Federation of American Hospitals®

Charles N. Kahn III
President and CEO

June 28, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1752-P
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: 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 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program; 86 Federal Register 25,070 (May 10, 2021)

Dear Administrator Brooks-LaSure:

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

The FAH appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) about the above referenced Proposed Rule on Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program.

EXECUTIVE SUMMARY

Medicare Advantage Negotiated Rate Reporting and Relative Weight Methodology

The FAH strongly supports CMS' proposal to repeal the requirement that a hospital report on the median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage organization payers, by MS-DRG and to repeal the market-based MS-DRG relative weight methodology that was adopted effective for FY 2024. The FAH appreciates CMS' responsiveness to the significant stakeholder feedback on this policy, and urges CMS to finalize the proposed repeals.

COVID-19 and the Use of Pre-Pandemic Data

The Proposed Rule indicates that CMS ordinarily uses the latest updates to the electronic claims database (MedPAR) and Medicare Hospital Cost Report Information System (HCRIS) to determine MS-DRG relative weights for the following fiscal year. However, the latest MedPAR and HCRIS files for FY 2022 would be from FY 2020 (MedPAR) and FY 2019 (HCRIS) and the data in these files would span the period of the COVID-19 public health emergency (PHE) that has existed in the United States since January 27, 2020 - a period when the utilization of inpatient services was generally markedly different for certain types of services in FY 2020 than would have been expected in the absence of the PHE. There are a number of reasons why these data may be atypical, including guidance from the Department of Health and Human Services advising hospitals to delay or cancel elective procedures and the presence of an extraordinarily high number of respiratory cases being treated with mechanical ventilation.

The FAH agrees with CMS' complex analysis demonstrating that: 1) FY 2020 Medicare utilization is atypical; 2) FY 2019 Medicare utilization is likely to be more representative of FY2022 Medicare utilization; and 3) there would be an impact on the FY 2022 MS-DRG relative weights from using the anomalous FY 2020 utilization data rather than the more representative the FY 2019 utilization data. ***The FAH therefore supports CMS' proposal to use older pre-pandemic data to set the FY 2022 MS-DRG relative weights.***

CMS also proposes to use FY 2019 Medicare LTCH claims data from the March 2020 update of the FY 2019 for purposes of calculating the proposed MS-LTC-DRG for FY 2022. This proposal is consistent with the proposal to use pre-COVID-19 data for purposes of setting FY 2022 MS-DRG relative weights, and ***the FAH agrees with CMS' proposal to use pre-COVID-19 Medicare LTCH claims data to set the FY 2022 MS-LTC-DRG relative weights.***

Quality Measure Suppression for Hospital Pay for Performance Programs

In response to the COVID-19 PHE, CMS voices concern that, absent policy interventions, payments and penalties of its pay for performance (P4P) programs (including the Hospital Readmissions Reduction Program, Value Based Purchasing, and Hospital Acquired Condition Reduction Program) could be inequitable across hospitals, especially those treating large numbers of COVID-19 patients. CMS proposes a cross-program measure suppression policy and factors applicable to all three P4P programs along with separate proposals for scoring and payment adjustments tailored to each. ***The FAH supports the Measure Suppression Factors as proposed for application to all three hospital P4P programs.***

Additionally, CMS proposes to report performance results calculated using available data to hospitals and to continue public data reporting of performance results according to the previously established policies of each P4P program. The agency states that publicly reported information would be accompanied by an explanation of the source data limitations due to the COVID-19 PHE. ***The FAH agrees with reporting P4P performance results confidentially to hospitals, as the data, despite their flaws, could help hospitals assess the strengths and weaknesses of their responses to the PHE. However, the FAH disagrees with public reporting of the results from P4P programs in which measures have been suppressed.***

DRG Add-on Payments

In the Proposed Rule, CMS acknowledges that there might be inpatient cases of COVID-19 beyond the end of the PHE, for which payments based on the assigned MS-DRG may not adequately reflect the additional cost of new COVID-19 treatments. For this reason, CMS proposes to extend the NCTAP through the end of the fiscal year in which the PHE ends. ***The FAH supports the proposed extension of NCTAP through the end of the fiscal year in which the PHE ends because it limits unnecessary volatility in IPPS payments for COVID-19 admissions involving new COVID-19 treatments.*** The same rationale applies to the 20 percent add-on to inpatient treatment of patients diagnosed with COVID-19. The FAH therefore requests that CMS use its exceptions and adjustments authority under 42 U.S.C. § 1395ww(d)(5)(I) to adopt a parallel policy that continues the 20 percent increase in the MS-DRG weight for discharges of patients diagnosed with COVID-19 through the end of the fiscal year in which the COVID-19 emergency period ends.

Wage Index

The FAH strongly supports the indefinite continuation of the transition policy for FY 2021 that applies a 5 percent cap on any decrease in a hospital's wage index from the hospital's final wage index regardless of whether or not the hospital was adversely impacted by the updates in OMB Bulletin 18-04 or benefited from the 5 percent cap in FY 2022, and urges CMS to apply the transition policy in a non-budget neutral manner. The unprecedented and ongoing COVID-19 PHE has placed significant financial strain on hospitals, and a wage index transition policy helps to insulate hospitals from any additional financial volatility that would otherwise be produced by excessive wage index reductions.

In addition, the FAH supports CMS' efforts to address the use of rural reclassifications as a mechanism for statewide wage index manipulations. The wage index is designed to capture actual differences in relative hospital wage levels, and the coordinated use of rural reclassifications to manipulate the wage index on a statewide basis undermines the integrity of the wage index system. ***The FAH supports the proposed amendments to section 412.103(g), but requests that CMS limit the cancellation requirements in proposed section 412.103(g)(4) to the cancellation of rural reclassifications that are effective on or after October 1, 2020.***

Medicare Disproportionate Share Hospital Payments

The FAH urges CMS to reconsider the assumptions and methodology used to estimate Factor 1 of the Uncompensated Care Disproportionate Share Hospital (UC-DSH) calculation for FY 2022 ($10,573,368,841.28) in order to account for the skewing impact of FY 2020 and FY 2021 data. The COVID-19 PHE creates a significant complication for projecting Factor 1 because the PHE has altered utilization and other factors in drastic and unprecedented ways that are not indicative of expectations for FY 2022. The use of data for fiscal years heavily impacted by the COVID-19 PHE to update baseline data results in the understatement of Medicare DSH payments for FY 2022. With rising vaccination rates, declining COVID-19 infection rates, the elimination of stay-at-home orders, the resumption of elective procedures, and rising beneficiary confidence in infection control measures, the FAH expects that, when April 2021 and subsequent data become available, it will show a significant increase in discharges and that this increase will continue in FY 2022. In fact, according to a study by KaufmanHall, year-over-year discharges have increased 33.4% as of April 2021 and have only declined 0.4% year to date despite the decline in inpatient COVID-19 cases.[1] The data is even more striking with respect to adjusted discharges: year-to-date adjusted discharges were up 5.9%, year-over-year adjusted discharges were up 66.4% as of April 2021.

Closing the Gap on Health Inequities

The FAH offers its full commitment to working with CMS, HHS, and others on what must be a continuous and sustained effort to ensure health care equity nationwide. We commend CMS for undertaking and sharing its strategic thinking. We believe that reporting stratified by race and ethnicity in the Hospital Readmission and Reduction Program is a tangible goal that can set the stage for thoughtful expansion over time to other measures and other CMS quality programs. The FAH also believes that practical work can begin on improving data collection, particularly the foundational steps of data element definition, a complete environmental scan of collection already occurring in the field, and exploration of strategies for safeguarding privacy at every step.

We endorse the general principle that confidential reporting to hospitals should always precede public display of performance data, and that public reporting should not begin until sufficient time has elapsed to allow testing messaging, conducting focus groups, and other techniques to ensure public data are comprehensible to the intended audience. We also thank

[1] KaufmanHall, National Hospital Flash Report (May 2021), *at* https://www.kaufmanhall.com/sites/default/files/2021-05/may-2021-national-hospital-flash-report.pdf.

CMS for its stated commitment that specific program measures and policies will occur only through the rulemaking process. We look forward to joining CMS on the exciting journey to health equity.

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I.B.1 Understated Standardized Amount

The FAH is concerned that the Proposed Rule fails to consider whether the proposed FY 2022 standardized amount is understated due to errors in the calculation of the "allowable operating costs per discharge of inpatient hospital services for . . . the most recent cost reporting period for which data are available"[2] when first implementing the IPPS in 1983. Hospitals have argued that the 1981 data that was used to calculate average costs per discharge erroneously characterized transfers of patients from one hospital to another as patient discharges, thus overstating the number of discharges and understating the allowable operating costs, which are calculated on a "per discharge" basis.[3] Because the standardized amount determined in 1983 is used in determining the standardized amount in future fiscal years, any errors that caused the 1983 standardized amount to be understated would continue to cause the standardized amount to be understated in each subsequent fiscal year if the issue is not addressed by CMS.

The FAH, therefore, strongly urges CMS to ensure that any error in the initial calculation of the average costs per discharge in 1983 is rectified so that the FY 2022 standardized amount is not improperly understated. In addition, the FAH requests that CMS release the data used to calculate the average cost per discharge in 1983, along with any data used to determine an adjustment that prospectively eliminates the impact of any such error, in order to facilitate public comment.

II.C.3. FY 2022 MS-DRG Documentation and Coding Adjustment

CMS proposes making a permanent 0.5 percentage point positive adjustment to the standardized amount for FY 2022, following the 0.4588 percentage point adjustment in FY 2018 and its 0.5 percentage point adjustments in FYs 2019, 2020, and 2021, stating that these adjustments are consistent with section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"), which delays restoration of the one-time negative recoupment adjustments implemented under section 631 of the American Taxpayer Relief Act of 2012 ("ATRA"). The FAH continues to maintain, however, that CMS misinterpreted the relevant statutory authority, which explicitly assumes that the ATRA section 631 recoupment would result in an estimated 3.2 percent adjustment in FY 2017. Instead, CMS should have made an additional 0.7 percent positive adjustment to the standardized amount in FY 2018, and the FAH believes that the excess 0.7 percent ATRA adjustment has been improperly continued in FYs 2018, FY 2019, 2020, and 2021. Regardless of the correct interpretation of section 414 of MACRA, the FAH urges CMS—as it has previously—to exercise its discretion under 42 U.S.C.

[2] 42 U.S.C. §1395ww(d)(2)(A) (emphasis added).

[3] *See, e.g.*, *St. Francis Med. Ctr. v. Azar*, 894 F. 3d 290, 293 (D.C. Cir. 2018).

§ 1395ww(d)(5)(I) and apply a positive adjustment of 0.7 percentage points in addition to the 0.5 percentage point adjustment proposed. This 0.7 percent positive adjustment would not only stop the continuation of a recoupment adjustment that no longer serves any recoupment purpose, but it would help restore hospital IPPS rates at a time when hospitals are experiencing the significant, adverse financial impacts of the COVID-19 PHE.

PROPOSED CHANGES TO SPECIFIC MS-DRG CLASSIFICATIONS

The FAH acknowledges that CMS considered the impact of COVID-19 and the public health emergency (PHE) on the claims data submitted for rule making and the implications for MS-DRG classifications and rate setting for FY 2022.

For this Proposed Rule, CMS' MS-DRG analysis is based on claims data from the March 2020 update of the FY 2019 MedPAR file, which contains hospital bills received from October 1, 2018 through March 31, 2020, for discharges occurring through September 30, 2019. In addition, CMS noted they also analyzed ICD-10 claims data from the September 2020 update of the FY 2020 MedPAR file, which contains hospital bills received from October 1, 2019 through September 30, 2020, for discharges occurring through September 30, 2020. CMS referred to these claims data as the "March 2020 update of the FY 2019 MedPAR file" and "the September 2020 update of the FY 2020 MedPAR file" in terms of the proposed MS-DRG reclassification changes.

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 2022, except as indicated below.

II.D.1. Changes to Coding System and Basis for Proposed FY 2022 MS-DRG Updates

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 finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split.

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

In the analysis of the MS-DRG classification requests for FY 2022 that CMS received by November 1, 2020, as well as any additional analyses that were conducted in connection with those requests, CMS applied these criteria to each of the MCC, CC, and NonCC subgroups, as described in the below table included in Proposed Rule.

Criteria Number	Three-Way Split 123 (MCC vs CC vs NonCC)	Two-Way Split 1_23 MCC vs (CC+NonCC)	Two-Way Split 12_3 (MCC+CC) vs NonCC
1. At least 500 cases in the MCC/CC/NonCC group	500+ cases for MCC group; and 500+ cases for CC group; and 500+ cases for NonCC group	500+ cases for MCC group; and 500+ cases for (CC+NonCC) group	500+ cases for (MCC+CC) group; and 500+ cases for NonCC group
2. At least 5% of the patients are in the MCC/CC/NonCC group	5%+ cases for MCC group; and 5%+ cases for CC group; and 5%+ cases for NonCC group	5%+ cases for MCC group; and 5%+ cases for (CC+NonCC) group	5%+ cases for (MCC+CC) group; and 5%+ cases for NonCC group
3. There is at least a 20% difference in average cost between subgroups	20%+ difference in average cost between MCC group and CC group; and 20%+ difference in average cost between CC group and NonCC group	20%+ difference in average cost between MCC group and (CC+NonCC) group	20%+ difference in average cost between (MCC+ CC) group and NonCC group
4. There is at least a $2,000 difference in average cost between subgroups	$2,000+ difference in average cost between MCC group and CC group; and $2,000+ difference in average cost between CC group and NonCC group	$2,000+ difference in average cost between MCC group and (CC+ NonCC) group	$2,000+ difference in average cost between (MCC+ CC) group and NonCC group
5. The R2 of the split groups is greater than or equal to 3	R2 > 3.0 for the three way split within the base MS-DRG	R2 > 3.0 for the two way 1_23 split within the base MS-DRG	R2 > 3.0 for the two way 12_3 split within the base MS-DRG

CMS' analysis indicated that approximately 32 MS-DRGs would be subject to change based on the three-way severity level split criterion finalized in FY 2021. Specifically, CMS found that applying the NonCC subgroup criteria to all MS-DRGs currently split into three severity levels would result in the deletion of 96 MS-DRGs (32 MS-DRGs x 3 severity levels = 96) and the creation of 58 new MS-DRGs. These updates would also involve a redistribution of cases, which would impact the relative weights, as well as the payment rates proposed for particular types of cases.

In light of the COVID-19 PHE, CMS noted concerns about the impact of implementing this volume of MS-DRG changes at this time, indicating that it may be appropriate to delay application of the NonCC subgroup criteria to existing MS-DRGs in order to maintain more stability in the current MS-DRG structure.

As a result, CMS is proposing to delay the application of the NonCC subgroup criteria to existing MS-DRGs with a three-way severity level split until FY 2023, and proposing for FY 2022 to maintain the current structure of the 32 MSDRGs that currently have a three-way severity level split (total of 96 MS-DRGs) that would otherwise be subject to these criteria.

The FAH strongly agrees with CMS' proposal to delay the application of the NonCC subgroup criteria to existing MS-DRGs with a three-way level split and to maintain that current structure of these 32 MS-DRGs. In preparing for future consideration on this topic – the FAH respectfully requests the following:

- The FAH requests that CMS provide data transparency that illustrates volumes by MS-DRG that supports the proposal to reduce the 96 MS-DRGs, especially because there are some MS-DRGs that are moving to single tiers as per Table 6P.1c., *i.e.*:
  - 283-285 MI Expired
  - 411-413 Cholecystectomy with CDE

- 423-425 Other Hepatobiliary or Pancreas OR Procedure
- 783-785 C-Section with Sterilization
- 796-798 Vaginal Delivery with Sterilization and/or D&C
- 817-819 Other antepartum Disorders

- The FAH requests that there be additional consideration in light of the pandemic as this could impact the potential to have 500 cases in the NonCC subgroup/tier with increased severity of COVID-19 patient mix. We especially make note of this as CMS indicates in the Proposed Rule that a two-year time period of MedPAR data would be used and this would not be retroactive.

- The FAH requests that CMS provide data transparency for the new MS-DRGs proposed so that the weight impact is available for review for these reduced tiers.

- The FAH requests that CMS re-review and consider patient mix in terms of volumes, especially since the Medicare population would not have the volume/patient mix for some of the MS-DRGs such as Obstetrics, *i.e.*,
  - MS-DRGs with C-section without sterilization (MS-DRGs 786-788) will maintain the three tiers; however MS-DRGs with C-section with sterilization (MS-DRGs 783-785) will not maintain three tiers.
  - This is repeated with vaginal delivery as well (with sterilization MS-DRGS 796-798 vs. without MS-DRGs 805-807).

- The FAH requests that additional consideration be given to the distribution of the 96 revised MS-DRGs, which included 54 surgical and 42 medical MS-DRGs. The impact of this appears to be much higher in the surgical realm, which may result in more complex cases losing tiers.
  - The weight range for surgical MS-DRGs is 0.8273 to 10.4301.
  - The weight range for medical MSDRGs is 0.4964 to 6.0501.

II.D.2. Pre-MDC MS-DRG 018 Chimeric Antigen Receptor (CAR) T-cell Therapy

CMS is proposing to revise the title for MS-DRG Pre-MDC MS-DRG 018 "Chimeric Antigen Receptor (CAR) T-cell Immunotherapy" to "Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies"

In the FY 2021 IPPS/LTCH PPS final rule, CMS stated that if additional cellular therapies should become available, CMS would continue to use the established process to determine the MS-DRG assignment. This was in response to public comments expressing concern that Pre-MDC MS-DRG 018 is specific to one mechanistic approach to cellular therapy, and, for those who sought clarification on how future CAR T-cell and non-CAR T-cell therapy products would be assigned.

The commenters at that time also requested that CMS provide flexibility for future cellular therapies, as they are made available and not restrict Pre-MDC MS-DRG 018 to CAR T-cell therapies alone. The FAH acknowledges this concept and approach noted by the

commenters. However, as more CAR T-cell type therapies—including tumor-infiltrating lymphocytes (or TIL), Natural Killer (NK) Cell Therapy, AlloCAR T™ , etc.—become available through the FDA approval process, the FAH respectfully requ**ests** that CMS continue to assess the appropriateness of these therapies being grouped with MS-DRG 18 Chimeric Antigen Receptor (CAR)T-Cell Therapy. As the available data expands and technology advances in this area, the FAH also requests that consideration be made for the development of new MS-DRGs to further distinguish the differences in the clinical characteristics and resource consumption that may exist among these populations.

II.D.3.b MDC 03 (Diseases and Disorders of Ear, Nose and Throat) - Other Ear, Nose, Mouth and Throat O.R. Procedures

CMS received a request to reconsider the MS-DRG assignments for a list of 82 procedure codes from Table 6P.1d currently assigned to MS-DRGs 143, 144 and 145 (Other Ear, Nose, Mouth And Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) when reported in conjunction with a principal diagnosis code from MDC 03. CMS proposed to maintain the current structure for MS-DRGs 143, 144, and 145 for FY2022 for the 82 ICD-10-PCS procedure codes.

The FAH requests that CMS re-review the data within MS-DRGs 143-145 as it appears that the majority of the 82 procedure codes are not related to the principal diagnosis in MDC 03**.** The FAH requests transparency for the logic and data for the exclusion of these 82 procedure codes and anticipates CMS may not have any data for these procedures within the MS-DRGs 143-145 that were created in FY 2021. For example, while we understand that some of the procedures may be related to the evaluation or treatment of metastasis originating from conditions in MDC 03, it is unclear what clinical scenarios would result in the following procedure codes being assigned with a diagnosis in MDC 03:

- 02JA4ZZ Inspection of heart, percutaneous endoscopic approach;
- 02JY4ZZ Inspection of great vessel, percutaneous endoscopic approach;
- 06HY0DZ Insertion of intraluminal device into lower vein, open approach;
- 06HY3DZ Insertion of intraluminal device into lower vein, percutaneous approach; and/or
- 06HY4DZ Insertion of intraluminal device into lower vein, percutaneous endoscopic approach.

II.D.5.a MDC 05 (Diseases and Disorders of the Circulatory System) – short-term external heart assist device

CMS is proposing to reassign the three ICD-10-PCS codes used to describe short-term external heart assist devices placed intraoperatively and removed at the conclusion of the procedure from MS-DRG 215 to MS-DRGs 216, 217, 218, 219, 220 and 221. The three specific procedure codes are as follows:

- 02HA3RJ (Insertion of short-term external heart assist system into heart, intraoperative, percutaneous approach);

- 02HA0RJ (Insertion of short-term external heart assist system into heart, intraoperative, open approach); and
- 02HA4RJ (Insertion of short-term external heart assist system into heart, intraoperative, percutaneous endoscopic approach).

CMS reviewed claims from the March 2020 update of the FY 2019 MedPAR file and the Sept 2020 update of the FY 2020 MedPAR files to assess and compare average costs and average length of stay for MS-DRG 215 cases (in the aggregate and disaggregated based on the use of one of the three procedure codes with and without cardiac catherization with MCC, CC, and non MCC/CC) and MS-DRGs 216, 217 and 218. MS-DRGs 216 – 218 are defined by the presence of cardiac catheterization in addition to the cardiac valve/major cardiothoracic procedure. Of note, CMS expanded this analysis to include MS-DRGs 219, 220 and 221 to incorporate those procedures with cardiac valve/major cardiothoracic procedures without the presence of a cardiac catheterization.

MS_D	MDC	TYPE	DRG Description	V38Number of Discharge	Arithmetic Mean LO	Diff between V38 and V	Number of Discharg	Arithmetic Mean LOS
215	05	SURG	OTHER HEART ASSIST SYSTEM IMPLANT	7744	7.8357	-3335	4409	8.6387
216	05	SURG	CARDIAC VALVE AND OTHER MAJOR CARDIOTHORACIC PROCEDURES WITH CARDIAC CATH	5603	16.6652	1914	7517	14.7321
217	05	SURG	CARDIAC VALVE AND OTHER MAJOR CARDIOTHORACIC PROCEDURES WITH CARDIAC CATH	1885	9.531	725	2610	7.8774
218	05	SURG	CARDIAC VALVE AND OTHER MAJOR CARDIOTHORACIC PROCEDURES WITH CARDIAC CATH	210	6.6143	269	479	4.2443
219	05	SURG	CARDIAC VALVE AND OTHER MAJOR CARDIOTHORACIC PROCEDURES WITHOUT CARDIAC C	15599	10.8972	211	15810	10.8505
220	05	SURG	CARDIAC VALVE AND OTHER MAJOR CARDIOTHORACIC PROCEDURES WITHOUT CARDIAC C	15078	6.5289	149	15227	6.4868
221	05	SURG	CARDIAC VALVE AND OTHER MAJOR CARDIOTHORACIC PROCEDURES WITHOUT CARDIAC C	2419	4.4903	67	2486	4.4075

CMS clinical advisors indicated that, based on their review of the clinical issues and claims data, cases reporting a procedure code describing intra-operative insertion of short-term external heart assist devices are generally less resource intensive and are clinically distinct from other cases describing the insertion of other types of heart assist devices currently assigned to MS-DRG 215.

The FAH agrees that the claims data analysis supports cases with intra-operative insertion of short-term external heart assist devices are generally less resource intensive and should be moved from MS-DRG 215.

Based on the below analysis from data in Table 7A, to illustrate percent change, the majority of these cases (87%) are moving to MS-DRGs 216-218 with this proposal. In cases where a cardiac catheterization is not performed, MS-DRGs 219-221, while Impella procedures are intra-cardiac heart assist devices that also typically involve the use of diagnostic catheters, fluoroscopy, and hemodynamic monitoring similar to resources that are utilized during a cardiac catheterization, we understand that this may be a case where MS-DRGs 216-221 still remain the best clinically aligned options. The FAH requests re-consideration of MS-DRGs 219-221 in light of the fact that the volume of change with the current and proposed grouper is small within those MS-DRGs (427 accounts) as well as a review of the weights for MS-DRG 219-221 to ensure they reflect the external heart assist device.

Table 7	ent System Selected Percentile Lengths of Stay; FY 2019 20 — Grouper V39 MS-DRGs - Proposed Rule															
MS_DRG	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile	Cases 38 Grouper	Change	2022 Weights	2021 Weights	% Chg in Weights	2022 Weighted Cases	2021 Weighted Cases	Abs Change		Cases Moving 215 to 221	
215	1	2	6	12	20	7,744	(3,335)	10.5614	11.1579	-5.3%	46,565	81,787	3,335			
216	5	8	13	19	27	5,603	1,914	10.0426	10.4301	-3.7%	75,490	56,269	1,914	25%		
217	2	5	7	10	14	1,885	725	6.4853	6.4928	-0.1%	16,927	12,225	725	20%		
218	1	1	4	6	9	210	269	6.1165	5.1432	18.9%	2,930	1,284	269	33%	2,908	87%
219	4	6	9	13	20	15,599	211	8.0591	8.0551	0.0%	127,414	125,714	211			
220	4	5	6	8	10	15,078	149	5.4068	5.3999	0.1%	82,329	81,524	149			
221	1	3	4	6	7	2,419	67	4.5823	4.5523	0.7%	11,392	11,085	67		427	13%

Additionally, recognizing that MS-DRG 215 has had significant revisions for the last four fiscal years, the FAH respectfully requests that CMS consider (1) re-evaluating the data once the MedPAR data is normalized from the COVID-19 PHE and (2) assessing this normalized, post-pandemic claims data to consider structure revisions for these MS-DRGs (*e.g.*, intra-operative only vs. maintain device instead of heart catheterization, etc.).

II.D.5.b MDC 05 (Diseases and Disorders of the Circulatory System) - Type II Myocardial Infarction

CMS received a request to review the MS-DRG assignment of ICD-10-CM diagnosis code I21.A1 (Myocardial infarction type 2). During the review that CMS completed, it was noted that code I21.A1 (Myocardial infarction type 2) is currently one of the listed principal diagnoses in the GROUPER logic for MS-DRGs 222 and 223 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI, HF or Shock with and without MCC, respectively). However, code I21.A1 is not currently recognized in these same MS-DRGs when coded as a secondary diagnosis. As a result, when coded as a secondary diagnosis in combination with a principal diagnosis in MDC 05, MS-DRGs 224 and 225 (Cardiac Defibrillator Implant with Cardiac Catheterization without AMI, HF, or Shock with and without MCC, respectively) are instead assigned when reported with a listed procedure code.

Acknowledging that coding guidelines instruct to code I21.A1 after the diagnosis code that describes the underlying cause, the CMS clinical advisors recommended adding special logic in MS-DRGs 222 and 223 to have code I21.A1 also qualify when coded as a secondary diagnosis in combination with a principal diagnosis in MDC 05 since these diagnosis code combinations also describe acute myocardial infarctions.

As a result, CMS is proposing modifications to the GROUPER logic to allow cases reporting diagnosis code I21.A1 (Myocardial infarction type 2) as a secondary diagnosis to group to MS-DRGs 222 and 223 when reported with a listed procedure code for clinical consistency with the other MS-DRGs describing acute myocardial infarction.

This logic change, however, will make the code not act as a MCC (excluded), but the Proposed Rule does not provide a rationale for the resulting exclusion. The FAH requests that data be provided on when this code would not act as a MCC. Of note, MS-DRG 224 was provided as an example in the Proposed Rule. However, the FAH would like to also make note that this MCC designation would not go away for other MS-DRGs like it would for MS-DRG 224.

II.D.11.a - Operating Room (O.R.) and Non-O.R. Issues – Background

The Proposed Rule outlined the process for evaluating requests pertaining to changes in O.R. and non-O.R. designations. Specifically, for each procedure, the CMS clinical advisors considered for FY 2022:

- Whether the procedure would typically require the resources of an operating room;
- Whether it is an extensive or a non-extensive procedure; and
- To which MS-DRGs the procedure should be assigned.

II.D.11.b. (1) O.R. Procedures to Non-O.R. Procedures - Open Drainage of Subcutaneous Tissue and Fascia

CMS is proposing to remove 22 ICD-10-PCS codes from O.R. designation status due to the clinical advisors concluding that these procedures do not typically require an operating room and are not surgical in nature. All of these procedure codes describe an "open approach" drainage of the subcutaneous tissue and fascia specific to anatomical sites, including but not limited to, chest, (Drainage of chest subcutaneous tissue and fascia, open approach); abdomen (Drainage of abdomen subcutaneous tissue and fascia, open approach) and perineum (Drainage of perineum subcutaneous tissue and fascia, open approach, pelvic sites).

The FAH acknowledges that these 22 ICD-10-PCS codes all describe an open approach for drainage. Although there may be certain circumstances in which these procedures do not require an operating room, these procedures are not consistently conducive to being performed at bedside and may therefore typically require an operating room. The FAH strongly encourages CMS to reconsider these 22 ICD-10-PCS procedure codes and maintain the current O.R. designation status.

II.D.11.c. (16) Non-O.R. Procedures to O.R. Procedures - Endoscopic Fragmentation and Extirpation of Matter of Urinary Tract

CMS proposes to maintain 2 of the ICD-10-PCS codes that describe endoscopic extirpation from a urinary body part as non-O.R. procedures (0TCB8ZZ, 0TCC8ZZ). Additionally, the CMS clinical advisors are proposing to move 6 ICD-10-PCS codes from O.R. to non-O.R. procedures that are similar and "not surgical in nature" that also describe endoscopic extirpation from a urinary body part. These six codes include 0TC08ZZ, 0TC18ZZ, 0TC38ZZ, 0TC48ZZ, 0TC68ZZ and 0TC78ZZ)

The FAH acknowledges that the extirpation of matter is within various urinary tract locations. CMS clinical advisors noted the removal of the O.R. designation on these codes as they considered these "not surgical in nature." The extirpation of matter of these urinary tract locations such as ureter, kidney, etc. would require the use of an operating room as they would not be performed at bedside. The FAH strongly encourages CMS to reconsider these 8 procedures codes and maintain the current O.R. designation for the six codes and revise the two codes from Non-O.R. to O.R. procedure codes.

II.D.12.c Proposed Changes to the MS-DRG Diagnosis Codes for FY 2022 – Potential Change to Severity Level Designation for Unspecified Diagnosis Codes for FY 2022:

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

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

The Proposed Rule notes CMS' continued work to address the comprehensive review of the severity designations of ICD-10-CM diagnosis codes over the past two years. CMS stated in the Proposed Rule that the goal of the comprehensive analysis is to create stratification for reimbursing inpatient hospitalization in the fewest amount of categories with the most explanatory power in a clinically cohesive way and that CMS believes more robust claims data would facilitate this effort to determine the impact on resource use and inform the decision-making in determining the most appropriate CC subclass (NonCC, CC, or MCC) assignment for each diagnosis as a secondary diagnosis.

The Proposed Rule includes a table showing the total number of ICD-10-CM codes impacted by the proposal within each ICD-10-CM Chapter and the resulting percent change in the number of codes. The FAH requests that CMS provide transparency with this table on the distribution of volume within these codes for a better representation of the impact. For example, this table indicates that only 4% of the neoplasm codes would be impacted under the proposal; however, when reviewing the distribution of cases it appears that neoplasms were actually heavily impacted with the highest volume of cases, especially with neoplasm of the lung, ovary, kidney that were assigned as secondary diagnoses and missing the laterality designation. When reviewing the data provided by CMS with volumes within the top 10 codes sorted by highest volume, neoplasm codes are 5 of the top 10, with the first four being the highest of all codes using the FY 2019 MedPAR data case counts as follows: C3490 (59,359 cases), C7800 (44,609 cases), C569 (12,257 cases), C649 (8,906 cases), and C7970 (5,124 cases).

The FAH acknowledges that the proposal to change to the severity level designations for these "unspecified" ICD-10-CM diagnosis codes involves 3,490 diagnosis codes. All of the impacted diagnosis codes appear to be mostly attributed to laterality rather than further specificity of anatomical site.

The FAH supports encouraging overall documentation that provides the most concise level of specificity resulting in the accurate and complete capture of diagnosis code assignment

and claim capture. The FAH generally supports the concept of CMS' 9 guiding principles which are referenced for consideration in determining the MCC or CC designation. However, laterality is not part of the current 9 guiding principles for what would be considered for MCC or CC designation. The FAH requests that CMS provide insight pertaining to how the laterality of the condition impacts the severity of the diagnosis, especially with internal locations not visible to the eye. The condition/diagnosis itself is still being addressed and treated as applicable.

The following scenarios and considerations highlight issues relating to the laterality of the condition and the severity of diagnosis:

- A lung cancer patient is referred to an infectious disease consulting physician and admitted for sepsis. It is unclear how the laterality of the lung cancer would impact clinical evaluation, therapeutic treatment, diagnostic procedures, extended LOS, increased nursing care and/or monitoring. The fact that the diagnosis/condition itself exists impacts the clinical evaluation and therapeutic treatment, etc. even without the consideration of laterality as the same severity of illness exists without performing an unnecessary x-ray to determine laterality.

- A patient that is admitted for surgery with deep vein thrombosis (DVT) maintained on Eliquis® that is being monitored is still going to obtain the same medication for the DVT regardless of the laterality.

- Patients may not be able to provide laterality context in circumstances where a higher occurrence of dementia or altered mental status exists, especially when obtaining the patient's history.

- Coding guidelines provide direction as to when any provider vs. only the physician can provide the source documentation for ICD-10 code assignment. It is important to consider that revisions to guidelines, where applicable, could impact ability to allow for other provider documentation to support code laterality specificity.

The FAH recommends that CMS re-consider and delay the change of the MCC/CC designation for the 3,490 ICD-10-CM diagnosis codes described in Table 6P.2a. At a minimum, the FAH disagrees with removing the MCC/CC designation of any laterality of an anatomical site that is internal to the body and cannot be visualized externally. This would include all of the codes involving condition of internal organs, vessels or body parts (e.g. neoplasm, DVT, etc.) This is mainly due to consideration of the current 9 guiding principles where this is not listed as a factor in determining MCC or CC designation. And, while laterality is important in terms of data capture, it is not typically crucial to clinical evaluation, therapeutic treatment, and severity of illness of each case – the diagnosis/condition itself is still addressed regardless.

II.D.14.e Proposed Changes to the Medicare Code Editor (MCE) – Unspecified Codes

CMS is requesting comment on the potential creation of a new MCE edit involving "unspecified" codes. This is in conjunction with the proposal to change severity level

designations for "unspecified" ICD-10-CM diagnosis codes for FY 2022 as outlined in section II.D.12.c. of the Proposed Rule.

As stated previously, the FAH supports advocating for overall documentation that provides the most concise level of specificity resulting in the accurate and complete capture of diagnosis code assignment and claim capture. Conversely, the FAH strongly urges CMS to reconsider and delay the change of the MCC/CC designation for the 3,490 ICD-10-CM diagnosis codes described in Table 6P.2a.

As far as a new MCE edit to address "unspecified" codes, this effort could be appropriate if, for example, it were based on a phased in approach of "unspecified" codes rather than all of these "unspecified" codes at one time. This may assist hospital teams with documentation improvement initiatives and could better prepare teams to adapt to potential operational challenges in addressing these edits industry wide.

II.D.15. Proposed Changes to Surgical Hierarchies

CMS is proposing revisions to the surgical hierarchy for MDC 05 Diseases and Disorders of the Circulatory System. Specifically, CMS is proposing to sequence:

- MS-DRGs 231-236 above MS-DRGs 222-227 and below MS-DRGs 216-221
- MS-DRGs 222-227 above MS-DRGs 266-227 and below MS-DRGs 231-236
- MS-DRGs 266-267 above MS-DRGs 268-269 and below MS-DRGs 222-227
- MS-DRGs 228-229 above MS-DRGs 319-320 and below MS-DRGs 268-269

The FAH acknowledges the decision rule (*i.e.*, the surgical hierarchy that resides within the GROUPER to address inpatient stays that entail multiple surgical procedures). The application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS-DRG associated with the most resource-intensive surgical class in which the hierarchy is based on ensuring the higher weighted MS-DRGs are within the hierarchy.

The FAH would like to call attention to the wide range within the (CABG) Coronary Bypass MS-DRGs 231-236 which is a unique MS-DRG grouping for Bypass procedures in conjunction with other procedures specifically with PCI (231-232), cardiac catheterization (233-234) and without cardiac catheterization (235-236).

Table 7A - Medicare Prospective Payment System Selected Percentile Lengths of Stay; FY 2019 MedPAR Update March 2020 — Grouper V39 MS-DRGs - Proposed Rule							
MS_DRG	Number of Discharges	Arithmetic Mean LOS	10th Percentile	25th Percentile	50th Percentile	75th Percentile	90th Percentile
215	4409	8.6387	1	2	6	12	20
216	7517	14.7321	5	8	13	19	27
217	2610	7.8774	2	5	7	10	14
218	479	4.2443	1	1	4	6	9
219	15810	10.8505	4	6	9	13	20
220	15227	6.4868	4	5	6	8	10
221	2486	4.4075	1	3	4	6	7
222	2081	10.6372	4	6	9	13	19
223	404	5.646	2	3	5	7	10
224	2119	9.3346	3	5	8	12	18
225	1629	4.8717	2	3	4	6	8
226	5317	7.8384	2	4	6	10	15
227	4202	3.8755	1	2	3	5	7
228	2747	9.5519	3	4	7	12	19
229	3515	4.0464	1	2	3	5	8
231	1060	12.5321	6	8	11	15	21
232	720	8.5292	4.5	6	8	10	13
233	13060	12.859	7	9	11	15	21
234	14510	8.7236	5	6	8	10	13
235	12482	9.9023	5	6	8	12	17
236	20895	6.4691	4	5	6	7	10
239	9939	13.1741	4	7	11	16	24
240	7800	8.5785	3	5	7	11	15

The majority of the cases fall in the "without cardiac catheterization" range for CABG MS-DRGs which would be MS-DRGs 235-236, as illustrated in CMS tables 7A referenced above.

Therefore, it is probable that if CABG was considered before the defibrillator, this would not account for the higher cost of the defibrillators.

Therefore, after reviewing the CMS data the FAH agrees with all of the resequencing proposed by CMS with the exception of MS-DRGs 231-236. The FAH requests that CMS reconsider that Cardiac Defibrillator MS-DRGs (222-227) be higher than CABG MS-DRGs (231-236).

In other words:

- CMS is proposing the following surgical MS-DRG hierarchy: 215, 216-221, 231-236, 222-227, 266-267, 268-9, 228-9, 319-320.
- The FAH is requesting consideration for the following surgical MS-DRG hierarchy: 215, 216-221, 222-227, 231-236, 266-267, 268-9, 228-9, 319-320.

The following excerpt from Table 5 of the Proposed Rule shows all the above noted MS-DRGs:

TABLE 5.—LIST OF MEDICARE SEVERITY DIAGNOSIS-RELATED GROUPS (MS-DRGS), RELATIVE WEIGHTING FACTORS, AND GEOMETRIC AND ARITHMETIC MEAN LENGTH OF STAY—FY 2022 Proposed Rule						
MS-DRG	MDC	TYPE	MS-DRG Title	Weights	Geometric mean LOS	Arithmetic mean LOS
219	05	SURG	CARDIAC VALVE AND OTHER MAJOR CARDIOTHORACIC PROCEDURES WI	8.0591	8.9	10.9
220	05	SURG	CARDIAC VALVE AND OTHER MAJOR CARDIOTHORACIC PROCEDURES WI	5.4068	5.9	6.5
221	05	SURG	CARDIAC VALVE AND OTHER MAJOR CARDIOTHORACIC PROCEDURES WI	4.5823	3.8	4.4
222	05	SURG	CARDIAC DEFIBRILLATOR IMPLANT WITH CARDIAC CATHETERIZATION WI	7.9546	8.8	10.6
223	05	SURG	CARDIAC DEFIBRILLATOR IMPLANT WITH CARDIAC CATHETERIZATION WI	5.8025	4.7	5.6
224	05	SURG	CARDIAC DEFIBRILLATOR IMPLANT WITH CARDIAC CATHETERIZATION WI	7.5198	7.6	9.3
225	05	SURG	CARDIAC DEFIBRILLATOR IMPLANT WITH CARDIAC CATHETERIZATION WI	5.6203	4.2	4.9
226	05	SURG	CARDIAC DEFIBRILLATOR IMPLANT WITHOUT CARDIAC CATHETERIZATIO	6.5664	6.1	7.8
227	05	SURG	CARDIAC DEFIBRILLATOR IMPLANT WITHOUT CARDIAC CATHETERIZATIO	5.2140	3.0	3.9
228	05	SURG	OTHER CARDIOTHORACIC PROCEDURES WITH MCC	5.3326	7.0	9.6
229	05	SURG	OTHER CARDIOTHORACIC PROCEDURES WITHOUT MCC	3.4422	3.0	4.0
231	05	SURG	CORONARY BYPASS WITH PTCA WITH MCC	8.7192	10.8	12.5
232	05	SURG	CORONARY BYPASS WITH PTCA WITHOUT MCC	5.9538	7.7	8.5
233	05	SURG	CORONARY BYPASS WITH CARDIAC CATHETERIZATION WITH MCC	7.9389	11.5	12.9
234	05	SURG	CORONARY BYPASS WITH CARDIAC CATHETERIZATION WITHOUT MCC	5.3596	8.2	8.7
235	05	SURG	CORONARY BYPASS WITHOUT CARDIAC CATHETERIZATION WITH MCC	6.1743	8.6	9.9
236	05	SURG	CORONARY BYPASS WITHOUT CARDIAC CATHETERIZATION WITHOUT MC	4.1286	6.0	6.5
266	05	SURG	ENDOVASCULAR CARDIAC VALVE REPLACEMENT AND SUPPLEMENT PRO	7.0489	3.2	5.2
267	05	SURG	ENDOVASCULAR CARDIAC VALVE REPLACEMENT AND SUPPLEMENT PRO	5.6003	1.7	2.1
268	05	SURG	AORTIC AND HEART ASSIST PROCEDURES EXCEPT PULSATION BALLOON V	6.9654	6.3	9.3
269	05	SURG	AORTIC AND HEART ASSIST PROCEDURES EXCEPT PULSATION BALLOON V	4.3177	1.6	2.2
319	05	SURG	OTHER ENDOVASCULAR CARDIAC VALVE PROCEDURES WITH MCC	4.3169	7.7	10.0
320	05	SURG	OTHER ENDOVASCULAR CARDIAC VALVE PROCEDURES WITHOUT MCC	2.4053	2.4	3.5

II.D.16. Maintenance of the ICD-10-CM and ICD-10-PCS Coding Systems

The Proposed Rule notes that the ICD-10 Coordination and Maintenance Committee addresses updates to the ICD-10-CM and ICD-10-PCS coding systems. This Committee is a Federal interdepartmental committee co-chaired by the Centers of Disease Control and Prevention's National Center for Health Statistics and is responsible for approving coding changes, and developing errata, addenda and other modifications to the coding systems to reflect newly developed procedures and technologies and newly identified diseases.

At the March 9-10, 2021 ICD-10 Coordination and Maintenance Committee meeting, CMS announced its consideration of an April 1 implementation date for ICD-10-CM diagnosis and ICD-10-PCS procedure codes. This April 1 code update would be in addition to the existing April 1 update under 42 U.S.C. § 1395ww(d)(5)(k)(vii) for diagnosis or procedure code revisions needed. CMS explained this additional April 1 implementation date for new codes would allow for earlier recognition of diagnoses, conditions, and illnesses as well as procedures, services, and treatments in the claims data noting this a beneficial for reporting, data collection, tracking clinical outcomes, claims processing, surveillance, research, policy decisions and data interoperability. CMS noted that if the new April 1 implementation date is adopted, they would assign the codes approved for an April 1 update to an MS-DRG using their established process for Grouper assignments for new diagnosis and procedure codes. "Specifically, consistent with our established process for assigning a new diagnosis and procedure codes, we would review the predecessor code and MS-DRG assignment most closely associated with the new diagnosis or procedure code, and in the absence of claims data, we would consider other factors that may be relevant to the MS-DRG assignment, including the severity of illness, treatment difficulty,

complexity of service and the resources utilized in the diagnosis and/or treatment of the condition."

The FAH supports timely maintenance of the ICD-10-CM and ICD-10-PCS code updates including the potential of an additional April 1 update to the code set with caution due to the operational impact with contracting, systems, providers, etc. The FAH does not support the potential to update a grouper without a comment period. The FAH requests transparency as to how two unique code sets for reporting in a single fiscal year could be implemented to minimize MS-DRG shifts that impact data analysis for determination of future rule impact.

GROUPER updates currently involve extensive regulatory and billing processes that require a minimum of three months to test, analyze, educate and implement code updates. The system updates are complex as there are limits as to how many versions of GROUPERS that can be maintained and mapped. The current GROUPER allows for a comment period prior to implementation in October of the new GROUPER and it is important to note that revisions are made from the proposed and final GROUPER considerations especially for totally new codes. For example, in FY2021, the comment period was important to allow CMS to consider provider feedback on the proposed MCC/CC designations for new ICD-10-CM codes which also provided specificity for the grades of Cytokine Release Syndrome which were all proposed to be NonCC severity level. After review of the comments, the codes for Grades 3, 4, 5 (D89.833, D89.834, D89.835) were revised by CMS to a CC Severity Level.

The ICD-10-CM and ICD-10-PCS code sets are not limited to the use of CMS providers as all providers utilize the ICD-10 codes and may not be able to turnaround code updates as quickly as CMS. The code set is used to update computer systems, contracts, reimbursement systems not limited only to MS-DRGs. There are providers currently that do not incorporate the annual update timely, so it is important for systems to be able to adapt to the version of the code set in place for the provider.

I.F. & II.E. Recalibration of the FY 2022 MS-DRG Relative Weights; and VIII.A.4 & VIII.B.3. Development of the Proposed FY 2022 MS-LTC-DRG Relative Weights

Under 42 U.S.C. § 1395ww(d)(4)(C)(i), CMS is required to make annual adjustments to the MS-DRG classification and relative weights to reflect changes in treatment patterns, technology and other factors which may change the relative use of hospital resources. The Proposed Rule indicates that CMS ordinarily uses the latest updates to the electronic claims database (MedPAR) and Medicare Hospital Cost Report Information System (HCRIS) to determine MS-DRG relative weights for the following fiscal year. However, the latest MedPAR and HCRIS files for FY 2022 would be from FY 2020 (MedPAR) and FY 2019 (HCRIS) and the data in these files would span the period of the COVID-19 public health emergency (PHE) that has existed in the United States since January 27, 2020.

CMS indicates in the Proposed Rule that the FY 2020 MedPAR claims file and the FY 2019 HCRIS dataset both contain data significantly impacted by the COVID-19 PHE; the utilization of inpatient services was generally markedly different for certain types of services in FY 2020 than would have been expected in the absence of the PHE. There are a number of

reasons why these data may be atypical, including guidance from the Department of Health and Human Services advising hospitals to delay or cancel elective procedures and the presence of an extraordinarily high number of respiratory cases being treated with mechanical ventilation.

Given the atypical utilization of inpatient hospital services in FY 2020, CMS hypothesized that FY 2019 utilization may be a better approximation of Medicare utilization in FY 2022 for use in determining the MS-DRG relative weights. While FY 2020 utilization may be atypical, CMS first explored whether trends in the data from FY 2020 would continue into FY 2021 and FY 2022 (e.g., while the utilization from FY 2020 may be atypical relative to FY 2019 and earlier years, if the FY 2020 trends continue into FY 2021 and FY 2022, it still may be representative of FY 2022 utilization). CMS then focused on why FY 2022 is likely to be more similar FY 2019 prior to the PHE than FY 2020 when COVID-19 cases were spreading rapidly, hospitals were treating high numbers of respiratory cases, and COVID-19 vaccinations were not available.

The Proposed Rule notes that vaccines for treating COVID-19 first became available in the United States on December 14, 2020. As of April 15, 2021, CMS indicates that 80 percent of Medicare aged beneficiaries have received at least one dose of vaccine and 63.7 percent are fully vaccinated. CMS further indicates that the continuing rapid increase in vaccinations coupled with the overall effectiveness of the vaccines calls into question the applicability of inpatient data from FY 2020 to the FY 2022 time period. The FAH believes these trends have been continuing since April 15, 2021 and agrees that Medicare utilization will likely be returning to prior patterns in FY 2022. **The FAH agrees with CMS' conclusion that FY 2022 Medicare utilization is likely to be more similar to FY 2019 than FY 2020 utilization**.

CMS indicates atypical utilization on its own is not a sufficient reason to use FY 2019 in place of FY 2020 data to set the MS-DRG relative weights. CMS indicates that the atypical utilization would also need to impact the relative weight determination compared to its traditional practice of using the latest available data. The Proposed Rule presents a complex analysis showing that there is a differential impact on case mix from using the FY 2020 utilization compared to the FY 2019 utilization to determine the relative weights. The FAH agrees with CMS' analysis. As CMS' analysis demonstrates: 1) FY 2020 Medicare utilization is atypical; 2) FY 2019 Medicare utilization is likely to be more representative of FY 2022 Medicare utilization; and 3) there would be an impact on the FY 2022 MS-DRG relative weights from using the anomalous FY 2020 utilization data rather than the more representative the FY 2019 utilization data. **The FAH therefore supports CMS' proposal to use older pre-pandemic data to set the FY 2022 MS-DRG relative weights**.

CMS also proposes to use FY 2019 Medicare LTCH claims data from the March 2020 update of the FY 2019 for purposes of calculating the proposed MS-LTC-DRG for FY 2022. This proposal is consistent with the proposal to use pre-COVID-19 data for purposes of setting FY 2022 MS-DRG relative weights, and **the FAH agrees with CMS' proposal to use pre-COVID-19 Medicare LTCH claims data to set the FY 2022 MS-LTC-DRG relative weights.**

Additionally, CMS' traditional practice would be to apply a "normalization" factor (a budget neutrality adjustment) to ensure that the average case weight for the payment year (FY

2022) is equal to the average case weight from the base year (FY 2021) using a single year of utilization. This normalization factor is applied so that the revised relative weights for FY 2022 do not increase or decrease payments compared to the FY 2021 relative weights. CMS' analysis in the Proposed Rule (86 FR 25088) indicates that it has observed an increase in real case mix that averages 0.5 percent annually (and is estimated to be 3.0 percent for FY 2020 as a result of COVID-19 effect).

By using FY 2019 utilization in place of FY 2020 data, the base year weights (FY 2021) will not reflect any changes in case mix that would occur from using FY 2020 compared to FY 2019 utilization. Thus, CMS will be making the payment year weights (FY 2022) budget neutral to a base year that does not reflect any change in real case mix as would normally occur. If CMS were to duplicate this policy for FY 2023, absent any intervention, CMS would be applying a normalization factor that does not allow for any real changes in case mix for two years.

If CMS were then to return to its normal practice of using the latest available utilization data (FY 2022 utilization for FY 2024), CMS would then be normalizing the relative weights to a base that reflects a 3-year change in real case mix (FY 2019 through FY 2022). The FAH requests that CMS consider whether to reflect an adjustment to the base year average case weight for an increase in case mix between FY 2019 and FY 2020 that would occur if CMS were to follow its normal practice (*i.e.*, normalize to a base year average case weight that is increased by 0.5 percent for CMS' assumption of the average real increase in annual case mix).

II.F.4 - Proposed FY 2021 Status of Technologies Approved for FY 2020 Add-On Payments

There were 23 add-on payment categories approved for FY 2021 that were previously discussed in the FY 2020 proposed rule. The FAH agrees with CMS' proposal on the continuation of all the add-on payments based on the anniversary date of the product's entry.

II.F.5. Proposed FY 2022 Applications for New Technology Add-On Payments (Traditional Pathway)

The FAH provides specific comments on the following FY 2022 applications for New Technology Add-On Payments:

- The FAH agrees and supports CMS in that II.F.5.c Breyanzi® (lisocabtagene maraleucel) needs additional data and comment to illustrate support that cost, clinical improvement and newness criterion to support NTAP status. Specifically, the FAH does not believe that this is significantly different from the current two FDA approved CAR T-cell products, YESCARTA® and KYMRIAH® for the treatment of Diffuse Large B-cell lymphoma (DLBCL). There have not been any head-to-head clinical trials performed to support the request from Bristol-Myers Squibb Company.
- The FAH requests that CMS re-review the ICD-10-PCS codes cited in the Proposed Rule to identify lisocabtagene maraleucel.
    - XW033N7 (Introduction of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7) and
    - XW043N7 (Introduction of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 7)

    - The above noted codes are inconsistent with the ICD-10-PCS codes and narrative descriptions provided for use to identify these procedures and that are currently assigned to MS-DRG 18
        - XW23376 (transfusion of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 6)
        - XW24376 (transfusion of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 6)
- The FAH agrees and supports CMS in that II.F.5.r Tecartus™ (brexucabtagene autoleucel) needs additional data and comment to illustrate support that this meets the cost, clinical improvement and newness criterion to support NTAP status.
- The FAH disagrees with CMS that II.F.5.d Ciltacabtagene autoleucel would not be considered "new" for purposes of new technology add-on payment. The FAH supports that this product is different from the currently FDA approved products to treat Multiple Myeloma. If this product receives FDA approval prior to July 1, 2021**,** the FAH supports Ciltacabtagene autoleucel receiving NTAP status.
- The FAH disagrees with CMS that II.F.5.h ABECMA® (idecabtagene vicleucel) would not be considered "new" for purposes of new technology add-on payment. The FAH supports that this product is different from the currently approved products treating patients with Multiple Myeloma and therefore supports that ABECMA® (idecabtagene vicleucel) receive NTAP status.

II.F.8. Proposal to Extend NCTAP Through the End of the FY in Which the PHE Ends and Extension of 20 Percent Increase in Payment for Treating COVID-19 Cases

For discharges occurring during the COVID-19 PHE, section 3710 of the Coronavirus Aid, Relief and Economic Security Act requires the Secretary to increase the final IPPS payment by 20 percent for patients diagnosed with COVID-19. Additionally, CMS established the New COVID-19 Treatment Add-on Payments (NCTAP) under the IPPS for COVID-19 cases meeting certain requirements—generally those cases treated with innovative new drug and biological products approved for emergency use or approved to treat COVID-19 (85 FR 71155).

Effective for discharges occurring on or after November 2, 2020 and until the end of the PHE, CMS established the NCTAP to pay hospitals the lesser of (1) 65 percent of the operating outlier threshold for the claim or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment, for certain cases that include the use of a drug or biological product currently authorized for emergency use or approved for treating COVID-19 (85 FR 71142, 71155).

In the Proposed Rule, CMS acknowledges that there might be inpatient cases of COVID-19 beyond the end of the PHE, for which payments based on the assigned MS-DRG may not adequately reflect the additional cost of new COVID-19 treatments. For this reason, CMS proposes to extend the NCTAP through the end of the fiscal year in which the PHE ends. ***The FAH supports the proposed extension of NCTAP through the end of the fiscal year in which the PHE ends because it limits unnecessary volatility in IPPS payments for COVID-19 admissions involving new COVID-19 treatments.***

CMS' rationale for extending NCTAP through the end of the fiscal year in which the PHE ends also applies to the 20 percent add-on to inpatient treatment of patients diagnosed with COVID-19. The FAH therefore requests that CMS use its exceptions and adjustments authority under 42 U.S.C. § 1395ww(d)(5)(I) to adopt a parallel policy that continues the 20 percent increase in the MS-DRG weight for discharges of patients diagnosed with COVID-19 through the end of the fiscal year in which the COVID-19 emergency period ends.

WAGE INDEX

III.A.2. Proposed Transition for Hospitals Negatively Impacted

The FAH strongly supports the indefinite continuation of the transition policy for FY 2021 that applies a 5 percent cap on any decrease in a hospital's wage index from the hospital's final wage index and urges CMS to apply the transition policy in a non-budget neutral manner. The unprecedented and ongoing COVID-19 PHE has placed significant financial strain on hospitals, and a wage index transition policy helps to insulate hospitals from any additional financial volatility that would otherwise be produced by excessive wage index reductions. Consistent with the objective of reducing volatility in IPPS payments, the FAH urges CMS to adopt a transition policy that caps reductions to wage index values relative to values in the immediately preceding fiscal year at 5 percent, regardless of whether or not the hospital was adversely impacted by the updates in OMB Bulletin 18-04 or benefited from the 5 percent cap in FY 2021.

This transition policy should be continued indefinitely to reduce volatility for the duration of the PHE and during fiscal years where wage index data may be impacted by the PHE and/or the incorporation of data from the 2020 decennial census. Despite optimism concerning the outlook for the COVID-19 PHE, there is no reason to believe that the financial strain on hospitals due to the pandemic will be eliminated in the near future, and removing the prospect of excessive wage index volatility in the coming fiscal years will aid hospitals as they budget for an uncertain future. In addition, once the PHE ends, hospitals expect that the ramifications of the PHE will continue to be felt for some time as PHE-impacted data is used to set the wage index in future fiscal years, making it appropriate to insulate hospitals from significant wage index reductions indefinitely.

Overall, the PHE has had an uneven impact on hospital wage levels. Some hospitals confronted temporary or longer-lasting labor shortages due to PHE-prompted workforce departures and COVID-19 surges, necessitating the use of more expensive contract and traveling agency nurses, expansion of overtime pay, other wage increases, and temporary staffing modifications to ensure adequate coverage. Some of the increases in labor costs over the course of the PHE will, in some cases, be temporary, but in other cases, the impacts on the hospital labor market may persist for some time. And the increases in labor costs due to the PHE are uneven among hospitals in light of the variation in the pandemic's regional impact. In fact, in markets where the PHE produced a significant drop in inpatient and outpatient volume as elective procedures were suspended, the pandemic may have necessitated layoffs and pay reductions for some providers. Thus, while the COVID-19 PHE has had a marked impact on hospital wage levels, the extraordinary variability of that impact between hospitals and over time

means that the wage index—which captures *relative* differences in hospital wage levels—will be volatile in the coming years. The FAH supports robust stakeholder engagement in preparing for the data challenges that the pandemic will pose in post-pandemic years, but at this time, an indefinite transition policy would provide needed assurance that wage index reductions will be avoided or limited.

For similar reasons, the FAH urges CMS to adopt the transition policy in a non-budget neutral manner. Although CMS has previously used its exceptions and adjustments authority under 42 U.S.C. § 1395ww(d)(5)(I)(i) to budget neutralize transition wage index policies, the statute neither authorizes nor requires budget neutrality, as explained further below in the context of the Low Wage Index Hospital Policy. Moreover, even if CMS' exceptions and adjustments authority authorizes budget neutrality adjustments, such an adjustment is not appropriate to fund a policy that is designed to address the extraordinary nationwide impact of a PHE on hospitals. A budget neutrality adjustment, on the other hand, would put undue financial pressure on hospitals that do not benefit from the transition policy (including hospitals that will experience wage index increases due to the extraordinary impact of the pandemic on hospital wage levels in their labor markets). The FAH strongly recommends, therefore, that CMS not apply budget neutrality to offset the costs of a transition policy that caps any reductions to their wage index values in FY 2022 and thereafter.

III.C. Exclusion of Verifiable Wage Data

The Proposed Rule indicates that CMS identified and excluded 86 hospitals with "aberrant data that should not be included in the wage index." Previously, in the FY 2020 IPPS Proposed Rule, CMS identified two of these hospitals along with five of their affiliates for exclusion based on CMS' belief that these hospitals' wage index data did not accurately reflect the economic conditions in their respective labor markets.[4] Notably, at that time, CMS did not identify any concerns with the accuracy or verifiability of these hospitals' wage index data,[5] and CMS ultimately and properly included the hospitals' data in the FY 2020 wage index.[6] The current Proposed Rule likewise fails to identify any concerns with the accuracy or verifiability of these two hospitals' wage index data, and the FAH is concerned that the proposed exclusion again improperly substitutes actual, free-market wage data with CMS' judgment of reasonable wage levels. 42 U.S.C. § 1395ww(d)(3)(E) focuses on actual market conditions and does not give the Secretary the authority to second-guess the wages actually and lawfully paid by a hospital. In addition, even if the Secretary has the discretion to exclude accurate and verifiable wage index data on the basis of a "reasonableness" standard, the Secretary has not created such a standard through formal notice-and-comment rulemaking as required under the Administrative Procedure Act and the Medicare Act. See 5 U.S.C. §553; 42 U.S.C. § 1395hh. Allina Health Services v. Price, 863 F.3d 937, 944 (D.C. Cir. 2017) affirmed by Azar v. Allina Health Services, No. 17- 1484 (U.S. Supreme Court Jun. 3, 2019). Hospitals lack any ability to understand whether or when the wages they pay might be subject to exclusion on the basis of

[4] 84 Fed. Reg. at 19375 (May 3, 2019).

[5] *Id.* at 19376.

[6] 84 Fed. Reg. at 42302-03 (Aug. 16, 2019).

CMS' *post hoc* assessment of the reasonableness of those wages. ***Thus, the FAH strongly opposes the use of the wage index verification process to exclude accurate and verifiable wage index data.***

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

In FY 2020, CMS adopted a policy that would increase 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 continued this policy in FY 2022 IPPS Proposed Rule and intends to keep this policy in place for four years because there is a four-year lag between the hospital cost reporting year (FY 2020) where wages are paid and the federal fiscal year (FY 2024) that is used to determine the wage index. In the FY 2022 IPPS Proposed Rule, CMS proposes to continue this policy for the 3rd of four consecutive fiscal years.

Although this policy is not limited to rural hospitals, it is more likely to benefit rural hospitals that have traditionally had lower wage index values compared to hospitals in urban areas. Rural hospitals play a critical role in ensuring access to care for the approximately 60 million Americans that live in rural areas across the United States. Dependence on rural hospitals is particularly acute for Medicare beneficiaries—close to one-quarter of Medicare beneficiaries live in rural areas and depend on rural hospitals for care.[7] Because Medicare beneficiaries disproportionately rely on rural providers to access care, Medicare reimbursement tends to have a greater influence on rural hospitals' revenue as compared to non-rural hospitals. The wage index, however, has aggravated rather than ameliorated financial problems for many rural hospitals. As CMS observes, 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 problem is compounded by other market and social factors that contribute to an aging rural workforce. As a result, Medicare beneficiaries in rural areas encounter what CMS has described as "a stretched and diminishing rural workforce." CMS Rural Health Strategy (May 8, 2018).

The FAH believes that CMS policy should address the acute problems that rural hospitals face and ensure that Medicare reimbursement formulas do not operate to magnify the stress on the rural health delivery system and access issues for Medicare beneficiaries living in rural areas. Therefore, the FAH supports CMS' proposal to increase the wage index values for hospitals with a wage index value in the lowest quartile of the wage index values across all hospitals. 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 applauds CMS' recognition of 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 through an increase to the wage index values of low wage index hospitals.

[7] MedPAC June 2018 Data Book, Section 2: Medicare Beneficiary Demographics (July 20, 2018).

In the FY 2020 IPPS final rule, CMS invokes 42 U.S.C. § 1395ww(d)(3)(E) and its exceptions and adjustments authority under § 1395ww(d)(5)(I)(i) as the basis for raising low wage index values.[8] CMS made this policy budget neutral for FY 2020 and 2021 and proposes to make this policy budget neutral for FY 2022 through adjustments to the IPPS standardized amounts.

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." 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 also cites the exceptions and adjustments authority under 42 U.S.C. § 1395ww(d)(5)(I)(i) as the statutory basis for its low wage index hospital policy.

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

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

Because the statute explicitly restricts the Secretary's authority to adopt budget neutrality adjustments in connection with adjustments for transfer cases, budget neutrality is neither required nor authorized in other circumstances. Moreover, it is also worth noting that where Congress has amended § 1395ww(d)(3)(E) to mitigate the impact of the wage index on certain low wage index hospitals (clause (ii)) and hospitals in frontier states (clause (iii)), it has expressly done so in a non-budget neutral manner, instructing CMS to disregard the impact of clauses (ii) and (iii) in developing any budget neutrality adjustment under subsection (d)(3)(E)(i). This legislative history indicates that, contrary to CMS' assertion in the FY 2020 IPPS final rule,[9] 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 policy adopted under 42 U.S.C. § 1395ww(d)(5)(I)(i) may not be adopted 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 policy.

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[8] 84 Fed. Reg. 42,044, 42,329 (Aug. 16, 2019).

[9] Id. at 42,331 ("[W]e would consider it inappropriate to use the wage index to increase or decrease overall IPPS spending.").

III.K. Cancellations of Reclassifications from Urban to Rural

The FAH supports CMS' efforts to address the use of rural reclassifications as a mechanism for statewide wage index manipulations. The wage index is designed to capture actual differences in relative hospital wage levels, and the coordinated use of rural reclassifications to manipulate the wage index on a statewide basis undermines the integrity of the wage index system. CMS proposes amending its regulation at 42 C.F.R. § 412.103(g) to provide that written requests to cancel rural reclassifications cannot be made less than one calendar year after the effective date of the rural reclassification and that such cancellation is not effective until the beginning of the Federal fiscal year that begins in the calendar year following the calendar year in which the cancellation request is submitted.

The FAH supports the proposed amendments to section 412.103(g), but requests that CMS limit the cancellation requirements in proposed section 412.103(g)(4) to the cancellation of rural reclassifications that are effective on or after October 1, 2020. The Proposed Rule identifies issues with hospitals timing a series of applications for and cancellations of rural reclassifications around the "lock-in dates" in order to receive their State's rural wage index without having their wage data included to impact wage index factor and average hourly wage calculations. This practice inappropriately skews the wage index, particularly when rural reclassification applications and cancellations are coordinated among a State's hospitals, and the FAH agrees that the additional cancellation requirements proposed in section 412.103(g)(4) are appropriately designed to prospectively address this behavior. The FAH, however, is concerned that the new cancellation requirements would also apply to hospitals that have not engaged in such practices and have in fact had their rural reclassifications in place for a number of years. These hospitals should be entitled to cancel their rural reclassification under the requirements of existing section 412.103(g)(3), preserving an appropriate level of flexibility for these hospitals while appropriately restricting cancellations for hospitals without longstanding rural reclassifications. To target the proposed regulation, the FAH recommends revising proposed section 412.103(g)(3) and (4) as follows:

> (3) *Cancellation of rural reclassification on or after October 1, 2019, and before October 1, 2021, and of rural reclassification effective before October 1, 2020*. For all written requests submitted by hospitals on or after October, 1, 2019, and before October 1, 2021, to cancel rural reclassifications, and all written requests to cancel rural reclassifications effective before October 1, 2020, a hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 120 days prior to the end of a Federal fiscal year. The hospital's cancellation of the classification is effective beginning with the next Federal fiscal year.
>
> (4) *Cancellation ~~of rural reclassification~~ on or after October 1, 2021 of rural reclassification effective on or after October 1, 2020*. For all written requests submitted by hospitals on or after October 1, 2021, to cancel rural reclassifications effective on or after October 1, 2020, a hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 1 calendar year after the effective date of the rural reclassification.

The hospital's cancellation of the classification is effective beginning the Federal fiscal year that begins in the calendar year following the calendar year in which the cancelation request is submitted.

DISPROPORTIONATE SHARE HOSPITAL PAYMENTS

V.E.4.a. Proposed Calculation of Factor 1 for FY 2022

The FAH urges CMS to reconsider the assumptions and methodology used to estimate Factor 1 of the Uncompensated Care Disproportionate Share Hospital (UC-DSH) calculation for FY 2022 ($10,573,368,841.28) in order to account for the skewing impact of FY 2020 and FY 2021 data. The COVID-19 PHE creates a significant complication for projecting Factor 1 because the PHE has altered utilization and other factors in drastic and unprecedented ways that are not indicative of expectations for FY 2022. The use of data for fiscal years heavily impacted by the COVID-19 PHE to update baseline data results in the understatement of Medicare DSH payments for FY 2022.

In accordance with section 3133 of the ACA, Factor 1 of the UC DSH calculation relies on an estimate of the amount that would have been paid under 42 U.S.C. § 1395ww(d)(5)(I) in the absence of subsection (r), reduced by 25 percent. In the Proposed Rule, CMS' Factor 1 calculation begins with 100 percent of empirically justified Medicare DSH payments in a baseline year (FY 2018 for FY 2022 UC DSH payments), and this number is then adjusted based on increase factors applied by the Office of the Actuary (OACT) to determine estimated FY 2021 empirically justified Medicare DSH payments. Factor 1 equals 75 percent of this amount.

In the Proposed Rule, the calculation of Factor 1 starts with baseline data from FY 2018 that is then updated using increase factors designed to account for the IPPS update, changes in fee-for-service discharges, case mix, and a residual of all other factors affecting Medicare DSH payments (including changes in Medicaid enrollment). Although the baseline data predates the COVID-19 PHE, the increase factors reflect data from FY 2020 and FY 2021, heavily skewing the estimate of Medicare DSH payments that would otherwise be made in FY 2022. In particular, CMS proposes updating FY 2018 discharges by nearly -13.9% over five years, a number that is heavily driven by estimated declines in discharges for FY 2020 (-14.7%) and FY 2021 (an additional -3.2%).[10] The COVID-19 PHE and the associated public health response (including the cancellation or delay of elective procedures) significantly reduced Medicare discharges between March 2020 and March 2021. But, with rising vaccination rates, declining COVID-19 infection rates, the elimination of stay-at-home orders, the resumption of elective procedures, and rising beneficiary confidence in infection control measures, the FAH expects that, when post-March 2021 data become available, the data will show a significant increase in discharges and that this increase will continue in FY 2022. In fact, according to a study by KaufmanHall, year-over-year discharges have increased 33.4% as of April 2021 and have only declined 0.4%

[10] The Proposed Rule applies a discharge factor of 0.97 for FY 2019, 0.853 for FY 2020, 0.968 for FY 2021, and 1.075 for FY 2022, which produces a five-year cumulative discharge factor of 0.861, or a 13.9% five-year reduction in discharges. 86 Fed. Reg. at 25,446.

year to date despite the decline in inpatient COVID-19 cases.[11] The data is even more striking with respect to adjusted discharges: year-to-date adjusted discharges were up 5.9%, year-over-year adjusted discharges were up 66.4% as of April 2021.[12] Thus, it appears that discharge data for the second half of FY 2021 will differ markedly from data for the first half of the fiscal year. Unfortunately, for purposes of FY 2022 estimates, actual claims data from this critical time period is not available, compounding the challenge of projecting FY 2022 discharges.

The Proposed Rule indicates that "OACT intends to use more recent data that may become available for purposes of projecting the final Factor 1 estimates for the FY 2022 IPPS/LTCH PPS final rule,"[13] but the FAH is concerned that the use of more recent data alone will not sufficiently capture discharge trends in the second half of FY 2021. In light of the historic and unprecedented impact of the COVID-19 PHE, the FAH urges CMS to work with OACT to carefully monitor changes in discharge volume and to make appropriate methodological changes to emphasize post-March 2021 trends in discharges and mitigate the skewing effect of discharge data reflective of utilization during the height of the pandemic and prior to widespread uptake of the COVID-19 vaccination.

Historical data concerning changes in MedPAR IPPS discharges as reported in Table 7A of the annual IPPS final rules further indicate that the projected -13.9% five-year change in discharges is highly aberrant and understates anticipated FY 2022 discharges. Between FY 2010 and FY 2014, discharges declined from 10,789,979 to 9,612,187, for a -10.9% five-year change in discharges. In subsequent years through FY 2019 (the last year for which MedPAR IPPS discharge data is reported), the five-year change in discharges has averaged -6.6% and has never exceeded -11%.

MedPAR Fiscal Year	**Number of Discharges***	**Year-to-Year % Change**	**5-Year % Change**
2010	10,789,979	—	—
2011	10,771,161	-0.2%	—
2012	10,290,934	-4.5%	—
2013	10,023,303	-2.6%	—
2014	9,612,187	-4.1%	-10.9%
2015	9,704,817	1.0%	-10.4%
2016	9,582,139	-1.3%	-7.1%
2017	9,628,457	0.5%	-4.1%
2018	9,448,796	-1.9%	-1.7%
2019	9,161,522	-3.0%	-5.7%
		Average 5 year decline	***-6.6%***

[11] KaufmanHall, National Hospital Flash Report (May 2021), *at* https://www.kaufmanhall.com/sites/default/files/2021-05/may-2021-national-hospital-flash-report.pdf.

[12] *Id.*

[13] 86 Fed. Reg. at 25,445.

*Source: MedPAR discharge data as shown in Table 7A of IPPS Final Rules for FY 2012 through FY 2021.

When considered alongside the qualitative factors and emerging data indicating that FY 2022 discharges will deviate markedly from the heavily depressed numbers seen in FY 2020 and the first half of FY 2021, this historic data indicates that the proposed -13.9% five-year change in discharges significantly overstates the expected decline in discharges between FY 2018 and FY 2022. ***In short, it appears unlikely that FY 2022 discharges would reasonably be expected to fall more than 10% or 11% from FY 2018 numbers, and the FAH urges CMS to work with the OACT to reevaluate its discharge adjustments for FY 2021 and FY 2022 to account for expected significant increases in discharges in the latter half of FY 2021 and over FY 2022.***

The FAH is also concerned with the lack of transparency with regard to the OACT's calculation of Factor One. In particular, the table showing the factors CMS applied to update the FY 2018 data for FY 2022 includes an "Other" column, but the Proposed Rule fails to adequately explain the factors purportedly captured in this "Other" column, let alone present a detailed methodology explaining how the "Other" value for all years was calculated by OACT. Without this essential explanation and methodological information, the FAH and other stakeholders are unable to replicate and comment on the Factor One calculation.

For FY 2021, the Proposed Rule indicates that "other" factors depress the Medicare DSH estimate by 2.46% (a factor of 0.9754), when in other years, the "other" factor is applied to increase estimated Medicare DSH expenditures. The Proposed Rule does not include a specific explanation of which other factors in FY 2021 are projected to depress estimated Medicare DSH payments. In fact, most of the other factors identified in the Proposed Rule would be expected to increase estimated Medicare DSH payments—*i.e.*, the increase in Medicaid enrollment and the 20 percent add-on payment for COVID-19 discharges—or would have a negligible impact on Medicare DSH payments (*i.e.*., the impact of the change in rates for the 2-midnight stay policy, which has been in place for a number of years).

The only other factor identified in the Proposed Rule is the difference between total inpatient hospital discharges and IPPS discharges, but it is unclear how any relative reduction in IPPS discharges could offset the increase in estimated DSH payments due to the other factors discussed above to produce a cumulative 2.46% reduction in estimated DSH payments due to these factors for FY 2021. ***The FAH urges CMS to provide further explanation for its apparent projection that the difference between total inpatient hospital discharge and IPPS discharges will significantly depress the "other" factor along with OACT's quantitative analysis of the interplay between the various factors grouped together as "other" factors impacting estimated DSH payments.*** In addition, although the FAH acknowledges that IPPS discharges declined faster than other inpatient hospital discharges in FY 2020 and the beginning of FY 2021, it is reasonable to expect that the data for the second half of FY 2021 will trend back toward historic numbers, with IPPS discharges comprising a growing proportion of total discharges. The FAH therefore encourages CMS to work with the OACT to address the expected increase in IPPS discharges as a percentage of total inpatient hospital discharges in the latter half of FY 2021 and

the impact of these FY 2021 data trends on the "other" factors impacting estimated DSH Medicare payments for FY 2021.

V.E.4.c. Calculation of Proposed Factor 3 for FY 2022

The FAH commends CMS for its efforts over the past several years to: (1) better define the costs of uncompensated care, in particular by including the cost of uninsured discounts into the definition of charity care for Worksheet S-10 ("WS S-10") purposes to be consistent with ACA section 3133's mandate; (2) better define the terms of its instructions to providers for the preparation of Worksheet S-10 so that costs are more accurately and consistently reported by hospitals; (3) allow providers to amend their Worksheet S-10s to comply with CMS' revised instructions; and (4) develop, engage in, and improve an audit process aimed at more accurately allocating and disbursing UC-DSH payments to providers. Given the relative weights Factor 3 assigns to hospitals, the FAH appreciates CMS' recent efforts to rigorously audit hospitals' reported data to ensure hospitals are reporting costs consistently and accurately. In particular, the audits of FY 2018 cost reports were extensive, widespread, and comprehensive, producing audited Worksheet S-10 data that better captures reliable, relative differences in hospitals' uncompensated care levels.

CMS proposes using FY 2018 Worksheet S-10 data for purposes of calculating Factor 3 in FY 2022 because they are from the most recent year of audited Worksheet S-10 data and reflect improvements to the Worksheet S-10 instructions. The FAH supports CMS' proposal to use a single year of audited data (FY 2018 cost report data) for FY 2022. The audits of FY 2018 Worksheet S-10 data have been the most extensive yet, with significantly more hospitals having undergone Worksheet S-10 audits for FY 2018. In addition, the FAH believes that FY 2018 Worksheet S-10 data will be more accurate than data from prior years because the audit process has improved both hospitals' and MACs' understanding of the Worksheet S-10 instructions.

Although the FAH supports the use of a single year of audited data for FY 2022, the FAH encourages CMS to consider returning to the use of two to three years of audited data in future fiscal years. The use of multiple years of audited data would tend to smooth over any remaining anomalies in the data and thus result in a more accurate allocation of UC-DSH payments in future years. In light of the extensiveness of FY 2018 audits, the FAH does not expect a significant increase in the numbers and intensity of audits of FY 2019 Worksheet S-10 data as compared to FY 2018. Because Worksheet S-10 audits are expected to be more uniform moving forward, CMS will again be able to blend multiple years of data in allocating UC-DSH funds, thereby minimizing volatility in UC-DSH payments.

CMS also makes several technical proposals related to the S-10 data. First, in making DSH payments, CMS calculates an interim amount per discharge for each DSH hospital, based on the hospital's estimated DSH total uncompensated care payment divided by the hospital's most recently available three-year average number of discharges. CMS proposes to modify this calculation for FY 2022 in light of the COVID-19 PHE. The agency proposes to use the average of FY 2018 and FY 2019 discharge data rather than its traditional use of a three-year average. We support this proposal.

V.F. Counting Days Associated With Section 1115 Demonstration Projects in the Medicaid Fraction

The FAH opposes CMS' proposal to limit section 1115 patient days that hospitals may include in the Medicaid fraction of their Medicare DSH calculations. CMS proposes to amend 42 C.F.R. § 412.106(b)(4) to limit the patient days associated with a section 1115 demonstration waiver that may be included in the computation of the Medicaid fraction of the Medicare Disproportionate Share Hospital ("DSH") adjustment: "For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient . . . *directly receives inpatient hospital insurance coverage on that day under a waiver authorized under section 1115(a)(2) of the Act*, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver."[14] The Proposed Rule focuses on two types of section 1115 demonstrations that CMS has approved but is nonetheless concerned are not sufficiently similar to traditional Medicaid benefits—uncompensated care pools and premium assistance programs. CMS lacks the authority under the Medicare Act to exclude certain section 1115 waiver days from the DSH calculation once CMS has approved the section 1115 waiver. Further, CMS' proposal to limit allowable section 1115 waiver days by deeming as "eligible for Medicaid" only those section 1115 waiver days explicitly providing "inpatient hospital insurance coverage on that day" to individual patients conflicts with the Medicare Act, the congressionally ratified existing regulations, and recent court decisions.

Neither the plain language of the Medicare DSH statute nor the plain language of the applicable regulations permit CMS to limit the section 1115 patient days that may be counted in the Medicaid fraction of Medicare DSH payment adjustment to waiver days that CMS believes are "comparable to traditional Medicaid benefits."[15] Courts that have considered CMS' recent attempts to limit the section 1115 waiver days counted in the Medicaid fraction in this manner have found CMS' limitations unlawful.[16] In addition, CMS' proposal to limit section 1115 waiver days that may be counted to those resembling traditional Medicaid insurance runs afoul of the purpose of both the Medicare DSH payment statute (where the counting of Medicaid days serves only as a proxy for capturing the relatively higher costs associated with providing services to low-income patients), and the section 1115 demonstration waivers, which by their very nature are innovative and differ from traditional Medicaid insurance. Finally, the proposed 42 C.F.R. § 412.106(b)(4) would inappropriately reduce hospitals' capacity to provide needed care to low-income populations, after hospitals have legitimately relied on CMS' section 1115 waiver approval. ***Therefore, the FAH urges CMS to abandon the proposed amendment to 42 C.F.R. § 412.106(b)(4).***

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

[14] 86 Fed. Reg. at 25,695, proposing revision to 42 C.F.R. § 412.106(b)(4)(i) and deletion of 42 C.F.R. § 412.106(b)(4)(ii)(emphasis added).

[15] 86 Fed. Reg. at 25,458.

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

CMS' proposed amendment to 42 C.F.R. § 412.106(b)(4) conflicts with the plain text of the Medicare DSH statute. The Medicare DSH statute provides for "an additional payment amount for each subsection (d) hospital which serves a significantly disproportionate number of low-income patients."[17] Congress enacted the Medicare DSH adjustment in recognition of the relatively higher costs associated with providing inpatient services to low-income patients, who are disproportionately sicker than other hospital patients. In establishing the statutory calculation methodology for Medicare DSH, Congress used entitlement to Supplemental Security Income ("SSI") and eligibility for Medicaid programs as proxies for capturing the low-income patients a hospital serves on an inpatient basis.

In order to compute the Medicaid fraction of the Medicare DSH calculation, the calculation *must* include in the numerator patients who are "eligible for medical assistance under [the Medicaid] State plan." 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II). But the Secretary may also include "patients *not so eligible* but who are *regarded as such* because they receive benefits under" a section 1115 waiver. *Id.* (emphasis added). In other words, Congress authorizes CMS to "regard[]" patients as Medicaid eligible for purposes of the Medicare DSH calculation as long as they "receive benefits under" an approved section 1115 waiver program.[18] The statutory text does not require patients covered under section 1115 waivers to enroll in a health insurance plan in order to be "regarded as such" under the Medicare DSH statute's Medicaid fraction computation.

CMS, however, suggests that it does not intend to regard uninsured patients that actually receive inpatient hospital services under section 1115 demonstration projects that fund uncompensated care pools as eligible for Medicaid, saying "we do not believe that the[se] uninsured patients . . . can be 'regarded' as being eligible for Medicaid as required under" 42 U.S.C. § 1395ww(d)(5)(F)(vi) because the patients do not directly receive medical coverage benefits comparable to traditional Medicaid.[19] This interpretation of the statute has already been rejected by two Federal courts. In the *Bethesda Health* case, which rejected CMS' exclusion of uncompensated care pool patient days from the Medicare DSH calculation, the D.C. District Court concluded: "The government's proposed interpretation would informally add new and limiting phrases to a statute that is already clear when unadorned."[20] Likewise, the Fifth Circuit in *Forrest General Hospital* interpreted the Medicare DSH statute to expressly authorize treating 1115 waiver uncompensated care pool patients as being eligible for Medicaid for Medicare DSH purposes: "[T]he statute means that patients who aren't actually Medicaid-eligible still count towards the Medicaid fraction's numerator if they're considered or accounted to be capable of receiving a demonstration project's helpful or useful effects by reason of a demonstration

[17] 42 U.S.C. § 1395ww(d)(5)(F)(i)(I).

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

[19] 86 Fed. Reg. at 25,458.

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

project's authority. There's only one plausible way to read this."[21] This analysis applies with equal force to premium assistance programs, which subsidize coverage for inpatient services.

The proposed amendment to 42 C.F.R. § 412.106(b)(4)(i) is also contrary to law insofar as it would permit the exclusion of section 1115 days *after* CMS has already approved a section 1115 waiver. The Medicare DSH statute allows the Secretary to include in the Medicaid fraction "patient days of patients not so eligible [for medical assistance under a State plan] but who are regarded as such because they receive benefits under a demonstration project approved under subchapter XI."[22] Once the Secretary approves a section 1115 waiver, he cannot thereafter change course and exclude those section 1115 demonstration days from the DSH calculation. Courts reviewing the statutory provision and CMS' existing implementing regulation have held similarly. In *Forrest General Hospital*, 926 F.3d at 233, the Fifth Circuit held that once "the Secretary authorizes a demonstration project, no take-backs. The statutory discretion isn't discretion to exclude populations that the Secretary has already authorized and approved for a given period; it's discretion to authorize the inclusion of those populations in the first place." Similarly, in *Bethesda Health*, 389 F. Supp. 3d at 52,[23] the D.C. District Court held that the Secretary must exercise his discretion *prospectively*, not "after a demonstration project has already been fully approved and implemented and the bill comes due." Thus, CMS cannot exclude section 1115 patient days under existing, CMS-approved demonstration projects from the Medicare DSH calculation. In other words, even if the proposal were lawful and appropriate when applied prospectively (it is not), CMS must confine any such amendment to patient days under section 1115 waivers approved on or after the effective date of such an amendment.

In its Proposed Rule, CMS fails to acknowledge this statutory authority and proceeds under the mistaken assertion that the courts found CMS' exclusion of section 1115 waiver days unlawful *only* under the plain language of CMS' currently applicable *regulations*.[24] CMS highlights three recent cases, including the above-referenced *Forrest General Hospital* and *Bethesda Health*, and states that "courts have decided in a series of cases . . . that, based on the current language of the *regulations*, CMS is required to count in the numerator of the Medicaid fraction patient days for which hospitals have received payment from an uncompensated care pool authorized by a section 1115 demonstration and the days of patients who receive premium assistance under a section 1115 demonstration program. These courts have concluded that if a hospital received payment for otherwise uncompensated inpatient hospital treatment of a patient, that patient is 'eligible for inpatient hospital services' within the meaning of the current regulation."[25] ***However, as discussed above, the courts in both Forrest General Hospital and Bethesda Health also held that the Medicare Act itself bars the Secretary from excluding section 1115 days for inpatient hospital services once the Secretary approves the section 1115 waiver.*** Therefore, simply amending the regulation at 42 C.F.R. § 412.106(b)(4)(i) will not

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

[22] 42 U.S.C. § 1395ww(d)(5)(F)(i)(I)

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

[24] 86 Fed. Reg. at 25,458.

[25] 86 Fed. Reg. at 25,458-59 (emphasis added).

allow CMS to exclude section 1115 days from the DSH calculation once the Secretary approves a section 1115 waiver.

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

The proposed regulatory amendment would reduce hospitals' ability to serve indigent populations, directly contravening the purpose of the Medicare DSH statute. As discussed, Congress enacted the DSH adjustment to provide additional Medicare reimbursement to hospitals for the increased cost of providing services to their low-income patients. *See* 42 U.S.C. § 1395ww(d)(5)(F)(i)(I). The statutory mandate setting forth the Medicaid fraction computation similarly focuses on including days of patients eligible for medical assistance under a State plan or regarded as eligible for medical assistance under a State plan "because they receive benefits under a demonstration [waiver]." 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II). CMS, however, proposes excluding inpatient days under approved 1115 waivers for uncompensated care pool patients, premium assistance patients, and patients in any other section 1115 demonstration program that does not directly provide inpatient hospital insurance coverage, stating that these demonstration programs are not sufficiently similar to traditional Medicaid benefit programs and may provide benefits to individuals with higher incomes. The former assertion is divorced from the Medicare DSH statute's language and purpose, and the latter is unsupported by evidence or the terms of any approved demonstration program.

Instead of supporting the purpose of the DSH payment adjustment, CMS appears to disregard that purpose in its proposal requiring that a section 1115 waiver provide inpatient hospital *insurance coverage* to patients in order for those days to be counted. CMS states in the Proposed Rule that "[p]atient days associated with a section 1115 waiver program that does not similarly directly provide *inpatient hospital insurance coverage* to specific individuals are not comparable to the days of patients receiving traditional Medicaid benefits, and therefore, should not be counted in the numerator of the Medicaid fraction."[26] But distinguishing whether a section 1115 waiver directly provides for hospital *insurance coverage* is not the purpose of the DSH payment or the Medicaid fraction. The purpose of the DSH payment is to provide "an additional payment amount for each subsection (d) hospital which serves a significantly disproportionate number of low-income patients." 42 U.S.C. § 1395ww(d)(5)(F)(i)(I), and the statute uses Medicaid or section 1115 waiver days as a readily available proxy for low-income patient days, 42 U.S.C. § 1395ww(d)(5)(F)(vi).

CMS' proposed amendment would depress lawful and expected Medicare DSH payments to hospitals (including safety-net hospitals) in states with section 1115 waivers in place. The sheer prevalence and penetration of section 1115 waivers would cause significant repercussions for the many states and providers who rely on approved section 1115 waivers as drivers of significant reimbursement. As of June 9, 2021, there are 63 approved section 1115 waivers.[27] And a significant number of 1115 waivers innovate with uncompensated care pools (*e.g.*,

[26] 86 Fed. Reg. at 25,459 (emphasis added).

[27] CMS, State Waivers List, *at* https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/index.html.

Florida, Tennessee, and Texas) or premium assistance (*e.g.*, Arizona, Arkansas, Indiana, Iowa, Kentucky, Michigan, Montana, New Hampshire, New Mexico, Ohio, Pennsylvania, South Carolina, Wisconsin, and Utah). CMS' counterintuitive proposal to limit Medicare DSH payments to those waiver days that most closely resemble traditional Medicaid insurance coverage completely disregards the purpose of the section 1115 waiver authority. Further, proposing to make such a regulatory change without regard for the reliance interests of providers and states and disregard for the practicalities of the section 1115 waiver approval process unfairly disadvantages providers in states with more innovative section 1115 waivers.

With respect to CMS' assertion that patients benefitting from section 1115 demonstration programs that do not directly provide inpatient hospital insurance coverage are of higher income than other Medicaid beneficiaries, this assertion is unsupported by any evidence. CMS does not make this argument with respect to demonstration projects that use uncompensated care pools, nor could it. CMS does, however, argue that "individuals who receive premium assistance under an expansion waiver program may be significantly wealthier than traditional Medicaid beneficiaries." But this suggestion is not supported by any evidence. In fact, premium assistance under these waiver programs is largely limited to individuals that fall at or below the Medicaid income threshold under the Affordable Care Act, meaning that the income of these patients would be no higher than the income of beneficiaries enrolled in Medicaid in traditional expansion states. And in fact, some 1115 expansion waiver programs that use premium assistance apply even lower income limits (*e.g.*, Georgia and South Carolina). Thus, based on the terms of the expansion waiver programs approved by CMS, it appears that patients enrolled in section 1115 waivers do not have higher incomes as compared to traditional Medicare beneficiaries in states that have implemented the ACA's Medicaid expansion. In short, the exclusion of section 1115 waiver patient days from the numerator of the Medicaid fraction is not premised on any actual dissimilarity between these waiver patient days and Medicaid patient days, and the 1115 waiver patient days should appropriately be regarded as Medicaid patient days for purposes of the Medicare DSH calculation.

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

Value Based Payment Programs and COVID-19 Measure Suppression Policy

V.G., V.H. and V.I. Cross-Program Measure Suppression Policy for Hospital Readmissions Reduction Program (HRRP), Hospital Value-Based Purchasing Program (HVBP), and Hospital-Acquired Condition Reduction Program (HAC RP)

CMS expresses concern that the COVID-19 public health emergency (PHE) has impacted the Medicare program's quality data collection, reporting, and results in ways that are significant and largely outside of the control of hospitals, such as rapid changes in patterns of disease type and severity, patient acuity, and procedural volume. Appropriate hospital responses to the clinical exigencies of the PHE have further affected quality measures and subsequent performance scores. For example, the purposeful minimizing of close, in-person interactions

between clinicians and patients, necessary to decrease otherwise rampant viral transmission, is likely to have degraded the patient's perceived experience of care.

In response to the COVID-19 PHE, CMS has broadly applied its discretionary authority to support continuous delivery of patient-centered care by hospitals and their personnel by granting policy waivers and adopting regulatory flexibilities. The FAH is extremely grateful to CMS for its prompt and nimble responses to date that have allowed our members to maintain our steadfast commitment to delivering the best possible care, despite unprecedented challenges, to every patient whose life we are privileged to touch. Among the exceptions granted by CMS were modifications and cancellations of data reporting requirements for most of Medicare's inpatient hospital quality programs for the first and second quarters of calendar year 2020 (Q1 and Q2 CY 2020).[28]

In the proposed rule, CMS describes its data review and analysis of the potential downstream effects of the Q1 and Q2 CY 2020 data reporting exceptions on the hospital inpatient P4P programs. Based on its analyses, CMS voices concern that, absent policy interventions, payments and penalties of its pay for performance (P4P) programs (including the HRRP, VBP, HAC RP discussed in the IPPS rule) could be inequitable across hospitals, especially those treating large numbers of COVID-19 patients. CMS proposes a cross-program measure suppression policy applicable to all three P4P programs along with separate proposals for scoring and payment adjustments tailored to each. The cross-program policy would begin in FY 2022 and apply for the duration of the PHE. The program-specific adjustments have varying applicability dates, with some beginning as early as FY 2022.

Under the cross-program policy, CMS could suppress the use of data from one or more measures in a P4P program were the agency to conclude that PHE-related circumstances have significantly compromised that program's measure data and resulting performance scores. Consistent with the statutory constraints and operational framework of a specific program, CMS would design performance scoring and payment formula modifications to preserve payment equity across hospitals required to participate in the program.

Regardless of measure suppression, CMS proposes to report performance results calculated using available data to hospitals and to continue public data reporting of performance results according to the previously established policies of each P4P program. The agency states that publicly reported information would be accompanied by an explanation of the source data limitations due to the COVID-19 PHE. ***The FAH agrees with reporting P4P performance results confidentially to hospitals, as the data, despite their flaws, could help hospitals assess the strengths and weaknesses of their responses to the PHE. However, the FAH disagrees with public reporting of the results from P4P programs in which measures have been suppressed.*** The P4P programs are complex and difficult to translate into accessible, comprehensible, and meaningful information for patients and families absent unprecedented health care system

[28] See the March 22, 2020, CMS announcement at https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting. Also see the March 27, 2020, CMS guidance memo at https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.

impacts by a PHE. We are skeptical that easily understood descriptions of data limitations due to COVID-19 effects for FY 2022 can be crafted. At a minimum, public reporting should be delayed for the agency to obtain input from beneficiary advocates and to allow full testing of data disclaimer language through focus groups.

CMS requests comment on adoption of the proposed measure suppression policy. The FAH appreciates the agency's concern about ensuring fairness within its hospital P4P programs given the disruptive effects of the COVID-19 PHE on the nation's hospitals and health care delivery system. ***We support the necessity and propriety of a cross-program measure suppression policy for the COVID-19 PHE and we generally support the policy as proposed***. ***We ask CMS to clarify what is meant by policy adoption "for the duration of the COVID-19 PHE"***. Does this automatically correspond to the expiration date of the most recently issued renewal of the declared PHE or will an end date for the purpose of this policy be explicitly stated? We note that several program-specific proposals describe measure suppression or scoring adjustments as "*beginning"* in a specific FY without explicitly specifying end dates.[29] Perhaps CMS intends a uniform end date for all of the program-specific proposals as well as the cross-measure policy, but clarification is needed. A fact sheet with start and end dates for each specific proposal would be helpful.

The FAH also observes that, although the PHE has lessened in intensity since effective vaccines have become available, hospitals continue to admit new cases, and the acute care needs of some chronically ill COVID-19 survivors ("long haulers") are largely unknown, as is the likelihood of COVID-19 resurgence due to mutated viruses that could require booster vaccinations. Therefore, the duration of the PHE remains speculative at this time. Does CMS intend to update the cross-measure suppression policy as part of IPPS rulemaking for each new fiscal year into which the PHE extends? ***The FAH believes that transparency would best be served by explicitly addressing the cross-program measure suppression policy annually through rulemaking, proposing revisions as needed, rather than updating through guidance processes.***

CMS proposes and invites comment about a set of Measure Suppression Factors to guide its decision making in determining whether measure data and performance scores in a P4P program have been significantly compromised by circumstances related to COVID-19, such as significant deviation in national measure performance from recent years or rapidly changing clinical guidelines. ***The FAH supports the Measure Suppression Factors as proposed for application to all three hospital P4P programs. We ask CMS to clarify if and through what process (e.g., rulemaking) the agency would expand the set of factors if, as yet undetected PHE effects on measures or scoring, were to be identified.***

CMS requests comments about development of a measure suppression policy for future PHEs under which measure suppression could be activated by the agency without notice-and-comment rulemaking. The FAH appreciates and respects the rapid and responsible ways in which CMS has exercised regulatory flexibility to date during the COVID-19 PHE, but we

[29] For example, see Section V.G.6 concerning the HRRP pneumonia readmission measures and Section V. H.1.b.(5) regarding the HVBP pneumonia mortality measure.

would like to better understand the extent of future discretion that CMS is seeking. We agree that CMS should have discretion to establish and use measure suppression factors to determine whether measures and performance scores have been significantly and adversely by a future PHE without going through rulemaking. However, ***we would have reservations about the agency, having identified measure and scoring challenges, proceeding directly to implementation of scoring adjustments and related payment changes to the hospital P4P programs outside of rulemaking***. The clinical characteristics of the next PHE are likely to differ substantially from the COVID-19 PHE, so that novel approaches to scoring and payment may be needed to ensure fair and equitable treatment of hospital participants in each P4P program. For example, the impacts on hospitals and on quality measurement of a viral illness PHE resembling measles or polio would likely look quite different from those of the SARS-CoV-2 virus (COVID-19).

CMS invites comments on whether there should be regional adjustment of measure suppression factors, such as population density, and whether partial rather than total suppression of a measure's associated data should be considered. The FAH does not believe that a valid judgement for or against regional adjustment or partial measure suppression can be made without context. Whether regional, partial, or any other-than-total measure suppression is appropriate should be determined based on the clinical characteristics of the PHE and the results of relevant data analysis by CMS at that time. We also have a general concern about increasing the complexity of the cross-program measure suppression policy or its tailored applications to each of the P4P programs by regional or partial suppression. ***Therefore, the FAH does not recommend regional or partial measure suppression for future PHEs.***

V.G. Hospital Readmissions Reduction Program (HRRP)

CMS proposes to suppress the pneumonia readmission measure for FY 2023,[30] an excess readmission ratio based on this measure will not be used in payment reduction calculations for hospitals. ***The FAH supports this proposal.*** Relatedly, CMS will make technical measure specification updates through an existing subregulatory process for the remaining five condition/procedure-specific measures to exclude cases with COVID-19 diagnoses from the measures' cohorts.[31] ***The FAH agrees with the exclusion of cases with COVID-19 diagnoses from calculations for payment reductions to hospitals under the HRRP.***

CMS solicits comments on confidentially reporting to hospitals their HRRP results, stratified using indirectly estimated race and ethnicity, in addition to the currently reported results stratified using dual eligibility. The FAH believes that stratification when properly designed and implemented can be a useful tool in identifying and understanding facility performance disparities. ***The FAH supports the continued evaluation by CMS of stratified quality results reporting but we have concerns about indirect estimations of race and ethnicity,*** as described more fully in our response to the comprehensive Request for Information (RFI) about health equity in this rule (see IX.B. below).

[30] Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506)

[31] Acute Myocardial Infarction, Coronary Artery Bypass Grafting, Chronic Obstructive Pulmonary Disease, Heart Failure, and Total Hip/Total Knee Arthroplasty)

CMS also specifically requests comments on publicly reporting HRRP results, stratified by dual eligibility and indirectly estimated race and ethnicity, on Care Compare after at least one year of confidential reporting and further rulemaking. The FAH has long endorsed public reporting of hospital quality performance results that are meaningful to patients and families (formerly on Hospital Compare and now on Care Compare) and reported in a manner that is easily accessed and understood**.** ***We also endorse public reporting of stratified HRRP results but only after several years of confidential hospital-only reporting and subsequent rulemaking***. One year of confidential reporting is inadequate, does not allow time for evaluation and improvement, and we advise against setting an arbitrary timetable at this early stage of race and ethnicity stratified reporting.

HRRP dual-eligibility stratified results as currently reported to hospitals have a very short track record, a large part of which has occurred during the atypical times of a public health emergency. There must be a period of confidential reporting ample enough to develop, test, and implement data review and correction mechanisms, as well as data validation processes. The race and ethnicity data collected for stratification must have demonstrated a high degree of reproducibility before contemplating public release of results that could easily be misinterpreted and inadvertently damage hard-won reputations. Time must also be sufficient to permit for unanticipated consequences of data release to surface.

Prior to public reporting the FAH also recommends that CMS undertake focus groups to test messaging and understanding of the data, so that the results reported are clear and actionable for patients, families, and caregivers and less likely to be seen as inflammatory. Consideration also should be given by CMS to an extensive outreach campaign to educate the public about the strengths and limitations of the data. Data privacy concerns cannot be overstated in the context of the very sensitive data involved. Finally, all of our public reporting concerns are heightened even further in the context of hospital P4P programs where data inaccuracy could lead to incorrect and unjustified payment adjustments.

CMS further requests comments relative to the HRRP on topics that are identical to those raised under the cross-measure suppression policy and we refer you to our comments above on that policy. Finally, CMS also refers to an RFI concerning improving data collection to better measure and analyze health care disparities across CMS programs, including the HRRP. We refer you to our response to that RFI later in this letter (see IX.B below).

V.H. Hospital Value-Based Purchasing Program (HVBP)

For the FY 2022 program year, CMS proposes to suppress all measures in the domains of Person and Community Engagement, Safety, and Efficiency and Cost, and to apply a special scoring and payment rule. Under that rule, a Clinical Outcomes domain score would be calculated, but total performance scores (TPSs) would not be calculated based on these limited data. As usual, CMS would make the statutory 2 percent reduction to each hospital's base operating DRG payment amount. The agency would also assign to each HVBP participant hospital a value-based incentive payment percentage whose application would be budget-neutral.

Thus, the amount lost through the DRG payment rate reduction would be returned to each hospital and its base operating DRG payment would remain unchanged for FY 2022.

The FAH supports measure suppression and the special scoring policy as proposed for the HVBP for FY 2022. We appreciate the rational approach that CMS proposes to maintain stability and payment equity across hospitals under the HVBP for a program year heavily impacted by the COVID-19 PHE. We similarly support the proposed suppression of the pneumonia mortality measure for FY 2023 and technical updates of the other measures in the Clinical Outcomes domain for FY 2023 to exclude cases with COVID-19 diagnoses from measure calculations.

CMS Patient Safety and Adverse Events Indicator Composite Measure (CMS PSI 90)

CMS proposes to remove the CMS PSI 90 measure from the HVBP measure set beginning with the FY 2023 payment year. This measure has been controversial and remains so despite undergoing significant revisions. ***The FAH supports removal of the CMS PSI 90 measure.***

CMS also requests comments relative to the HVBP on topics that are identical to those raised under the cross-measure suppression policy and we refer you to our comments above on that policy. We also note that CMS refers to sections IX.A and IX.B of the rule that contain RFIs concerning transforming CMS' quality programs, such as the HVBP, to digital platforms and improving data collection to better measure and analyze health care disparities across CMS programs, respectively. We refer you to our responses to both RFIs below (see IX.A and IX.B below).

V.I. Hospital-Acquired Condition Reduction Program (HAC RP)

In addition to the quality data reporting exception for Q1 and Q2 CY 2020 under CMS quality programs including the HAC RP, the agency proposes for the HAC RP to suppress Q3 and Q4 CY 2020 data for the CMS PSI 90 measure and all of the National Health Safety Network (NHSN) Hospital Associated Infection (HAI) measures (CAUTI, CLABSI, SSI, MRSA bacteremia and CDI). CMS notes that some states and other entities may require hospitals to report to CDC the NHSN measures for other purposes such as epidemiologic surveillance. In response to queries, the agency states that a hospital required to submit data for such purposes may request an individual ECE for exclusion of these data from any total HAC score calculations.

Given the statutory structure of the mandatory penalty HAC RP, the FAH accepts the proposed measure suppression approach as reasonable. The FAH, however, regards as burdensome the agency's decision to require hospitals that must submit NHSN HAI measure data for surveillance purposes to also apply for individual extraordinary circumstance exceptions (ECEs) in order for those data not to be used by CMS in total HAC score calculations. ***We recommend that CMS develop a streamlined subregulatory process for HAC RP participant hospitals who must continue NHSN HAI data submission to self-identify to CMS and thereby be automatically granted the necessary ECEs.***

CMS also requests comments relative to the HAC RP on topics that are identical to those raised under the cross-measure suppression policy and we refer you to our comments above on that policy. We note that CMS also refers RFIs found in IX.A and IX.B of the rule about transforming CMS' quality programs, such as the HAC RP, to digital platforms and improving data collection to better measure and analyze healthcare disparities across CMS programs. We refer you to our responses to both RFIs later in this letter (see IX.A and IX.B below).

PAYMENTS FOR INDIRECT MEDICAL EDUCATION (IME) AND DIRECT GRADUATE MEDICAL EDUCATION (DGME) COSTS

V.J.2.a. Distribution of Additional Resident Positions

Section 126 of the Consolidated Appropriations Act, 2021 (CAA) (Pub. L. 116-260), division CC, makes available 1,000 new Medicare-funded GME positions (but not more than 200 new positions for a fiscal year) to be distributed beginning in FY 2023, with priority given to hospitals in 4 statutorily-specified categories.

1. Hospitals located in rural areas or treated as rural for IPPS purposes;
2. Hospitals that are training more residents than their FTE cap;
3. Hospitals in states with new medical schools or additional locations and branches of existing medical schools; and
4. Hospitals that serve areas designated as Health Professional Shortage Areas (HPSAs).

As CMS is limited by statute in the number of additional resident slots it may award per year and it expects to receive applications from more than 200 qualifying hospitals, CMS is proposing to limit any qualifying hospital to no more than 1.0 FTE per hospital per year. ***The FAH supports CMS' proposal to limit each hospital to no more than 1.0 additional FTE resident position per year because the demand for additional residency positions far exceeds the statutory limit and applying a 1.0 FTE limit promotes the widespread distribution of additional residency slots among a wider range of qualifying hospitals.*** For this same reason, the FAH further recommends that in subsequent years, CMS prioritize those qualifying hospitals that have not yet received a new residency position under the statute such that no hospital receives a second residency position award until all other qualifying hospitals have received their first residency position award.

V.J.2.b. Rural Training Tracks (RTT)

Section 127 of the CAA makes statutory changes relating to the determination of both an urban and rural hospital's FTE resident limit for DGME and IME payment purposes. These changes address shortcomings of the prior statute that generally only provided exemption from FTE caps to urban hospitals participating in RTTs and not the rural hospitals that provided training sites. These provisions also did not provide RTTs with exemptions from the 3-year rolling average count of residents or the cap on the intern and resident to bed (IRB) ratio at the ratio from the prior year for determining IME payment. The 3-year rolling average and the IRB

cap allow hospitals to be fully (but not immediately) subsidized for increases in the number of residents over a transition period.

CMS describes RTTs as "hub" and "spoke" programs with the urban hospital being the hub and the rural hospital being the spoke. To implement the CAA, CMS is proposing that each time an urban hospital establishes a new spoke, both the urban and rural hospital would receive a 5-year exemption for the new program from the DGME and IME FTE caps to allow the program to grow to full capacity. Both hospitals would also receive 5-year exemptions from the 3-year rolling average and the IRB cap. These policies would allow for the creation of new RTT spokes with corollary hub increases, but would not allow for growth of existing RTT hubs and spokes. ***The FAH supports CMS' proposed policy of allowing for a 5-year exemption from the FTE caps, the 3-year rolling average and the IRB cap each time an urban hub hospital establishes a new rural spoke and believes these changes will increase rural training opportunities, which in turn benefit rural beneficiaries. However, we seek clarification that new programs at all allowed RTT training settings, including rural non-hospital clinical sites will receive the benefits of the 5-year exemption.***

Section 127 of the CAA further removes the words "separately accredited" from the RTT provisions of the statute. In light of the "separately accredited" requirement under the prior statute, existing policy limits RTT cap adjustments to programs in family practice even though other specialty programs may have been designed to train physicians for rural practice. CMS proposes that any program where more than 50 percent of the training occurs in a rural area can qualify as an RTT for the 5-year exemption to the DGME and IME FTE cap, the three-year rolling average and the IRB cap. ***The FAH supports this proposal, which makes RTT cap adjustments more broadly available, consistent with section 127 of the CAA.***

V.J.2.c. Resident Caps and Per Resident Amount for Hospitals that Hosted a Small Number of Residents for a Short Duration

Some hospitals may serve as training sites for residents on rotations from other hospitals where the predominant amount of training occurs. These hospitals may have a low DGME per resident amount (PRA) or IME and DGME FTE caps. Section 131 of the CAA makes statutory changes to the determination of DGME PRA and DGME and IME FTE resident limits of hospitals that hosted a small number of residents for a short duration. This provision allows particular hospitals that may have established a low PRA or an FTE cap based on a small number of residents rotating from another hospital's residency program to have their PRA and FTE caps reset.

The CAA establishes different thresholds for resetting the PRA and FTE cap, and the Proposed Rule would permit the PRA and FTE cap to be reset for hospitals that meet the applicable statutory thresholds. CMS proposes that a hospital can reset a PRA when training residents in a new or existing program between December 27, 2020 and December 26, 2025, but can only reset its FTE cap when it begins training residents in a new residency program in a cost reporting period on or after December 27, 2020 and December 26, 2025. ***The FAH supports CMS' implementation of section 131 of the CAA.*** For years, hospitals that unwittingly triggered their PRA and/or FTE caps by hosting rotating residents have confronted very low, and

permanent, PRAs and/or FTE caps, and section 131 of the CAA provides an appropriate opportunity to reset these PRAs and/or FTE caps. With respect to resetting FTE caps, however, the FAH is concerned with CMS' proposal to narrowly interpret the statutory reference to a hospital that "begins training residents in a new approved medical residency training program or programs." Hospitals that inadvertently triggered the FTE cap, but nonetheless incurred the significant costs of training residents in a residency program prior to December 27, 2020 on the understanding that the FTE cap could never be reset should not be treated less favorably than hospitals that were similarly situated but declined to train residents without a statutory fix.

The FAH also supports CMS' proposal that a qualifying hospital will not reset its PRA until such hospital trains the required number of FTEs on or after December 27, 2020 and before December 26, 2025. For PRAs, CMS notes that subsequently training more FTEs than the triggering threshold for Category A or Category B Hospitals before December 27, 2020, does not prevent a qualifying hospital from resetting its PRA once it starts training a resident from a new or existing approved program between December 27, 2020 and December 26, 2025. This statutory change and CMS' implementation will allow these hospitals to reset their PRAs in a way that will significantly benefit the teaching hospitals.

The FAH further appreciates CMS' plan to issue instructions to the MACs and to hospitals to provide for an orderly process of request and review for the purpose of receiving replacement PRAs and FTE caps. The FAH urges CMS to use these instructions to clarify how hospitals that qualify for a PRA and/or FTE cap reset will be identified (including a process by which a qualifying hospital can provide the MAC with the necessary information, as appropriate), as well as when the PRA and/or FTE cap recalculation is triggered on or after December 27, 2020 and on or before December 26, 2025.

V.L. Repeal of Market-Based MS-DRG Relative Weight Policy (42 C.F.R. § 413.20)

The FAH strongly supports CMS' proposal to repeal the requirement that a hospital report on the median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage organization payers, by MS-DRG and to repeal the market-based MS-DRG relative weight methodology that was adopted effective for FY 2024. The FAH maintains that CMS lacks statutory authority for either policy, that the use of median payer-specific negotiated rates for weighting MS-DRGs would produce skewed or distorted data, and that the reporting obligation would produce significant and inappropriate burdens on hospitals. The FAH appreciates CMS' responsiveness to the significant stakeholder feedback on this policy, and urges CMS to finalize the proposed repeals, including by finalizing the proposed amendment to 42 C.F.R. § 413.20(d)(3) and by revising the forthcoming revision of the associated Information Collection Request currently approved under OMB control number 0938-0500.

IX.A. Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospitals Quality Programs – Request for Information

Through this RFI, CMS poses numerous questions about moving to a fully digital quality enterprise by 2025 across its quality and value-based purchasing programs.[32] The agency indicates that feedback received will be used solely for planning purposes, and that any subsequent updates to specific quality programs would occur through rulemaking. CMS describes an overarching goal of giving access to transparent and timely quality of care information to all of the intended users of their data, subject to privacy and security safeguards. By so doing, CMS envisions that patients, providers, policymakers, and payers will be empowered as participants in a value-driven health system. Foundational concepts for transforming the agency's quality enterprise discussed in this RFI include the following: data standardization, interoperable health information exchange, adoption of emerging health information technology (health IT), data accessibility, data aggregation, enhanced patient voice, and alignment.

To provide context for this RFI, CMS offers several high-level observations. In response to increasing demand and rising expenditures, Medicare has embarked on transitioning from a Fee-for-Service (FFS) structure to value-based purchasing (VBP). Value is defined by both costs and quality of care, and quality measurement requires health care data. Data are plentiful but often not useful: they are fragmented, cannot be collated across the care continuum, and cannot be accessed by all of a beneficiary's clinicians and other providers. Data collection routinely is burdensome and costly. Measure results are not always transparent, comprehensible, timely, and actionable for providers and patients. CMS provides an illustrative example: despite the agency having focused heavily and carefully on CEHRT use policies and regulations for hospital participants in the Promoting Interoperability Program (PIP), stakeholders continue to find that required quality data reporting via electronic health records (EHRs) to CMS is highly burdensome, consumes disproportionate resources, and doesn't readily incorporate the patient voice (e.g., patient-reported outcome measures (PROMs) or patient-generated health data (PGHD)).

The FAH welcomes the opportunity to respond to this seminal RFI. We have long supported efforts to achieve comprehensive interoperability and data liquidity – the free flow of meaningful, actionable information that support and enhance patient care within and across settings. We also have favored moving forward expeditiously with proposals to improve electronic health information exchange whenever health IT advances can facilitate improved quality and access to care while being cost-effective and without introducing provider burden.

General Considerations

The FAH commends CMS for thinking strategically and aspirationally about its quality enterprise. The agency is well-positioned in many ways to be a leader in this arena: a broad-

[32] Hereafter in this section "quality programs" will have the meaning of CMS-administered quality and value-based purchasing activities, unless otherwise specified.

based portfolio of quality programs yielding abundant data; a funded laboratory for testing value-based interventions (i.e., the CMS Innovation Center (CMMI)); an established close working relationship with the Office of the National Coordinator for Health Information Technology (ONC)); the ability to sponsor public-private partnerships; a clear responsibility to beneficiaries to ensure their optimal care; an equally clear responsibility to the Congress to be fiscally prudent with finite taxpayer resources; and the leverage that accrues to being a dominant health care payer. The future of health information exchange clearly is digital, and CMS appropriately is looking ahead. Our comments are founded on the following principles:

- First and foremost, the CMS digital strategic plan must support a system in which data are collected and reported once and only once, regardless of the number of downstream uses of the data.
- Only those measures that truly make a difference in patient health and are predictors of value should be implemented in CMS quality programs.
- Quality program measures, policies, and regulations must reflect the patient's voice whenever feasible.
- Public reporting of provider data should be transparent and focused on those that are reliable, valid, and useful for patients and their families.
- Adoption of health IT advances by CMS must be aligned with the real-world practice of medicine and related requirements must be consistent between the hospital and physician promoting interoperability programs.
- Patients and their representatives should have prompt access to their electronic health information with minimal effort.

Definition of Digital Quality Measures

CMS notes having previously described digital quality measures (dQMs) as measures which originate from sources of health information that are captured and can be transmitted electronically and via interoperable systems.[33] Potential sources cited by CMS for dQMs are diverse, such as EHRs and wearable devices. In this RFI, CMS asks for feedback on and enhanced definition, such that a dQM would be "a software that processes digital data to produce a measure score or measure scores". CMS indicates its view that the updated definition would facilitate the deployment of dQMs to interface with application programming interfaces (APIs) based on Health Level 7's Fast Healthcare Interoperability Resources standards (HL7® FHIR®).

The FAH supports the additional clarity and specificity that is offered by the enhanced definition. Standardized and clear definitions for all terms in all phases of the digital transformation initiative will be necessary. (We note that a later section of this RFI offers more details about potentially desirable characteristics of dQMs that we will address further below.) We are particularly appreciative of the broad interpretation that CMS has provided for potential sources of data for use in dQMs.

[33] Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.

Use of FHIR® for Current eCQMs

CMS reiterates that stakeholders continue to express concerns about the current state of eCQMs reporting: technology barriers, imposed provider burden, and associated costs. In response, the agency has been exploring the utility of FHIR® as a framework for eCQM structure and data submission and has actually started converting some current eCQMs to the FHIR® standard and testing the converted measures.

The FAH thanks CMS for responding to concerns we and others have voiced about current eCQM reporting by exploring potential solutions such as the FHIR® standard. We would ask that CMS promptly share examples of the converted measures and share testing results that demonstrate real world applications (e.g., across a wide range of vendor systems, facility sizes and locations) and not wait until all measures have been converted and tested. It is difficult for us to comment intelligently whether eCQM conversion to FHIR® is a valuable and burden-reducing strategy without such information. If conversion to FHIR®-based eCQMs will entail revised measure specifications and changed data submission processes, we respectfully suggest that CMS promptly begin a moratorium on new and revised eCQMs and the current associated reporting and scoring requirements and policies until the FHIR®-based measures are available for comment through rulemaking. Also, the previously finalized increases to the number of measures and reporting quarters for the CY 2022 EHR reporting period and future years should be paused indefinitely as CMS introduces the FHIR®-based measures and providers become facile with their reporting.

With regards to the question of the potential benefits of "real-time quality measure scores," we again cannot answer meaningfully without more information from CMS, such as a fuller description of what is meant by "real-time" and examples of measures for which such scores might become available. At present, our members would find great value simply in receiving more frequent, reliable, and comprehensible feedback about their performances on current measures.

Advancing Digital Quality Measurement and Transitioning to Digital Quality Measures by 2025

<u>Changes under Consideration: Digital Data</u>

CMS describes requiring data for use in EHR-derived measures to be standardized, interoperable, and suitable for acquisition using FHIR®-based APIs. CMS notes the potential opportunity to capture types of data beyond traditional clinical, administrative, and claims data through standards-based APIs. CMS also states a commitment to validation of digital data submitted to the Hospital Inpatient Quality Reporting (Hospital IQR) program for completeness, accuracy, alignment with standards, and data cleaning.

The FAH conceptually agrees that data for use in dQMs should be standardized and interoperable. We note that standardization should not be overemphasized to the point of negating the utility of the data for specific CMS quality programs; for example, appropriate data for some inpatient hospital measures may differ from what is optimal for some post-acute care measures. Flexibility to define nuanced data requirements when appropriate should not be

sacrificed to standardization. The FAH further conceptually supports that digital data for use in CMS quality programs should also be interoperable, but we again recommend retaining flexibility should conflicts arise between standardization and interoperability. We fully support the agency's commitment to incorporating robust data validation as part of its digital quality strategy.

We acknowledge the potential for FHIR®-based standards as part of a digital quality strategy, but we are reluctant at this time to agree definitively that they are the best choice without at least an outline of how the digital strategy might be implemented for at least one of the existing CMS quality programs. We are somewhat disturbed by what appears to be a clear commitment by CMS to proceeding with FHIR®-based standards in the agency's quality programs as evidenced by the extensive materials outlined at https://ecqi.healthit.gov/FHIR®?qt-tabs_FHIR®=2, when CMS ostensibly through this RFI is seeking input about the utility and propriety of such commitment. In addition, as new and improved standards become available, this strategy should be designed to evolve and adapt to include them where appropriate.

Changes under Consideration: Digital Quality Measure Design

Building on its enhanced definition of a dQM as "a software that processes digital data to produce a measure score or measure scores," CMS states a belief that its future dQMs should be self-contained, end-to-end reporting tools that are able to perform three functions:

- Retrieve data from primarily FHIR®-based resources maintained by providers, payers, CMS, and others via automated queries from a broad set of digital data sources;
    - Starting with EHRs
- Calculate measure score(s); and
- Produce measure score reports.

CMS also provides a detailed list of additional desirable properties and functionalities for its dQMs.

The FAH has no objections to the aspirational list of dQM properties, but we are unable to comment further in the absence of examples from the agency of potential dQMs.

Changes under Consideration: Building a Pathway to Data Aggregation

CMS suggests that the current challenge of data fragmentation might be addressed through policies that incorporate data aggregators into the dQM reporting process and mentions health information exchanges (HIEs) and qualified clinical data registries (QCDRs) as potential aggregators. CMS indicates that data aggregation policies would be developed to maintain the integrity of its measure-reporting process.

The FAH supports incorporation of data aggregators into digital quality reporting within CMS programs. Our members have suggested to us that aggregation by HIEs and/or others may, in addition to serving as a repository collating fragmented data, have the capabilities to at least partially overcome variable submission requirements by entities such as state public health agencies. For example, easy and inexpensive access to aggregators potentially could obviate the

adoption of FHIR® standards as a prerequisite to usable PDMP information exchange. However, we note that currently data aggregators are unevenly distributed geographically and their services are costly, making their use infeasible for many providers, especially those that are smaller or in rural locations. We encourage CMS to further explore the potential impact that this shift may have such as the potential number of data aggregators with whom one facility may be required to exchange data and the associated costs and resources required for this data sharing. Creating a new source of reporting burden would be contrary to the goals of this strategy and additional guidance and solutions may be needed to minimize or eliminate these concerns.

Changes under Consideration: Aligning Measure Requirements

CMS states a commitment "to using policy levers and working with stakeholders to solve the issues of interoperable data exchange" as part of transforming its quality measurement enterprise to be digital. CMS describes the "future potential development and multi-staged implementation" of a common dQM portfolio across its own programs and extending to those of other governmental agencies and private payers, and seeks input on priority areas of focus (e.g., measure requirements, data standards).

The FAH enthusiastically welcomes this commitment by CMS to full alignment within its programs wherever feasible and appropriate, an initiative that we have repeatedly urged become a top priority. We note and applaud the agency's recent efforts to align measures and processes between the Hospital IQR program and the PIP. The implications for reduced provider burden and costs are substantial.

We are concerned about the lower priority and prolonged timeline that come to mind for us given the agency's use of language such as "future potential development and multi-staged implementation." Our members view alignment as a priority at least on par with interoperability. We strongly recommend that CMS commit to using policy levers to solve the issues of alignment, not just those of interoperable data exchange. We further strongly recommend that CMS move actualizing this commitment to top line priority status and begin now to do so across its quality measurement enterprise, related Department of Health and Human Services (HHS) activities, and other federal health care programs (e.g., military and veterans' health care). We would view further delay of CMS, HHS, and other federal alignment to reach the worthy but aspirational goal of extending alignment across all states and all payers as unacceptable. Finally, we fully support the continued importance of the roles played by the National Quality Forum (NQF) and the NQF-convened Measures Application Partnership (MAP).

In response to the agency's query about priority areas of focus (e.g., measure requirements, data standards), the FAH recommends a more holistic but targeted approach. We have some concern about the utility of a strategy that focuses first on a quality program component (e.g., requirements) in isolation and the implied sequential development of the remaining components. Instead, we strongly suggest a strategy of choosing a few, well-established, validated, and meaningful measures for which a digital implementation model for use within one CMS program can be created and tested, optimally in a real-world setting (e.g., voluntary provider participation that is incented by exemption from multiple current requirements and awarding of full PIP scoring credit) or at least in robust and transparent

simulation. Lessons learned could then be used in a rapid-cycle fashion to accelerate this important work.

Conclusions

The FAH recommends that CMS undertake the following near-term actions:

- Aggressively pursue alignment of quality initiatives across CMS, HHS, and other federal health care programs;
- Promptly share with all stakeholders the design and results of CMS efforts to convert current eCQMs to dQMs;
- Design and test proof-of-concept models and feed testing results into a rapid-cycle process;
- Convene appropriate stakeholders to make recommendations about the role of data aggregators; and
- Adopt as a fundamental tenet that providers be required to collect and report the data only one time.

In addition to the principles stated in our section on General Considerations, the FAH concludes our comments with several key points as follows:

- We applaud the strategic thinking and proactivity by CMS as evidenced in this RFI. The RFI is consistent with our repeated recommendation for periodic, holistic assessment of the PIP's success in meeting its intended goals of better patient care, reduced provider and patient burden, and reduced costs.
- We agree that the future is digital. However, if the next step of the process is an actual ongoing dialogue with stakeholders (which is much needed), rather than a proposal of major revisions to specific programs, the total transformation of CMS quality programs as described in this RFI by 2025 is unrealistic.
    - The agency should more often follow a pathway of evolution than revolution.
    - Trials of well-focused model initiatives with rapid-cycle learning seem most appropriate.
    - Overreliance on a single system, approach, or standard (e.g., FHIR®) should be avoided until successful model elements can be identified.
    - Changes and timelines should be considered in the context of how health care delivery stabilizes into a post-COVID-19 PHE "new normal."
    - CMS should actively monitor the progress of the numerous public and private initiatives in this arena and allow them reasonable time to mature before imposing CMS' solutions.
- The special interoperability challenges of smaller, rural, and other providers with more constrained resources must be addressed.
- We concur with CMS that better understanding of the patient's role as an active EHR end-user could point the way to health information exchange that is structured to be more useful to patients in health care decision-making and is more likely to result in patient activation.
    - Facilitating inclusion of PROMs and PGHD could add value.
    - Privacy and security of patients' health information must be ensured.

    - Use of a "self-reported health" measure as an enterprise-wide metric of CMS quality program success should be promptly explored.
- There will be significant costs to "going digital". Who will bear those costs?

IX.B. Request for Information: Closing the Health Equity Gap in CMS Hospital Quality Programs

Differences in health care outcomes for patients with one or more social risk factors have been well-documented and referred to as health disparities or inequities.[34] CMS recognizes that disparities are multifactorial but is concerned that provision of lower quality health care contributes importantly to inequities for many Medicare beneficiaries. Through this Equity RFI, the agency seeks input about changes to Medicare's quality programs that could better identify disparities and facilitate addressing any inequities found. Questions posed for comment focus on expanding the current CMS Disparity Methods through 1) stratifying quality measure results; 2) improving collection of social risk factor data; and 3) creating a summary quality metric for hospitals.

The FAH and its members are keenly aware of the undeniable health disparities uncovered by the COVID-19 PHE, including the increased rates of infections, complications, and death among Black, Hispanic, and Native Americans compared to Whites. We strongly agree that closing the health equity gap is an essential part of transitioning as a nation towards a value-based health care system. We support the widely-inclusive definition of equity adopted by CMS for its Equity RFI, derived from Executive Order 13985 issued on January 25, 2021.[35] The FAH welcomes the opportunity to respond to this RFI, and we are excited about and committed to working closely with CMS and the Administration to address health inequities. We concur that building on the current CMS Disparity Methods represents a viable strategy.

<u>Stratification of Quality Measure Results by Race and Ethnicity</u>

CMS recently began providing confidential hospital-specific reports (HSRs) of facility-level performance on measures from Medicare's Hospital Readmissions Reduction Program (HRRP) stratified by dual eligibility. For the 2020 reporting period, application of the CMS Disparity Methods to six condition/procedure-specific readmission measures showed worse outcomes across the majority of hospitals on all measures. The agency seeks input about adding race and ethnicity as stratification parameters to its quality programs, focusing attention on standardized definitions and indirect estimation statistical methods for those parameters.

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[34] Social risk factors as used herein includes items sometimes also categorized as demographic variables, sociodemographic status (SDS), socioeconomic status (SES) and social determinants of health (SDOH).

[35] The consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.

The FAH agrees with the choice of race and ethnicity as the initial parameters for future stratified reporting and the absolute necessity of standardized definitions of these terms across all sources of performance measurement data (e.g., claims, EHRs, Social Security Administration [SSA] database). We recommend as a starting point the compact, easily understood, OMB minimum standard comprised of five racial and one ethnicity categories. The much more granular CDC Race & Ethnicity coding system should be reserved for situations where added precision is essential and actionable. We note that CMS is still early in its experience with stratified reporting and strongly advise that process of expanding parameters not be tied to an arbitrary completion date. Addressing health equity is too important a goal to accept trading validity and credibility for speed.

Indirect Estimation for Imputing Race and Ethnicity

In addition to well-defined parameters, investigating health disparities through stratification requires accurate individual data. CMS does not itself routinely collect race, ethnicity, and other social risk factor data, and substantial information gaps in its source, the SSA database, have been described. Self-reporting of race and ethnicity is established as the gold standard but complete and reliable collection of information accessible to CMS does not currently occur. The agency, therefore, is considering the statistical technique of indirect estimation to increase the accuracy of the data available. Indirect estimation of race and ethnicity uses one or more other data elements to impute values for data that are missing or of questionable accuracy. CMS views indirect estimation as a temporary solution until improved data collection, addressed further below, becomes a reality.

The FAH strongly agrees with CMS that the definitive solution to data accuracy is improved collection of demographic information from patients themselves. However, to allow the work of addressing health disparities to begin now, the FAH supports the application of indirect estimation to race and ethnicity data for use by CMS on a trial basis. We note that the agency's experience to date in using imputed race and ethnicity data has been confined to the Medicare Advantage (MA) program, where such information is part of stratified reporting of some quality measures at the MA contract level. We urge CMS to first establish the feasibility and validity of translating indirect estimation of race and ethnicity from use in the MA program to application across other Medicare quality programs; this could take the form of simulation and modeling followed by real-world, smaller-scale exploration such as pilot projects. Hasty adoption that leads to flawed results reporting would seriously derail the vital work of addressing disparities. More immediately, we ask that CMS share with stakeholders more complete information about its experiences with indirect estimation in the MA program.

Improving Demographic Data Collection

CMS states that robust, accurate, stratified equity reporting would be facilitated by collection of a standardized set of social, psychological, and behavioral interoperable data elements by hospitals at the time of inpatient admission. CMS further states that criteria adopted into the 2015 Edition of CEHRT by ONC would enable such data collection, though acknowledges that the functionality for those criteria is not now included in the EHR

requirements for hospitals under the Promoting Interoperability Program (PIP). The agency also notes that additional hospital resources would be necessary to create optimum conditions for a large set of sensitive data to be collected.

The FAH appreciates the potential value of the extensive, standardized, granular dataset described by CMS. We note that hospitals already often collect certain demographic data (e.g., date of birth) and some information that could link to certain social risk factors (e.g., place of residence). Current collection is quite variable, driven by demands from states, insurers, and public health agencies, amongst others. The timing of data collection varies and involves the admission and discharge planning processes. We agree conceptually that hospitals are positioned to participate in enhanced data collection and want to support CMS in this effort.

However, the FAH believes that much remains to be described and clarified before the agency's vision for improved data collection by hospitals for use by CMS can move forward, including clearly-defined and standardized data elements; methods of data submission and validation; and financing the associated collection burden. We strongly advise small first steps and an incremental approach developed deliberately and through transparent collaboration with hospitals and other stakeholders. An initiative in which some hospitals would voluntarily attempt to collect race, ethnicity, and language preference for submission to CMS and would receive incentives for meeting a reporting threshold could be a first step. The timing of data collection should be left to hospitals so as not to interfere with clinical care. We further advise CMS to explore multiple data sources (e.g., insurers, health plans) and venues for data collection (Medicare enrollment, school registration).

Potential Creation of a Hospital Equity Score

CMS believes that a summary score, derived from results aggregated across multiple quality measures that are stratified for multiple social risk factors, would add to the value and utility of disparities reporting. CMS describes the potential adaption of the Health Equity Summary Score (HESS) developed for use in the MA program to create a publicly reported Hospital Equity Score (HES) applicable to IPPS hospitals. The agency also invites input into interventions available to hospitals for improving low equity scores.

The FAH understands the intrinsic appeal of a single metric for hospital equity performance and its potential utility for evaluating progress towards closing the equity gaps in our nation's health care system. We stand willing to work with CMS in development of a potential summary score. We strongly believe that anything much beyond a conceptual discussion is premature at this time. The HESS score, described by its developers as a "proof of concept" and having not yet been applied to real-world circumstances, is not yet ready to serve as a foundation for a HES or other derivatives. Of nearly 400 MA plans evaluated by the HESS developers, scores for both HEDIS and CAHPS performances by plans were calculable for only

44 percent of plans. Smaller plans and those with less typical demographic distribution patterns were seldom evaluable.[36]

The FAH strongly advises CMS first to gain real-world experiences by attempting HESS scoring of all MA plans and publishing a formal, independent evaluation of the result. Concomitantly a test of the metric's utility to MA plan enrollees should be undertaken and reported publicly. If results are promising, deliberate and initial steps in HES development then would seem rational. Hasty design and implementation processes could cause long-term harm to the important and necessary work of addressing health care inequities. While the HESS is being tested, we urge CMS to proceed with refining the goal and potential uses of the HES; for example, is the focus on patient and family decision-making or on value-based program payment? We note the rather recent overhaul of the Hospital Star Rating scoring methodology and suggest that beneficiary use with the revised scoring be assessed for lessons potentially transferable to HES design.

Conclusion

The FAH emphasizes its full commitment to working with CMS, HHS, and others on what must be a continuous and sustained effort to ensure health care equity nationwide. We commend CMS for undertaking and sharing its strategic thinking. We believe that reporting stratified by race and ethnicity in the HRRP is a tangible goal that can set the stage for thoughtful expansion over time to other measures and other CMS quality programs. The FAH also believes that practical work can begin on improving data collection, particularly the foundational steps of data element definition, a complete environmental scan of collection already occurring in the field, and exploration of strategies for safeguarding privacy at every step. Although HES development seems the most futuristic of the initiatives upon which CMS is seeking input through the Equity RFI, even there first steps can be taken soon such as rigorous evaluation of beneficiary responses to the revised Hospital Star Rating scoring system.

Finally, we endorse the general principle that confidential reporting to hospitals should always precede public display of performance data, and that public reporting should not begin until sufficient time has elapsed to allow testing messaging, conducting focus groups, and other techniques to ensure public data is comprehensible to the intended audience. We also thank CMS for its repeatedly stated commitment that specific program measures and policies will occur only through the rulemaking process. We look forward to joining CMS on the exciting journey to health equity.

[36] Agniel D, Martino SC, Burkhart Q, et al. Incentivizing Excellent Care to At-Risk Groups with a Health Equity Summary Score. J Gen Intern Med. Published online November 11, 2019. doi:10.1007/s11606-019-05473-x

IX.C. Hospital Inpatient Quality Reporting (IQR) Program

Proposals to Adopt New Measures into the Hospital IQR Measure Set

- Maternal Morbidity Structural Measure ("Maternal Morbidity Measure")

This proposed measure would determine the number of hospitals currently participating in a structured State or national Perinatal QI Collaborative and whether participating hospitals are implementing the safety practices or bundles embedded in these QI initiatives beginning with IQR program payment year FY 2021.

While the FAH strongly supports efforts to address pregnancy-related morbidity and mortality, we are unable to support inclusion of this measure at this time due to the lack of clear linkages that participation in quality improvement collaboratives can improve outcomes in this area. In addition, we believe that there is significant potential for the measure to already be or quickly become topped out. The FAH encourages CMS to explore other measures that are more directly linked to quality improvement and accountability while also minimizing reporting burden for hospitals.

- Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure with Claims and Electronic Health Record Data (NQF #3502) ("Hybrid HWM Measure")

This proposed hybrid measure (based on both claims and electronically submitted clinical data) intends to more comprehensively measure the mortality rates of hospitals and to improve its ability to measure mortality rates in smaller volume hospitals beginning with Hospital IQR program payment year FY 2026.

The FAH agrees that hospitals should measure and track mortality rates for quality improvement purposes but any measure that is proposed for use in Hospital IQR program should be evidence-based and demonstrated to be reliable and valid.

The FAH does not believe that the rationale and underlying research for this measure provides sufficient evidence that a death in the 30 days following an inpatient admission is a predictor of the quality of care provided by a hospital and may well be due to other factors outside of a hospital's control. During the National Quality Forum (NQF) review of this measure, we noted that the articles and research cited to demonstrate the importance and underlying evidence to support the measure were solely focused on inpatient mortality and no empirical data was provided that demonstrates a relationship between 30-day mortality and at least one process, intervention or service that could be attributed to an individual hospital.

The FAH has significant concerns on whether CMS has demonstrated that the measure provides valid assessments of the quality of care provided to patients by hospitals since only face validity testing was submitted during the NQF review. The FAH encourages CMS to test whether a correlation with the Hospital-wide All-Cause Risk-Standardized Readmission measure exists prior to inclusion in Hospital IQR program since this measure is intended to be a

complement to the existing readmission measure and allow CMS to evaluate trends in hospital performance.

In addition, the FAH continues to believe that the risk adjustment for this measure as well as many of the risk-adjusted outcome measures finalized in the Hospital IQR program and other payment programs should address social risk factors. CMS must move beyond examining the impact of only a handful of variables such as dual eligibility status and the Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) Index Score and this testing must consider new methods for testing rather than the current approach of "adding on" factors after the model is developed. New approaches would assist hospitals and others in understanding how the inclusion of social risk factors could impact the model and provide additional information for groups examining this issue such as the NQF and Office of the Assistant Secretary for Planning and Evaluation. The FAH urges CMS to continue to identify new approaches to testing and expand to new factors that are known to affect these rates and are beyond the hospital's control such as availability of health care providers and access to pharmacies and transportation as well as patient-level information such as education and language proficiency.

The FAH also questions the usefulness of this measure given the limited variation in performance scores. During the NQF review, testing demonstrated that only six hospitals were identified as statistically worse than the national average and the majority of the hospitals (92.4%) were no different than the national average. We do not believe that this measure provides any new information that would be useful to hospitals and patients.

- COVID-19 Vaccination Coverage among Healthcare Personnel

This proposed measure would assess the percentage of COVID-19 vaccination coverage in health care personnel providing care in hospitals.

The FAH supports the intent of this measure but urges CMS to consider postponing its inclusion in the Hospital IQR program until the measure specifications have been finalized and the COVID-19 vaccines have been given full FDA approval, not just for Emergency Use Authorization. The underlying evidence for this measure is still emerging, additional vaccines are in development, methods for addressing measure collection challenges related to anticipated "booster" shots may be required, full approval by the NQF has not yet occurred, and feedback from the field is needed to ensure that this measure reflects the most current knowledge and evidence and can be easily collected and reported.

Additionally, this measure would be duplicative at present because CMS already has vaccination status data from hospitals through HHS's contract with Teletracking. Further, because we anticipate that this measure will undergo substantial changes within and across reporting years, the FAH does not believe that it should be used for payment decisions, nor should it be publicly reported until the underlying evidence is stable and reporting of the measure has occurred for several years. Ultimately, the FAH generally believes that measures that increase the reporting burden and leverage specifications that are not aligned with other measures should be avoided.

- Hospital Harm – Severe Hypoglycemia Electronic Clinical Quality Measure (eCQM) (NQF # 3503e)

This proposed measure would track the rate at which severe hypoglycemia events occur after hospital administration of antihyperglycemic medications.

The FAH appreciates the recent revisions made to this eCQM to improve its ability to distinguish good versus poor quality and that the complementary measure on severe hyperglycemia is also proposed. Based on the recent submission to the NQF, the FAH identified that measure testing was only completed across six hospitals and two electronic health record systems (EHRs). The FAH strongly encourages CMS to assess the feasibility and validity of collecting the required data elements from additional hospitals and EHRs. Thorough assessments of each data element and the required calculations and logic must be vetted across more hospitals and vendor systems to truly understand whether this measure is ready for implementation. If the measure is not determined to be feasible and valid in the majority of vendor systems currently used, then it would be prudent for CMS to delay implementation until these gaps can be addressed.

The FAH is also concerned that the differences in scores may be minimal and may not yield reliable and valid representations of performance across the hospitals should the eCQM data be publicly reported. Testing across the six hospitals provided scores ranging from 2.52 to 2.96%. The FAH questions whether these results would ensure that comparisons in the quality of care can be made and are useful to allow patients and families to distinguish higher quality of care and by hospitals for quality improvement.

In addition, the proposed version of this measure assesses whether one event occurred during an admission rather than the previous approach of counting the number of events per patient days, which is still used for the severe hyperglycemia measure. While we support this change as we believe that it reduces the complexity of the measure, the two hospital harm measures (hypoglycemia and hyperglycemia) are no longer aligned. The FAH urges CMS to hold off on including either measure in the Hospital IQR program until both are aligned, are more widely tested, and scores demonstrate sufficient variation in performance.

- Hospital Harm – Severe Hyperglycemia Electronic Clinical Quality measure (eCQM) (NQF # 3533e)

This proposed measure would track the rate at which severe hyperglycemia events occur among hospitalized diabetic patients.

The FAH appreciates the focus of this eCQM on an important patient safety event. Based on the last submission to the NQF in 2020, the FAH identified that measure testing was only completed across seven hospitals and three EHRs. The FAH strongly encourages CMS to assess the feasibility and validity of collecting the required data elements from additional hospitals and EHRs, particularly given the complexity of the numerator. Thorough assessments of each data element and the required calculations and logic must be vetted across more hospitals and vendor systems to truly understand whether this measure is ready for implementation. If the measure is

not determined to be feasible and valid in the majority of vendor systems currently used, then it would be prudent for CMS to delay implementation until these gaps can be addressed.

In addition, this eCQM assesses the number of events per patient days, which is different than the eCQM on severe hyperglycemia, which reports whether one event occurred during an admission. As a result, the two hospital harm measures (hypoglycemia and hyperglycemia) are no longer aligned. The FAH urges CMS to hold off on including either measure in the Hospital IQR program until both are aligned using the new approach of one event per admission and are more widely tested.

Proposals to Remove Measures from the Hospital IQR Measure Set

CMS proposes to remove five measures from the Hospital IQR Program for the FYs 2023 through 2026 payment determinations.

- Deaths Surgical Inpatients w/Serious Treatable Complications
- Exclusive Breast Milk Feeding eCQM
- Admit decision time to ED departure (ED-2) eCQM
- Anticoagulation Rx for Atrial Fibrillation/Flutter eCQM
- Discharged on Statin Medication eCQM

The FAH supports removal of these five measures from the Hospital IQR program as the cost to collect and report each measure outweighs any potential benefits.

Considerations for Future Measures

- 30-Day All-Cause Mortality Measure for Patients Admitted With COVID-19 Infection (COVID-19 mortality measure)

CMS is considering the development and inclusion of a hospital-level measure of all-cause mortality for Medicare beneficiaries admitted with COVID-10 infection to assess how the burden of the PHE impacts hospitals' abilities to care for patients.

The FAH cautions CMS on moving forward too quickly with any measure related to COVID-19 since the underlying evidence to support the prevention and treatment of this virus is still emerging with therapies, treatment protocols, and additional vaccines still in development. Any measure that is used in Hospital IQR program should be based on evidence and testing that demonstrates a death in the 30 days following an inpatient admission for COVID-19 infection is a predictor of the quality of care provided by a hospital and these data are not yet available. We also anticipate that any measure examining an outcome such as mortality related to this virus would require risk adjustment and potential clinical variables will be difficult to identify and validate at this time. The FAH believes that no measure development in this area should be undertaken until the evidence to support a measure becomes more stable and a robust data set over multiple years is available.

- Hospital-Level, Risk-Standardized Patient Reported Outcomes (PRO) Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) Performance Measure (THA/TKA PRO-PM)

CMS is considering the future inclusion of the THA/TKA patient-reported outcomes performance measure (PRO-PM) in the Hospital IQR Program.

The FAH supports the development and implementation of PRO-PMs but we also believe that additional questions and work remain before this or any other PRO-PM are implemented in the Hospital IQR program. These analyses should include the degree to which multiple PRO-PMs could lead to survey fatigue for patients, the potential impact additional PRO-PMs may have on the reporting of well-established measures such as HCAHPs, and what level of data collection burden for an individual PRO-PM is acceptable for a hospital or other health care provider.

This PRO-PM requires the collection of multiple data points beyond the typical clinical variables to ensure that the performance scores are adequately risk adjusted. The FAH supports the inclusion of these data points but we are concerned that CMS has not provided sufficient information on how these data are collected and what additional workload and time will be required. For example, several of the data elements needed for risk adjustment are derived from patient-reported surveys, which must be collected within 0-90 days pre-operative. No information is available on the processes used by the hospitals such as whether it required coordination with orthopedic practices or if the burden of the additional data collection was placed on hospital staff on the day of surgery. To what extent did these requirements impact clinical workflows and were additional staff resources required? What additional costs might an individual hospital encounter as a result of implementation of this PRO-PM? Alternatively, from the patient's perspective, did the additional questions seem relevant and was the point in time during which these additional data were collected appropriate?

It will also be critical to understand whether there is a potential for individuals to prioritize the completion of one survey over another and therefore lead to negative unintended consequences on response rates for other PRO-PMs such as HCAHPS. Analysis of response rates for HCAHPS from 2008 (33%) to 2017 (26%) revealed a percentage change of -22% overall and an average 0.8 percentage point drop per year.[37] This erosion of participation from patients will likely only increase as PRO-PMs become more prevalent.

The FAH believes that CMS must develop solutions to these concerns prior to implementation of this measure in the Hospital IQR Program. These solutions must be widely tested across multiple hospitals and should determine the feasibility of implementation based on specific characteristics such as hospital size and location and the potential impact on other survey-based measures. In addition, the current public health emergency must be over and day-to-day operations back to "normal" before CMS considers asking hospitals to collect and report the data required for this PRO-PM.

[37] 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.

Potential Future Efforts to Address Equity in the Hospital IQR Program

- Confidential Stratified Reporting for the Hospital-Wide All-Cause Unplanned Readmission Measure Using Both Dual Eligibility and Race/Ethnicity

CMS requests input on a potential measure that would build on the current stratified reporting under the HRRP using dual eligibility status. We have already addressed stratified reporting, indirect estimation of missing data, and the timing of confidential versus public reporting in our comments above on the broader CMS Equity RFI (IX.B)

- Potential Future Reporting of a Structural Measure to Assess the Degree of Hospital Leadership Engagement in Health Equity Performance Data

CMS requests comments about the future adoption of an attestation-based structural measure that can assess organizational commitment to health equity. The agency appears to envision a set of measures covering several priority domains as follows:

  - Examining existing organizational algorithms for bias;
  - Creating and actively maintaining a disparities impact statement;
  - Actively maintaining an updated language plan;
  - Actively maintaining an updated communication access plan;
  - EHR capabilities for demographic data collection; and
  - Hospital staff training regarding best practices when collecting demographic data.

CMS explicitly states its vision of an incremental approach to required reporting by measure implementation using an initial voluntary reporting period. CMS also acknowledges potential added burden of new measures and reporting requirements.

The FAH and its members are fully committed to achieving equity in the provision and quality of health services. We believe that many of the agency's priority domains are already being addressed in our hospitals and health systems. Many already have in place language and communication access plans woven into their frameworks for ongoing provision of culturally competent care to patients with limited English proficiency and hearing or vision disabilities. These plans typically form part of the curricula for onboarding and refresher training of our members' patient-facing staff. Our members also maintain CEHRT capabilities as required under the CMS Promoting Interoperability Program for hospitals.

The activities just described in many cases overlap with accreditation requirements of hospitals generally or of special hospital programs (e.g., accreditation of bariatric surgery programs that mandates culturally competent care of morbidly obese patients). Also, hospital associations already have underway a variety of programs addressing equity, including organizational focus and leadership. The FAH urges CMS to first catalogue what hospitals are already doing before establishing new measures or requirements to preclude burden caused by overlap and redundancy. A complete environmental scan, listening sessions, focus groups, and/or a Technical Expert Panel could be helpful.

The FAH encourages CMS to think broadly when crafting leadership structural measures; for example, how could the characteristics of the community served by a hospital and the community outreach activities of that hospital be incorporated into a measure. The initial use of process measures may be a good first step, allowing hospitals and CMS to gain experience with achievable and actionable efforts in this area; such measures could also point the way to valid outcome measures.

We fully support the concept of incremental measure implementation as stated by CMS. In addition to initial voluntary reporting by hospitals, we strongly encourage CMS to start with one measure or a very limited set of measures until hospitals and the agency gain experience with these new domains. Prompt, confidential performance feedback to hospitals will be essential. Conversion to mandatory measures and consideration of public data reporting should be deferred until the performance characteristics of these new measures are well established, particularly validity and actionability.

The FAH asks CMS to clarify what is meant by a disparities impact statement, as the document referenced by the agency appears to be an action plan outline rather than a list of principles or similar material than a statement typically connotes. We also ask CMS to explain and provide examples of what is meant by organizational algorithms that are to be assessed for inherent bias, as many hospital departments use algorithms to guide operations that seem unrelated to inequities (e.g., algorithms that order various hospital units in order of priority for environmental, laundry, and food-service activities). Finally, the FAH is ready now to begin collaborating with CMS and other stakeholders to advance organizational equity efforts by hospitals, such as sharing staff training curricula and best practices in mentoring a diverse pool of future leaders. We look forward to an ongoing dialogue with the agency on this and other measures aimed at closing health equity gaps.

The FAH refers CMS to our detailed comments on the Equity RFI.

Form, Manner, and Timing of Data Submission

- Procedural Requirement Updates § 412.140

CMS proposes to update two references in this section to the QualityNet website to the current and replace the terms QualityNet Administrator and QualityNet System Administrator with QualityNet security official in two places to align with other CMS quality programs.

The FAH supports these changes to simplify and streamline processes.

- Proposed Updates to Requirements for eCQM Reporting

CMS proposes to require hospitals to use only certified technology consistent with the 2015 Edition Cures Update beginning with CY 2023 reporting/FY 2025 payment determinations.

The FAH supports this change to align reporting requirements with the 2015 Edition Cures Update.

- Proposed Updates to Requirements for Hybrid Measure Reporting

CMS proposes to require hospitals to use only certified technology consistent with the 2015 Edition Cures Update beginning with CY 2023 reporting/FY 2025 payment determinations.

The FAH supports this change to align reporting requirements with the 2015 Edition Cures Update.

- Reporting and Submission Period Updates for New Structural and NHSN Measures

CMS proposes several reporting and submission period updates based on the new measures on maternal mortality and COVID-19 vaccine coverage among HCP.

Given the FAH's concerns with the Maternal Mortality Structural and COVID-19 Vaccination Coverage Among HCP measures, we believe that public reporting of either measure is premature at this time.

- IQR Program Data Validation Educational Review Process

CMS proposes to use the corrected scores that result from educational reviews for all four quarters of data validation beginning with payment year FY 2024; if an error is identified during the fourth quarter, the corrected quarterly score would be used to compute the final confidence interval used in making payment determinations.

The FAH supports these changes to ensure accurate reporting of scores.

IX.E. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

LTCH QRP Measures

- New Measure: COVID-19 Vaccination Coverage among Healthcare Personnel

The FAH urges CMS to postpone its inclusion of the new COVID-19 vaccination coverage in health care personnel in the LTCH QRP until the COVID-19 vaccines receive full FDA approval. The underlying evidence for this measure is still emerging, additional vaccines are in development, methods for addressing measure collection challenges related to anticipated "booster" shots may be required, the additional quality measures are fully endorsed by the NQF, and feedback from the field is needed to ensure that this measure reflects the most current knowledge and evidence and can be easily collected and reported.

Additionally, this measure would be duplicative at present because CMS already has vaccination status data from hospitals, including LTCHs, through HHS's contract with Teletracking. Further, because we anticipate that this measure will undergo substantial changes within and across reporting years, the FAH does not believe that it should be used for payment decisions, nor should it be publicly reported until the underlying evidence is stable and reporting of the measure has occurred for several years. Ultimately, the FAH generally believes that

measures that increase the reporting burden and leverage specifications that are not aligned with other measures should be avoided.

- Updated Measure: Transfer of Health Information to the Patient-Post-Acute Care (TOH-Patient-PAC)

The FAH supports the addition of this exclusion as it serves to avoid counting these patients in both TOH measures in the LTCH QRP. This update will further improve the validity and usefulness of the measure and FAH appreciates CMS' responsiveness to this issue.

IX.E.7 <u>Closing the Health Equity Gap in Post-acute Care Quality Reporting Programs – Request for Information (Equity RFI)</u>

Appropriately accounting for social risk factors is necessary to accurately assess health care provider performance for CMS' public reporting and accountability programs, including the LTCH QRP. We also believe that when social risk factors affect patient outcomes in ways that are beyond the control of providers, quality measures and any related payment consequences must be carefully constructed to avoid unfairly penalizing providers and thus potentially worsening inequities by reducing care access for at-risk patients.

Any quality measures or measurement domains designed to address health equity, should feature the following essential characteristics:

- Data-driven and based upon well-documented outcome disparities with clear associations to well-defined social risk factors.
- Designed to yield performance results that are actionable for providers.
- Constructed to facilitate timely performance result calculations and prompt feedback to providers, as aging data quickly becomes irrelevant. Process, claims-based, and electronic measures may be particularly suited to meet this goal.
- Aligned across CMS and with other federal, state, and other payer collection and reporting requirements.
- Pragmatic in terms of CMS operational capabilities and the ongoing clinical demands made on LTCHs so as to avoid inadvertent disruption of care delivery and payment.

The FAH discourages expanding the SPADEs requirement at this time. The SPADE development process was protracted, and the full burden of SPADEs reporting has not yet become clear as its implementation is incomplete due to the PHE. Existing SPADEs related to sensory disability (e.g., vision, hearing) and high-risk drugs (e.g., opioid or antipsychotic) should be assessed as potential correlates of inequity.

The FAH supports stratification of facility-level quality measure results by social risk factors, when properly designed and implemented, as a useful tool for understanding facility performance disparities. The FAH supports dual-eligibility, race, and ethnicity as reasonable stratification variables for initial use in the LTCH QRP and using both the within- and across-facility CMS Disparity Methods.

IX.F. Proposed Changes to the Medicare Promoting Interoperability Programs (PIP)

The FAH supports the goals of the PIP for eligible hospitals and CAHs. Key principles for productively moving forward include the following:

- It is essential to ensure that improvements in technology align with the real-world practice of medicine, including alignment by CMS of the hospital and physician PIP requirements.
- Only those measures that truly make a difference in patient health and are predictors of value should be implemented in the PIP.
- Public reporting of provider data should focus on those that are transparent, reliable, valid, and useful for patients and their families.
- The hospital PIP should periodically be reassessed holistically to determine whether it is meeting its intended goals of better patient care, reduced provider and patient burden, and reduced costs.

Electronic Health Record (EHR) Reporting Period

The FAH appreciates that CMS has proposed to continue the minimum EHR reporting period for CY 2023 as any continuous 90-day period within the year. This proposal enhances the stability and predictability of the PIP program and facilitates the determinations by hospitals about allocations of scarce resources. CMS also proposes to extend the minimum EHR reporting period to any continuous 180-day period in CY 2024 and subsequent years under the belief that this would increase the comprehensiveness and reliability of data for providers and patients and improve interoperability and health information exchange.

The FAH does not support the proposal to extend the EHR reporting period to 180 days. We are concerned that CMS does not articulate what specific deficits would be addressed by the required additional reporting and describes the burden imposed on hospitals by doubling the required reporting period as minimal. We also note the increased flexibility offered by a 90-day period versus a 180-day period to a hospital that undergoes an EHR vendor transition or system upgrades during the reporting year. Transitioning providers often have difficulty obtaining and combining data from one certified EHR with data from another certified EHR; for example, the source vendor may provide the data in a format that is not combinable with the receiving EHR. While the latter particular obstacle should be resolved once the "EHI Export" 2015 Edition Cures Update CEHRT criterion (patient population use case) is fully implemented, we are several years away from the planned 2023 timeline for that criterion even if no unexpected implementation speedbumps are encountered (e.g., during the required "real-world testing").

The FAH is also concerned about the proposed changes to the Hospital IQR program and believes a more comprehensive testing of that platform is needed before any changes are made to the reporting period. Our member hospitals continually encounter issues using the QualityNet platform, which leads to additional provider data entry burden and delays in completing the

attestation process. The QualityNet platform should be completely functioning at the start of the reporting submission period before considering any changes to the length of the reporting period.

Given the concerns outlined above, the FAH urges the agency to maintain the current 90-day period. Should CMS persist and finalize the proposed 180-day period, the FAH strongly recommends that the agency permanently adopt an exception that allows a 90-day reporting period for hospitals undergoing EHR vendor transitions or system upgrades in any given year (e.g., allowing affected hospitals to attest to being in transition or undertaking upgrades to qualify for a 90-day reporting period).

Performance-Based Scoring Threshold Increase

CMS proposes to increase the PIP's minimum performance scoring threshold to reach meaningful user status from 50 points to 60 points beginning with the CY 2022 EHR reporting period. CMS notes that over 98 percent of participating eligible hospitals and CAHs met the 50-point minimum for CY 2019. ***The FAH supports the proposed increase, but questions the implementation timing.*** We note that CY 2019 was the first full year of the performance-based scoring methodology, finalized in the FY 2019 IPPS/LTCH final rule after major revisions, and what would have been the second full reporting year, CY 2020, was impacted by the COVID-19 PHE. Some ongoing PHE impact can realistically be expected for CY 2021. The proposed increase, therefore, would take effect before the likelihood of provider success in reaching the 60-point threshold can be assessed with more than one full year of actual performance data. We are particularly concerned that smaller and rural hospitals, newly emerging from PHE impacts, will struggle with the 60-point threshold and fail to qualify as meaningful users. ***The FAH urges CMS to delay increasing the minimum performance scoring threshold until CY 2023, and to further delay implementation if warranted based on analysis of actual performance data for CY 2021, including subanalyses for small and rural providers.***

Query of Prescription Drug Monitoring Program Measure (PDMP)

For the CY 2022 EHR reporting period, CMS proposes maintaining the Query of PDMP measure as optional and to increase the associated bonus points for its successful reporting from 5 to 10 points. ***The FAH fully supports this proposal.*** Additionally, CMS requests public comment on a series of questions designed to assess the remaining barriers to transitioning the Query of PDMP measure from attestation-based to performance-based.

First, the FAH notes the protracted history of this measure since its initial proposal, and we agree with CMS that Query of PDMP is still not ready for prime time as a performance-based measure as evidenced by the agency's references to "emerging standards" and "prototype testing." The barriers to readiness remain primarily those of interoperability and ease of information exchange across systems and jurisdictions. Our members with multi-hospital systems, particularly those with units that cross jurisdictional boundaries (e.g., interstate), continue to be unable to routinely query PDMPs due to varying state requirements and to be unable to integrate PDMPs into their clinical workflows due to PDMP configurations that are not easily accessed by all EHR products. A performance-based version of Query of PDMP would need to allow exclusions for providers who encounter such barriers.

We regard the agency's question as to when state PDMPs will be ready to effectively exchange data with provider systems using Health Level 7's Fast Healthcare Interoperability Resources standards (HL7® FHIR®) as beyond our ability to accurately answer. Our members have suggested to us that information exchanges and/or data aggregators may have the capabilities to at least partially overcome the described barriers but aggregators are unevenly distributed geographically and their services are costly, making this strategy infeasible for many providers, especially those that are smaller or in rural locations. We further note that easy and inexpensive access to aggregators potentially could obviate the adoption of FHIR standards as a prerequisite to usable PDMP information exchange. Requiring EHR vendors to build into their products all of the elements to support Query of PDMP and its interoperability also seems to be a viable strategy.

Provide Patients Electronic Access to Their Health Information Measure

CMS is proposing to modify this measure such that each hospital would be required to maintain each patient's electronic access to their health information indefinitely, and to do so via the application of the patient's choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the hospital's CEHRT. The requirement would apply beginning with the CY 2022 EHR reporting period and would include all patient health information from encounters on or after January 1, 2016. The agency considered alternative start dates of January 1, 2012 and January 1, 2019. ***The FAH fully supports the principle that patients should have prompt access to their electronic health information with minimal effort***. We are concerned, however, about the breadth and depth of this proposed requirement, including the implications of the term "indefinitely" and the retrospective time period. For example, the ever-growing volume of information for which each hospital is responsible will likewise require ever-growing resource investments for storage capacity and ongoing essential maintenance by hospital health IT personnel.

The FAH recognizes that full implementation of the EHI-Export criterion should mitigate hospital burden related to providing patient access, but the planned 2023 timeline for that criterion assumes that no substantive speedbumps are encountered before then (e.g., during the required "real-world testing"). Further, we note that a similar requirement for other entities (e.g., MA organizations, CHIP managed care entities, Medicaid FFS programs) became effective January 1, 2021, although CMS has announced enforcement discretion for that requirement until July 1, 2021. Therefore, we are quite concerned that CMS, having had little or no hands-on experience with administering this type of patient electronic health information access requirement, now proposes its very broad expansion to hospitals over a very short timeline.

The FAH is also troubled by other confounders. For example, the types and amount of stored and potentially retrievable patient data has grown each year. Will hospitals be required to make an effort to backfill what are considered information gaps by current standards for years going back through January 1, 2016? Additionally, states have varying timeframes on which certain information must be maintained and stored, and it is not clear from the rule how CMS will align the state and federal policies in time for the proposed CY 2022 requirement implementation date.

Considering all of the foregoing, the FAH does not support proceeding with the proposed modifications to the Provide Patients Electronic Access to Their Health Information Measure at this time. We recommend that CMS defer adoption of the modified measure until at least two years of experience has been gained with the analogous MA/Medicaid/CHIP requirement and until the EHI-Export criterion has in fact been successfully implemented by vendors as shown through real-world testing**.** We also urge CMS to structure the measure initially to allow hospitals to become compliant using an application of the hospital's choice before being required to support any API a patient might choose. ***Should CMS proceed with modifying this measure, we recommend starting the data availability lookback period on or after January 1, 2019 and providing exceptions for situations in which hospitals cannot access the historical data (e.g., EHR conversions, ransomware).***

In addition, the FAH continues to urge CMS to work with other agencies and the private sector to develop a privacy and security framework to ensure patient information is accessed and used in accordance with their expectations by non-HIPAA-covered third-party applications.

Health Information Exchange (HIE) Bi-Directional Exchange Measure

CMS proposes the addition of a measure for bi-directional exchange of health information that could be voluntarily reported in place of two existing measures: Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information, beginning with the CY 2022 EHR reporting period. Hospitals reporting this measure would be required to attest (Yes/No) to the following about their HIE participation:

- The HIE enables secure, bi-directional exchange of information for all unique patients admitted to or discharged from the hospital or emergency department (ED) and all unique patient records stored or maintained in the EHR for these departments during the reporting period.
- The HIE can exchange information across broad network of unaffiliated exchange partners and does not engage in exclusionary behavior when determining exchange partners.
- The hospital uses CEHRT functions to support their bi-directional exchange with the HIE.

CMS indicates that the new measure is intended to incent eligible hospitals to participate in HIEs simultaneously with establishing high information sharing performance standards among health care providers. CMS also states a desire to allow regulatory flexibility that suffices to support multiple ways in which providers could use certified health IT to engage in data exchange with HIEs.

The FAH supports the addition of the new HIE Bi-Directional Exchange measure as an option for reporting by attestation under the PIP's Health Information Exchange Objective for the CY 2022 EHR reporting period. However, before the measure is finalized, we ask for guidance from CMS about what documentation from hospitals would serve as acceptable evidence of meeting the measure's criteria. The FAH would not support this measure for

required reporting, whether through attestation or performance scoring, until several issues are addressed.

First, although CMS states that nearly 70 percent of hospitals reported participating in a national HIE network, our members report that many "participate" in information sharing but do not engage in bi-directional exchange. CMS itself describes current HIEs as having non-uniform capabilities, employing different models of data storage, and utilizing a variety of business models. Specific and credible data that nearly all hospitals have the capability for bi-directional exchange and are doing so with an HIE must be publicly available before making this measure's reporting mandatory. Further, we note that numerous HIEs (including some states) pass along their expenses as "subscription costs" to providers, so that bi-directional exchange through an HIE is unaffordable for some hospitals. Also, we ask for clarification about whether bi-directional exchange for a hospital system with an enterprise HIE could satisfy the measure's criteria. We are apprehensive that this new measure could be rushed to mandatory reporting prematurely, based on our members' experiences of their ongoing struggles to successfully report the two current and less rigorous information exchange measures (Support Electronic Referral Loops). Finally, the FAH has consistently opposed for required reporting and scoring those measures that contain "all-or-nothing" components, such as the "all unique records" and "all unique patients" elements of the proposed HIE Bi-Directional Exchange measure. We would want CMS to clarify the meanings of these terms and to create exceptions and/or exclusions as appropriate, incorporating the agency's experience gained about compliance with these terms by those entities who began reporting a similar bi-directional measure on January 1, 2021 (e.g., MA plans, Medicaid and CHIP managed care organizations).

<u>Public Health and Clinical Data Exchange Objective Modifications</u>

CMS proposes several changes to the Public Health and Clinical Data Exchange Objective beginning with the CY 2022 EHR reporting period, believing that the great value of this measure set has been amply demonstrated by the COVID-19 PHE. Hospitals currently may choose 2 of 6 measures for reporting. Going forward CMS proposes that:

- Reporting would be required for 4 measures –
  - Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting.
  - Yes/No response to each item is required.
  - Syndromic Surveillance Reporting measure would be revised to include only Emergency Department (ED) data reporting instead of "urgent care".
  - Exclusions are available for each measure and would continue unchanged, except substitution of ED-only data reporting for urgent care in the Syndromic Surveillance Reporting measure.
- Reporting would be optional for 2 measures and eligible for a maximum of 5 bonus points –
  - Public Health Registry Reporting and Clinical Data Registry Reporting.
  - Exclusions for these 2 measures would be eliminated.

The FAH strongly supports the intent of the package of proposed revisions – to strengthen early warning, fast public health response, and effective and efficient vaccine

uptake during future PHEs. However, we cannot support that the entire package of proposed revisions be mandatory starting with the CY 2022 EHR reporting period. Our members report ongoing difficulties with reporting several of the required measures. Contrary to the agency's assertions in the preamble, real-world experience has shown that not all states are prepared to receive and process the data reported by hospitals. Reporting is further confounded by non-uniform state requirements and significant variation in states' health IT readiness that seriously impact multi-state health system facilities as well as those individual hospitals who serve a population crossing any state line. CMS itself notes that there remain major gaps in syndromic surveillance coverage, outdated manual methods continue to be used for reporting, the eCR electronic case reporting FHIR-based API and associated platform have only recently been widely adopted and development of the necessary EHR capabilities is lagging, and that hospital laboratories will be challenged to satisfy the requirement for electronic reportable result reporting. Finally, we note the costs that hospitals will incur to satisfy the entire package of revised measures, without any tangible return on investment.

The FAH recommends improving the public health reporting infrastructure and incentivizing public health agencies to engage proactively with hospitals and other health care providers. The FAH also strongly recommends a slower, more incremental adoption of the revised Public Health and Clinical Data Exchange measure package. Options might include two required and two voluntary (of the remaining four original measures) revised measures initially followed by adoption of an additional required measure each of two subsequent years; other option combinations - including the awarding of bonus points - are certainly possible and could be tailored to priorities set by CMS. We support the proposed changes to scoring under this objective after an appropriate phase-in of the four required measures. We also support the proposal for optional reporting and bonus point availability as proposed for the Public Health Registry Reporting and Clinical Data Registry Reporting measures.

Safety Assurance Factor for EHR Resilience Guides (SAFER Guides Measure)

CMS is proposing to add a new measure for the CY 2022 EHR reporting period under the PIP's Protect Patient Health Information Objective incorporating the mandatory use by hospitals of ONC's SAFER Guides. Each hospital would be required to attest once annually (Yes/No) to having conducted a "complete" self-assessment using the SAFER Guides. The complete assessment would entail that the hospital assess itself against the checklists of recommended practices present in each of the nine Guides. CMS clarifies that each hospital should tailor those practices to its own organizational structure and population and that a hospital would not be asked to confirm that all practices have been implemented fully in all areas.

The FAH fully supports the goal of ensuring that hospitals regularly assess the safety of their EHRs and their potential responses to system disruption, failure, or natural disaster, or other emergencies. However, we question measure's utility to the PIP, as well as the value of adding a measure based on best practices that were last updated in 2016, as well as the overlap between the SAFER Guides and the HIPAA Security Risk Analysis in certain content areas. The SAFER Guides do not improve interoperability, but do create a significant burden on hospitals in the form of a manual review of the Guides' questions and, for health care systems, tracking down answers for multiple hospitals.

The FAH recommends, therefore, that CMS not transition this measure to performance scoring at this time given the burden of nine checklists and sets of recommended practices involved. Should CMS move forward with performance scoring in some form, the FAH urges the agency to consider making it optional with bonus points, phasing in the Guides, and/or requiring alternate year reporting of a HIPAA security risk analysis or a SAFER Guide self-assessment, rather than performance of both activities each year. CMS should also offer guidance as to what documentation would be required of a hospital as evidence of compliance and, in so doing, be mindful of adding to the new burden that already is being created by reviewing multiple checklists.

Information Blocking

Starting the CY 2022 EHR reporting period, CMS proposes to streamline the attestation statements associated with the prevention of information blocking, decreasing them from three items to a single item (the current statement 1). ***The FAH fully supports this change as proposed.***

Electronic Clinical Quality Measures (eCQMs)

CMS makes a number of proposals that would maintain the alignment of measures reported via CEHRT (eCQMs) between the PIP and the Hospital IQR program. For CY 2023 and subsequent years' reporting, CMS would adopt two new NQF-endorsed measures (Hospital Harm – Severe Hypoglycemia and Hospital Harm – Severe Hyperglycemia) and would require hospitals to report their eCQMs using the 2015 Edition Cures Update. For CY 2024, CMS would remove four eCQMs (Anticoagulation Therapy for Atrial Fibrillation/Flutter; Discharged on Statin Medications; Exclusive Breast Milk Feeding; and ED Boarding Time) that are being replaced by improved measures or are no longer consistent with current practice. ***The FAH appreciates the ongoing commitment of CMS to maintain PIP alignment with the Hospital IQR program, and we support the changes as proposed.***

Request for Information (RFI): Additional Objectives or Measures Adopting FHIR®-based API Standards

CMS states that APIs based on the FHIR® standard could substantively improve health data exchange by consistently providing all users with security, performance, scalability, and structure. For example, the 2015 Edition Cures Update standards-based API criterion could support connections to an HIE that would allow hospitals to satisfy the current rule's proposed PIP measure for engagement in bi-directional exchange through an HIE. Through this RFI, CMS seeks comments about how the measures of the HIE and Public Health and Clinical Data Exchange Objectives of the PIP could be integrated with HL7® FHIR® standard-based API functionality.

The FAH commends CMS for its efforts to explore and adopt advances in health IT into the PIP. The ultimate promise of universal interoperability as a lever to move health care delivery and quality forward is unassailable. We have some concern, however, that a focus on

emerging technologies could be premature and provide a distraction from addressing more fundamental and persistent health information exchange challenges. The substantial variability in public health reporting requirements across states will not be solved by FHIR-based APIs, nor will the equally variable levels of readiness for state and regional agencies to digest the data hospitals are being mandated to provide. Similarly, lack of alignment between federal, state, tribal, and other public health entities does not have a technical solution. The finite resources available to hospitals and other providers to attempt to meet requirements of CMS, other payers, and locoregional governmental entities are already stretched, and how providers can fund the purchases of new hardware, software, and connectivity purchases remains unclear. In addition, reliable high-speed connectivity remains absent for many rural providers and smaller communities.

The FAH recommends that CMS focus time and energy on assessing and improving its own IT profile before requiring providers to embrace additional expensive IT solutions. The IT capabilities of CMS are challenged by current programmatic demands, and the agency must make sure it can meet its obligations to providers in areas such as data submission, measure scoring, and prompt patient-level feedback. We support the agency's pursuit of FHIR®-based APIs that can make CMS IT more reliable, nimble, and user-friendly. While CMS does so, the many health IT-related initiatives underway in the private sector may produce affordable solutions applicable to hospitals and other providers and time should be allotted for such development.

Request for Information (RFI): Patient Access Outcomes Measure

The FAH concurs with CMS that better understanding of the patient's role as an active end-user of EHRs could lead to health information exchange that is more useful to patients in health care decision-making and that is more likely to result in patient activation. The FAH members report that patients continue to use online portals more often than APIs to access their EHRs, perhaps being more trusting about sharing sensitive information with known partners such as their hospital systems than of third-party API vendors. Patient choice of access method seems likely to be driven by factors such as availability, ease-of-use, patient demographics (e.g., age), health literacy level, and computer/smart phone usage proficiency. The FAH has previously commented on the tradeoff between patient privacy and broader access to information, particularly by non-HIPAA-covered third-party applications, and continues to urge CMS to work with other agencies and the private sector to develop a privacy and security framework to ensure patient information is accessed and used in accordance with their expectations.

Superficial population-wide metrics should largely be avoided, such as login frequency or number of messages sent, both of which would be higher for patients with active diseases or conditions and thereby less likely to be meaningful measures of access by younger and healthier patients. The FAH opposes the concept of requiring hospitals or other providers to track the third-party applications used by patients as burdensome and of unclear value. We recommend that CMS consider settings of care in designing patient electronic access outcome measures; for example, outpatient test results are more likely to be sought electronically by patients whereas inpatients are more likely to expect to hear those results from their clinicians during the course of their inpatient care. Care must be taken to avoid unintended consequences such as interfering

with clinician-patient relationships by incenting patients to retrieve results from tests that require nuanced interpretations and explanations by clinicians. Finally, we recommend that any PIP measure and/or scoring changes be deferred until patient access choice is more fully explored and understood.

Request for Information (RFI): Clinical Notes

CMS observes that clinical notes typically contain structured and unstructured data and may address patient assessment, diagnosis, care plan, and patient education, among other functions. CMS also describes the adoption of CEHRT criteria and standards to support eight types of clinical notes. The agency, citing the ongoing work of the Open Notes movement (https://www.opennotes.org), now asks for suggestions to make clinical notes more accessible to patients and about a potential new, mandatory, scored PIP measure for clinical note types that are supported by CEHRT.

The FAH reiterates our full support for the principle that patients should have prompt access to their electronic health information with minimal effort. Our members and their associated clinicians report that patterns of patient access to and use of the information in their EHRs are still actively evolving. Concerns persist about the potential for unintended consequences, such as patient misinterpretation of test results and diagnoses when information is read by patients without the benefit of simultaneous explanation by a clinician. While we commend CMS for thinking proactively and strategically, we believe that much remains to be learned about how patient use of clinical notes is best accomplished in the context of a patient's overall care. We do not think that a meaningful answer about the types of clinical note that are commonly sought by patients, but are inaccessible to patients, is possible at this early stage. We advise CMS to monitor ongoing work of others and to examine its own data about beneficiary use of Medicare's Blue Button data service before designing new measures; similar usage information from other federal programs could also be informative (e.g., military and Veterans Affairs EHRs). We do not support proceeding at this time with development of a new, mandatory, scored PIP measure for clinical note types that are supported by CEHRT, particularly when CMS is proposing a substantial expansion of EHR content retention and access to begin with the CY 2022 reporting period, as discussed above under the Provide Patients Electronic Access to Their Health Information Measure. If finalized, that proposed measure would have implications for clinical notes and their access by patients, which would need to be considered as part of any new clinical notes initiative by CMS.

Request for Information (RFI): Designating High Performing Hospitals

CMS notes the emergence of industry-sponsored models for scoring and ranking hospitals for their adoption and utilization of EHR functionality and seeks feedback as to whether CMS should engage in designating high performing facilities in the context of EHR excellence. Relatedly, the agency requests feedback on developing a Star Rating for Promoting Interoperability (PI), or addition to existing Star Rating programs of a PI category.

The FAH has significant concerns about CMS engagement in a program to designate hospitals based on "EHR excellence." As noted by the agency, most existing designation programs are industry-driven and serve as marketing tools for public recognition. Who would

define "EHR excellence" and set criteria or standards for its achievement? How would such a program intersect with the requirements of CMS-recognized accrediting bodies? What "EHR excellence" is being recognized that would be of importance to patients other than ease of access, user friendliness, and timely availability of new materials – all of which are or could be captured within a patient's experience of care rather than creating a new infrastructure? Our members find it challenging even within their own systems to accurately identify high performing hospitals given the variation across hospital populations, services, and settings that must be taken into account. Given these concerns, we instead urge CMS to direct its finite resources to other fundamental IT efforts such as upgrading CMS data systems.

The FAH is also equally concerned about the concept of a PI category Star Rating. The hospital Star Rating system has been controversial and underwent a recent overhaul; performance of the overhauled system is years away from definitive, accurate evaluation of its strengths and weaknesses. Modifications to support health equity are likely to be needed over the near-term. The addition of a new category of unclear meaning for and value to beneficiaries does not seem warranted at this time.

X.A. Medicaid Enrollment of Medicare Providers and Suppliers for Purposes of Processing Claims for Cost-Sharing for Services Furnished to Dually Eligible Beneficiaries

In the Proposed Rule, CMS proposes adding a new subsection (d) to 42 C.F.R. § 455.410 to specify how States must meet their obligations regarding claims for Medicare cost-sharing relating to dual eligible beneficiaries.[38] ***The FAH strongly supports CMS' proposed amendment, which would require State Medicaid programs to accept enrollment of all Medicare-enrolled providers, if the providers otherwise meet all federal Medicaid enrollment requirements, for purposes of processing Medicare cost-sharing claims***.[39] The FAH applauds CMS' efforts to remind States of their overarching and existing federal statutory obligations concerning the processing of cost-sharing claims and issuance of the Medicaid remittance advice (RA).[40] As the Proposed Rule notes, there are States that do not comply with these Federal statutory requirements. This failure on the part of certain States results in provider appeals, and some States have persisted in their non-compliance notwithstanding CMS' past efforts to clarify State obligations with respect to crossover claims.[41]

Given this history and because States are already statutorily required to process these crossover cost-sharing claims, we encourage CMS to work proactively with States to ensure that any new Medicaid enrollment processes do not unnecessarily burden providers and that States appropriately process all crossover cost-sharing claims. For example, some States fail to enroll out-of-state Medicare providers, when each state Medicaid program should instead permit any Medicare provider that furnishes Medicare-covered services to a dually eligible beneficiary to enroll for the limited purpose of processing crossover cost-sharing claims. Therefore, the FAH

[38] 86 Fed. Reg. at 25,654-56.

[39] 86 Fed. Reg. at 25,705, proposing adding paragraph (d) to 42 C.F.R. § 455.410.

[40] *E.g.*, 42 U.S.C. §§ 1396a(a)(10)(E), 1396a(n)(1) and (2), 1396b(a)(3)(A)(i).

[41] 86 Fed. Reg. at 25,655-56.

urges CMS to clarify that the reference to "all Medicare-enrolled providers and suppliers" in proposed section 455.510(d) includes out-of-state Medicare providers. The FAH also urges CMS to finalize this amended regulation as part of more comprehensive monitoring and enforcement of the existing statutory requirements that States process crossover cost-sharing claims, in order to proactively address other inappropriate State requirements that have resulted in crossover cost-sharing claims not being properly processed (e.g., State requirements that the claim meet Medicaid state plan requirements, the failure to enroll Medicare providers in Medicaid retroactive to the date of service, and the imposition of Medicaid timely billing rules that preclude appropriate processing of crossover claims). Further, the FAH strongly encourages the continuation of the Medicaid RA alternative documentation policy developed in the FY 2021 IPPS rulemaking for the foreseeable future because it provides necessary pragmatic flexibility to providers that would otherwise be disadvantaged by a State's failure to issue a Medicaid RA, whether that failure is due to inappropriate enrollment restrictions or other processes that result in the failure to properly process certain types of crossover cost-sharing claims. Finally, the FAH agrees with CMS that this proposal should have the positive effect of reducing the number of costly bad debt appeals by ensuring that certain Medicare-enrolled providers can enroll with State Medicaid programs, receive a Medicaid RA, and claim Medicare bad debt.

X.B. Organ Acquisition Payment (Part 413, Subpart L)

Medicare organ acquisition payment policy has long presumed that all cadaveric kidney transplant recipients are Medicare beneficiaries. This policy has also applied to non-renal organs because of limitations in organ tracking capabilities. CMS now believes that organ tracking capabilities allow transplant hospitals (THs) and organ procurement organizations (OPOs), including hospital OPOs (HOPOs), to discern organ recipients' health insurance payer information so that organ acquisition costs can be more appropriately assigned to the Medicare program for organs transplanted into Medicare beneficiaries. As a result, CMS proposes to replace its presumption and require THs, OPOs, and HOPOs to accurately count and report Medicare usable organs and total usable organs on their Medicare hospital cost reports and retain supporting documentation.

For cost reporting periods beginning on or after October 1, 2021, for THs, OPOs, and HOPOs, CMS is proposing that Medicare usable organs include only organs transplanted into Medicare beneficiaries (including kidneys for Medicare Advantage (MA) beneficiaries with dates of service after January 1, 2021), organs for which Medicare has a secondary payer liability for the organ transplant, and pancreata procured for the purpose of acquiring pancreatic islet cells acquired for transplantation for Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial.

The FAH disagrees with the assertion by CMS that organ tracking capabilities allow THs, OPOs, and HOPOs to discern organ recipients' health insurance payer information. The issue arises when a TH excises an organ that is transplanted in another hospital. In this case, CMS' proposal would require the TH to trace organs surgically procured at their hospitals by the OPO, contact the other transplant programs to determine the insurance coverage for every recipient of a deceased donor organ recovered at their hospital. This responsibility would fall on the TH because OPOs do not have the responsibility or expertise to ascertain or question primary

insurance types, question retroactive eligibility periods for kidney transplants, nor ascertain if a recipient transplanted has Medicare where Medicare is the secondary payer.

CMS notes that each OPO must be a member of, participate in, and abide by the rules and requirements of the Organ Procurement Transplantation Network (OPTN). OPTN policy provides that OPOs use organ tracking capability, and some THs also optionally use organ tracking capability. Per OPTN policies, THs, histocompatibility laboratories, and organ procurement organizations enter data into the OPTN database that links all 57 OPOs, 254 THs and 150 histocompatibility labs to list patients for transplant, match patients with available donor organs and submit required OPTN data. While the Proposed Rule is accurate on these points, the FAH notes that it does not suggest that data elements in the OPTN database include critical health care coverage and insurance information.

The Scientific Registry of Transplant Recipients (SRTR) is the contractor responsible for providing statistical and other analytic support to OPTN. THs use the SRTR for a variety of purposes. While the SRTR reflects primary insurance coverage, there is no field to reflect secondary insurance. Under CMS' policy, an organ would be counted in the reasonable cost apportionment if Medicare had secondary liability. However, if Medicare is the secondary payer, there is no way to identify the patient as having Medicare on the SRTR. Under current policy, the presumption would allow the organ to be counted as Medicare in the apportionment. Under the proposed policy, the hospital would be unable to document that the patient had Medicare as a secondary payer. Even though the hospital would be entitled to count the organ as a Medicare organ under CMS' policy, it would be unable to do so because of the lack of documentation available on the SRTR.

There would be other problems associated with using the SRTR. For instance, the SRTR will not reflect retroactive Medicare coverage. It is not unusual for a transplant recipient to be retroactively qualified for Medicare. If the transplant occurs before Medicare eligibility is determined, the patient will not be listed on the SRTR as Medicare eligible on the date of the transplant even though the patient later became Medicare eligible, effective on or before the date of transplant.

Another issue is Medicare eligible patients that do not enroll in Medicare. FAH members have generally seen nearly all transplant patients qualify for premium-free Medicare Part A based on their work history but still choose to only retain their commercial insurance coverage. These patients often do not enroll in Medicare Part B because they do not want to incur Part B premiums. While they could enroll in Part A and not incur any premium, they instead choose to retain commercial insurance. These patients will not be reflected as Medicare on the SRTR even though they are Medicare eligible. Under current policy, these patients are counted for the Medicare apportionment. Under the proposed policy, they would not. While we understand that CMS' policy would preclude organs transplanted in non-enrolled Medicare eligible beneficiaries from being counted as Medicare organs, we raise this issue as an example of a policy that will result in reduced payments to THs making donor excision less likely.

As detailed above, the FAH believes CMS' proposed policy, if adopted, will significantly reduce payments to THs and OPOs. Despite the likely reduction in revenues to THs, OPOs and

HOPOs, the Proposed Rule does not include a detailed regulatory impact analysis of this policy. Nevertheless, it seems likely that the proposed policy would significantly reduce revenues to these organizations, imperiling their ability to continue providing organ donor services that they have been providing for many years. THs have invested in dedicated operating room capacity to handle organ excisions, relying on the current Medicare organ payment policy rules. This new policy would have the unfortunate consequence of reducing resources available for organ procurement capacity and likely reduce the number of available organs to Medicare beneficiaries given the adverse financial impact of the proposed Medicare organ count policy.

In principle, CMS' policy is logical; Medicare should only pay for its share of organ acquisition costs where it can be documented that the organ recipient is a Medicare beneficiary. However, the practicality of the policy is questionable given the limitations of the SRTR database. ***The FAH recommends that CMS not finalize this policy at this time.*** Instead, the FAH urges CMS to work with OPTN and SRTR to update the SRTR database to better detail patient insurance information and allow THs and OPOs to revise contractual arrangements with non-Medicare payers.

X.G. Medicare Shared Savings Program—Proposed Policy Changes (42 C.F.R. § 425.600)

The FAH supports CMS' proposal to permit accountable care organizations (ACOs) participating in the BASIC track's glide path to opt out of automatic advancement from their current level of participation for performance year (PY) 2022 in light of the continuing uncertainty created by the COVID-19 PHE. Previously, CMS finalized 42 C.F.R. § 425.600(a)(4)(i)(B)(2)(iii) to permit ACOs in the BASIC track to opt for a one-year risk "freeze" for PY 2021. A second such "freeze" in PY 2022 would provide ACOs with critically needed flexibility as the COVID-19 PHE continues. As noted in the Proposed Rule, ACOs face uncertainties and challenges due to the PHE's direct and indirect impacts on beneficiary health and utilization, the disruption of population health activities, and the costs of providing care during the pandemic. All of these factors weigh in favor of CMS' proposal to permit ACOs currently participating in the BASIC track's glide path to maintain their current participation level for PY 2022.

OUTLIER PAYMENTS FY 2022

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

For FY 2022, CMS has proposed that a case will be eligible for 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 $30,967. The present threshold, which has been in effect since October 1, 2000, is $ 29,064. This nearly $2,000 proposed increase is on top of an increase of more than $5,000 in the threshold between FYs 2017 and 2021. CMS indicates that it has used the same methodology to calculate the fixed loss threshold as it has since FY 2014, with limited exceptions in prior years (including, beginning in FY 2020, CMS' methodology accounts for the estimated impact of outlier reconciliation, and it uses public, FY data to calculate the charge inflation factor). For the FY

2022 rulemaking, CMS has proposed using data predating the period of the COVID-19 public health emergency (PHE) to establish the fixed-loss threshold. Alternatively, using the more recent data that includes a significant portion of the PHE, CMS has calculated an alternative fixed loss threshold of $36,843. With all indications that FY 2020 was a substantially aberrant year, the FAH supports CMS' proposal to use data predating the PHE. However, just as with the past several year's rule-makings, we are concerned that the Proposed Rule fails to appropriately address the impact of very high charge cases on the fixed-loss threshold calculation. Overall, the proposed threshold for FY 2022 represents an increase of nearly $7,400 over the outlier threshold CMS used for FY 2017, with no clear basis in the data made available to commenters to explain why such a dramatic increase in the threshold would be required to approximate the 5.1% target for outlier payments as a portion of total DRG payments.

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

CMS proposes to again apply key methodological refinements that were first applied in the FY 2020 IPPS rulemaking, with some changes in the data sets that CMS used. First, CMS proposes to again account for outlier reconciliation in the FY 2022 outlier threshold calculation. The FAH has repeatedly requested that CMS release information on the outlier reconciliation process and data showing the amounts recovered so that it can evaluate the impact of the reconciliation process on the outlier threshold, and we again commend CMS for proposing to continue addressing the impact of outlier reconciliation in setting the FY 2022 fixed-loss threshold. Watson Policy Analysis (WPA) matched CMS' calculation of a -0.01% reconciliation factor, using the December 2020 cost report data CMS used for the Proposed Rule; however, WPA noted that the March 2021 cost report data, which CMS is expected to use for the final rule, produced a higher reconciliation factor of -0.02%.

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

B. Extreme Charge Cases Significantly Skew the Fixed Loss Threshold

As we have in past years, the FAH also asks CMS to consider whether it is appropriate to include extreme cases when calculating the fixed-loss threshold and whether recent volume increase in such cases points to a larger problem that CMS should investigate. WPA conducted various examinations and probing of data to understand the factors that drove CMS to increase the threshold over $5,000 between FY 2017 and FY 2021, and to propose to increase the threshold an additional almost $2,000 in FY 2022, 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.[42]

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 2021 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 2022 Proposed Rule Table

Trim threshold	Number of cases removed	Calculated FLT	Percentage of cases trim removes
None	-	$31,007	0.000%
$2,000,000	1,399	$28,725	0.017%
$1,750,000	2,040	$28,251	0.025%
$1,500,000	3,159	$27,564	0.039%
$1,250,000	5,150	$26,666	0.063%
$1,000,000	5,943	$25,255	0.073%
$750,000	16,885	$23,082	0.207%
$500,000	46,781	$19,280	0.574%

The FY 2022 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 (1,399 cases) drives the threshold down almost $2,300. Removing all cases at certain other thresholds, lower than $2,000,000, but still high enough to be considered extreme high cost cases, drives the threshold down even further. For example, removing all cases with total charges above $1,000,000 (5,943 cases) drives the threshold down approximately $5,800, and removing all cases with charges above $500,000 (46,781cases) drives the threshold down almost $12,000.

[42] See the attached WPA report *Summary of Research Modeling FY 2022 Proposed Inpatient Prospective Payment System Outlier Payments* (Attachment A). All of the tables contained in this comment are set forth in and derived from the WPA Report with non-material formatting changes.

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

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	3,580	0.0464%	469

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

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

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

The FAH believes that ordinarily it is important to the process for setting the outlier threshold that CMS accurately calculate prior year actual payment comparisons to the 5.1% target. Without doing so, it is impossible for CMS to appropriately modify its methodology to achieve an accurate result. However, CMS established the FY 2020 fixed-loss threshold before the start of the PHE, which significantly changed the claims environment during FY 2020 as compared to prior years. Thus, CMS' estimate of 5.42% of outlier payments as a percentage of MS-DRG payments for FY 2020 may speak more to the unusual claim patterns and costs-per-case that the PHE occasioned rather than to an ongoing trend of any kind.

CMS' estimates of past outlier payments also routinely exceed the calculations of outlier payments based on HCRIS cost report data, as demonstrated in the table below from the WPA

Report at p. 4. Furthermore, the use of more recent HCRIS data (*i.e.*, the March file versus the December file) also has a significant impact on the calculation of the actual outlier payment level:

Federal Fiscal Year (Month of HCRIS release)	Number of cost reports	IPPS Payments Net of IME, DSH and Outlier amounts	Outlier Payments	Outlier Payment Level (%)	Target Outlier Payments (5.1%)	Shortfall in Outlier Payments
FY 2013 (December)	2,875	$75,513,803,937	$3,820,292,807	4.82%	$4,058,170,707	($237,877,900)
FY 2013 (March)	3,047	$80,760,714,604	$4,270,125,578	5.02%	$4,340,143,777	($70,018,199)
FY 2014 (December)	2,388	$63,505,784,324	$3,085,415,408	4.63%	$3,412,850,369	($327,434,961)
FY 2014 (March)	3,054	$82,479,662,313	$4,343,131,876	5.00%	$4,432,521,368	($89,389,492)
FY 2015 (December)	2,850	$78,849,610,927	$3,847,264,205	4.65%	$4,238,185,938	($390,921,733)
FY 2015 (March)	3,036	$84,552,076,553	$4,283,484,754	4.82%	$4,543,853,974	($260,369,220)
FY 2016 (December)	2,852	$81,185,256,122	$4,223,366,030	4.94%	$4,362,921,000	($139,554,970)
FY 2016 (March)	3,048	$87,553,087,944	$4,689,098,313	5.08%	$4,705,190,000	($16,091,687)
FY 2017 (December)	2,989	$79,429,360,478	$3,912,972,441	4.70%	$4,268,623,000	($355,650,559)
FY 2017 (March)	3,244	$88,346,767,109	$4,686,222,555	5.04%	$4,747,820,000	($61,597,445)
FY 2018 (December)	2,790	$84,057,274,313	$4,265,424,988	4.83%	$4,517,329,000	($251,904,012)
FY 2018 (March 2021 HCRIS data update from before)	2,933	$88,836,943,282	$4,674,326,383	5.00%	$4,774,210,000	($99,883,617)
FY 2019 (March)	3,129	$84,889,614,212	$4,571,900,758	5.11%	$4,562,000,000	$9,900,758
FY 2020 (March)	149	$3,199,635,025	$144,640,368	4.33%	$171,951,000	($27,310,632)

Note: 2020 data does not have all providers' cost report yet.

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

D. Using Most Recent Data to Calculate the Threshold

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

FY	Proposed	Final	Variance	% of Variance
2009	$ 21,025	$ 20,045	$ (980)	-4.66%
2010	$ 24,240	$ 23,140	$ (1,100)	-4.54%
2011	$ 24,165	$ 23,075	$ (1,090)	-4.51%
2012	$ 23,375	$ 22,385	$ (990)	-4.24%
2013	$ 23,630	$ 21,821	$ (1,809)	-7.66%
2014	$ 24,140	$ 21,748	$ (2,392)	-9.90%
2015	$ 25,799	$ 24,626	$ (1,173)	-4.55%
2016	$ 24,485	$ 22,544	$ (1,941)	-7.93%
2017	$ 23,681	$ 23,573	$ (108)	-0.46%
2018	$ 26,713	$ 26,537	$ (176)	-0.66%
2019	$ 27,545	$ 25,769	$ (1,776)	-6.45%
2020	$ 26,994	$ 26,552	$ (442)	-1.63%
2021	$ 30,006	$ 29,064	$ (942)	-3.31%
2022 Proposed	$ 30,967			
2022 Alternative	$ 36,843			

Although the FAH can only speculate as to why this drop in the threshold occurs, the FAH believes the decline is most likely due to the use of updated CCRs and/or additional/other data in calculating the final threshold. This again emphasizes that CMS must ordinarily use the most recent data to appropriately calculate the outlier threshold. However, as discussed, FY 2022 is an exception because using more recent data will mean using data that is likely skewed by the PHE and that will thus generate a threshold that is unlikely to produce total aggregate payments reaching CMS' 5.1% target.

With regard to the current rule-making WPA was able to replicate the threshold within $24. Thus, we have high confidence that WPA understands CMS' methodology and has accurately modeled that methodology.

The FAH is not proposing a threshold for FY 2022. While we have confidence in the work of WPA, its work is dependent on large variables in the outlier calculation. We also note that the impact of the inclusion of extreme cases in the calculation of the fixed loss threshold is significant and we urge CMS to carefully study this trend and whether outlier payment policy should be adjusted so that it is fair to all hospitals that fund outlier payments. Finally, we recognize that with the release of the MedPAR final data with additional claims, which will lead to new weights being calculated, and with updated cost to charge ratios, it is appropriate to recalculate the fixed loss threshold from the data that will be released with the final rule.

* * *

The FAH appreciates the opportunity to submit these comments. If you have any questions, please contact me at 202-624-1534, or Steve Speil, Executive Vice President Policy, at sspeil@fah.org or 202-624-1529.

Sincerely,

Enclosure: Attachment A

ATTACHMENT A

Summary of research modeling

FY 2022 Proposed Inpatient Prospective Payment System

Outlier Payments

Date: June 14, 2021

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) 2022 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 25717 of the Federal Register.[1] We attempted to replicate the CMS logic and then compared our results and made a variety of adjustments to assess the impact of using different parameters. This report summarizes our findings.

Note: Due to the Covid-19 Public Health Emergency (PHE), CMS is proposing a change in policy this year in terms of what data is used. CMS is proposing to use the FY2019 data to set FY 2022 weights and the high cost outlier thresholds. However, CMS is leaving open the option to use the FY 2020 data instead. This uncertainty leads to most reporting here being completed on both years of data.

Summary

A summary of findings is as follows:

- WPA was able to come close to the CMS calculation of the Fixed Loss Threshold (FLT). CMS published $30,967. WPA calculated $30,943 for weights based on the 2019 data. For weights based on the 2020 data, CMS published $36,843, while WPA calculated: $37,135.
- 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. CMS reported a charge inflation of 20.4% over three years while WPA calculated 20.6%.

[1] "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2022 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program. Published in Federal Register, Vol. 86, No. 88, Monday, May 10, 2021.

Background on outlier payments

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

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

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

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

Analysis 1: Replication of the CMS estimated FY 2022 outlier payment from the FY 2022 IPPS proposed rule

WPA estimated payments, including outlier payments from the FY 2019 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 2022 proposed file: contains inpatient hospital claims from FY 2019 that were used by CMS to model proposed FY 2022 payments,
- Table 5 – Weight file: contains the proposed weights for FY 2022,
- Impact file: contains hospital specific characteristics and payment factors,
- DSH Supplemental File: contains uncompensated care per claim payment amounts for providers,
- The FY2022 Proposed IPPS rule, in particular information on cost and charge inflation factors, and
- Inpatient Provider of Services File: contains provider specific information.
- Hospital Cost Reporting Information System (HCRIS) data containing cost reports from providers. This information was used to calculate the adjustment to the outlier target based on the historical outlier reconciliation.

All of these analyses were then repeated using the "alternative" versions of the files based on the FY 2020 data.

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 FY 2019 data, WPA calculated a fixed loss threshold of: $30,943 versus the published number of $30,967, a difference of $24 or about 0.08%.

Using the FY 2020 data, WPA calculated a fixed loss threshold of: $37,135 versus the published number of $36,843, a difference of $292 or about 0.79%.

WPA did update the replication to account for the payment of clinical trial CAR-T cases at 17% of the normal payment rate for the proposed modeling and 25% for the alternative modeling. WPA's replication of these figures were slightly lower.

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

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

As part of the analysis, we compared the CCRs included in the impact file (used in modeling the FLT) with the CCRs from the Provider Specific File (PSF).

For the modeling using the FY 2019 data, CMS had used the March 2020 release of the PSF file. Comparing the 3,272 providers listed in the impact file and the March 2020 release of the PSF file, we had a match rate of 96.36% (3,153 providers) for operating CCRs.

Using this data, the average difference in operating CCRs between the impact file and the PSF file (weighted by discharges) was -0.021% when all providers were used, and -0.700% when just providers with differences were used.

For the modeling using the FY 2020 data, used the December 2020 release of the PSF file. Comparing the 3,234 providers listed in the impact file and the December 2020 PSF file, we had a match rate of 96.35% (3,116 providers).

Using this data, the average difference in operating CCRs between the impact file and the PSF file (weighted by discharges) was -0.648% when all providers were used, and -0.687% when just providers with differences were used.

For the modeling using the FY 2020 data, used the March 2021 release of the PSF file. Comparing the 3,234 providers listed in the impact file and the March 2021 PSF file, we had a match rate of 68.49% (2,215 providers).

Using this data, the average difference in operating CCRs between the impact file and the PSF file (weighted by discharges) was -0.208% when all providers were used, and -0.699% when just providers with differences were used.

These results are in line with previous years.

Analysis 3: Outlier payments from Medicare cost reports

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

Federal Fiscal Year (Month of HCRIS release)	Number of cost reports	IPPS Payments Net of IME, DSH and Outlier amounts	Outlier Payments	Outlier Payment Level (%)	Target Outlier Payments (5.1%)	Shortfall in Outlier Payments
FY 2013 (December)	2,875	$75,513,803,937	$3,820,292,807	4.82%	$4,058,170,707	($237,877,900)
FY 2013 (March)	3,047	$80,760,714,604	$4,270,125,578	5.02%	$4,340,143,777	($70,018,199)
FY 2014 (December)	2,388	$63,505,784,324	$3,085,415,408	4.63%	$3,412,850,369	($327,434,961)
FY 2014 (March)	3,054	$82,479,662,313	$4,343,131,876	5.00%	$4,432,521,368	($89,389,492)
FY 2015 (December)	2,850	$78,849,610,927	$3,847,264,205	4.65%	$4,238,185,938	($390,921,733)
FY 2015 (March)	3,036	$84,552,076,553	$4,283,484,754	4.82%	$4,543,853,974	($260,369,220)
FY 2016 (December)	2,852	$81,185,256,122	$4,223,366,030	4.94%	$4,362,921,000	($139,554,970)
FY 2016 (March)	3,048	$87,553,087,944	$4,689,098,313	5.08%	$4,705,190,000	($16,091,687)
FY 2017 (December)	2,989	$79,429,360,478	$3,912,972,441	4.70%	$4,268,623,000	($355,650,559)
FY 2017 (March)	3,244	$88,346,767,109	$4,686,222,555	5.04%	$4,747,820,000	($61,597,445)
FY 2018 (December)	2,790	$84,057,274,313	$4,265,424,988	4.83%	$4,517,329,000	($251,904,012)
FY 2018 (March)	2,926	$88,630,962,545	$4,661,913,364	5.00%	$4,763,126,000	($101,212,636)
FY 2018 (March 2021 HCRIS data update from before)	2,933	$88,836,943,282	$4,674,326,383	5.00%	$4,774,210,000	($99,883,617)
FY 2019 (March)	3,129	$84,889,614,212	$4,571,900,758	5.11%	$4,562,000,000	$9,900,758
FY 2020 (March)	149	$3,199,635,025	$144,640,368	4.33%	$171,951,000	($27,310,632)

Note: 2020 data does not have all providers' cost report yet.

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

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

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

Analysis 4: Fixed Loss Threshold over time

By examining the fixed loss threshold in proposed rules and final rules, we notice 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	$ 25,743	$ 27,545	$ (1,776)	-6.45%
2020	$ 26,552	$ 26,994	$ (521)	-1.93%
2021	$ 29,064	$ 30,006	$ (942)	-3.31%
2022 Proposed		$ 30,967		
2022 Alternative		$ 36,843		

Analysis 5: Outlier Reconciliation

In the FY2020 IPPS rule, CMS finalized a new methodology to adjust the outlier target percentage to account for outlier reconciliation. This reconciliation factor is combined with the 5.1% target to account for WPA was successful in replicating the CMS calculations exactly given the logic described. WPA matched their calculation of -0.01% when using the December 2020 cost report data. However, using the March 2021 cost report data which is what CMS will most likely use in the final rule, WPA found a slightly different reconciliation factor of -0.02%. This change highlights the issue of small changes in data and the sensitivity to small changes in the data.

Analysis 6: Explorations on high charge cases

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

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

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

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

To examine this issue, WPA tested trimming out cases with covered charges greater than particular thresholds. This removed the case if the *covered charges* were greater than a threshold. (Note: For the actual calculation of cost for the Fixed Loss Threshold, covered charges are used. In previous years of this memo, total charges were used. However, covered charges are a more direct representation.)

The following table shows the results at different trim points when using the proposed (FY 2019) data.

Scenario	Cases	Removed cases	FLT	Percentage of cases removed
Base	8,149,147	-	$ 31,007	0.000%
Trim at: 2,000,000	8,147,748	1,399	$ 28,725	0.017%
Trim at: 1,750,000	8,147,107	2,040	$ 28,251	0.025%
Trim at: 1,500,000	8,145,988	3,159	$ 27,564	0.039%
Trim at: 1,250,000	8,143,997	5,150	$ 26,666	0.063%
Trim at: 1,000,000	8,143,204	5,943	$ 25,255	0.073%
Trim at: 750,000	8,132,262	16,885	$ 23,082	0.207%
Trim at: 500,000	8,102,366	46,781	$ 19,280	0.574%

The equivalent table with the alternative proposal (FY 2020 data) is as follows:

Scenario	Cases	Removed cases	FLT	Percentage of cases removed
Base	7,007,141	-	$ 37,135	0.000%
Trim at: 2,000,000	7,010,623	(3,482)	$ 34,074	-0.050%
Trim at: 1,750,000	7,009,877	(2,736)	$ 33,412	-0.039%
Trim at: 1,500,000	7,008,561	(1,420)	$ 32,529	-0.020%
Trim at: 1,250,000	7,006,248	893	$ 31,337	0.013%
Trim at: 1,000,000	7,001,428	5,713	$ 29,609	0.082%
Trim at: 750,000	6,991,304	15,837	$ 26,796	0.226%
Trim at: 500,000	6,954,340	52,801	$ 22,181	0.754%

(Note: Reason for negative values is that based on the differences in thresholds, some providers shifted between IPPS payments and payment as a Sole Community Hospital, which led to the net increase in cases in certain special circumstances.)

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 FY2020 data, this trend continued. There is an increase at a much faster rate than previous years for this 2020 data. (Note: 2019 data has also been updated to the final rule.)

Year	Number of cases over $1.5 million	Percentage of total cases	Number of unique providers
2011	926	0.0088%	272
2012	994	0.0098%	272
2013	1,092	0.0111%	283
2014	1,329	0.0141%	306
2015	1,539	0.0161%	320
2016	1,733	0.0185%	334
2017	2,291	0.0250%	403
2018	2,650	0.0286%	398
2019	3,128	0.0348%	441
2020	3,580	0.0464%	469