast error previously not adjusted for the years FY 2021 through FY 2023.** If CMS were to adopt the FAH’s recommendation, the update would be the market basket of 3.0 percent plus 4.3 percentage points for forecast error correction less 0.4 percentage points for productivity or 6.9 percent.

The Proposed Rule Would Unlawfully Continue to Apply Adjustments Under TMA § 7(b)(1)(B) in FY 2025

The Proposed Rule, like the FY 2024 IPPS/LTCH Final Rule, would violate the express statutory mandate that the adjustments under section 7(b)(1)(B) of the TMA, Abstinence Education, and QI Program Extension Act of 2007, Pub. L. No. 110-90 as amended¹³ (“TMA”), be fully reversed and not continue to apply to discharges after FY 2023. **The FAH strongly urges CMS to eliminate this error for FY 2025 with a positive 0.9657% adjustment to the standardized amount, which consists of the remaining 0.9412% adjustment under section 7(b)(1)(B) of the TMA, inflated by the 2.6% proposed FY 2025 applicable percentage increase to the standardized amount.**

Beginning with FY 2014,¹⁴ CMS has made the following adjustments under section 7(b)(1)(B)(ii) and (iii) of the TMA:

and their overall FFS Medicare margin across service lines declined to a record low, both in aggregate and for relatively efficient hospitals. These low all-payer and FFS Medicare margins were largely driven by higher-than-expected input price inflation in 2022.” Report to Congress: Medicare Payment Policy, Ch. 3, p. 51 (Mar. 15, 2024), available at https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_MedPAC_Report_To_Congress_SEC.pdf.

¹² 89 Fed. Reg. 23,428 (Apr. 3, 2024).

¹³ Section 7 of the TMA was amended by the American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 631(b) (“ATRA”) in 2013, by Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, § 414 (“MACRA”) in 2015, and by the 21st Century Cures Act, Pub. L. No. 114-255, § 15005 in 2016.

¹⁴ Under section 7(b)(1)(B)(i), CMS also adopted a –2.9% adjustment in FY 2011 and then retained that adjustment in FY 2012. 76 Fed. Reg. 51,475, 51,497 (Aug. 18, 2011). In recognition of the TMA’s prohibition on continuing to apply these adjustments in FY 2013, the adjustments were fully reversed in FY 2013 with a +2.9% adjustment, thereby returning the standardized amount “to the appropriate baseline.” 77 Fed. Reg. 53,257, 53,276 (Aug. 31, 2012).

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FY	Adjustment	Cumulative Adjustment
2014	-0.8%	-0.8%
2015	-0.8%	-1.6%
2016	-0.8%	-2.4%
2017	-1.5%	-3.9%
2018	+0.4588%	-3.4412%
2019	+0.5%	-2.9412%
2020	+0.5%	-2.4412%
2021	+0.5%	-1.9412%
2022	+0.5%	-1.4412%
2023	+0.5%	-0.9412%

The FY 2014 through FY 2017 adjustments were made under section 7(b)(1)(B)(ii) of the amended TMA, followed by the adjustments for 2018 through 2023, which were made under amended section 7(b)(1)(B)(iii) of the TMA. *See* 82 Fed. Reg. 37,990, 38,008–009 (Aug. 14, 2017); 87 Fed. Reg. 48,780, 48,799–48,800 (Aug. 10, 2022). All of these adjustments, both positive and negative, are adjustments under section 7(b)(1)(B) of the TMA, and thus are all subject to section 7(b)(4), which prohibits continuing any section 7(b)(1)(B) adjustments into years beyond FY 2023.

TMA § 7(b)(4) provides that “[n]othing in this section shall be construed as providing authority to apply the adjustment under paragraph (1)(B) other than for discharges occurring during fiscal years 2010, 2011, 2012, 2014, 2015, 2016, and 2017 and each succeeding fiscal year *through fiscal year 2023*” (emphasis added). This language makes clear that **CMS must fully eliminate the payment adjustment under section 7(b)(1)(B) for any year not listed in section 7(b)(4)**. And, in fact, that is precisely what CMS did in the FY 2013 Final Rule by fully eliminating the section 7(b)(1)(B) adjustment at that time with a one-time positive 2.9% adjustment. 77 Fed. Reg. at 53,276.

As illustrated in the above table, the series of negative and positive adjustments made under TMA section 7(b)(1)(B) between FYs 2014 and 2023 have produced a cumulative, net adjustment of negative 0.9412%. As such, in order to comply with Congress’ mandate that the adjustment under section 7(b)(1)(B) not apply to any year after FY 2023, CMS was required to fully eliminate this remaining section 7(b)(1)(B) adjustment with a one-time, offsetting positive adjustment of 0.9412% for FY 2024. CMS, however, failed to do so in FY 2024, and the standardized amount for FY 2024 remains impermissibly reduced by the section 7(b)(1)(B) adjustments. In response to comments on this issue, in the FY 2024 IPPS/LTCH Final Rule, CMS focused on its authority to adopt and apply the adjustments under section 7(b)(1)(B)(ii) and (iii) of the TMA in past fiscal years.¹⁵ 88 Fed. Reg. 58,640, 58,654 (Aug. 28, 2023). But, the FY 2024 IPPS/LTCH Final Rule failed to discuss or give any meaning to Congress’s clear and

¹⁵ In the FY 2024 IPPS/LTCH Final Rule, CMS also stated that it was not “persuaded that it would be appropriate to use the Secretary’s exceptions and adjustments authority under section 1886(d)(5)(I) of the Act to adjust payments in FY 2024 [and] restore any additional amount of the original 3.9 percentage point reduction” in light of the adjustment requirements in section 7(b)(1)(B)(iii) of the TMA.

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unequivocal prohibition under section 7(b)(4) on applying any of these section 7(b)(1)(B) adjustments to discharges after FY 2023 and Congress's prohibition in section 7(b)(2) on the inclusion of an adjustment under section 7(b)(1)(B) "in the determination of the standardized amounts for discharges occurring in a subsequent year." Put simply, Congress' instruction to adopt and apply the adjustments under section 7(b)(1)(B)(ii) and (iii) in FY 2014 through 2023 does not authorize the continuation of these adjustments in FY 2024 and subsequent years, and such a continuation is expressly prohibited under section 7(b)(2) and (4) of the TMA. And the Proposed Rule, if finalized, would continue this error in FY 2025 by again continuing the adjustments adopted under section 7(b)(1)(B) as permanent reductions to the standardized amount.

The FY 2024 IPPS/LTCH Final Rule and the FY 2025 Proposed Rule provide no rationale for diverging from CMS' established approach to eliminating section 7(b)(1)(B) adjustments to comply with section 7(b)(4) of the TMA with a one-time offsetting restoration to the standardized amount. Nor does either rulemaking cite to any authority for making the section 7(b)(1)(B) adjustments permanent. In light of the foregoing concerns and express limitations on CMS' authority, **the FAH urges CMS to end the erroneous continuation of section 7(b)(1)(B) adjustments in FY 2025 with a one-time, offsetting positive adjustment of 0.9412%, inflated by the applicable percentage increase to the standardized amount (i.e., 0.9657%, if the proposed applicable percentage increase of 2.6% is finalized).**

OUTLIER PAYMENTS FY 2025

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

For FY 2025, 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 \$49,237. This proposed threshold is more than a fifteen percent and a \$6,487 jump from the current fixed loss threshold of \$42,750, which has been in effect since October 1, 2023, and remains significantly elevated over the level at which CMS set the threshold before the COVID-19 PHE.

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 2025 CMS is proposing to modify its method for estimating total expected outlier reconciliation, based on the revised reconciliation criteria set forth in CMS' March 28, 2024 Transmittal 12594 with Change Request 13566 (CR 13566).

The proposed increase in the fixed loss threshold is excessive and appears to be significantly driven by data showing an anomalous—but temporary—spike in cost to charge ratios (CCRs), which are believed to have been the result of rapid cost inflation due to acute labor costs and other factors during the COVID-19 PHE. Because more recent data shows the trend is

reverting to the norm of a decrease in CCRs, it is unreasonable to expect the one-time increase in CCRs to occur again in FY 2025. The FAH urges CMS to apply a CCR adjustment factor that is less than 1.00, which would be consistent with the pre-COVID-19 PHE CCR data, as well as CCR trends seen in the most recent cost report data. Applying an appropriately negative CCR adjustment factor will help to set the threshold at a level that both is likely to produce total outlier payments at CMS' 5.1 percent target and ensure that all hospitals, including rural and safety-net hospitals, whose DRG payments are offset 5.1 percent to fund outlier payments, can access outlier payments.

With regard to CMS' proposed reconciliation adjustment factor, the FAH continues to support an outlier development methodology that appropriately accounts for the impact of outlier reconciliations. However, because the new outlier reconciliation criteria are a change in the substantive policy for payment of outlier claims, they should not be applied until after they have been submitted through notice and comment rulemaking.

1. Continuation of Methodological Changes Adopted for FY 2020, with Modified Calculation of Estimated Reconciliation of Outlier Payments

Projecting Outlier Reconciliation. CMS proposes to again apply methodological refinements that were first applied in the FY 2020 IPPS rulemaking and also to resume using the most recent data sets: MedPAR files from FY 2023 for claims and from FYs 2022 and 2023 for computing charge inflation; and the December 2022 and 2023 PSF updates for computing the CCR adjustment factor. First, CMS proposes to again account for outlier reconciliation in the FY 2025 outlier threshold calculation. The FAH has repeatedly requested that CMS release information on the outlier reconciliation process and data showing the amounts recovered or refunded 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 2025 fixed-loss threshold. CMS is proposing to modify its method for calculating the sum of outlier reconciliation by estimating additional reconciliation using the new criteria set forth in CR 13566. Watson Policy Analysis (WPA) matched CMS' calculation of a -0.04 percent reconciliation factor, using FY 2019 cost report data CMS used for the Proposed Rule. As explained further below, however, the FAH objects to CMS' application of the new reconciliation criteria without first going through notice and comment rulemaking.

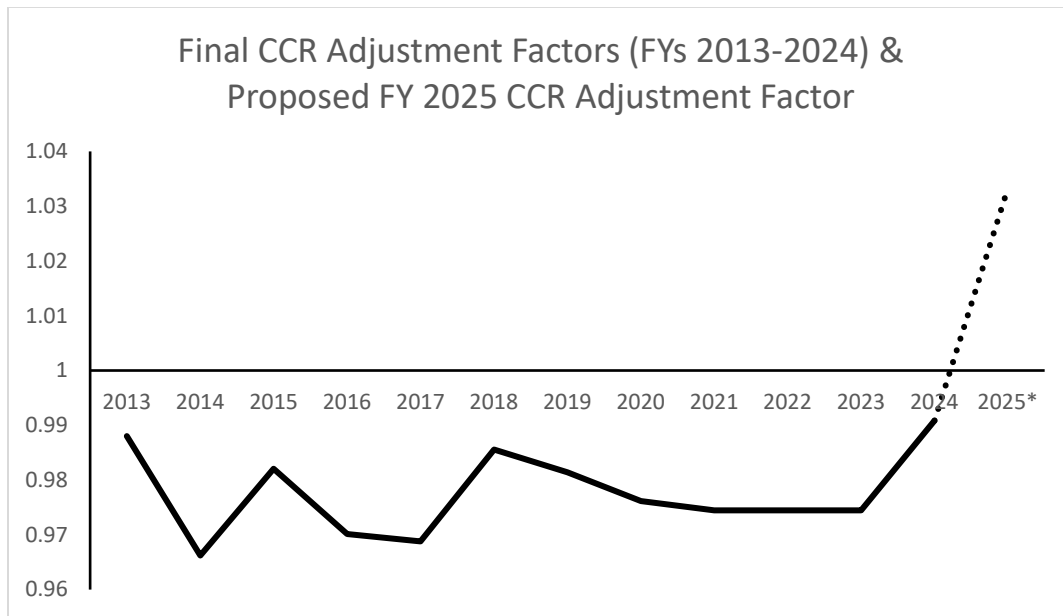
Projecting Charge Inflation. Second, the Proposed Rule charge inflation factor calculation conceptually mirrors the method CMS adopted in the FY 2020 final rule, relying on charge data from the most recent publicly available MedPAR files to compute the one-year charge inflation factor. Using the FY 2022 and FY 2023 MedPAR data files, CMS has computed a one-year charge inflation factor of 4.142 percent and has converted that into a two-year charge-inflation-factor of 8.4555 percent. However, unlike with the LTCH PPS high-cost outlier threshold (LTCH threshold), CMS does not propose to apply any trims to the charge data in the FYs 2022 and 2023 MedPAR data files. Specifically, for the LTCH threshold, CMS has appropriately proposed "to remove all claims from providers whose growth in average charges was a statistical outlier." 89 Fed. Reg. at 36,591. CMS explained, "We remove these statistical outliers prior to calculating the charge inflation factor because we believe they may represent aberrations in the data that would distort the measure of average charge growth." *Id.* Yet CMS has not articulated

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any principled basis not to apply similar trims to the charge inflation data used to set the IPPS outlier threshold. If not removed from the IPPS charge inflation data, the statistical outliers “will distort the measure of average charge growth” for IPPS hospitals. We therefore urge CMS to apply such trims when computing the final charge inflation factor. We also 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.

Projecting CCRs. Third, the Proposed Rule applies the same method, first adopted in the FY 2014 IPPS Rule, to project the change in CCRs. For FY 2025, CMS has proposed comparing the CCRs in the December 2022 update of the PSF to the CCRs in the December 2023 update of the PSF and has computed a proposed positive one-year national operating CCR adjustment factor of 1.03331. As shown by the below chart of CMS’ final CCR adjustment factors since FY 2013, CMS’ proposed CCR adjustment factor for FY 2025 is anomalous and would be the first use of a projected increase in the CCRs.

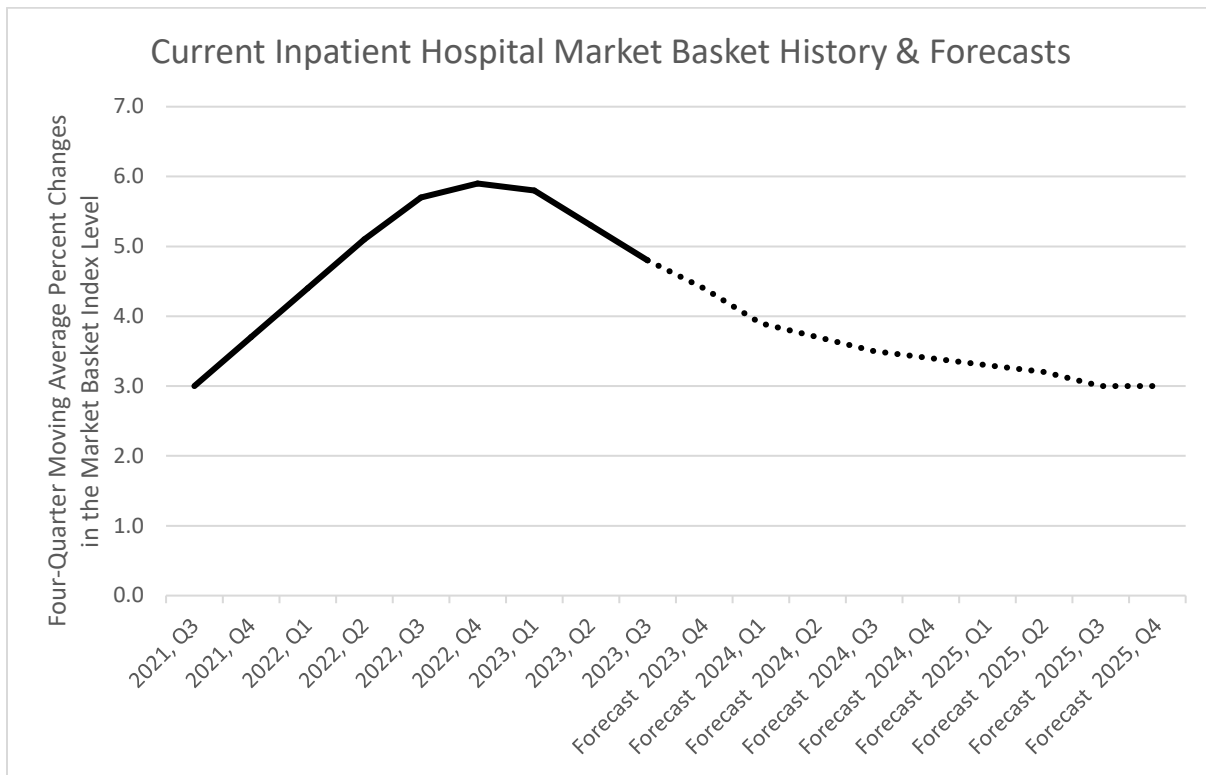


The anomalous first-time year-over-year increase in CCRs, used for the proposed FY 2025 adjustment factor, is driven by CCRs skewed by costs—largely labor costs—incurred during the peak inflationary period of the COVID-19 PHE in 2022 and early 2023. Indeed, CMS’ projection of a 1.033 change in CCRs suggest that average costs per case increased by over 7 percent, given that CMS estimated average charge inflation of about 4.4 percent from FY 2022 to FY 2023. However, CMS’ current data and projections reflect a Q4 2022 peak in the

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four-quarter moving average percent change to the market basket index level followed by a slowing in cost inflation, as shown in the below graph.¹⁶



Likewise, shifting to a comparison of the March 2023 and March 2024 updates of the PSF (in lieu of the December 2022 and December 2023 updates of the PSF used in the Proposed Rule) reveals that CCRs are again declining such that a CCR adjustment factor greater than 1.0 is unreasonable. Although the FAH anticipates that the use of more recent data in the final rule will itself produce a lower CCR adjustment factor, we are concerned that a CCR adjustment factor calculated from this data will continue to be skewed by data from an anomalous period of rapid inflation. In fact, a preliminary review of HCRIS data indicates that CCRs are in fact declining in ways that are not yet reflected in the PSF. Therefore, we urge CMS to not only use more recent data from the PSF when finalizing a CCR adjustment factor, but also to affirmatively address the skewing impact of older CCR data (namely that from 2022 and earlier) in the PSF so as to develop a CCR adjustment factor that reasonably projects CCR changes in FY 2025.

The FAH notes that, in the past, CMS has deviated from its general methodology for calculating the CCR adjustment factor when necessary to ensure that the CCR adjustment factor provides a more reasonable approximation of anticipated CCR trends. For example, for the FY 2023 IPPS, CMS declined to apply its usual methodology because it would have produced an “abnormally high” CCR adjustment factor of approximately 1.03. Concluding that it would be

¹⁶ CMS, Summary Market Basket History and Forecasts (Apr. 15, 2024), available at <https://www.cms.gov/files/zip/summary-market-basket-history-and-forecasts.zip>.

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unreasonable to assume that CCRs would continue to increase at these “abnormally high rates,” CMS instead applied a CCR adjustment factor from the last 1-year period prior to the COVID-19 PHE. 87 Fed. Reg. 48,780, 48,797 (Aug. 10, 2022). Looking to FY 2025, it is likewise unreasonable to assume that CCRs will continue to increase at the abnormally high rates seen during a period of rapid and significant cost increases (particularly labor costs). The FAH therefore urges CMS to modify its method for FY 2025 to develop a CCR adjustment factor that is consistent with established CCR trends over the past decade and that reflects the most recent CCR data, all demonstrating a consistent trend of decreasing CCRs.

2. 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 more than 80 percent between FY 2017 and FY 2024, and to propose to increase the threshold more than an additional 15 percent for FY 2025, 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.¹⁷

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 2025 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 2024 Proposed Rule Table

Trim threshold	Cases remaining	Removed cases	FLT	Percentage of cases removed
None	6,720,056	-	\$49,252	0.00%
\$3,500,000	6,719,289	767	\$45,890	0.011%
\$3,000,000	6,719,034	1,022	\$45,376	0.015%
\$2,750,000	6,718,699	1,357	\$44,713	0.020%
\$2,500,000	6,718,331	1,725	\$44,057	0.026%
\$2,250,000	6,717,788	2,268	\$43,256	0.034%
\$2,000,000	6,716,857	3,199	\$42,150	0.048%
\$1,750,000	6,715,538	4,518	\$40,935	0.067%
\$1,500,000	6,713,602	6,454	\$39,571	0.096%

¹⁷ See WPA Report at p. 7. The tables from the WPA report have been reproduced here with minor editing for formatting purposes.

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\$1,250,000	6,710,162	9,894	\$37,740	0.147%
\$1,000,000	6,703,251	16,805	\$35,250	0.250%
\$750,000	6,686,367	33,689	\$31,667	0.501%
\$500,000	6,632,659	87,397	\$25,930	1.301%
\$250,000	6,345,801	374,255	\$15,901	5.569%

The FY 2025 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 (3,199 cases) lowers the threshold over \$5,000. 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 (16,805 cases) drives the threshold down over \$14,000, and removing all cases with charges above \$500,000 (87,397 cases) drives the threshold down almost \$25,000.

Furthermore, these high charge 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:¹⁸

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	4,719	0.0650%	530
2022	5,482	0.0803%	594
2023	6,533	0.0971%	600

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

¹⁸ See WPA Report at p. 8.

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separate outlier mechanism should apply to these cases that more closely hews outlier payments to marginal costs.

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.

3. Using the Most Recent Data to Calculate the Threshold

We also note that with each IPPS rulemaking for more than a decade (with the exception of FY 2022 and FY 2024), 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 table below derived from WPA Report at p. 5 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	\$ (521)	-1.93%
2021	\$ 30,006	\$ 29,064	\$ (942)	-3.31%
2022	\$ 30,967	\$ 30,988	\$ 21	0.07%
2023	\$ 43,214	\$ 38,859	\$ (4,355)	-11.21%
2024	\$ 40,732	\$ 42,750	\$ 2,018	4.95%
2025	\$ 49,237			

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.

With regard to the current rule making WPA was able to replicate the threshold within \$103. Thus, we have high confidence that WPA understands CMS' methodology and has accurately modeled that methodology.

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4. New Outlier Reconciliation Criteria Established by Sub-Regulatory Guidance

The FAH is concerned that CMS has added new criteria for determining which hospitals shall have their outlier payments reconciled in CR 13566, published on April 26, 2024. The new criteria are on top of the original reconciliation criteria, with the exception that reconciliation is mandatory for the first cost report for all new hospitals. CMS has not explained the grounds for the new criteria or its retention of the old criteria, and the new criteria were adopted without notice and comment rulemaking. The new reconciliation criteria constitute a substantive change to CMS' payment policy that cannot be adopted without notice and comment rulemaking.¹⁹ Therefore, the FAH urges CMS to withdraw the transmittal.

5. FY 2025 Outlier: Conclusion

The FAH is not proposing a threshold for FY 2025. While we have confidence in the work of WPA, its work is dependent on a large number of 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 after affirmatively addressing the impact of data that skews the threshold, including the anomalous CCR data in the development of a CCR adjustment factor, and that is not reflective of reasonable expectations for FY 2025.

AREA WAGE INDEX

III.B Proposed Changes to Labor Market Area Delineations

Background

CMS adjusts a portion of IPPS payments for area differences in the cost of hospital labor—the wage index. Section 1886(d)(3)(E) of the Act requires an annual update to the wage index based on a survey of wages and wage-related costs (fringe benefits) of short-term, acute care hospitals, which the agency collects on Medicare cost reports. All changes made to the wage index annually are required to be budget neutral.

Hospitals are assigned to labor market areas and the wage index reflects the weighted (by hours) average hourly wage reported on Medicare cost reports. CMS uses Office of Management and Budget (OMB) Core-Based Statistical Area (CBSA) delineations as labor

¹⁹ See *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019); HHS Office of the General Counsel, Advisory Opinion 20-05 on Implementing Allina (Dec. 3, 2020), available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101111604-mh-advisory-opinion-20-05-on-implementing-allina_12.03.2020_signed.pdf.

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market areas. CMS is currently using OMB delineations from 2015 (based on the 2010 census) updated by OMB Bulletin numbers 13-01, 15-01, 17-01, 18-04 and 20-01.

On July 21, 2023, OMB released Bulletin No. 23-01. Bulletin No. 23-01 reflects changes to CBSA delineations based on the 2020 Standards for Delineating Core Based (86 FR 37770 through 37778) and the application of those standards to Census Bureau population and journey-to-work data (e.g., the 2020 Decennial Census, American Community Survey, and Census Population Estimates Program data). CMS is proposing to use these revised delineations to calculate the IPPS wage index beginning in FY 2025.

CMS is generally following policy for the revised CBSA delineations that it has followed in the past. **The Federation generally supports CMS following the same practices that it has in the past except as noted below.**

Summary of Proposals

1. Urban Counties Becoming Rural. When an urban hospital becomes rural, its DSH payments are affected due to the inequities in the statutory DSH payment formulas that undermine rural hospitals. Existing regulations will result in a phase-down of any reductions in DSH payments to a hospital in this situation over three years where payment is based on 2/3 of the urban DSH adjustment and 1/3 of the rural adjustment in the first year; 1/3 of the urban DSH adjustment and 2/3 of the rural adjustment in the second year and 100 percent of the rural DSH adjustment in the third year.
2. Rural Counties Becoming Urban. Any Critical Access Hospitals (CAHs) in rural counties that are becoming urban will lose their CAH status unless they apply for an urban to rural reclassification. Existing regulations provide for a two-year period for CAHs to apply for an urban to rural reclassification in order to maintain CAH status

Other special hospital designations (such as Sole Community Hospital (SCH) and Medicare Dependent Hospital (MDH)) that require rural status may also end if the hospitals do not apply for an urban to rural reclassification. CMS advises these hospitals to apply for urban to rural reclassification before October 1, 2024 to avoid a termination of their special status (that is, unlike CAHs, these hospitals are not provided with a two year window to regain rural status before their special hospital designation is terminated).

The FAH agrees with CMS' proposal to provide CAHs with two years to apply for urban to rural reclassification to maintain CAH status and urges CMS to adopt the same policy for MDHs and SCHs.

3. Transitioning Wage Index Impacts. In the past, CMS adopted changes to the wage index based on revised CBSA delineations over a two-year period by determining the 50 percent of the wage index based on the current delineations and 50 percent of the wage index based on the revised delineations. (85 FR 32706). However, CMS does not believe a similar transition is needed for changes to the wage index being proposed for FY 2025 because of a policy CMS previously adopted to apply a 5 percent annual limit

on reductions in a hospital's wage index.

The FAH supports the 5 percent cap on reductions to a hospital's wage index from the prior year and obviates the need to transition the new CBSA delineations over two years.

B. III.G.1 Proposed Application of the Rural Floor

In order to provide greater transparency and permit a more meaningful evaluation of CMS' policy with respect to implementation of the rural floor, the FAH requests that CMS provide an impact table with the FY 2025 final rule and with subsequent rulemakings showing the number of hospitals and total payments impacted by the policy, with results aggregated at the state level. In the FY 2024 Proposed Rule, CMS acknowledged the "significant financial consequences" that may result from the proposed policy, 88 Fed. Reg. at 26,974, and the FAH believes it is appropriate to carefully monitor these impacts, which can be done most effectively with state-level data.

C. III.G.4 and Addendum II.A.4.f. Proposed Continuation of the Low Wage Index Hospital Policy and Budget Neutrality Adjustment

The FAH supports CMS' proposal to continue its low wage index hospital policy but urges CMS to eliminate the associated, unlawful budget neutrality adjustment. 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 2021) where wages are paid and the federal fiscal year (FY 2024) that is used to determine the wage index and to revisit the duration of the policy as CMS gains experience under the policy.²⁰ In the FY 2025 IPPS Proposed Rule, CMS noted that the single year of relevant data currently available (from FY 2020) was not sufficient for a proper evaluation of the low wage index hospital policy. Therefore, CMS continued the low wage index hospital policy and associated budget neutrality adjustment for FY 2024.

In the FY 2025 IPPS proposed rule, CMS indicates that the COVID-19 PHE complicates its ability to evaluate the low wage policy and its ability to determine whether low wage hospitals have been provided a sufficient opportunity to increase employee compensation as hospitals received significant financial assistance due to the COVID-19 PHE. CMS analyzed the distribution of the changes in the average hourly wages of the low wage index hospitals and non-low wage index hospitals and found a similar distribution of the changes in the average hourly wages. To the extent that wage index disparities for a subset of low wage index hospitals has diminished, it is unclear to what extent that is attributable to the low wage index hospital policy given the effects of the COVID-19 PHE and additional funding provided to hospitals.

²⁰ 87 Fed. Reg. at 28,369.

The COVID-19 PHE ended in May of 2023 (during FY 2023) and CMS has already extended the policy by 1 year through FY 2024. For this reason, CMS is proposing to extend the policy for 3 more years through FY 2027. This proposal will allow for a 4-year lag period between the end of the COVID-19 PHE and the time wage data will first become available for use under the FY 2028 IPPS reflective of the effect of the low wage index policy on hospital average hourly wages.

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.

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 61 million Americans that live in rural areas across the United States.²¹ 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.²² Because Medicare beneficiaries disproportionately rely on rural providers to access care, Medicare payments tend 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,”²³ a problem which has only been exacerbated as rural hospitals continue to face workforce shortages and facility closures due to the impact of COVID-19.²⁴

The FAH appreciates CMS’ much needed efforts to continue addressing the acute problems that rural hospitals face. CMS policy must ultimately ensure that Medicare payment formulas do not operate to magnify the stress on the rural health delivery system and contribute

²¹ CMS Framework for Advancing Health Care in Rural, Tribal, and Geographically Isolated Communities (Nov. 2022). <https://www.cms.gov/files/document/cms-geographic-framework.pdf>.

²² CMS, Improving Health in Rural Communities: FY 2021 Year in Review, 1 (Nov. 2021).

²³ CMS, Rural Health Strategy, 2 (May 8, 2018); *see* CMS, Improving Health in Rural Communities: FY 2021 Year in Review, 1 (Nov. 2021).

²⁴ CMS Framework for Advancing Health Care in Rural, Tribal, and Geographically Isolated Communities (Nov. 2022). <https://www.cms.gov/files/document/cms-geographic-framework.pdf>.

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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 2025 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.

In the FY 2020 IPPS Final Rule, CMS invoked 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.²⁵ CMS made this policy budget neutral for FY 2020 through 2024 and proposes to continue budget neutral implementation in FY 2025 through a 0.25 percent budget neutrality adjustment. The FAH continues to urge CMS to provide the much-needed rural relief under the low wage index hospital policy in a non-budget neutral manner.

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."²⁶ 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.²⁷

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.

²⁵ 84 Fed. Reg. 42,044, 42,329 (Aug. 16, 2019).

²⁶ See *Bridgeport Hospital, et. al. v. Becerra*, No. 1:20-cv-01574, at *9 (D.D.C. Mar. 2, 2022).

²⁷ 84 Fed. Reg. 19,158, 19,396 (May 3, 2019).

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 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,²⁸ 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 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 2023, 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.

DISPROPORTIONATE SHARE HOSPITAL PAYMENTS

IV.E.2 Calculation of Proposed Factor 2 for FY 2025

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 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 2025, OACT estimates the uninsured rate as 8.7 percent. The 2013 uninsured rate is calculated at 14 percent. Based on this difference, OACT estimates that Factor 2 is equal to 0.6214. When multiplied by Factor 1 (\$10.457 billion), proposed Factor 2 produces a UC-DSH pool of only \$6.498 billion.

The FAH is concerned that the proposed calculation of Factor 2 uses NHEA projections that understate the impact of the maintenance of eligibility requirements on Medicaid enrollment and the expected continued decline in coverage in FY 2025 following the end of the COVID-19 PHE. In describing the assumptions underlying the proposed calculation of Factor 1, CMS states that, “[b]ased on the most recent available data, Medicaid enrollment is estimated to be . . . –13.9 percent in FY 2024, and –4.3 percent in FY 2025.” 89 Fed. Reg. at 36,192. These assumptions, however, are not accounted for in the calculation of proposed Factor 2. In fact, the NHEA projections estimate a change in Medicaid enrollment of only –6.9 percent for FY 2024 and –

²⁸ 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.”).

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2.75 percent for FY 2025.²⁹ This disparity is particularly significant in light of data showing that more than 40 percent of adults who lose their Medicaid coverage (beyond a temporary loss) due to Medicaid unwinding are uninsured and do not secure other coverage.³⁰ The FAH urges CMS to closely examine data and projections so as to ensure that UC-DSH payments appropriately account for significant changes that are and will continue to increase the uninsured burden in FY 2025. The FAH strongly urges CMS and the OACT to broaden their data sources to more fully reflect current estimates of the uninsured rate in FY 2025 in light of the profound impact of the unwinding of the PHE. 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 0.5 percentage point of growth in the uninsured rate in FY 2025 (9.2 percent uninsured, reflecting a projection of approximately 1.4 million additional uninsured individuals), would increase the proposed UC-DSH pool by approximately \$373 million above CMS' proposal.

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

The FAH is concerned that the per-discharge amount of interim UC-DSH payments continues to be understated due to the impact of older data that overestimates discharges in the coming fiscal year. The FAH believes it is inconsistent to project falling discharges for purposes of the Factor 1 calculation (thereby reducing the UC-DSH pool) but not similarly assume falling discharges for purposes of projecting the discharges used to calculate the per-discharge amount (thereby reducing interim UC-DSH payments). The overestimation of discharges depresses interim UC-DSH payments, producing cash flow issues for hospitals, and inadequate interim payments compromise the UC-DSH program's effectiveness in supporting hospital care for uninsured and underinsured patients. Therefore, the FAH urges CMS to modify its methodology to use a discharge estimate that better reflects the anticipated volume of discharges in FY 2025, which would in turn improve the effectiveness of the UC-DSH program and reduce overreliance on the reconciliation process for UC-DSH payments.

Instead of using a three-year average to estimate FY 2025 discharges, the FAH urges CMS to consider using the average of the two most recent years of data (FY 2022 and FY 2023) or applying a national adjustment factor to normalize the data based on projected discharge trends. Although a three-year average may be used to mitigate the impact of year-to-year variations that are not the part of a larger trend, the mixing of older and newer data risks erasing trends that must be addressed in any plausible and verifiable projection of FY 2025 estimates. In the case of discharge volumes, there may be year-to-year variations, but the FAH believes that there are also larger trends that reflect changing treatment patterns,

²⁹ NHE Projections, Table 17, Health Insurance Enrollment and Enrollment Growth Rates, *available at* <https://www.cms.gov/files/zip/nhe-projections-tables.zip> <https://www.cms.gov/files/document/nhe-projections-forecast-summary.pdf>. These numbers are the product of NHEA's calendar year projections (-0.9% for 2023, -8.9 for 2024, and -0.7 for 2025), and a weighting based on the portion of the calendar year that falls within a fiscal year.

³⁰ A survey conducted in the first quarter of 2024 of individuals who were disenrolled in the unwinding found that 47 percent reenroll in Medicaid, 28 percent obtained commercial or other coverage, and 23 percent were uninsured. Lunna Lopes, et al., *KFF Survey of Medicaid Unwinding* (Apr. 12, 2024), *available at* <https://www.kff.org/medicaid/poll-finding/kff-survey-of-medicaid-unwinding/>. Looking only to the 53 percent that remain without Medicaid coverage, approximately 43 percent were uninsured.

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technology, Medicare Advantage penetration, and other factors. Therefore, the FAH supports a methodology that incorporates more than one year of data to appropriately temper volatility in year-to-year changes in discharges, but also appropriately weight more current data. Such a methodology might use a two-year average of discharges or might incorporate a national adjustment factor so that the three-year average of discharges can be trended forward. But, the FAH opposes the proposed use of the three-year average discharge volume to calculate interim UC-DSH payments and the proposed incorporation of the three-year average methodology into CMS' interim UC-DSH regulation at 42 C.F.R. § 412.106(i)(1).

V.D Low Volume Hospitals (LVH)

Section 1886(d)(12) of the Act provides a payment in addition to a hospital's IPPS payment for each qualifying LVH beginning in FY 2005. To qualify as an LVH, 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. Through December 31, 2024, the hospital must be more than 15 miles from another IPPS hospital and have less than 3,800 total discharges to qualify for LVH status. Beginning January 1, 2025, the hospital must be more than 25 miles from another IPPS hospital and have fewer than 200 total discharges to qualify for LVH status.

Like MDH status, the expanded LVH criteria have been set to expire but extended by Congress. 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 2024, serve as critical lifelines to many rural hospitals that have been maintaining vital hospital services in their communities during the COVID-19 PHE but are seeing shrinking or negative margins and record inflation. CMS estimates that an average of 600 hospitals qualified for the LVH adjustment for FYs 2019 through 2024. Under the criteria that were in place between FYs 2005 and 2010 that will be applicable January 1, 2025 absent a change in law, CMS indicates that fewer than 10 hospital qualified for the LVH adjustment. The FAH supports Congressional action to extend these programs and provide other relief to these critical community hospitals.

CMS has established provisions for both the expiration of the expanded LVH program and its extension beyond December 31, 2024. CMS is proposing to continue the past process for hospitals to apply for LVH status. Hospitals must submit a written request for LVH status to its MAC by September 1, 2024 that includes sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria. Hospitals must use the latest submitted Medicare cost report for discharge information. Use of a web-based mapping tool may be used to demonstrate that the mileage criterion has been met. If a hospital's written request for LVH status for FY 2025 is received after September 1, 2024, CMS proposes that any approval will be effective prospectively within 30 days of the date of the MAC's determination.

As the criteria for receiving the LVH adjustment will change effective January 1, 2025, CMS is proposing a parallel process for a hospital to be eligible for the adjustment for the remainder of FY 2025 after December 31, 2024. That is, hospitals must submit a written request for LVH status to its MAC by December 1, 2024 that includes sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria effective January 1, 2025 to be eligible for the LVH adjustment on or after that date.

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Alternatively, CMS is providing the option for hospitals to submit a single request for an LVH adjustment for both the portion of FY 2025 beginning on October 1, 2024 and ending December 31, 2024 and the portion of FY 2025 beginning on January 1, 2025 through September 30, 2024 by the September 1, 2024 deadline. This option would allow the hospital to continue receiving the LVH adjustment after December 31, 2024 provided it continues to qualify for it based on the revised criteria.

While the FAH appreciates the provisions CMS has built into its regulations to allow the very few LVHs that will continue to be eligible for the program to transition seamlessly, we believe it is critical for Congress to timely extend the expanded program to avoid interruptions in LVH payments. We ask CMS to clarify in the rule that LVH payments will continue to be made uninterrupted if Congress were to extend the expanded program before its statutory expiration date.

V.E. Medicare Dependent Hospitals (MDH)

Section 1886(d)(5)(G) of the Act provides special payments under the IPPS to an MDH through December 31, 2024. Beginning with discharges occurring on or after January 1, 2025, all hospitals that previously qualified for MDH status will no longer be eligible for this special payment methodology. There are currently 173 MDHs, of which CMS estimates 114 have been paid under the blended payment of the Federal rate and hospital-specific rate while the remaining 59 would have been paid based on the IPPS Federal rate. With the expiration of the MDH program, all these providers will be paid based on the IPPS Federal rate beginning with discharges occurring on or after January 1, 2025.

While the MDH program was set to expire many times previously, it has always been extended by Congress. Nevertheless, at this time, CMS is advising hospitals of the MDH program expiration and the potential to ameliorate the associated reduction in payment through becoming an SCH.

When the MDH program was set to expire at the end of FY 2012, CMS revised the SCH regulations to allow MDHs to apply for SCH status in advance of the expiration of the MDH program. These regulations allow SCH status to begin the day following the MDH program's expiration. In order for an MDH to receive SCH status effective January 1, 2025, the MDH must apply for SCH status at least 30 days before the expiration of the MDH program, or by December 2, 2024. The MDH also must request that, if approved, the SCH status be effective with the expiration of the MDH program. If the MDH does not apply by the December 2, 2023 deadline, the hospital would instead be subject to the usual effective date for SCH classification, which is the date the MAC receives the complete application.

The FAH urges CMS to retroactively reinstate the MDH status of hospitals that participated in the MDH program through the first quarter of FY 2025 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 MDH status to qualifying hospitals without the need for the hospital to apply for MDH classification. However,

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this 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 December 31, 2024 including hospitals that became SCHs and hospitals that cancelled rural status.

V.I End State Renal Disease (ESRD) Add-On

Under current regulations, Medicare will provide an add-on payment to hospitals where they provide kidney dialysis to more than 10 percent of their patients where the patient is not receiving a kidney transplant or has a principal diagnosis of renal failure. The add-on equals the product of the average length of stay of ESRD beneficiaries in the hospital, expressed as a ratio to 1 week, the estimated per treatment cost of dialysis times three (as maintenance dialysis is typically furnished three times per week) and the number of patients where the add-on is applicable. The add-on payment is intended to reflect the additional costs hospitals have of providing kidney dialysis to these patients and is based on the payment rate made to ESRD facilities for maintenance kidney dialysis.

The average direct cost of dialysis was determined from data used to establish the ESRD dialysis composite rate paid to ESRD facilities that provide outpatient maintenance dialysis. This rate has not been updated since 2013 when payment to dialysis facilities reflected a blend of the ESRD PPS payment system and the composite rate. CMS is proposing to change the methodology used to calculate the ESRD add-on payment under current regulations to the ESRD PPS base rate used under the ESRD PPS beginning October 1, 2024 for FY 2025. For subsequent years, CMS will use the updated ESRD PPS base rate for the ESRD add-on payment.

The Federation supports CMS' proposed update to the ESRD add-on. We commend CMS for updating the ESRD add-on that has not been updated for more than 11 years and for ensuring that it will reflect annual updates to the ESRD base rate.

V.J Separate IPPS Payment for Establishing and Maintaining Access to Essential Medicines

CMS proposes to make separate payments to smaller, independent hospitals under the IPPS for establishing and maintaining access to a six-month buffer stock of one or more essential medicines to foster a more reliable, resilient supply. CMS is not proposing to make this payment adjustment budget-neutral under the IPPS. CMS is also utilizing the HHS Office of the Assistant Secretary for Preparedness and Response's (ASPR) Advanced Regenerative Manufacturing Institute's List (ARMI List) to prioritize 86 essential medicines, as either critical for minimum

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patient care in acute settings or important for acute care or acute care of respiratory illnesses/conditions.

The FAH appreciates CMS' and the Administration's efforts to address drug shortages. However, we remain concerned that the proposal incentivizing independent hospitals, specifically hospitals with 100 beds or less, to maintain a buffer inventory standard of up to a six-month supply of generic drugs may lead to less-than-optimal results. We are particularly concerned by the proposal that a hospital that has established and was maintaining a buffer stock of a medicine prior to a shortage would continue to be eligible for separate buffer stock payment for that medicine for the duration of the shortage. This policy would inappropriately incentivize hospitals to continue replenishing their buffer stocks during an active shortage, creating additional pressure on the already precarious supply of the drug.

In addition, while we understand the intent to ensure an adequate supply of one or more of the medications on the ARMI List, the creation of a large buffer inventory could result in significant disadvantages for providers, potentially diverting resources from other critical areas of patient care. If CMS moves forward with this proposal, we urge CMS to allow an adjustment of all essential drugs and not try to apportion the drugs solely to Medicare's portion or the Medicare inpatient portion of the costs.

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

Finally, the FAH is concerned that the proposed policy does nothing to address the leading causes of drug shortages. We believe that incentivizing hospitals to stockpile drugs beyond patient needs may lead to inequitable distribution of drugs across the health system. To achieve the Administration's goal of addressing drug shortages, the FAH recommends that HHS focus its efforts on the supply by aligning upstream incentives for manufacturers and wholesalers to encourage them to maintain adequate drug inventories and enhance their quality. We also urge the Administration to implement measures to ensure a stable supply of API and drugs.

NEW MEDICAL RESIDENCY TRAINING PROGRAMS

Background:

When the Balanced Budget Act (BBA) of 1997 capped the number of residents a hospital may count for DGME and IME, it also provided authority for CMS to establish rules that allowed the caps to be adjusted for hospitals that had not previously trained residents and established "new medical residency training programs." In order to address a concern that hospitals could move an existing program to a new teaching hospital in order to train more

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residents at its own hospital inconsistent with the BBA1997, CMS defined the term “new medical residency training program.”

The three primary criteria are that: 1) the residents are new, 2) the program director is new and 3) the teaching staff are new. Over the years, CMS has received questions as to whether a program may still be considered new if the three criteria were partially but not fully met. CMS has responded that a residency program’s newness would not be compromised as long as the “overwhelming majority” of the residents or staff are not coming from previously existing programs in that same specialty.

Rulemaking Issues:

CMS is using the FY 2025 IPPS proposed rule to further develop policy on the meaning of “new medical residency training program.” However, it is unclear whether CMS intends to propose new policy effective October 1, 2024—at least with respect to policy on establishing a percentage threshold for “overwhelming majority” of residents—or merely engaging in a request for information (RFI) on these issues in preparation for proposing future policy.

The proposed rule indicates “we discuss the items we are proposing and the items on which we are soliciting public input through a Request for Information (RFI).” The item on “Faculty and Program Director” is clearly labeled as an RFI so the FAH’s understanding is that these items are for discussion and comment only. CMS is not establishing any new policy and may use the input it receives to make a future proposal.

However, the item on “Newness of Residents” does not indicate that it is an RFI in the heading and uses the language “we are proposing” with respect to establishing a threshold of 90 percent of the residents must be new (without any prior training) for the residency program to be considered new. But CMS does not propose any changes to the CFR making it unclear whether this is a policy change or a discussion item as well.

If this item is intended to be a proposed change in policy, its application is not specified. One possibility is that it would establish a percentage threshold for “overwhelming majority” of residents for a program to be considered new effective October 1, 2024, e.g., be given prospective effect. Alternatively, CMS could be applying a retroactive change to its definition of “overwhelming majority” of residents that affects Medicare payments effective October 1, 2024. If CMS intends the latter, CMS would be changing a substantive regulatory standard for its definition of a “new medical residency program”. As the 90 percent threshold would be a substantive change in policy, CMS could not construe it as a “clarification” that is effective retroactively. Section 1871(e)(1)(A) specifically prohibits application of substantive changes “retroactively to items and services furnished before the effective date of the change” unless it is to be in compliance with statute or failure to apply such change retroactively would be against public interest. Neither of those exceptions would apply in this circumstance.

The FAH urges CMS to clarify whether the policy being proposed with respect to a numerical standard of 90 percent constituting an “overwhelming majority” of residents is intended to be a regulatory change in policy (and, if so, how and when that change is

intended to be applied) or a discussion item where CMS plans to propose future changes to regulation.

Proposals:

Residents: CMS is proposing to further define “overwhelming majority” as meaning at least 90 percent of the individual resident trainees (not FTEs) must not have previous training in the same specialty as the new program. If more than 10 percent of the trainees (not FTEs) transferred from another program at a different hospital/sponsor in the same specialty, even during their first year of training, CMS proposes that this would render the program as a whole (but not the entire hospital or its other new programs, if applicable) ineligible for new cap slots.

The implication of CMS’ proposal is that a resident could not be considered a “new” resident if the resident was training beyond program year (PGY)-1. This proposal would mean that no resident training in a subspecialty or in an advance categorical program could be considered a new resident because all subspecialty fellowship programs require previous training. For example, a cardiovascular disease fellowship requires three years of successful training in an internal medicine residency program as a prerequisite for enrollment. Subspecialty fellowship programs obviously cannot meet a rule requiring enrollment of physicians with no prior training. One hundred percent of subspecialty fellows will have prior training.

Similarly, advanced categorical programs such as anesthesiology, child neurology, dermatology, interventional radiology, nuclear medicine, and radiation oncology enroll residents at the PGY-2 level, and require successful completion of a broad-based clinical year prior to appoint in the program. The Accreditation Council on Graduate Medical Education (ACGME) defines a broad-based clinical year as emergency medicine, family medicine, general surgery, internal medicine, obstetrics and gynecology, pediatrics, or transitional year programs accredited by the ACGME. Similar to subspecialty fellowships, residents enrolling in advanced categorical programs must have prior training.

The FAH urges CMS to clarify in the final rule that its policy is intended to allow a residency program to be considered new as long as 90 percent or more of the residents entering the program are in their first year of training in that specialty or subspecialty—not necessarily as a PGY-1. With this clarification, residents with prior training towards an initial specialty board certification as a prerequisite subspecialty training or a transitional year program accredited by the ACGME as a prerequisite for training in an advanced categorical program would not disqualify a program from being considered new.

The proposed rule indicates that the 90 percent criterion may be more difficult for small or rural-based programs to meet. For this reason, CMS requests comments on whether to define a “small residency program” as one that is accredited for fewer than 16 positions. The ACGME accredits programs with class size ranging from 1 resident or fellow, to more than 100 residents per class. The proposed definition of a small class size program of up to 16 residents or fellows is reasonable. However, the FAH believes CMS should adopt a more flexible threshold than 90 percent for small programs.

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In the proposed rule, CMS provides an illustrative example of how its policy would work with residency programs of 48 and 45 residents respectively. With the 48-resident program, 90 percent equals 43.2 rounded down to 43 allowing up to 5 residents with prior training in that specialty before the program is disqualified from being considered new. With the 45-resident program, 90 percent equals 40.5 rounded up to 41 allowing up to 4 residents with prior training in that specialty before the program is disqualified from being considered new.

If a hospital had a 14-resident program, 90 percent would be 12.6 residents which would be rounded up to 13 residents following CMS' example allowing just one resident with prior training before the program would be disqualified from being considered new. This example suggests that small programs should have more flexibility than the 90 percent proposed criterion. Small class size programs should be permitted to enroll up to 50 percent of their class with physicians who have had prior training. Rural programs will almost always be within the definition of small class size programs. Given the national interest in developing the physician workforce in rural communities, and the difficulty programs experience in recruitment of candidates, there should be no restrictions on enrollment of any number of physicians who have prior training.

Program Director and Faculty: CMS recognizes that a new medical residency program may want to recruit a director and faculty with prior experience so believes that a criterion of less than 90 percent should be applicable. However, CMS believes that there should be at least some threshold percentage to avoid recruiting only experienced staff from an existing residency program that could threaten the existing program's viability. CMS is not proposing a specific threshold but suggests that up to 50 percent of the faculty in a new program may come from an existing program in the same specialty but each of those staff members should come from a different previously existing program.

CMS has also been asked whether it would make a difference if a faculty member had previous teaching experience, but a certain amount of time has passed since they taught in a program in the same specialty (for example, because they accepted a non-teaching job in a different hospital, or the program where they previously taught has ceased to operate). The proposed rule indicates that in determining whether the presence of a faculty member might jeopardize the newness of a new residency program, it may make sense to consider whether a certain amount of time has passed since that faculty member last taught in another program in the same specialty. CMS is soliciting comments on whether 10 years, or some other amount of time, would be an appropriate period during which a faculty member should not have had experience teaching in a program in the same specialty in order to be considered "new."

Similarly, CMS understands that a new teaching hospital may also want to recruit an experienced program director. The proposed rule solicits comments on whether it would make sense to define a similar period of time (for example, 10 years or 5 years) during which an individual must not have been employed as the program director in a program in the same specialty in order to be considered a "new" program director.

As a threshold matter, **the FAH does not believe CMS should have any requirement that would preclude a program from being considered new merely because it hired more**

than 50 percent of its faculty and a program director with prior experience in these roles.

It should be sufficient that 90 percent or more of the residents are new to that specialty or subspecialty program for a residency or fellowship program to be considered “new.” The experience of the faculty and the residency program director should not be part of whether the program is considered a new medical residency training program.

Experienced faculty are foundational to the development and success of graduate medical education programs. Physicians who do not have experience teaching, conducting research and scholarly activity, evaluating performance of trainees, and serving as professional role models should make up a very small percentage of the total faculty for a given program. Ideally, all faculty will be experienced, highly qualified educators. Program Directors, Associate Program Directors, and Core Faculty are all expected to have significant experience as medical educators in order to meet the ACGME requirements for accreditation. The quality of a graduate medical education program reflects the experience and skill of the faculty who provide instruction, supervision, and guidance to their residents and fellows.

A requirement that fifty percent of faculty of new programs have no experience as medical educators would be severely detrimental to the quality of medical education at all new teaching programs. There should be no restriction on appointments of up to 100 percent of faculty with prior teaching experience, skill, and formal medical education training. It would be reasonable to set a criteria that not more than a threshold percentage of the faculty may come from a single program but it is unreasonable to expect 50 percent or more of the faculty to have no prior teaching experience. Similarly, there is only one residency program director. It is critical to the quality of a new program for that program director to be allowed to have prior experience in that role. CMS’ policy should not prohibit a residency program director from having prior experience in that role in order to be considered new.

VI. Capital DSH Payments

In the FY 2024 IPPS/LTCH final rule, CMS indicated that it would consider addressing the expansion of capital DSH to rural hospitals, and the FAH respectfully encourages CMS to take action on this issue. As CMS has observed, rural communities have higher poverty and age-adjusted mortality rates, are home to a higher proportion of older residents and persons living with a disability, and experience disparities in health outcomes compared to urban areas and national averages.³¹ In order to better support Medicare beneficiaries living in rural communities and to improve health equity, the FAH favors systematic action to protect rural hospitals.

As CMS has acknowledged, 42 U.S.C. § 1395ww(g) affords the Secretary “broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs.” 88 Fed. Reg. at 27,058 (CITE). In particular, CMS has the authority to adjust capital payments in a non-budget neutral manner to take into account variations in the relative costs of capital and construction for different types of facilities or areas, adjust capital payments to reflect hospital occupancy rates, and to make appropriate exceptions. 42 U.S.C. §

³¹ CMS Framework for Advancing Health Care in Rural, Tribal, and Geographically Isolated Communities (Nov. 2022), at <https://www.cms.gov/files/document/cms-geographicframework.pdf>.

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1395ww(g)(1)(B)(ii) – (iv). Using this broad grant of authority, CMS can extend capital DSH to rural hospitals that would otherwise be eligible under 42 C.F.R. § 412.320 but for their rural status, and CMS should do so as part of its concerted efforts to bolster the rural health care safety net.

The financial pressures facing rural hospitals have been well documented and extend to capital costs. Rural capital margins are deeply negative, contributing to the precarious situations of rural hospitals. Based on the cost report information in the March 31, 2023, HCRIS database, capital margins are deeply negative among rural hospitals (negative 33 percent), while capital margins among urban hospitals (negative 16 percent) are slightly more favorable than the national average (negative 17 percent). Moreover, occupancy rates in rural hospitals have been and continue to be lower than in urban hospitals. According to MedPAC, in 2019, “IPPS hospitals in rural non-micropolitan counties had a . . . low occupancy rate (34 percent), while those in micropolitan areas had a slightly higher occupancy rate (47 percent). In contrast, IPPS hospitals in metropolitan areas had an occupancy rate of 68 percent.”³² Faced with these financial pressures, nearly 150 rural hospitals have closed since 2010, and when rural hospitals close, the median distance to the most common health care services increases by 20 miles. The FAH believes that these disparities in occupancy rates alone (and the real financial pressure they create for rural hospitals) support an expansion of capital DSH under CMS’ broad authority under 42 U.S.C. § 1395ww(g).

The FAH appreciates CMS’ much needed efforts to continue addressing the acute problems faced by Medicare’s rural hospitals through the low wage index hospital policy and otherwise, but more is needed, including action to address inadequate capital payments to rural hospitals. The FAH estimates that extending capital DSH eligibility to rural hospitals would result in only approximately \$30 million in increased capital DSH payments, and these capital DSH payments would appropriately support Medicare beneficiary access in rural communities by reducing rural hospitals’ disproportionate capital pressures and mitigating the impact of low occupancy rates on capital payments to rural hospitals.

LONG TERM CARE HOSPITAL (LTCH) POLICIES

VIII. LTCH Market Basket Update

CMS is proposing an annual update to the LTCH PPS standard federal payment rate of 2.8 percent that is equal to the LTCH market basket of 3.2 percent less 0.4 percentage points for total factor productivity. For LTCHs failing to submit data to the LTCH Quality Reporting Program (QRP), the annual update would be further reduced by 2.0 percentage points. All of the same issues stated above for IPPS hospitals would also apply to the LTCH market basket. Below is a table that compares the LTCH update to the LTCH market basket based on later data since FY 2021:

³² Medicare Payment Advisory Commission, “Hospital Inpatient and Outpatient Services”, p. 62 (March 2021), available at https://www.medpac.gov/wpcontent/uploads/2021/10/mar21_medpac_report_ch3_sec.pdf.

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LTCH Market Basket	FY 2021	FY 2022	FY 2023	FY 2024
Forecast Used in the Update	2.3	2.6	4.1	3.5
Actual Based on Later Utilization	3.0	5.7	4.8	3.7
Difference	-0.6	-3.0	-0.7	-0.2

Like the IPPS market basket, these data show that CMS has understated the LTCH market basket by a combined 4.3 percentage points for FY 2021 – FY 2023. Preliminary data suggest that FY 2024 will be 4th straight year that CMS will have understated the LTCH market basket update based on a projection compared to the actual increase.

As we requested for the FY 2025 IPPS operating update, **the FAH requests that CMS also provide for a forecast error adjustment for the combined understatement of the FY 2021 through FY 2023 LTCH market baskets when updating the FY 2025 LTCH rates. Adopting our suggestion would make the market basket equal to 2.8 percent plus 4.3 percentage points for forecast error less 0.4 percentage points for total factor productivity or 6.7 percent.**

The FAH further notes that CMS is proposing an extraordinary increase to the LTCH outlier threshold from \$59,873 in FY 2024 to \$90,921 in FY 2025, an increase of nearly 52 percent. The FY 2023 high cost outlier threshold was \$38,518. CMS’ proposed outlier threshold for FY 2025 is 136 percent of the FY 2023 threshold.

In the proposed rule, CMS seeks “comments on both our proposed methodology for determining the FY 2025 fixed-loss amount and the alternative approach.”³³ Under the alternative approach, CMS would average the FY 2024 and FY 2025 fixed loss amounts of \$90,921 and \$75,397 and the resulting outlier payments would exceed 7.975 percent of total LTCH payments. While the FAH supports this approach to calculating the fixed loss threshold, we also note a higher market basket update would contribute to lowering the final rule LTCH outlier threshold. Not only would an adjustment for forecast error make overall LTCH rates more accurate long-term, it would also improve the accuracy of the outlier threshold by making it lower consistent with CMS’ comment solicitation.

LTCH High-Cost Outlier Fixed-Loss Amount

Under the LTCH PPS, Medicare makes additional payments for HCO cases that have extraordinarily high costs relative to the costs of most discharges. CMS sets a threshold each year at the maximum loss that an LTCH can incur under the LTCH PPS for a case with unusually high costs before the LTCH will receive these additional payments. Since FY 2018, CMS has set the HCO fixed-loss amount so that HCO payments will equal 7.975% of total LTCH PPS payments, as required by section 15004 of the 21st Century Cures Act.

Based on the current fixed-loss amount of \$59,873, CMS estimates that outlier payments in FY 2024 will equal 9.3% of total LTCH PPS standard Federal rate payments. Therefore,

³³ 89 FR 36,592 (May 2, 2024).

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CMS is proposing to increase the HCO fixed-loss amount for FY 2025 standard Federal payment rate cases to \$90,921 to ensure that estimated HCO payments will be 7.975% of total LTCH PPS standard Federal rate payments in FY 2025. Estimated total HCO payments are projected to decrease by approximately 1.3% from FY 2024 to FY 2025 under this proposal.

CMS acknowledges that this proposed fixed-loss amount is a “substantial” increase and is “significantly higher” than the FY 2024 fixed-loss amount of \$59,873.³⁴ However, unlike the previous years, CMS did not propose any policy changes or temporary adjustments to its methodology for setting the HCO fixed-loss amount. CMS also did not provide any explanation for this “substantial” proposed increase to the fixed-loss amount. Last year, CMS attributed the drastic increase in the fixed-loss amount to the lag in the data used for ratesetting and the increases in LTCH charges over the past few years. There is typically a two-year lag between the ratesetting year and the claims data CMS uses for ratesetting. Indeed, CMS is using LTCH claims from the FY 2023 MedPAR file to set the HCO fixed-loss amount for FY 2025.

CMS estimates that the FY 2023 fixed-loss amount of \$38,518 resulted in HCO payments comprising about 11.6% of total LTCH PPS standard Federal rate payments, which exceeds the 7.975% target. CMS also estimates that FY 2024 HCO payments will equal about 9.3% of total LTCH PPS standard Federal rate payments using the current \$59,873 fixed-loss amount. Thus, CMS says that the current fixed-loss amount for FY 2024 should have been set at approximately \$72,275. CMS concludes that, for FY 2025, a “large increase to the fixed-loss amount would be warranted to ensure that estimated outlier payments in FY 2025 return to our statutorily required budget neutral target of 7.975 percent.”

Due to this large increase in the fixed-loss amount for FY 2025, CMS is soliciting comments on its proposed methodology, as well as an alternative approach for determining the fixed-loss amount. Under the alternative approach CMS is considering, CMS would average the FY 2024 fixed-loss amount and the proposed FY 2025 fixed-loss amount based on the 7.975% statutory target. This results in an alternative fixed-loss amount of \$75,397 (*i.e.*, $(\$59,873 + \$90,921) / 2$). CMS says this alternative would provide a 1-year transition to the full increase in the fixed-loss amount. HCO payments would equal 9.5% of estimated FY 2025 LTCH PPS standard Federal rate payments and would therefore increase aggregate LTCH PPS payments by \$39 million. However, CMS says that it would not apply a budget neutrality adjustment to offset the increased payments from this alternative approach because the LTCH PPS budget neutrality requirement only applies to the first year of the implementation of the LTCH PPS (*i.e.*, FY 2003).

The FAH is extremely concerned with the proposed HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases, as well as with the significant increase to the fixed-loss amount for site-neutral rate cases as described earlier. We are concerned that the data for LTCH PPS ratesetting process and HCOs continues to use data that have not been adjusted to remove the extended impact of the COVID-19 pandemic. LTCHs served a critical role during the pandemic by treating ventilator patients and providing additional capacity for COVID-19 patients, and therefore saw high utilization rates well into 2023. With the expiration of the

³⁴ *Id.*

public health emergency on May 11, 2023, LTCHs have seen COVID-19 hospitalization rates decrease, but health care costs (particularly labor costs) dramatically increased in recent years.

The reinstatement of the site-neutral payment rate on May 12, 2023, has only exacerbated the challenges LTCHs are facing. The proposed increase to the HCO fixed-loss amount for LTCH PPS standard federal rate cases, from \$59,873 in FY 2024 to \$90,921 in FY 2025, would significantly cut Medicare payments to LTCHs for patients with the greatest resource needs. Increasing the fixed-loss amount to \$90,921 in one year means that LTCHs will not be compensated by Medicare for an additional \$31,048 in the costs of caring for high-cost outlier patients who meet the narrow patient criteria to be paid at the standard Federal rate. The two-year increase to the fixed-loss amount would be a staggering \$52,403. These are truly the most severely ill, medically complex Medicare beneficiaries in need of hospital inpatient care. Such a drastic reduction in Medicare payments for these high cost patients will have significant negative repercussions, including reduced access to LTCH care, increased backups at IPPS hospital intensive care units (“ICUs”), fewer discharge options, and almost assuredly additional LTCH hospital closures—right when LTCHs as a sector are trying to regain their footing after the conclusion of the COVID-19 pandemic.

1. CMS’ FY 2025 Fixed-Loss Amount is Based on a Flawed Assumption Regarding COVID-19 Hospitalizations in LTCHs

In the Proposed Rule, CMS abandoned the modified ratesetting methodology it utilized in FY 2023 and FY 2024. For FY 2025, CMS proposed to use unmodified FY 2023 claims data and FY 2022 cost report data to set the fixed-loss amount for standard Federal payment rate discharges. **However, CMS is incorrectly using a pre-pandemic methodology with pandemic data and factors to calculate the HCO fixed-loss amount. This mismatch is causing the excessive increase in the proposed fixed-loss amount, from \$59,873 to \$90,921.** This proposal incorrectly assumes that COVID-19 cases in FY 2025 will be as high as FY 2023, when there were still large surges in COVID-19 cases. CMS’ apparent assumption that COVID-19 hospitalizations will not be different in FY 2025 compared to FY 2023 is inconsistent with other actions by HHS.

CMS Needs to Account for the Systemic Effects of the LTCH PPS Dual Payment Rate Structure on HCO Ratesetting

The implementation of the dual rate LTCH PPS has created systemic problems that have contributed to historically abnormal and harmful increases in the proposed fixed-loss amount for standard Federal payment rate cases, including this proposed increase to \$90,921. LTCH claims are a small dataset, only making up 0.5% of all post-acute care discharges.³⁵ The dual rate system that was created to add site neutral LTCH payments divides this already small dataset into two payment rates, with separate fixed-loss amounts tied to different target amounts. Specifically, 29% of LTCH admissions are subject to the lower site neutral payment rate.³⁶

³⁵ Wen Tian, *An All-Payer View of Hospital Discharge to Postacute Care, 2013*, AHRQ (May. 2016), <https://hcup-us.ahrq.gov/reports/statbriefs/sb205-Hospital-Discharge-Postacute-Care.jsp>.

³⁶ 89 Fed. Reg. at 36,593.

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From FY 2016 to FY 2022, standard Federal payment rate cases have fallen over 40%. There were 74,294 standard Federal payment rate cases in FY 2016, but only 42,132 in FY 2022.³⁷ At the same time, the growth of MA has also reduced the number of LTCH discharges. About 50% of Medicare beneficiaries are enrolled in a MA plan, but only around 30% of LTCH discharges are MA beneficiaries. The remaining LTCH cases are more acute than they were prior to the dual payment rate system. The outlier-adjusted case mix index for standard Federal payment rate cases has increased from 2.18 in FY 2016 to 2.69 in FY 2022, an increase of 23%.³⁸ The average length of stay of HCO cases has also increased over the same period, from 53.9 days in FY 2016 to 66.47 days in FY 2022.³⁹ This is an increase of 23%, and shows that LTCHs are treating more acute patients, while having to absorb greater losses due to the drastic increases to the fixed-loss amount.

The American Hospital Association (AHA) found that, on average, LTCH cases paid under the site-neutral payment system will only have 45% of the treatment costs covered.⁴⁰ Prior to the dual rate payment system, LTCH growth was artificially restricted through new LTCH facility and bed moratoriums.⁴¹ From 2016 to 2019, during the phase-in of the dual rate payment system, the number of LTCHs paid under the LTCH PPS fell by approximately 4.2% per year, and by 3.6% between 2019 and 2020.⁴² Between 2017 and 2021, 19% of all LTCH facilities were forced to close.⁴³ LTCH cases have dwindled to such a degree that MedPAC no longer provides payment update recommendations in its annual reports.⁴⁴ At the same time, the ICU Criterion and Ventilator Criterion exceptions to site neutral payment have strongly incentivized LTCHs to prioritize admitting patients who are likely to be discharged with a higher paying MS-LTC-DRG. This has resulted in a high concentration of LTCH discharges assigned to only two MS-LTC-DRGs: 189 (Pulmonary edema and respiratory failure) and 207 (Respiratory system diagnosis with ventilator support 96+ hours). These two MS-LTC-DRGs alone account for more than 43% of FY 2023 LTCH stays paid at the standard Federal payment rate.⁴⁵

Due to this concentration, CMS should study splitting and refining, by complication or comorbidity and major complication or comorbidity, these high volume DRGs for the LTCH PPS. This has the potential to be a long-term solution to the escalating HCO fixed-loss amounts.

³⁷ AHA, *Medicare's LTCH Outlier Policy Needs Reforms to Protect Extremely Ill Beneficiaries* at 3 (Feb. 2024), <https://www.aha.org/system/files/media/file/2023/12/white-paper-medicare-ltch-outlier-policy-needs-reforms-to-protect-extremely-ill-beneficiaries.pdf>.

³⁸ *Id.* at 3.

³⁹ *Id.*

⁴⁰ AHA, *Fact Sheet: Long-term Care Hospitals* at 2 (Mar. 2019), <https://www.aha.org/system/files/media/file/2019/04/fact-sheet-ltch-0319.pdf>.

⁴¹ MedPAC, *Report to the Congress: Medicare Payment Policy*, Ch. 10 at 12 (Mar. 2022).

⁴² *Id.*

⁴³ *Id.*

⁴⁴ MedPAC, *Report to the Congress: Medicare Payment Policy*, Executive Summary at 3 (Mar. 2023).

⁴⁵ CMS, FY 2025 Proposed MS-LTC-DRG File (Table 11) (May 2, 2024), <https://www.cms.gov/files/zip/fy-2025-proposed-ms-ltc-drg-file-table-11.zip>.

CMS Should Make Changes to the Data Used to Calculate the HCO Fixed-Loss Amount

In addition to the alternatives discussed below to the proposed fixed-loss amount, the FAH recommends that CMS make changes to the data used to calculate the HCO. First, CMS should exclude LTCH dialysis patients from the dataset used for HCO to ensure that these costly cases are not skewing CMS projections. In addition, we recommend that CMS calculate the charge inflation factor using the quarterly market basket updates. This is the same approach that CMS used to determine charge inflation factors before FY 2022. For example, in the FY 2021 IPPS/LTCH PPS final rule, CMS calculated an inflation factor of 4.3% that was used to update FY 2019 costs for the FY 2021 projections for HCO ratesetting.⁴⁶ CMS arrived at the 4.3% inflation factor by dividing the average of the FY 2021 four quarter market basket values (1.093) by the FY 2019 average of the four quarter market basket values (1.047). Returning to this methodology would provide greater stability and predictability to LTCH HCO payments to help smooth out year-to-year changes in HCO fixed-loss amounts until CMS is no longer using data from the COVID-19 pandemic.

Alternative Methodologies to the Proposed FY 2025 HCO Fixed-Loss Amount

1. Cap the Current Fixed-Loss Amount And Pursue a Permanent Fix to the HCO Methodology with Stakeholders

The FAH urges CMS to cap the fixed-loss amount at its current level, \$59,873, until the agency is able to implement a permanent fix that prevents the drastic year-to-year increases in the fixed-loss amount. In addition to the cap, under this alternative approach, we recommend that CMS limit the budget neutrality adjustment to estimated HCO payments using the fixed-loss amount that is no higher than \$59,873 to offset non-HCO payments to LTCHs. This would be consistent with CMS' alternative approach discussed in the Proposed Rule appendix that also did not include a budget neutrality adjustment to account for the projected \$30 million in additional payments to LTCHs by setting the fixed-loss amount below the proposed fixed-loss amount based on the target percentage.

CMS already uses caps for other payment policies in the LTCH PPS. For example, CMS applies a 10% cap on decreases to the MS-LTC-DRG relative weights.⁴⁷ CMS adopted this 10% cap because CMS recognized that “predictability and stability of rates is one of the fundamental principles of a prospective payment system.”⁴⁸ Similarly, CMS applies a 5% cap on yearly decreases to LTCH wage index values.⁴⁹ When finalizing this cap, CMS explained that the “policy of applying a permanent cap to wage index decreases would provide greater predictability to LTCHs [because] the policy would smooth year-to-year changes in LTCHs' wage indexes and provide for increased predictability in their wage index and thus their LTCH

⁴⁶ FY 2021 IPPS/LTCH PPS Final Rule, 85 Fed. Reg. 58432, 59056 (Sept. 18, 2020).

⁴⁷ 42 C.F.R. § 412.515(b)(1) (“Beginning FY 2023, each LTC-DRG weight is subject to a maximum 10 percent reduction as compared to the weight for the same LTC-DRG for the prior fiscal year, except as provided in paragraph (b)(2) of this section.”).

⁴⁸ FY 2023 IPPS/LTCH PPS Final Rule, 87 Fed. Reg. 48780, 49152 (Aug. 10, 2022).

⁴⁹ 42 C.F.R. § 412.525(c)(1)(i)(B).

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PPS payments.”⁵⁰ This same rationale supports a temporary cap on the LTCH PPS fixed-loss amount. However, consistent with the alternative discussed in the appendix of the Proposed Rule, the temporary cap here should not have a related budget neutrality adjustment for the fixed-loss amount that CMS calculates above the cap. When CMS discovers a significant issue with one of its policies, it is common for the agency to pause or freeze the problematic policy while a permanent solution is developed.⁵¹ CMS should do the same here with the LTCH PPS HCO fixed-loss amount to give the agency time to develop and implement a permanent solution that prevents further large increases that will impede LTCH operations and beneficiary access to LTCH services.

2. Adopt CMS’ Alternative in the Proposed Rule Appendix With a Longer Transition Period of Four Years

The FAH also supports CMS’ alternative option for FY 2025 fixed-loss amount calculation that would average the FY 2024 fixed-loss amount and the proposed FY 2025 fixed-loss amount based on the 7.975% target. However, the FAH recommends that instead of using a one-year transition, we urge CMS to use a longer transition period of three to five years. Even an increase to \$75,397 in one year, after the massive increase in FY 2024, is too much for LTCHs to bear. A \$75,397 fixed-loss amount would be preferable to the proposed \$90,921, but this would still be a 460% increase to the fixed-loss amount from FY 2016 to FY 2025. Based on this massive increase, a transition period of three to five years will allow more time to phase in the full increase to the fixed-loss amount while CMS develops and implements a permanent solution to the spiraling fixed-loss amount.

3. New Outlier Reconciliation Criteria Established by Sub-Regulatory Guidance

As in described in our comments on the proposed IPPS outlier calculation, the FAH is concerned that CMS has added new criteria for determining which hospitals shall have their outlier payments reconciled in CR 13566, published on April 26, 2024. The new criteria are on top of the original reconciliation criteria, with the exception that reconciliation is mandatory for the first cost report for all new hospitals. CMS has not explained the grounds for the new criteria or its retention of the old criteria, and the new criteria were adopted without notice and comment rulemaking. The new reconciliation criteria constitute a substantive change to CMS’ payment policy that cannot be adopted without notice and comment rulemaking. **Therefore, the FAH urges CMS to withdraw the transmittal.**

By using one of the two alternatives above while data from the PHE remains significantly skewed by COVID-19, CMS will be able to continue the process of smoothing out increases to

⁵⁰ 87 Fed. Reg. at 49441.

⁵¹ See e.g., HHS Notice of Benefit and Payment Parameters for 2024 Final Rule, 88 Fed. Reg. 25740, 25746 (Apr. 27, 2023) (finalizing a proposal to pause the failure to file and reconcile (FTR) process until the agency is “able to implement the new FTR policy”); HHS Notice of Benefit and Payment Parameters for 2025 Final Rule, 89 Fed. Reg. 26218, 26311 (Apr. 15, 2024) (allowing the Secretary to temporarily pause periodic data matching (PDM) when there is a limited availability of data); CY 2024 Physician Fee Schedule Final Rule, 88 Fed. Reg. 78818, 79258-59 (Nov. 16, 2023) (pausing the Appropriate Use Criteria (AUC) program for advanced diagnostic imaging to “to facilitate thorough program reevaluation”).

the LTCH-PPS HCO fixed-loss amount, to provide more stability and predictability to payments for the highest cost LTCH patients. This also will give CMS and LTCHs time to develop a permanent solution and, if needed, to seek Congressional action on this issue, such as a reset of the statutory target for high-cost outlier payments.

Changes to LTCH Average Length of Stay (ALOS) Regulation

CMS is proposing to change the LTCH ALOS regulation at 42 C.F.R. § 412.23(e)(4). CMS says that the revisions are technical clarifications that are not changes to existing policy. CMS is proposing a new provision specifying that a hospital attempting to qualify as an LTCH must meet the ALOS requirement for at least 5 consecutive months in the 6-month qualifying period. This new provision at section 412.23(e)(4)(iii) would govern the ALOS qualifying period for new LTCHs. For the first time, the ALOS regulation would require that a hospital seeking to qualify as an LTCH meet the ALOS requirement for “at least 5 *consecutive* months of that 6-month qualifying period” (emphasis added). CMS also proposed revisions that it says make the regulation easier to read, including changes specifying which provisions apply to existing LTCHs and which apply to hospitals attempting to qualify as LTCHs.

CMS claims the changes it is proposing are only codifications of existing policies. However, the “5 *consecutive* months” policy for new LTCHs is not currently stated in any manual or other official CMS guidance. Therefore, this regulatory change at proposed section 412.23(e)(4)(iii) would be a new rule that is *not* based in official agency policy because it has not been published in writing and publicly available.

Since requiring consecutive months that meet the ALOS requirement is a new rule, not based in existing official agency policy, CMS should clarify this fact in the final rule, and *not* finalize this change to the ALOS regulation. However, if CMS continues to consider this change to the regulation, it must carefully consider all comments submitted during this comment period. The ALOS requirement is the primary regulatory requirement to qualify as a LTCH for Medicare reimbursement. Therefore, CMS must carefully weigh any proposed changes to this regulation against the possible impact on hospitals that seek to qualify as LTCHs and those that already qualify as LTCHs.

The 5 consecutive months standard that CMS is proposing is unnecessarily strict. The LTCH statute and current authorities do not require LTCHs to meet the ALOS in consecutive months to qualify for the LTCH PPS. Allowing the MACs to calculate the ALOS using non-consecutive months affords hospitals some additional flexibility when seeking LTCH classification. For example, patients can often make unexpected advances in their treatment, to be discharged earlier than anticipated at the time of admission. Also, LTCHs typically have fewer beds than other types of hospitals. When an LTCH patient is discharged earlier than expected, there is often a material impact on the hospital’s ALOS. When this happens, the hospital’s ALOS could drop below 25 days in any given month even though the hospital admitted LTCH appropriate patients and provided LTCH-level care throughout their stays. Allowing MACs to calculate the ALOS using non-consecutive months would provide greater flexibility when a small number of patients reduce the ALOS in certain months of the qualifying period.

The FAH urges CMS to withdraw its proposal to require that hospitals meet the LTCH ALOS requirement for 5 consecutive months during the minimum 6-month qualifying period. Consecutive months are not required in any existing official agency policy or rule. CMS also should explain in the preamble to the final rule that MACs can consider non-consecutive months during the qualifying period when calculating an LTCH's ALOS.

HOSPITAL QUALITY AND VALUE-BASED PAYMENT PROGRAMS

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

In CY 2022, CMS outlined 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 cautioned CMS on moving too quickly to mandatory reporting of the THA/TKA PRO-PM. Given the complexity of the measure, we expressed the belief that hospitals would need additional time and experience to ensure successful and sufficient reporting of the data required for this measure.

We asked CMS to reconsider the burdensome 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 was not clear whether hospitals would be able to produce this high degree of data completeness at the onset.

The response rates will be negatively affected due to the lengthy data collection period of over one year. There is also significant potential for hospitals to fail to meet the 50% requirement. **We urge CMS to delay the start of mandatory reporting to allow hospitals to gain more experience with the measure. We also urge CMS to lower the 50% response rate requirement and include a minimum threshold. The implications of not doing so will be catastrophic for hospitals.**

Specifically, CMS did not allow sufficient lead time for voluntary reporting, which started before CMS released a technical specification document or a means to report to IQR. The pre-surgery surveys are not data elements easily obtained through normal scheduling or billing practices. Additionally, there are no contingencies for patients who are scheduled as outpatients or experience complications – as these patients would not have been screened for pre-op before their surgeries. Screening everyone requires significant costs and resources.

Several unforeseen issues and challenges have made reporting difficult for hospitals and CMS' responses have often been conflicting and unclear. Yet CMS is still holding hospitals accountable. This measure is very expensive to implement, there hasn't been enough time to get processes in place and CMS continues to move the guardrails. The methodology also fails to account for low-volume sites. **We urge CMS to delay the mandatory reporting of this measure in IQR from July 1, 2024, to January 1, 2025, at the earliest, to give hospitals more time to prevent the payment penalties that potentially hundreds of hospitals will incur**

because CMS failed to properly specify, and field test this measure. We also urge CMS to lower the 50% response rate requirement and include a minimum threshold.

Data Submission and Reporting Requirements for Hybrid Hospital-Wide All-Cause Readmission (HWR) and Hybrid Hospital-Wide Risk-Standardized Mortality (HWM) Measures

Since the inclusion of the hybrid measures into the IQR program, FAH members have experienced challenges with the data submission and reporting requirements and we request that CMS reconsider not only the timing sensitivities with the HWS and HWM measures but also the expected percentage threshold for submission. Most of the deficits uncovered are due to the timing of vital signs, patient body weight, and various lab tests being conducted and captured in the EHR within the rigid time frames specified within the measures. For example, we have found the following patient admission scenarios to be problematic:

- Surgical cohort patients who are scheduled for a procedure with an anticipated admission. This population of patients proves to be problematic because of the following:
 - Laboratory diagnostics are primarily captured in an outpatient setting prior to the surgery date.
 - Weight may be captured through the PAT screening prior to the surgical procedure date.
 - Time-sensitive documentation elements such as weight, vital signs, and labs are impacted by the admission date/time, which can occur at any time during the surgical process at the surgeon's request. The problem with this scenario is that the patient can be under the care of the anesthesia team and surgeon mid-surgery while the admission takes place. The documentation of vital signs does not occur within an integrated system, as the anesthesia staff utilizes a standalone application. Furthermore, the patient may not be under the care of a clinician who would be documenting vital signs in the certified EHR until many hours later in some cases.
- Patient transfers from facilities in and outside of the organization.
 - For patients transferring from facilities within the organization, clinicians look at vital signs and lab values documented at the previous facility and exercise clinical judgment in many cases as to when to capture the next set of vital signs based on acuity.
 - For the patients transferring in from facilities outside the organization, the pattern of data missingness is unclear throughout the enterprise.
- Patients who are directly admitted through their PCP or otherwise. It is unclear why there is a pattern of data missingness throughout the enterprise.
- Patients in an observation status prior to inpatient admission.
 - Vital signs, weights, and pertinent lab tests are often captured in the ED prior to observation status.
 - Patients may remain in observation status for more than 24 hours for clinical decision-making prior to an inpatient admission.
- Patients admitted to inpatient rehabilitation within the facility. It is unclear at what point this population is excluded from the measure.

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In the cases reviewed, there was not an overall omission of these core clinical elements for patients; instead, we find the majority did receive the necessary assessments and lab values to guide clinicians in the plan of care and provide safe and effective patient care. However, there are often scenarios in which the appropriate care does not match the exact specifications of the measure.

It is also important to highlight that pre-anesthesia laboratory testing completed no later than 30 days before the planned surgical procedure is an industry-standard that is supported by the Association of periOperative Registered Nurses (AORN), particularly in the case of the surgical cohort patients. Additionally, CMS has stated that surgical patients require "A pre-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, performed within 48 hours prior to surgery or a procedure requiring anesthesia services" in the CFR §482.52 Conditions of participation: Anesthesia services. According to the American Society of Anesthesiologists (ASA), a pre-anesthesia evaluation often comprises a variety of components, one of which is diagnostic laboratory testing; the details of this practice parameter can be viewed here. At this time, we believe there should be further due diligence to ensure that the specification accurately reflects data capture, clinical expectations, and industry standards.

Moreover, this issue is affecting other healthcare entities as well. A review of the ONC-JIRA CMS Hybrid Measure issue tickets on the ONC Project website reveals that many other organizations are experiencing similar issues with the measure's complexity and the narrow timeframes in which these data elements can be captured in the EHR.

In addition to the items previously mentioned, there is significant apprehension around the lack of understanding and transparency as it relates to the calculation and output of results on the feedback reports. Specifically, there is a lack of understanding around when this will occur and how this impacts the percentage threshold for eCQM submission of core clinical data elements and linking variables. Several other healthcare entities have voiced concern about what is being produced within the output of their feedback reports on the ONC Jira Board, as well. Our members report that it can take several submission cycles to expose potential issues around submission calculation.

In bringing these concerns to light, **we urge CMS to review and reconsider not only the timing sensitivities with the HWS and HWM measures but also the expected percentage threshold for submission.** We understand that to acquire meaningful data, submission of these measures should be required. Also, we believe there is value in submitting this data to identify additional opportunities around the specification and calculation. Our concern is specifically around the IQR submission requirement for the expected percentage threshold associated with core clinical data elements and linking variable submission, and the potential update penalty for failure.

Hospital Value-Based Purchasing (HVBP) Program

Proposed Changes to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)

CMS proposes to adopt the updated Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey sub-measures (and scoring modifications) beginning with the FY 2030 program year once the updated survey has been publicly reported under the Hospital Inpatient Quality Reporting (IQR) program for one year.

The FAH provides detailed comments on the proposed updates to the HCAHPS Survey sub-measures under the Hospital IQR program section of this letter. However, we note in this section, that CMS should ensure that the resulting scores of the modified HCAHPS continue to be reliable and valid. If they are, we support the proposed scoring modifications that would be necessary to reduce the burden of reporting two surveys for hospitals.

General Comments

Request for Comment: Advancing Patient Safety and Outcomes Across the Hospital Quality Programs

CMS is seeking feedback on ways to build upon current measures in CMS quality reporting programs that account for unplanned patient hospital visits to incentivize hospitals to improve discharge processes, such as by introducing existing quality reporting measures into the value-based programs or by adopting new measures that better represent the range of patient outcomes post-discharge.

The FAH agrees that any unplanned return to an acute care setting should not be viewed as a desirable outcome of patient care and ongoing efforts should focus on reducing these occurrences. However, we also believe that hospitals should not be penalized across multiple quality programs for overlapping outcomes. For example, because the Excess Days in Acute Care (EDAC) measures include unplanned readmissions, which are already captured through the Hospital Readmissions Reduction Program, they should not be considered for another program, such as the HVBP Program. **The FAH encourages CMS to identify evidence-based, reliable, and valid measures that are not duplicative to those currently in existing programs that include payment incentives or penalties.** The FAH does not support the inclusion of any measures that would be viewed as double counting of patients and/or outcomes across programs.

The FAH urges CMS to provide quarterly reports on claims-based data, particularly if the measure will impact a hospital's star rating. Hospitals are unable to pivot in their performance if they are unable to see how they are doing along the way. Using the EDAC measure again as an example, it is difficult to understand what patients are included in the numerator and denominator criteria, as well as what is needed to improve. The timeliness of hospitals receiving the report detailing hospital performance, i.e. once a year, is insufficient to know what interventions need to be in place to affect improvement. **We urge CMS to provide reports quarterly to ensure hospitals can act in a meaningful way earlier than a year later.**

Hospital IQR Program

The hospital inpatient quality reporting (IQR) program is CMS' pay-for-reporting program in which hospitals must submit measures and meet other administrative requirements to avoid a payment reduction equal to one-quarter of the annual market basket update. The IQR program also requires hospitals to report on selected electronic health record (EHR) derived electronic clinical quality measures (eCQMs) using CMS-mandated reporting standards. The IQR eCQM reporting requirements align with the eCQM reporting requirements in the Promoting Interoperability Program.

CMS proposes to add seven new measures, remove five measures, and increase the total number of eCQMs required for reporting in the IQR program. Lastly, CMS proposes changes to the HCAHPS survey questions, resulting in changes in the sub-measures used to calculate performance.

Proposed Adoption of the Patient Safety Structural Measure

CMS proposes to add the Patient Safety Structural measure to the IQR for the CY 2025 reporting/FY 2027 payment years. The measure assesses whether hospitals are implementing 25 separate policies and practices across five domains. The measure is attestation-based – that is, hospitals would answer “yes” or “no” to whether they have implemented specific practices. Hospitals would receive a score out of five possible points, and CMS would score each measure domain as “all-or-nothing.” That is, for a given domain, if a hospital could not attest “yes” to all the practices within the domain, they would receive zero points.

Patient safety is a top priority for hospitals and health systems, and the FAH looks forward to continuing to work with the HHS leadership and infrastructure to heighten patient safety efforts to reduce and ultimately eliminate preventable patient harm. However, we disagree with the inclusion of this proposed patient safety structural measure for several reasons.

CMS has included in this measure activities that overlap extensively with existing CMS Conditions of Participation (CoPs), raising questions about the measure's appropriateness for the IQR program. For example, the Leadership and Strategic Planning domains largely reflect requirements already covered under the Quality Assessment and Performance Improvement (QAPI) CoP, 42 CFR 482.21(a)-(e) such as including patient safety in strategic plans, allocating resources, and ensuring executive-level accountability. Additionally, providing access to patient information, a requirement in Domain 5, practice 3 is an existing requirement of the Promoting Interoperability program. Several requirements fail to demonstrate a link to evidence-based protocols and ultimately to improved patient outcomes, are prone to inconsistent interpretations, and are inconsistent with other regulations. For instance, the attestation regarding the percentage of board meeting time dedicated to patient safety lacks evidence tying it to improved outcomes and fails to provide a standard to define a "regular board agenda" or "senior governing board" meeting.

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Additionally, the attestation requirement of reporting safety events to patient safety organizations (PSOs), 4B of the Accountability & Transparency Domain, appears to conflict with the voluntary reporting of patient safety information as outlined in the Patient Safety and Quality Improvement Act of 2005. By including this attestation, CMS is compelling PSOs to collect and report to the government patient safety events from hospitals that violate the Patient Safety Act. The Patient Safety Act was designed specifically to prevent federal agencies from turning the PSO program into a “Federal Reporting Program.”

The [Patient Safety Improvement] statute (“Patient Safety and Quality Improvement Act of 2005”) states that “[t]he Secretary shall facilitate the creation of, and maintain, a network of patients safety databases...[that shall] have the capacity to ...analyze nonidentifiable PSWP voluntarily reported by PSOs, providers, or other entities.” 42 USC § 299b-23(a). The Patient Safety Act and Rule “encourages the development of provider-driven, voluntary opportunities for improving patient safety” Patient Safety and Quality Improvement, Proposed Rule, 73 Fed. Reg. 8114 (Feb. 12, 2008). A CMS requirement mandating reporting to NPSD would directly conflict with the Patient Safety Act.

Importantly, patient safety work within the PSO environment is ongoing and extensive. Since the Patient Safety Act was ratified, PSOs and healthcare entities have continuously developed new programs and strategies resulting in dramatic improvements in patient safety and the quality of patient care. While we all are invested in the ongoing progress of these efforts, mandating reporting utilizing Common Formats would chill that momentum and create obstacles to PSO participation. As stated above, it is also inconsistent with the language of the statute and final rule which both clearly state that reporting is voluntary and that PSWP is privileged and confidential.

The Agency for Healthcare Research and Quality (AHRQ) has recognized that “[t]he work of federally listed PSOs and healthcare providers to reduce medical errors and increase patient safety in various clinical settings and specialties is highly valued, successful, and thriving.” Strategies to Improve Patient Safety: Final Report to Congress Required by the Patient Safety Act of 2005,” AHRQ, December 2021.

Furthermore, the statute is very intentional regarding safeguarding the privilege and confidentiality of patient safety work products including event reports. 42 USC § 299b-22(a)-(b). This is essential to encourage voluntary reporting without fear of retaliation or unauthorized disclosure. It fosters a culture of transparency within healthcare organizations, allowing for the identification and analysis of patient safety issues to improve the quality of healthcare and minimize future adverse events. It helps build critical trust within the healthcare workforce by ensuring that PSWP is handled appropriately in a nonpunitive environment including prohibiting the sharing of PSWP with regulatory agencies.

While the FAH recognizes the potential value of a more centralized, comprehensive process for the evaluation of Patient Safety Events and corrective measures (or the value of aggregating patient safety events to identify underlying patterns); we have concerns that the structural measure proposed by CMS requiring the reporting of Patient Safety Work Product utilizing Common Formats may not positively contribute to that goal. Current reporting systems

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are tailored to the specific needs of individual PSOs and requiring reporting to NPSD would in essence require use of a Common Format and disrupt the well-established systems of identifying and addressing barriers to patient safety. It would also add substantial expense, be time consuming and potentially result in the loss of or inability to make meaningful use of historical data for purposes of long-term trend analysis. It would most certainly discourage overall participation in PSOs.

To successfully expand the potential for participation in patient safety activities and comply with PSQIA mandates, it is critical to maintain the benefits of confidentiality and privilege protections, minimize the barriers to entry for listing as a PSO and preserve the “provider-driven, voluntary” spirit of the Patient Safety Act.

Lastly, there is a lack of hospital-specific field-testing data, as noted in the pre-rulemaking measure review process, including entity-level reliability testing, performance score reporting, workflow analysis, and empirical evidence of association with the study population, which means this measure is not ready accountability and transparency. **For these reasons, the FAH urges CMS not to adopt the measure in its current form.**

Proposed Adoption of Age-Friendly Hospital Measure

CMS proposes to adopt the Age Friendly Hospital measure, beginning with the CY 2025 reporting period/FY 2027 payment determination and for subsequent years. CMS proposes to add this measure to the IQR for the CY 2025 reporting/FY 2027 payment years. The measure assesses whether hospitals implement certain policies and practices that CMS believes are linked to better care and outcomes for older adults (i.e., age 65 and over). This structure measure is attestation-based and requires hospitals to respond yes or no to whether they have implemented specific practices. This measure consolidates two previously separate measures that CMS was considering.

The FAH does not support the inclusion of this measure in the Hospital IQR Program since it relies on attestation of a hospital’s performance against a broad set of criteria. We do not believe that the measure will drive meaningful improvement in patient outcomes nor does an aggregated score of many structural components help to inform patients in their decision-making process. The FAH believes that CMS should focus on developing and/or selecting outcome measures or process measures that are closely linked to outcomes rather than measures that rely on attestations, which are burdensome and result in non-standardized data collection.

Proposed Adoption of Two Healthcare-Associated Infection (HAI) Measures

CMS proposes to adopt the Catheter-Associated Urinary Tract Infection (CAUTI) Standardized Infection Ratio Stratified for Oncology Locations measure and the Central Line-Associated Bloodstream Infection (CLABSI) Standardized Infection Ratio Stratified for Oncology Locations measure, beginning with the CY 2026 reporting period/FY 2028 payment

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determination and for subsequent years. **The FAH supports the inclusion of these two measures in the Hospital IQR Program.**

Proposed Adoption of Hospital Harm - Falls with Injury eCQM

CMS proposes to adopt the Hospital Harm-Falls with Injury eCQM, beginning with the CY 2026 reporting period/FY 2028 payment determination and for subsequent years. The measure assesses the risk-adjusted ratio of hospitalizations with at least one fall with a moderate or major injury. The measure includes a risk adjustment model that CMS asserts would ensure hospitals that care for sicker and more complex patients are evaluated fairly. The risk adjustment model accounts for age and certain clinical risk factors for falls, such as weight loss or malnutrition, delirium, dementia, and other neurological disorders.

The FAH supports addressing important patient safety concerns during an inpatient stay but questions whether this measure demonstrates a sufficient performance gap to support its use in the Hospital IQR Program since the performance scores ranged from 0.0 to 0.258 across 12 hospitals.

In addition, the FAH also strongly encourages CMS 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. Assessment of how the measure performs using only two vendor systems and twelve hospitals should not be considered sufficient. Implementation of eCQMs requires significant resources and time for hospitals and only those eCQMs with demonstrated gaps in care should be included in CMS programs. 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.

Proposed Adoption of Hospital Harm - Postoperative Respiratory Failure eCQM

CMS proposes to adopt the Hospital Harm - Postoperative Respiratory Failure eCQM, beginning with the CY 2026 reporting period/FY 2028 payment determination and for subsequent years. The measure calculates the risk-adjusted rate of elective inpatient hospitalizations for patients aged 18 years and older without an obstetrical condition who have a procedure resulting in postoperative respiratory failure. At a high level, post-operative respiratory failure is defined as unplanned intubation or prolonged mechanical ventilation after an operation.

The FAH supports addressing important patient safety concerns during an inpatient stay but strongly encourages CMS to assess the feasibility of collecting the required data elements from EHRs and determine if the measure is reliable and valid across a broader set of EHRs vendors and hospitals. Assessment of how the measure performs using only three vendor systems and thirteen hospitals is insufficient to generalize the measure's suitability to a broader population of facilities. Implementation of eCQMs requires significant resources and time for

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hospitals and only those eQMs with demonstrated gaps in care should be included in CMS programs. We recommend that CMS continue to test this measure across a broad range of hospitals and vendor systems before the measure's inclusion in the Hospital IQR Program.

Proposed Adoption of Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) Measure

CMS proposes to adopt the Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) measure, beginning with the July 1, 2023 – June 30, 2025, reporting period/FY 2027 payment determination and for subsequent years. The measure calculates the rate of deaths among certain inpatients following a preventable hospital-acquired complication. The measure would replace PSI-04 (Death Among Surgical Inpatients with Serious Treatable Complications) which CMS has proposed to remove from the IQR.

The FAH is very concerned with the current reliability of this measure and notes that the recent consensus-based entity (CBE) review placed conditions on its endorsement since roughly half of the facilities tested had a reliability result of less than 0.6. Specifically, testing demonstrated that reliability was 0.231 using the measure's case minimum of 25 patients and it required roughly 600 patients to achieve 0.7. We believe that the measure requires a higher case minimum to improve its reliability and this additional testing should be completed and the conditions be removed from endorsement before the measure is used in the Hospital IQR Program.

Proposed Removal of Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI 04) Measure

CMS proposes to remove Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI 04) measure beginning with the July 1, 2023 – June 30, 2025, reporting period/FY 2027 payment determination. **The FAH supports the removal of this measure given our ongoing concerns with its reliability and validity.**

Proposed Removal of Four Clinical Episode-based Payment Measures

CMS proposes to remove four clinical episode-based payment measures, beginning with the July 1, 2021 – June 30, 2024, reporting period/ FY 2026 payment determination. These measures are:

- Hospital-level, Risk- Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI) measure;
- Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Heart Failure (HF) measure;
- Hospital-level, Risk- Standardized Payment Associated with a 30-Day Episode-of-Care for Pneumonia (PN) measure; and

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- Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure.

The FAH agrees that these measures are captured in the Medicare Spending per Beneficiary Hospital measure and supports their removal from the program.

Proposed Refinement to Global Malnutrition Composite Score (GMCS) eCQM

CMS proposes refinements to the Global Malnutrition Composite Score (GMCS) eCQM, beginning with the CY 2026 reporting period/FY 2028 payment determination and for subsequent years.

The FAH believes that the changes to this measure should be reviewed and approved by the CBE. We also strongly encourage CMS to assess the feasibility of collecting the required data elements from EHRs and determine if the measure is reliable and valid across a broader set of EHRs vendors and hospitals. Assessment of how the measure performs using only two vendor systems should not be considered sufficient. Implementation of eCQMs requires significant resources and time for hospitals and only those eCQMs with demonstrated gaps in care should be included in CMS programs. We recommend that CMS continue to test this measure across a broad range of hospitals and vendor systems before the measure's inclusion in the Hospital IQR Program.

Proposed Refinement to Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure

CMS proposes to make refinements to the HCAHPS Survey measure beginning with the 2025 reporting period/FY 2027 payment determination and adopt the updated HCAHPS Survey Measure and associated scoring modifications in the Hospital VBP program beginning with the FY2030 program year.

The FAH continues to advocate and support refinements to the HCAHPS Survey; specifically, we released a report in 2019 outlining a set of recommendations to modernize it.⁵² One of the key findings identified a trend of decreased response rates for HCAHPS from 2008 (33%) to 2017 (26%). This percentage change of -22% overall and an average 0.8 percentage point drop per year was concerning and we believe that these low rates continue to be a concern in subsequent years, particularly due to the public health emergency. We hope that this erosion of participation can be reduced and one avenue is to ensure that the topics addressed in HCAHPS remain relevant and capture what matters most to patients such as care coordination and efficiency and teamwork of the care team. The FAH is encouraged to see CMS move in this direction through these proposed changes.

⁵² Federation of American Hospitals. Modernizing the HCAHPS Survey. Released June 2019. Available at: https://www.fah.org/fah-ee2-uploads/website/documents/Modernizing_HCAHPS_-_Recommendations_from_PELs.pdf.

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We support refinements to the survey to ensure that it accurately captures patient perspectives on items such as care coordination but we are concerned that the updates may remain insufficient. For example, the hospital and health system patient experience leaders interviewed during our Modernizing the HCAHPS Survey report identified limitations in the “Information About Symptoms” since it does not assess if the patient had the information needed to know with whom to follow up once she/he was discharged. Rather they identified the opportunity to further enhance the question to not just capture whether the patient was handed written information, which is typically the reason why “yes” is selected. We encourage CMS to continue to refine these questions based not only on patient feedback but also from leaders such as those consulted for our report to ensure that the questions not only reflect patient perspectives but also enable hospitals to implement targeted and meaningful quality improvement strategies.

We are encouraged to see acceptable hospital reliability and Cronbach’s alpha results where applicable across the items but believe that analyses similar to previous validity testing submitted during the endorsement review in 2019 should be completed. Specifically, it is important to understand the strength of the correlations of the multi-item and single-item measures with the overall measures.

As a result, the FAH believes that CMS must complete the validity testing and receive CBE endorsement of these changes before implementation in the Hospital IQR or HVBP programs.

Promoting Interoperability Program for Hospitals

Antimicrobial Use and Resistance (AUR) Surveillance Measure

CMS proposes to split the AUR Surveillance measure into two measures, one for Antimicrobial Use (AU) Surveillance and one for Antimicrobial Resistance (AR) Surveillance, starting from the EHR reporting period in CY 2025; add a new exclusion for eligible hospitals or CAHs that do not have electronic access to the data elements needed for AU or AR Surveillance reporting; change the existing exclusions for the AUR Surveillance measure to apply to the AU Surveillance and AR Surveillance measures, respectively; and consider the AU Surveillance and AR Surveillance measures as two new measures for active engagement starting from the EHR reporting period in CY 2025.

The FAH supports this proposed change. There are different technical and data requirements for capturing each measure, so we agree with separating the measures, as the additional reporting burden associated with this proposed change is less than a minute per year for each eligible hospital and CAH. Additionally, each eligible hospital or CAH will still qualify for an exception for either or both measures, without a loss of total points available.

Scoring Threshold

CMS proposes increasing the performance-based scoring threshold for eligible hospitals and CAHs reporting from 60 points to 80 points beginning with the EHR reporting period in CY 2025.

The FAH does not support this change. In the proposed rule, it's noted that "the CY 2022 Medicare Promoting Interoperability Program's performance results indicate 98.5% of eligible hospitals and CAHs currently successfully meet the threshold of 60 points while 81.5% of eligible hospitals and CAHs currently exceed a score of 80 points. If this proposal is finalized, the 17% of eligible hospitals and CAHs that meet the current threshold of 60 points but not the proposed threshold of 80 points would be required to better align their health information systems with evolving industry standards and increase data exchange to raise their performance score or be subject to a potential downward payment adjustment." Based on this calculation, over 1,000 hospitals would not meet the new scoring threshold and would be adversely impacted by this change. The FAH recommends that the change in scoring be pushed back to CY 2027 to allow ample time for all hospitals to adjust to the reporting requirements.

Conditions of Participation Requirements for Hospitals and Critical Access Hospitals to Report Acute Respiratory Illnesses

In this proposed rule, CMS proposes to modify and permanently require hospitals and critical access hospitals (CAHs) to report data on acute respiratory illnesses, such as COVID-19, influenza, and respiratory syncytial virus (RSV). This data would include confirmed infections, hospital capacity, and limited patient demographics. The proposal also suggests the agency could increase reporting requirements during public health emergencies (PHEs) or potential PHEs.

Hospitals acknowledge the value of this data but have raised concerns about using Conditions of Participation (CoPs) to mandate data sharing, which is inconsistent with the purpose of CoPs, which is to establish health and safety standards. The FAH is also concerned about the lack of specificity in the proposed rule and the potential for CMS to change reporting requirements without notice and comment rulemaking. We support adopting a voluntary reporting process in the short term and building infrastructure for automated, efficient data sharing in the long run.

The proposed rule is not clear whether hospitals need to report data weekly or will have to report on every individual day once per week, similar to how the COVID-19 reporting shifted. If CMS proceeds with the CoP, **the FAH recommends allowing hospitals to report a snapshot of data weekly, providing more detailed information about the required data elements, and removing the proposal to allow increased reporting during potential PHEs.**

We also are seeking clarity from CMS regarding hospitals' required reporting of bed capacity statistics. CMS should provide hospitals with the rationale for providing this information outside of a PHE. The FAH is concerned that the publicly reported data will be used for other purposes beyond public health. Similarly, the FAH recommends CMS take a careful

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and measured approach, addressing issues related to maintaining patient confidentiality and ensuring a stable reporting process.

Overall, the FAH does not support the proposed CoP and urges CMS to consider alternative approaches, such as voluntary reporting and investment in infrastructure for efficient data sharing. We also recommend modifications to the proposed CoP if it is adopted, including allowing for weekly data snapshots, providing more specific data requirements, and removing the provision for increased reporting during potential PHEs.

Section X.B. Provider Reimbursement Review Board (PRRB) (§ 405.1845)

The FAH supports CMS' proposed amendment to 42 C.F.R. § 405.1845(a), concerning the requisite expertise of individuals appointed to the Provider Reimbursement Review Board (PRRB). Since the enactment of the Social Security Amendments of 1983, sec. 602(h)(4) (Pub. L. 98-21), Board Members have been required to be knowledgeable in the field of "payment of providers of services," and CMS' proposed amendment to its implementing regulation more appropriately reflects this statutory requirement.

The FAH, however, is deeply concerned with CMS' proposed relaxation of term limits that have been in place since the establishment of the PRRB in 1974. By statute, the "term of office" of each Board Member is limited to "three years." 42 U.S.C. § 1395oo(h). Although Congress may not have intended to permit the term of office of a Board Member to be extended beyond the statutorily specified term, the FAH recognizes that the implementing regulations have permitted a second consecutive term since they were originally adopted, 39 Fed. Reg. 34,514, 34,518 (Sep. 26, 1974), and that allowing for a second three-year term strikes a good balance of continuity and fresh perspectives. Now, CMS proposes to change this established two-term (six-year) limit on Board service to permit a Board member "to serve up to 3 consecutive terms (9 consecutive years total), and up to 4 consecutive terms (12 consecutive years total) in cases where a PRRB Member who, in their second or third consecutive term, is designated as Chairperson, to continue serving as Chairperson in the fourth consecutive term." 89 Fed. Reg. at 35,946. The FAH is concerned that this change will unnecessarily deprive the Board of the regular infusion of fresh experience and perspectives that new Board Members bring.

Moreover, the FAH does not believe that any recent developments necessitate or support any extension of term limits. As CMS acknowledges in the Proposed Rule, the PRRB's docket has remained relatively stable over recent decades, 89 Fed. Reg. at 36,495. In addition, the shift toward cases involving "broad-based legal challenges to regulatory interpretations" rather than "appeals of reimbursable expenses specific to individual providers," *id.*, has served to lighten the PRRB's burden as a larger proportion of cases are subject to expedited judicial review (or can be efficiently held in abeyance pending the final disposition of a lead case) and need not go to hearing.

While acknowledging the considerable time and effort that CMS and HHS have expended and continue to expend to maintain a fully staffed and capable Board, the FAH does not believe that the recent evolution of the PRRB's work supports dispensing with term limits

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that have served the PRRB well over fifty years. Rather, the FAH believes that the current term limits strike an appropriate balance between the statutorily mandated turnover and appropriate levels of efficiency, and therefore we oppose the proposed amendment to 42 C.F.R. § 405.1845(b).

Finally, the FAH urges to evaluate the operation of the PRRB more broadly with the intent of identifying opportunities to modernize the PRRB and to ensure that it is organized and operated in a manner that prioritizes the fair and efficient handling of appeals and appropriately serves the provider community and the Medicare program.

APPENDIX B:
Watson Policy Analysis of FY 2025 Outlier Payments

Summary of research modeling

FY 2025 Proposed Inpatient Prospective Payment System

Outlier Payments

Date: May 30, 2024

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) 2025 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 36566 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.

Summary

A summary of findings is as follows:

- WPA was able to come close to the CMS calculation of the Fixed Loss Threshold (FLT).
 - CMS published \$49,237
 - WPA calculated \$49,252
- 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.
- Using some alternative assumptions, WPA was able to generate alternative Fixed Loss Thresholds that may be more appropriate.

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).

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 2025 Rates; Quality Programs Requirements; and Other Policy Changes". Published in Federal Register, Vol 89, No. 86., Tuesday, May 2, 2024

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 2025 outlier payment from the FY 2025 IPPS proposed rule

WPA estimated payments, including outlier payments from the FY 2023 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 2025 proposed file: contains inpatient hospital claims from FY 2023 that were used by CMS to model proposed FY 2025 payments,
- Table 5 – Weight file: contains the proposed weights for FY 2025,
- Impact file: contains hospital specific characteristics and payment factors,
- DSH Supplemental File: contains uncompensated care per claim payment amounts for providers,
- The FY2025 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.

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: \$49,252 versus the published number of \$49,237, a difference of \$103 or about 0.03%.

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 2025 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 2023 data, used the December 2023 release of the PSF file. Comparing the 3,159 providers listed in the impact file and the December 2023 PSF file, we had a match rate of 93.89% (2,965 providers).

Using this data, the average difference in operating CCRs between the impact file and the PSF file (weighted by discharges) was -0.035% when all providers were used, and -0.72% when just providers with differences were used.

For the modeling using the FY 2023 data, used the March 2024 release of the PSF file. Comparing the 3,159 providers listed in the impact file and the March 2024 PSF file, we had a match rate of 72.30% (2,284 providers).

Using this data, the average difference in operating CCRs between the impact file and the PSF file (weighted by discharges) was 0.204% when all providers were used, and -0.721% when just providers with differences were used.

The table of matching statistics reported nearly nine 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%

Proposed 2023 – December 2021 update	75.23%	0.119%
Proposed 2023 – March 2022 update	78.59%	0.001%
Proposed 2024 – December 2022 update	96.34%	0.001%
Proposed 2024 – March 2023 update	73.40%	-0.002%

* 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: 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	\$ 38,859	\$ 43,214	\$ (4,355)	-11.21%
2024	\$ 42,750	\$ 40,732	\$ 2,018	4.95%
2025		\$ 49,237		

Note: FY 2023 is based on the proposed blended weight for weighting. Final rule FLT is also blended. Methodology for FY2023 final rule FLT is different than the proposed rule due to the

blending, so change from proposed to final should be viewed with caution and not a standard change.

Note: FY 2024 reverted back to not using blended weight or FLT.

Analysis 4: Outlier Reconciliation

In the FY2020 IPPS rule, CMS finalized a new methodology to adjust the outlier target percentage to account for outlier reconciliation. For the FY 2025 rule, CMS is proposing to update their methodology to account for the new criteria put forth in Change Request (CR) 13566 issued earlier this year. The CR instructs MACs to expand the criteria for cost reports that can be considered for outlier reconciliation. Instead of needing a discrepancy of +/- 20 “percentage points” between the actual operating CCR and the operating CCR used for outlier payment during the same time period, the new criterion is +/- 20 “percent”. This change results in more hospitals being evaluated for outlier reconciliation.

WPA was successful in replicating the CMS calculations exactly given the logic described. WPA matched their calculation of -0.04% when using the FY 2019 cost report data released with the December 2023 update of HCRIS and the CMS issued Public Use File for the imputed amounts calculated from data supplied by the MACs. The outlier target will stay at .949 (5.1%) regardless of the reconciliation factor.

The March 2024 release of HCRIS, the March 2024 update to the Provider Specific File, and presumably updated data from the MACs will be used in the final rule. As WPA does not have access to the data feed from the MACs, we cannot estimate the final rule results at this time.

Analysis 5: Explorations on high charge cases

As evidenced in Analysis 3, 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 remaining	Removed cases	FLT	Percentage of cases removed
Base	6,720,056	0	\$49,252	0.000%
Trim at: 3,500,000	6,719,422	614	\$46,269	0.009%
Trim at: 3,250,000	6,719,289	767	\$45,890	0.011%
Trim at: 3,000,000	6,719,034	1,022	\$45,376	0.015%
Trim at: 2,750,000	6,718,699	1,357	\$44,713	0.020%
Trim at: 2,500,000	6,718,331	1,725	\$44,057	0.026%
Trim at: 2,250,000	6,717,788	2,268	\$43,256	0.034%
Trim at: 2,000,000	6,716,857	3,199	\$42,150	0.048%
Trim at: 1,750,000	6,715,538	4,518	\$40,935	0.067%
Trim at: 1,500,000	6,713,602	6,454	\$39,571	0.096%
Trim at: 1,250,000	6,710,162	9,894	\$37,740	0.147%
Trim at: 1,000,000	6,703,251	16,805	\$35,250	0.250%
Trim at: 750,000	6,686,367	33,689	\$31,667	0.501%
Trim at: 500,000	6,632,659	87,397	\$25,930	1.301%
Trim at: 250,000	6,345,801	374,255	\$15,901	5.569%

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 FY2023 data, this trend continued. (Note: The FY2022 data as been updated to final rule data.)

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	4,719	0.0650%	530
2022	5,482	0.0803%	594
2023	6,533	0.0971%	600