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President and CEO

July 10, 2020

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
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 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals; 85 Fed. Reg. 32,460 (May 29, 2020)***

Dear Administrator Verma:

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 across settings in both urban and rural areas. Our members include teaching and non-teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals. They provide a wide range of acute, post-acute, emergency, children's, cancer care, and ambulatory services. The FAH appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) about the above referenced Notice of Proposed Rulemaking on the 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 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals.

## EXECUTIVE SUMMARY

### **Market-Based MS-DRG Data Collection and Relative Weighting Calculation Methodology**

The FAH strongly opposes CMS’s proposal to require the disclosure of median payer-specific negotiated rate data for MA plans and third-party payers, as well as the incorporation of such data into the MS-DRG weighting methodology. At its core, the proposal pursues an impermissible goal—shifting from a relative resource-based MS-DRG weighting system to one based on market rates. CMS lacks any authority to adopt a “market-based” MS-DRG weighting methodology because Congress has explicitly instructed CMS to weight MS-DRGs based on “relative hospital resources used with respect to discharges” for each MS-DRG in 42 U.S.C. § 1395ww(d)(4)(B). Moreover, although CMS has authority to collect certain information through annual cost reports, this authority only reaches that data that is necessary to determine appropriate payment amounts and does not permit the collection of market data that is wholly irrelevant to Medicare payment. Moreover, the Proposed Rule severely underestimates the operational burdens and costs of compliance and overestimates the value and utility of median payer-specific negotiated rate data. Although the FAH supports continued efforts to improve upon the accuracy and appropriateness of relative weight calculations, we oppose upending the current cost-based methodology through the use of payer-specific negotiated rate data. Therefore, the FAH strongly urges CMS to abandon the proposed market-based MS-DRG data collection and relative weighting calculation methodology as unlawful and inappropriate.

### **COVID-19 and the Use of FY 2020 and FY 2021 Data in Future IPPS Rulemaking**

The FAH urges CMS to convene a stakeholder group to address the impact of COVID-19 on Medicare data for FY 2020 and FY 2021 in advance of IPPS and LTCH rulemaking for FY 2022 and subsequent years. The COVID-19 public health emergency is the most significant national public health emergency since the establishment of the Medicare program and certainly since the adoption of Medicare prospective payment systems. Since the public health emergency was declared in January 2020, short-stay and long-term acute care hospitals have experienced significant and unprecedented changes in utilization, case mix, and relative costs. At this time, the long-term effects of the COVID-19 pandemic on hospital operations and the IPPS and LTCH PPS is still unknown, but we expect that, at a minimum, data from FY 2020 and FY 2021 will be heavily impacted by the COVID-19 public health emergency. Early engagement with stakeholders to identify and address this unprecedented situation will help to ensure that data distortions are appropriately addressed so that COVID-19 does not depress or inappropriately skew IPPS and LTCH PPS payments in future fiscal years.

More specifically, each years’ IPPS and LTCH PPS rulemaking relies on the analysis of a wide range of data from prior years in order to reweight MS-DRG classifications and relative weights, update the hospital wage index, establish the fixed-loss threshold for outlier claims, determine the uncompensated care DSH pool and payments, and otherwise update the respective payment systems. Since their adoption, CMS has refined methodologies in order to improve reliability and respond to legal and clinical changes. At times, CMS has made methodological adjustments to avoid payment distortions that would otherwise result from the use of aberrant or unreliable data. For example, in FY 2020, CMS appropriately shifted from using three years of

blended data to using only FY 2015, audited Worksheet S-10 data to calculate UC DSH Factor 3, recognizing that mixing audited and unaudited data could lead to a less smooth result. But, these small methodological adjustments to address the impact of relatively narrow data anomalies impacting only one component of the PPS do not provide an adequate precedent for developing an appropriate and comprehensive strategy for addressing the many varied impacts that COVID-19 will have on rate setting for later fiscal years that would normally rely on cost report, claims, and other data from FY 2020 and 2021. The FAH therefore respectfully requests that CMS convene a technical advisory panel before the start of FY 2022 IPPS and LTCH PPS rulemaking in order to foster early dialogue and feedback concerning expected data anomalies and to develop appropriate methodologies for addressing these anomalies.

### **Medicare Disproportionate Share Hospital (DSH) Payments**

In light of the profound, ongoing consequences of COVID-19, the FAH and economic observers expect that hospitals' disproportionate patient percentages will largely increase nationwide in FY 2021, increasing the projected, aggregate amount of traditional Medicare DSH payments (*i.e.*, those Medicare DSH payments that would be paid under subsection (d)(5)(F) in the absence of 42 U.S.C. § 1395ww(r)) well above levels projected based on FY 2017 data and the economic assumptions and actuarial analysis used to develop the President's Budget estimates in February 2020. Likewise, the percentage of individuals expected to be uninsured in FY 2021 is expected to significantly surpass the CMS's Office of the Actuary's (OACT) projections, which expressly "do not take into account the impacts of COVID-19 because of the timing of the report and the highly uncertain nature of the pandemic." The FAH therefore strongly urges CMS to revisit its calculation of Factor One and Factor Two in order to ensure that its uncompensated care (UC) DSH payments are sufficient and grounded in reasonable, supportable estimates that appropriately address the ongoing impact of COVID-19 and healthcare, coverage, and the economy.

### **Medicare Bad debt**

The Proposed Rule includes amendments to 42 C.F.R. § 413.89(b), (c), (e), and (f) that would revise the reasonable collection efforts requirement and the standards for bad debt accounting. Although some of the proposed amendments to § 413.89 represent appropriate clarifications and policies supported by the FAH, the FAH is concerned with CMS's overly expansive use of retroactive rulemaking and proposal that contractual allowances cannot be treated as bad debt amounts. On the other hand, the FAH strongly supports adoption of the alternative approaches for providers to comply with the must-bill policy and evidence a State's cost-sharing liability (or absence thereof) for dual eligible beneficiaries when a State does not process a Medicare crossover claim and issue a Medicaid remittance advice (RA) because this alternative proposal represents a pragmatic and equitable approach to holding providers harmless for a State's non-compliance with the Federal statutory requirements concerning the processing of crossover claims and issuance of the Medicaid RA.

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### **II.C.3. FY 2021 MS-DRG Documentation and Coding Adjustment**

CMS proposes making a permanent 0.5 percentage point positive adjustment to the standardized amount for FY 2021, following the 0.4588 percentage point adjustment in FY 2018 and its 0.5 percentage point adjustments in FYs 2019 and 2020, 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, and 2020. 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. § 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 public health emergency.

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

For this Proposed Rule, CMS’s MS-DRG analysis is based on claims data from the September 2019 update of the FY 2019 MedPAR file, i.e., discharges/hospital bills occurring through September 30, 2019. The FAH generally supports the proposed changes recommended for MS-DRG and/or ICD-10 code classification changes for FY 2021 as set forth in the Proposed Rule, except as set forth below.

**In addition, the impact of COVID-19 on hospital operations beginning in March of this year is unprecedented. It is possible that hospitals will not return to normal operations for a number of months. To that end, the FAH strongly urges CMS consider the impact of COVID-19 on the claims data currently being submitted that will form the basis for future rulemaking and the implications for MS-DRG classifications and rate setting in FY 2022.**

#### **II.D.2.a. Pre-MDC – Bone Marrow Transplants**

CMS is proposing to re-designate MS-DRGs 014 (Allogeneic Bone Marrow Transplant), 016 (Autologous Bone Marrow Transplant with CC/MCC or T-Cell Immunotherapy) and 017 (Autologous Bone Marrow Transplant without CC/MCC) from surgical MS-DRGs to medical MS-DRGs. CMS’s clinical advisors consider bone marrow transplant procedures to be similar to blood transfusion procedures that do not utilize the resources of an operating room and are not surgical procedures.

CMS is proposing to re-designate 8 ICD-10-PCS procedure codes from O.R. to non-O.R. procedures, affecting their current MS-DRG assignment for MS-DRGs 016 and 017, effective October 1, 2020 for FY 2021.

ICD-10-PCS Code	Code Description
30230AZ	Transfusion of embryonic stem cells into peripheral vein, open approach
30230G0	Transfusion of autologous bone marrow into peripheral vein, open approach
30230X0	Transfusion of autologous cord blood stem cells into peripheral vein, open approach
30230Y0	Transfusion of autologous hematopoietic stem cells into peripheral vein, open approach
30240AZ	Transfusion of embryonic stem cells into central vein, open approach
30240G0	Transfusion of autologous bone marrow into central vein, open approach
30240X0	Transfusion of autologous cord blood stem cells into central vein, open approach
30240Y0	Transfusion of autologous hematopoietic stem cells into central vein, open approach

While bone marrow transplant procedures are not surgical in nature, the resources utilized, including growth factor injections to stimulate stem cell production, apheresis procedures, cannot be overlooked. Further, these patients have an increased risk for many different side effects making them more resource intensive, and as such, should remain as part of the pre-MDC MS-DRGs groupings.

**The FAH strongly disagrees** with CMS’s proposal to re-designate the eight listed procedure codes as non-O.R. procedures in light of these clinical factors. In addition, to the extent that the Proposed Rule suggests that any of these eight procedure codes would be reassigned to another MS-DRG, the FAH opposes this change. The Proposed Rule only states that the re-designation of these 8 ICD-10-PCS procedure codes as non-O.R. procedures would “affect[] their current MS-DRG assignment” for FY 2021, without providing any detail as to how the codes would be reassigned or setting forth any supporting rationale that could be evaluated and addressed by commenters. As a result, the FAH believes the more appropriate step would be NOT to re-designate these 8 procedure codes until more information (e.g., a clear outline showing the MS-DRG(s) to which these 8 procedure codes would be assigned and if the resulting MS-DRGs would remain as a pre-MDC) is provided in future rulemaking.

#### **II.D.2.b – Pre-MDC - Chimeric Antigen Receptor (CAR) T-Cell Therapy**

**The FAH agrees with and supports** CMS’s proposal to create and implement the proposed new MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy) for FY 2021. The FAH also agrees with CMS’s proposal to continue to identify these cases with the following ICD-10-PCS codes:

- XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3) or
- XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3).

**The FAH also agrees** with CMS’s proposal to revise the title for MS-DRG 016 from “Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy” to “Autologous Bone Marrow Transplant with CC/MCC” as CAR T-cell cases would no longer group to MS-DRG 016.

The FAH acknowledges that CMS has collected more comprehensive clinical and cost data in considering the creation of a new MS-DRG assignment for CAR T-cell therapy. The FAH also acknowledges the many factors that requestors had previously submitted were included in the consideration to create this new MS-DRG. Most notably, the inclusion of a distinguishing factor between clinical trial and non-clinical trial cases given the high cost of the CAR T-cell product is provided without cost as part of a clinical trial as well as the consideration of statistical outliers. Comments on the weighting and clinical trial adjustment methodologies found in Parts II.E.2.b. and IV.I. of the Proposed Rule are set forth below.

#### **II.D.4. – MDC 3 (Diseases and Disorders of Ear, Nose and Throat): Temporomandibular Joint Replacements**

**The FAH generally agrees** with CMS’s proposal to delete MS-DRGs 129, 130, 131, 132, 133, and 134, and create six new MS-DRGs, that includes the creation of two new base MS-DRGs 140 and 143 with a three-way severity level split:

- new MS-DRGs 140, 141, and 142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively)
- and new MS-DRGs 143, 144, and 145 (Other Ear, Nose, Mouth And Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

However, based on the Proposed Rule, there is not a clear understanding of the scope of the proposed changes. Specifically, the MedPar data included in the Proposed Rule speaks to temporomandibular joint replacements; however, the procedure listing for the MS-DRGs extends beyond these procedures. Tables 6P.2a and 6P.2b include procedures on vessels, lymphatic and other organs in the head and neck. The procedures noted in the tables cross multiple MS-DRGs such as 853, 857, 856, 571, 264, 570, 463, and 902 which were not discussed in the Proposed Rule. **The FAH requests** that CMS provide clarity on this topic.

#### **II.D.7.b – MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue): Hip and Knee Joint Replacements**

CMS proposes to create new MS-DRG 521 (Hip Replacement with Principal Diagnosis of Hip Fracture with MCC) and new MS-DRG 522 (Hip Replacement with Principal Diagnosis of Hip Fracture without MCC) to distinguish hip replacement procedures performed for hip fractures. We appreciate that CMS has recognized this important clinical distinction and associated high cost of these often-emergent procedures in a more medically complex patient population. Hip fracture patients are often older and in poorer baseline health than their CJR counterparts. These patients are seen on an emergent basis, rather than being electively admitted during daylight hours on a weekday and postoperatively after total hip arthroplasty (THA). The most common treatment for hip fracture (internal fixation) is a materially different procedure

than THA, requiring different surgical implants and equipment, and in some communities the procedures are performed by different surgeons (trauma versus total joint orthopedic subspecialists). Discharge planning for the patient who has sustained an unexpected major decrease in mobility (hip fracture) is distinctly different than for someone who has knowingly chosen THA and its associated postoperative rehabilitation.

CMS states that its data analysis provided in the Proposed Rule reflects that hip replacement cases due to hip fracture were higher in average costs. This statement is inconsistent with proposed weights for these new DRGs. While the FAH does not dispute the data analysis, we are concerned that the current weights proposed are similar notwithstanding the significant difference in the geometric mean LOS. —The LOS for proposed new MS-DRG 521 (Hip Replacement with Principal Diagnosis of Hip Fracture with MCC) is twice the length of stay for MS-DRG 469 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC OR Total Ankle Replacement). We believe the current weights provided by the CMS analysis are not in alignment with provider experience, and additional information and analysis is warranted. **The FAH urges CMS to reexamine and refine the data analysis before proceeding in finalizing this proposal and to share any additional analysis that would further explain this discrepancy before moving forward.**

MS-DRG	FY 2021 NPRM Post-Acute DRG	FY 2021 NPRM Special Pay DRG	Weights	Geometric mean LOS	Arithmetic mean LOS
469	Yes	No	3.0989	3.1	4.2
470	Yes	No	1.9104	1.8	2.0
521	Yes	Yes	3.0652	6.2	7.2
522	Yes	Yes	2.1943	4.1	4.5

In addition, CMS requests comments on the effect the proposal to create new MS-DRGs 521 and 522 would have on the CJR model and whether to incorporate these new MS-DRGs, if finalized, into the CJR model's proposed extension to December 31, 2023.

Given the COVID-19 Public Health Emergency (PHE), the FAH has urged CMS to end the CJR model at the original termination date of December 31, 2020, without the proposed three-year extension. The lasting impacts of this PHE will endure well beyond the currently unknown timeline for the formal declaration of the end of this PHE and PY 5, as it will take time for hospitals to return to normal volumes and processes. Alternatively, CMS could establish a simple streamlined pathway by which a hospital could voluntarily become an Episode Initiator (non-convenor participant) for the BPCI-Advanced site-neutral lower extremity joint replacement episode that is already underway.

**However, should CMS proceed in finalizing its proposal to extend the CJR program, as noted above, the FAH urges CMS to first provide additional analysis regarding the weights for the proposed new DRGs so that we can more fully understand the patient population. For example, accounting for these new MS-DRGs in the CJR program would have implications for risk adjustment and target pricing and would necessitate rulemaking so that providers would have an opportunity to review these**

**proposals in depth and respond accordingly. Lastly, providers would need enough time to augment clinical protocols and ensure that the quality measures are sufficient in accurately reporting quality of care and patient outcomes.**

#### **II.D.11 - Operating Room (O.R.) and Non-O.R. Issues**

CMS noted in the FY 2020 IPPS Proposed Rule that a long period of time has elapsed since the original O.R. and non-O.R. designations were established. With the incremental changes that have occurred to these procedure code lists and the way inpatient care is delivered, CMS proposed a multi-year plan to conduct a comprehensive review of designations on procedure codes for O.R. and non-O.R. in light of the long span of time between initial designation and revision since established.

While CMS has typically evaluated procedures on the basis of whether or not they would be performed in an operating room, CMS also acknowledged there may be other factors to consider in regard to resource utilization, particularly with the implementation of ICD-10.

CMS is again soliciting public comments on what factors or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD-10-PCS classification system for future consideration by October 20, 2020.

There was no mention or indication of feedback received from the public in response to the November 1, 2019 request for comments on this topic in the Proposed Rule. CMS indicated in this current rule the following as intentions for consideration of O.R. and non-O.R. designation:

- Resources used and how a procedure should affect the MS-DRG assignment
- The effect of surgical approaches to evaluate whether to subdivide specific MS-DRGs based on surgical approach
- Utilize available MedPAR claims data as a basis for this review as well as input from clinical advisors
- Evaluate the MS-DRG assignment of the procedures and the current surgical hierarchy as both of these factor into the process of refining the ICD-10 MS-DRGs to better recognize complexity of service and resource utilization.

**The FAH continues to support** CMS's proposal for a multi-year comprehensive review of this topic. Outside of the above CMS noted intentions for consideration, and as the FAH stated in response to this topic in the FY 2020 Proposed Rule, **the FAH continues to request** that additional data for each ICD-10-PCS procedure code be provided so a thorough analysis can be completed. If CMS cannot provide the additional data in a sufficient amount of time that would allow for a complete and thorough analysis prior to providing comments by October 20, 2020 submission date, the FAH requests a **new date** for comment submission.

**The FAH continues to believe** that thorough data analysis with provider input is critical to allow for appropriate insight in providing comments. As stated in response to the FY 2020 Proposed Rule on this topic, the FAH recommended that CMS consider a technical advisory



panel (TEP) comprising industry stakeholders and experts to review methodologies for O.R. determination. The continued expertise of a TEP is critical in light of industry and technological advancements with procedures and delivery of care to encompass all patient settings. The TEP could assist in providing guiding principles for O.R. determination. **The FAH, again, strongly recommends and advocates** for CMS to consider a technical advisory panel (TEP of clinical, coding, and other stakeholders and experts to review methodologies for O.R. determination.

The FAH recognizes that reviewing O.R. and non-O.R designations is a considerable undertaking that may significantly restructure MS-DRGS. The FAH believes procedure designations should be performed in all settings as there may be variations based on geography, hospital size, resource consumption and physician specialty that would impact the setting where the procedure is performed. It will be important to consider hybrid O.R.s, specialized procedure rooms in addition to a general multi-purpose O.R room.

**The FAH strongly advocates** that CMS proceed cautiously and provide advanced notice of its proposed methodology along with transparent data for each ICD-10-PCS procedure code considered for change. As noted above, **the FAH also strongly cautions** CMS that the data for FY2020 related to procedures will not be representative of typical procedures performed by facilities in light of the COVID-19 pandemic impact which resulted in postponing and cancelling elective surgeries.

#### **II.D.11c – Operating Room (O.R.) and Non-O.R. Issues: Non-O.R. Procedures to O.R. Procedures**

CMS continues to seek feedback outside the rulemaking process on proposals to change OR designations of specific ICD-10-PCS procedure codes. While not all of the submissions were discussed in the Proposed Rule, a number of these proposals were cited, and CMS has requested comment. Unfortunately, this section of the Proposed Rule was difficult to follow in that not all ICD-10-PCS codes were clearly indicated regarding a proposed move from non-O.R to O.R. designation. In other words, there were procedure codes within the O.R. to Non O.R. section that were actually the opposite, meaning O.R. designations to move to non-O.R. **The FAH strongly requests** that CMS give careful consideration to this section in future rulemaking to ensure that:

- the specific ICD-10-PCS codes are clearly and succinctly identified as O.R. or non-O.R, and
- the sections are kept separate, i.e., all codes moving from O.R. to non-O.R. are in one section and all codes moving from non-O.R. to O.R. are in a separate section to allow straightforward and clear information of what is being proposed.

**The FAH supports** the CMS proposal of O.R. to non-O.R. procedures involving endoscopic revision of feeding tubes. **The FAH also supports** CMS's proposal to shift from non-O.R. to O.R. designation the following: percutaneous/endoscopic biopsy of mediastinum, chemical pleurodesis, excision of stomach, percutaneous endoscopic drainage, control bleeding peritoneal cavity and inspection of penis.

Under the section of non-O.R. to O.R. procedures for percutaneous endoscopic excision of the stomach, the following procedures 0DB63Z3, 0DB63ZZ, 0DB67Z3, 0DB67ZZ, 0DB68Z3 (description below) were noted to shift from O.R. to Non O.R.

ICD-10-PCS Code	Code Description
0DB63Z3	Excision of stomach, percutaneous approach, vertical
0DB63ZZ	Excision of stomach, percutaneous approach
0DB67Z3	Excision of stomach, via natural or artificial opening, vertical
0DB67ZZ	Excision of stomach, via natural or artificial opening
0DB68Z3	Excision of stomach, via natural or artificial opening endoscopic, vertical

**The FAH does not support** this proposal and believes these procedures should maintain the O.R. designation. These procedures are similar to procedures 0DB64ZZ (Excision of Stomach percutaneous endoscopic approach) and 0DB64ZX (Excision of stomach, percutaneous endoscopic approach, diagnostic) which are also codes for excision of stomach that are proposed by CMS to shift from non-O.R. to O.R. designation.

## **II.D.12 - Proposed Changes to MS-DRG Diagnosis Codes for FY 2021**

### **II.D.12.b – Overview of Comprehensive CC/MCC Analysis**

CMS described the historical process for establishing three different levels of CC severity that subdivide the diagnosis codes as MCC, CC, and Non-CC. CMS indicated that this approach included evaluation of each diagnosis code to determine the extent to which its presence as a secondary diagnosis increased hospital resources. Readers were referred to the FY 2008 IPPS Final Rule for a complete discussion of the approach.

CMS proposed changes to severity level designations for a significant number (1,492 to be exact) of ICD-10-CM diagnosis codes in the FY 2020 Proposed Rule and invited public comment. Many commenters, including the FAH, expressed concern with this proposal and recommended that CMS conduct further analysis prior to finalizing this proposal.

**The FAH commends CMS for not implementing this sweeping proposal in FY 2020, providing further opportunity for CMS to engage with stakeholders and make public methodological and clinical information, as requested by commenters.** On October 8, 2019, CMS convened a public listening session and provided to the public the methodology utilized and clinical rationale that was applied across the diagnostic categories.

To allow for more opportunity for analysis, CMS made available a test grouper for public use based on comments received in response to the FY 2020 IPPS Proposed Rule. **The FAH appreciates** the public availability of a test grouper. While this grouper appears to allow for a claim-by-claim analysis and a minimal batch analysis, it does not allow providers the opportunity to assess and analyze a large batch of claims. It would be beneficial to have a z/OS Batch version of the test grouper so that the data could be utilized for broader and more meaningful analysis. **The FAH requests** that CMS make a z/OS Batch version of the test grouper publicly available with all future IPPS Proposed Rules.

The FAH noted that CMS reconvened an internal workgroup comprised of clinicians, consultants, coding specialists and other policy analysts to further discuss this topic. Per the Proposed Rule, this workgroup developed proposed guiding principles to apply in evaluating whether changes to the severity level designations of diagnoses are needed and to ensure severity level designations are appropriately reflective of resource consumption. CMS noted that the goal in developing these guiding principles is to assist in determining whether the presence of the specified secondary diagnosis would lead to increased hospital resource use in most instances; thus consistent with the underlying foundation of the inpatient prospective payment methodology.

Using a combination of mathematical analysis of claims data as discussed in the FY 2020 IPPS Proposed Rule and the application of these guidelines, CMS plans to continue a comprehensive CC/MCC analysis and present the findings in future rule making. CMS is inviting public comments regarding the guiding principles (items 1-9 listed below) as well as other ways to potentially incorporate meaningful clinical indicators of clinical severity. The proposed guiding principles are:

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

**The FAH appreciates** the opportunity to comment on the guiding principles that are being proposed and that would be used in combination with the mathematical criteria. More information is needed to better understand CMS's intent on the priority or process for decision making for diagnosis severity levels. This level of detail is imperative to ensure public review and comments can be provided.

Examples of the specific information required to improve stakeholder's ability to comment includes how the mathematical criteria will be used in conjunction with the proposed guiding principles to determine the severity level for each diagnosis. It is important for commenters to know if CMS is proposing that the condition must meet both mathematical criteria and one of the guiding principles, or, only one of the two is considered. It is also unclear if there is a hierarchy for the guiding principles and clearly there can be no expectation that all of the guiding principles must be met in order for a condition to be designation as a complication/comorbidity (major or otherwise). The FAH recommends that the guiding

principles should only be used *after* the mathematical analysis is applied. In general, it is anticipated that the mathematical analysis and the application of the guiding principles will complement each other.

As noted in the FY2020 proposed changes CMS stated that “These mathematical constructs are used as guides in conjunction with judgment of our clinical advisors to classify each secondary diagnosis reviewed as MCC, a CC or a Non-CC.” **The FAH requested** further evaluation and greater transparency of the logic from CMS as the majority of the designation revisions in FY2020 did not appear to follow math logic outlined by CMS in the Proposed Rule. To illustrate, the FAH performed an analysis of some of the 1,492 codes that were proposed for revisions in FY2020 using the FY2021 proposed guiding principles. During that review, multiple challenges and inconsistencies were encountered. More details related to these challenges are noted below. However, as a result of this exercise, it became apparent that a thorough data analysis with stakeholder input regarding the guiding principles is needed. Once again, **the FAH strongly recommends** that CMS convene a technical advisory panel (TEP) comprising industry stakeholders and experts to review guiding principles and the practical application to the individual ICD-10-CM codes for severity designations of MCC/CC. The TEP should also consider the best approach to designate Complications or Comorbidities (CC) vs Major Complications or Comorbidities (MCC) for one another.

As mentioned previously, the FAH attempted to apply the proposed guiding principles to several ICD-10-CM diagnosis codes. Below are examples illustrating why it was generally difficult to answer a definitive “yes” when applied to ICD-10-CM codes which are specific by nature:

1. Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility
  - In FY2020 conditions such as Chronic Kidney Disease Stage 4 or 5, End Stage Renal Disease, Dissection of aorta, Sickle Cell in Crisis, Brain Death were proposed for revisions to their MCC designations to either CC or Non-CC despite meeting the CMS mathematical construct. The FAH would like the TEP to consider real examples such as these to determine if they represent end of life or advanced stage and provide transparency on how it would determine severity designation.
2. Denotes organ system instability or failure
  - In FY2020, conditions such as cardiac arrest or ventricular fibrillation (I462, I468, I469), STEMI (I21-I22) were proposed to shift away from MCC designation despite being supported by CMS mathematical construct. These conditions would represent failure or instability of the heart. The FAH would like clarification as to how this guiding principle would impact the condition’s severity determination.
3. Involves a chronic illness with susceptibility to exacerbations or abrupt decline
  - In FY2020 conditions such as Chronic Heart Failure I50.22 and I50.32 were proposed to shift from CC to Non-CC despite the mathematical support. The FAH would like clarification as to how this principle would impact the conditions

severity determination as heart failure is susceptible to and often results in exacerbation and abrupt declines.

- This principle may not be able to be applied across the board as many ICD-10-CM diagnosis codes do not distinguish exacerbation. There are conditions that have acute and chronic separate codes, combined acute/chronic in the same code, and some conditions for which the code does not indicate the specificity of acute or chronic.
4. Serves as a marker for advanced disease states across multiple different comorbid conditions
    - This guideline appears to be open to interpretation such as the following: How does the condition serve as a marker? What is advanced disease? How are multiple different comorbid conditions determined?
    - In FY2020 severe protein calorie malnutrition was proposed to shift from MCC to CC. Severe protein calorie malnutrition definitely has the potential to impact multiple conditions and could be a marker for advanced disease; however, it is not transparent how to apply this guideline.
  5. Reflects systemic impact
    - Conditions such as autoimmune anemias, pancytopenia, and Sickle Cell disorders all have the potential to be considered systemic; however, they were proposed in FY2020 for shifts (including CC to Non-CC, MCC to CC, and MCC to Non-CC) and it is unclear how CMS would apply this principle to determine severity.
  6. Post-operative condition/complication impacting recovery
    - There is a challenge with the ability to identify post-operative conditions as ICD-10-CM codes do not always identify post-operative in the code title nor are the codes designated within a specific chapter of the code book.
    - In FY2020, the FAH disagreed with the proposed change in severity from MCC to CC for Acute post procedural respiratory failure (J95.821) and requested a logic-driven explanation for how this condition would be designated under this guiding principle, especially as other respiratory failures are designated as MCCs.
    - The guideline indicates that the condition or complication impacts recovery and it is unclear how to make that determination with the use of the ICD-10-CM code.
  7. Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay)
    - The FAH requests clarification on how conditions meeting this principle would be determined and whether this is also addressed via the proposed mathematical calculations.
    - How would this principle be applied in evaluating conditions resulting from advance or new technological approaches or conditions that may not have the data available for mathematical equations?
    - Additional clarity and definition should be provided related to the greater number of caregivers, additional testing, and the other items in the parenthetical statement.

- Of note, this principle is similar to Section III of the ICD-10-CM Guidelines for Coding and Reporting regarding reportable secondary diagnosis. This guideline is referenced below:
  - For reporting purposes, the definition for “other diagnosis” is interpreted as conditions that affect patient care in terms of requiring: clinical evaluation or therapeutic treatment or diagnostic procedures or extended length of hospital stay or increased nursing care and/or monitoring.
- 8. Impedes patient cooperation and/or management of care
  - This principle seems overly subjective and, at face value, seems to have the potential to include many diagnoses of impaired judgment (e.g. psychiatric conditions, dementia, Alzheimer, confusion) or impaired sense of loss (e.g. loss of any sensation such as sight, hearing, etc.) or loss of movement (e.g. paralysis, severe BMI, pain, arthritis limitations, etc.) or social factor (e.g. homelessness, etc.) and/or any chronic condition of the patient. Is this a correct interpretation of this principle?
- 9. Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use
  - It will be important to provide clarity about this principle, especially in light of its subjective nature.

In addition, other considerations in the application of the proposed general principles include:

- Conditions such as OB diagnoses or congenital conditions are diagnoses that meet the mathematical calculation; however, further information is needed as to how these conditions would/would not be considered in the application of the guiding principles.
- ICD-10-CM code specificity greatly expanded, including for codes identifying laterality and anatomical information. This was evident in the hundreds of codes for various locations and stages for pressure ulcers. In FY2020 50 stage 3 and 4 ulcers were proposed to shift from MCC to CC while 100 stage 1 and 2 ulcers were proposed to shift from Non-CC to CC. The evaluation (and transparency on how the decision was made) for future designation of MCC, CC, and non-CC will be necessary. This evaluation should also ensure consistency is applied for conditions that are similar in nature.
- In FY2020, an analysis of Table 14 showed that there were approximately 767 neoplasm codes proposed to shift severity designation to Non-CCs. It appears that the majority of these meet the CMS mathematical constructs for MCC or CC designations. Additionally, it would appear that these neoplasm codes would meet several of the listed guiding principles (e.g. numbers 2, 3, 4, 5, 7, 8 and 9 and sometimes number 1 and 6 depending on the type, grade, location and metastasis of the neoplasm). For example, most neoplasms generally “involve chronic illness with susceptibility to exacerbations or abrupt declines”, “organ instability”, as well as become “systemic”, and “impact management of care” for

the patient. Contrary to last year's proposal, neoplasms seem to meet several of the criteria for MCC/CC designation.

- How will the guiding principles be used to differentiate between MCCs and CCs, which is generally the basis for the 3-tier severity level system in the MS-DRG system?

#### **II.D.12.b – Proposed Changes to the MS-DRG Diagnosis Codes for FY 2021**

The FAH agrees with the changes to the severity level designations as proposed in Tables 6I.1, 6I.2, 6J.1 and 6J.2 for FY2021. However, there are six new ICD-10-CM diagnosis codes for Cytokine Release Syndrome (CRS) effective October 1, 2020. These codes are assigned with a non-CC designation in Table 6A. In the absence of sufficient data to analyze use and resource consumption for these newly created codes, it is imperative to consider the clinical significance of the conditions so that a more appropriate severity level designation can be assigned.

Based on information published by the American Society for Transplantation and Cellular Therapy (ASTCT), there is a consensus grading definition for Cytokine Release Syndrome (CRS).<sup>1</sup> Clinical manifestations of CRS can range from mild, flu-like symptoms to a severe life-threatening systemic inflammatory response syndrome (SIRS) or death, respectively. As noted by ASTCT, Grades 3, 4 and 5 involve patients requiring acute hospital intervention to prevent further deterioration, and these grades meet the majority of the newly proposed guiding principles<sup>2</sup> for making changes to severity levels.

The FAH urges CMS to appropriately assign Grades 3, 4, and 5 CRS to an MCC designation and to assign grade 2 CRS to a CC designation based on clinical significance. Until more data becomes available and the clinical literature for Grade 1 CRS supports a change, the FAH agrees with the proposed non-CC designation for Grade 1 only.

TABLE 6A - NEW DIAGNOSIS CODES				
Diagnosis	Description	CC	MDC	MS-DRG
D89.831	Cytokine release syndrome, grade 1	N	16	814, 815, 816
D89.832	Cytokine release syndrome, grade 2	N	16	814, 815, 816
D89.833	Cytokine release syndrome, grade 3	N	16	814, 815, 816
D89.834	Cytokine release syndrome, grade 4	N	16	814, 815, 816
D89.835	Cytokine release syndrome, grade 5	N	16	814, 815, 816
D89.839	Cytokine release syndrome, grade unspecified	N	16	814, 815, 816

<sup>1</sup> Lee DW et al., ASTCT Consensus Grading for Cytokine Release Syndrome and Neurologic Toxicity Associated with Immune Effector Cells, *Biology of Blood and Marrow Transplantation* 25(2019)526-638, available at <https://www.sciencedirect.com/science/article/pii/S1083879118316914>.

<sup>2</sup> 85 Fed. Reg. at 32,550

For reference, the parameters for each CRS grade under ASTCT's CRS Consensus Grading is set forth in the table below:<sup>3</sup>

ASTCT CRS Consensus Grading

CRS Parameter	Grade 1	Grade 2	Grade 3	Grade 4
Fever*	Temperature $\geq 38^{\circ}\text{C}$	Temperature $\geq 38^{\circ}\text{C}$	Temperature $\geq 38^{\circ}\text{C}$	Temperature $\geq 38^{\circ}\text{C}$
		With		
Hypotension	None	Not requiring vasopressors	Requiring a vasopressor with or without vasopressin	Requiring multiple vasopressors (excluding vasopressin)
		And/or <sup>1</sup>		
Hypoxia	None	Requiring low-flow nasal cannula <sup>1</sup> or blow-by	Requiring high-flow nasal cannula <sup>1</sup> , facemask, nonrebreather mask, or Venturi mask	Requiring positive pressure (eg, CPAP, BiPAP, intubation and mechanical ventilation)

## **II.E.2.a – Payment Stabilization for MS-DRG 215**

In the Proposed Rule, CMS solicited comments on policies to adjust the relative weight for MS-DRG 215 (Other Heart Assist Implant), to prevent a 26 percent reduction in FY 2021 from a weight of 12.8861 in FY 2020 to a proposed weight of 9.4798. If adopted without payment stabilization, this change in the weight for MS-DRG 215 would result in a cumulative decline of more than 40 percent over four years. A decrease of this magnitude would have a significant negative impact on hospitals that care for critically ill cardiovascular patients who require the implantation of a heart pump in the operating room or cardiac catheterization laboratory after heart attacks or decompensating heart failure. In addition, the anticipated impact of such a decrease and the merits of payment stabilization strategies must be considered with a particular eye to the ongoing COVID-19 PHE. Where a patient presents with cardiac or multi-organ failure and develops a COVID-19 infection as a secondary diagnosis, the case would map to MS DRG 215 and be impacted by any reweighting.

In order to promote predictability and reliability in the IPPS, the FAH urges CMS to phase in substantial fluctuations in payment rates. We appreciated that CMS limited the payment decrease for MS-DRG 215 in FY 2019 and FY 2020, and **for FY 2021 we urge CMS to average the FY 2020 relative weight for MS-DRG 215 with the otherwise applicable FY 2021 relative weight.** We also recommend that CMS evaluate potential long-term solutions to stabilize payment for hospitals that treat the critically ill cardiovascular patients included in MS-DRG 215.

## **II.E.2.b. and IV.I – Relative Weight Methodology for CAR T-Cell Therapy and Payment Adjustment for Clinical Trial Cases (Proposed § 412.85)**

**The FAH supports CMS's proposal to control for clinical trials in the weighting methodology for MS-DRG 018 and to adjust reimbursement for CAR T-cell clinical trial cases.** CAR T-cell therapy cases present an unusual circumstance because the costs of the drug product constitute an extremely large portion of the total cost of care. As a result, clinical trial cases result in costs that are a small fraction of the costs of non-clinical trial cases involving CAR T-cell therapy. Therefore, it is appropriate to adopt a weighting and reimbursement

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<sup>3</sup> Grade 5 CRS is defined as death due to CRS in which another cause is not the principle factor leading to this outcome.



methodology that accounts for these stark differences in cases. **The FAH also supports CMS’s proposed weighting methodology, which identifies clinical trial cases based on the reporting of ICD-10-CM diagnosis code Z00.6 on the claim or the reporting of standardized drug charges of less than \$373,000 (the average sales price of KYMRIA and YESCARTA).** This identification process assures that clinical trial claims reported without diagnosis code Z00.6 are still identified as clinical trial cases based on their aberrantly low or non-existent drug charges. In determining the relative weight for MS-DRG 018, the average cost of clinical trial and non-clinical trial CAR T-cell claims are compared to develop an adjustor that is applied to the clinical trial claims.

With respect to reimbursement for CAR T-cell clinical trial claims, CMS proposes to identify clinical trial claims based on the presence of diagnosis code Z00.6 and then apply the clinical trial adjustor (developed as described) to these claims. This payment adjustment is proposed to be codified at new 42 C.F.R. § 412.85. Although this approach will largely account for the vast differences in costs between clinical trial and non-clinical trial CAR T-cell therapy cases, it risks (1) underpaying CAR T-cell therapy claims that are not part of a clinical trial but are reported with diagnosis code Z00.6 because of the beneficiary’s participation in another clinical trial and (2) overpaying CAR T-cell therapy clinical trial claims that are reported without diagnosis code Z00.6. With regards to the underpayment risk, the FAH urges CMS to ensure appropriate payment in these rare cases by only applying the clinical trial adjustor to claims reporting diagnosis code Z00.6 if the 8-digit national clinical trial (NCT) number is associated with a CAR T-cell therapy clinical trial. Alternatively, CMS could address these cases by adopting a value code that identifies these CAR T-cell therapy claims involving non-CAR T-cell therapy clinical trials and ensures the clinical trial adjustor is not applied.

To address the overpayment risk, the FAH recommends applying the same two-step process for identifying CAR T-cell clinical trial claims that is applied in calculating the adjustment factor for clinical trials. Applying the adjustment factor to claims with drug charges that fall below \$373,000 despite the absence of diagnosis code Z00.6 assures that the clinical trial reimbursement methodology is appropriately applied to all clinical trial claims. Moreover, this change to the reimbursement methodology would avoid the anomalous result of a claim being identified as a clinical trial for purposes of calculating the adjustment factor but not being paid as a clinical trial under the reimbursement methodology. Along these lines, in light of the proposal to use diagnosis code Z00.6 to determine the applicability of the clinical trial adjustment factor for discharges assigned to MS-DRG 018, the FAH requests that CMS provide additional guidance concerning the use of diagnosis code Z00.6 or an alternative identifying code in cases where the patient receives CAR T-cell therapy using an “out of specification” (also called “expanded access use”) CAR T-cell therapy product.

Lastly, the FAH would like to raise a technical issue concerning the drug charges used in rate-setting for MS-DRG 018. In attempting to replicate the weighting methodology, it appears that CAR T-cell therapy product charges reported in revenue code 0891 (Special Processed Drugs – FDA-Approved Cell Therapy) were erroneously excluded. The Proposed Rule provides no rationale for this exclusion, which appears to be a technical error that suppressed data from

approximately 25 cases and would suppress a larger number of more recent claims.<sup>4</sup> The FAH therefore urges CMS to modify the proposed weighting methodology to appropriately incorporate revenue code 0891 CAR T-cell therapy product charges. In addition, for the purposes of IPPS rulemaking in future years, the FAH urges CMS to review the data dictionary and revise how certain revenue codes in the 081x-089x range are handled in rate-setting.

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

There were 18 add-on payment categories approved for FY 2020 that were previously discussed in the FY 2020 Proposed Rule. **The FAH agrees** with CMS's proposal on either the continuation or discontinuation of the add-on payment based on the anniversary date of the product's entry on the market, noting the exception of products that enter the U.S. market in the latter half of the fiscal year.

#### **II.G.5. Proposed FY 2021 Applications for New Technology Add-On Payments (Traditional Pathway)**

##### **II.G.5.c – ContaCT**

**The FAH supports the NTAP submission for ContaCT.** Viz.ai submitted an application for ContaCT, a radiological computer-assisted triage and notification system used by hospitals and clinicians to identify patients with a suspected large vessel occlusion on computed tomography angiogram (CTA) images of the brain. The system analyzes CTA images of the brain, sends notifications to a neurovascular specialist(s) that a suspected large vein occlusion (LVO) has been identified, and recommends review of those images. ContaCT consists of three individual components that are currently marked as VizLVO (for the algorithm), Viz Hub (for text messaging and calling platform), and Viz View (for the mobile image viewer).

In the Proposed Rule, CMS expresses concern that the use of artificial intelligence (AI), an algorithm, or software are not unique mechanisms of action and contemplates how updates to AI, an algorithm or software would affect an already approved technology or a competing technology for purposes of a new technology add on payment (NTAP).

The FAH does not share CMS's concerns. Rather technologies that utilize AI, an algorithm and/or software may be evaluated for newness in the same way as CMS evaluates any other medical device applying for NTAP. Such a technology would not be new if there is an existing FDA-approved technology that has been on the market for more than 2 to 3 years and that has the same mechanism of action, is assigned to the same DRGs, or is used in the same or similar type of disease and patient population. This would apply to both incremental changes to the same device as well as to competing devices

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<sup>4</sup> The use of revenue code 0891 for CAR T-cell therapy drug products arises from an April 1, 2019 National Uniform Billing Commission (NUBC) change that designates the 0891 revenue code as an extension of pharmacy so that cell therapy products can be reported separately from other drugs. As hospitals become more familiar with NUBC transaction set requirements for CAR T-cell therapy claims, it is expected that the volume of CAR T-cell therapy products reported using revenue code 0891 will increase.

**Therefore, the FAH supports the NTAP submission for ContaCT. Further we urge CMS to consider that evaluating technologies that use AI, an algorithm and/or software is no different than evaluating other technologies for purposes of the NTAP. Technologies are not required to have a specific type of mechanism of action to be eligible for NTAP, and as such, each submission must be evaluated independently.**

#### **II.G.5.i-j – KTE-X19 and Liso-Cel**

The following two new technologies are noted in the Proposed Rule as proposed applications for NTAPs:

- KTE-X19 – is a CD19 directed genetically modified autologous T-cell immunotherapy for the treatment of adult patients with relapse and refractory (r/r) mantle cell lymphoma (MCL). KTE-X19 is a form of chimeric antigen receptor (CAR) T-cell immunotherapy that modifies the patient’s own T-cells to target and eliminate tumor cells.
- Lisocabtagene Maraleucel (Liso-cel) - investigational, CD19-directed, autologous chimeric antigen receptor (CAR) T-cell immunotherapy that is comprised of individually formulated CD8 (killer) and CD4 (helper) CAR T-cells that the applicant anticipates to be indicated for the treatment of adult patients with relapsed or refractory (r/r) large B-cell lymphoma after at least two prior therapies.

The Proposed Rule notes that under the current coding system, cases involving the use of KTE-X19 or Liso-cel would be coded using ICD-10-PCS codes XW033C3 and XW043C3, which are also assigned for cases involving KYMRIA® and YESCARTA® and currently group to MS-DRG 016.<sup>5</sup>

CMS is proposing to assign cases reporting ICD-10-PCS procedure codes XW033C3 or XW043C3 to a proposed new MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy), which would also include cases reporting the use of KTE-X19 and Liso-cel, if approved and finalized.

Both applicants submitted a request for unique ICD-10-PCS codes to describe the use of KTE-X19 and Liso-cel beginning in FY2021.

There were two options presented in the March 2020 ICD-10 Coordination and Maintenance (C&M) committee meeting on the topic of ICD-10-PCS code assignment for these two new technologies:

- to assign the current available codes XW033C3 or XW043C3 for both of these new technologies (which is the same as for KYMRIA and YESCARTA CAR T-cell therapy) - OR
- to create new codes in section X, New Technology, to identify the transfusion of KTE-X19 and Liso-cel – with a XW0 series rather than an XW2 series.

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<sup>5</sup> 85 Fed. Reg. at 32,635 and 32,636.

CMS noted that these two new therapies are proposed to be assigned to the existing ICD-10-PCS codes for CAR-T cell; the two options presented at the C&M meeting were not included in the Proposed Rule. CMS also noted that the MS-DRG assignment of any applicable finalized codes describing the use of these technologies will be addressed in the final rule.

Each technology appears to be unique and specific to the condition for which it is an indication for treatment. Therefore, the FAH urges CMS to consider separately identifying these new technologies through ICD-10-PCS codes in conjunction with NDC numbers for new technology add-on payment purposes.

In short, the current ICD-10-PCS codes used for KYMRIA and YESCARTA should not become generic codes for widely varying types of CAR T-cell therapies. **The FAH urges CMS to consider the development of new ICD-10-PCS codes to distinctly identify similar therapies in future rule making.** Establishing new and distinct ICD-10-PCS codes for CAR T-cell therapies would ensure that as an ever wider range of CAR T-cell therapies become available for different indications, a ready process would be in place for appropriately identifying these distinctly different therapies.

If finalized, the FAH believes these new technologies should be assigned to the new MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy).

#### **IV.H.2. Proposed Payment for Allogeneic Hematopoietic Stem Cell Acquisition Costs (§ 412.113(e)(3))**

The FAH has significant concerns with CMS's proposal implementing section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116-94). Current CMS regulations allow transplant centers to bill their actual donor charges on transplant recipient accounts. This allows centers to bill for actual charges (*i.e.*, donor evaluation, donor work-up, testing, unrelated donor search and acquisition), regardless of whether the payer is CMS or a commercial plan. Likewise, the Provider Reimbursement Manual (Part 1, Section 2202.4) instructs hospitals to uniformly apply any service charge to all patients. The FAH urges CMS to codify these existing manual instructions, which enable hospitals to continue including actual donor search and cell acquisition charges applicable to each transplant recipient's case on the Medicare claim.

In the Proposed Rule, CMS instead proposes to require hospitals to formulate a standard acquisition charge based on costs expected to be reasonably and necessarily incurred in the acquisition of hematopoietic stem cells. This standard acquisition charge would apply to *all* allogeneic hematopoietic stem cell transplants, notwithstanding the actual costs of acquiring stem cells for the transplant at issue. In setting forth this proposal, CMS does not address the extraordinary variability of hematopoietic stem cell acquisition costs, which are impacted by the donor source and geography, with some hematopoietic stem cells being harvested and acquired internationally. These factors will render a "standard" acquisition charge inaccurate in most cases and substantially inaccurate in many cases. Moreover, the Proposed Rule wholly fails to address the potentially disruptive impact of the establishment of a standard acquisition charge on non-Medicare claims. **In light of the foregoing concerns, the FAH requests that CMS revise**

**proposed 42 C.F.R. § 412.113(e)(3) to enable hospitals to continue using actual hematopoietic stem cell acquisition charges on Medicare claims.**

## **WAGE INDEX**

### **III.A.2 Core-Based Statistical Areas for the FY 2021 Hospital Wage Index**

The wage index reflects the ratio of the weighted (by hours) average hourly wage reported on Medicare cost reports in a labor market area to the national average hourly wage. CMS uses OMB Core-Based Statistical Areas (CBSAs) delineations to assign a hospital to a labor market area. CMS is currently using OMB delineations from 2015 (based on the 2010 census) updated by OMB Bulletin numbers 13-01, 15-01 and 17-01. CMS proposes to use the CBSA delineations from the September 14, 2018 OMB Bulletin No. 18-04 for the FY 2021 labor market areas.

Typically, OMB bulletins issued between decennial censuses have only minor modifications to labor market delineations. However, the April 10, 2018 OMB Bulletin No. 18-03 and the September 14, 2018 OMB Bulletin No. 18-04 included more modifications to the labor market areas than are typical between decennial censuses. The new delineations have implications for the wage index and geographic reclassification.

Under the new OMB delineations, a total of 34 counties and 10 hospitals will change from urban to rural. A total of 47 counties that include 17 hospitals or critical access hospitals (CAH) will change from rural to urban. CMS also provides a list of 19 urban counties that would shift from one urban CBSA to a newly proposed or modified CBSA. ***The FAH supports CMS's proposal to use new OMB Bulletin No. 18-04 delineations.***

To be eligible for CAH status, a hospital must be treated as rural for IPPS purposes. For CAHs changing from rural to urban, CMS will allow them to retain CAH status for two years. This policy will allow sufficient time for CAHs to apply for an urban to rural reclassification under section 1886(d)(8)(E) of the Act and 42 CFR §412.103 in order to retain CAH status. ***The FAH also requests that CMS consider extending a similar 2-year extension of Medicare Dependent Hospital (MDH) and Sole Community Hospital (SCH) status as MDH and SCH designations are also dependent on rural status.***

#### **III.A.2.c. Proposed Transition for Hospitals Negatively Impacted**

CMS proposes to place a 5 percent cap on any decrease in a hospital's wage index from the hospital's final wage index for FY 2020, such that a hospital's final wage index for FY 2021 would not be less than 95 percent of its final wage index for FY 2020. The transition policy would not be limited to wage index reductions that result from the new labor market areas. Any change to a hospital's wage index (e.g. from new wage data, a change to a geographic reclassification, CBSA changes, etc.) would be subject to the 5 percent capped reduction. This policy is tantamount to a transition and would allow the full effects of the proposed adoption of the revised CBSA delineations and all other changes reducing a hospital's wage index to be

phased in over 2 years with no estimated reduction in the wage index of more than 5 percent in FY 2021. No cap would be applied in FY 2022.

***The FAH supports CMS's proposals to mitigate reductions in the hospital wage indexes from the change to using the new OMB delineations and all other factors.*** In reviewing CMS's data applying the 5 percent limit on reductions to the wage index in the FY 2021 IPPS Proposed Rule, the FAH has observed that the 5 percent limit is applied to the hospital's wage index from the FY 2020 IPPS final rule rather than the actual wage index that a hospital is being paid in FY 2020. After the FY 2020 IPPS final rule was completed, a number of hospitals reclassified as rural under section 1886(d)(8)(E) of the Act to receive a rural wage index. ***As the rural wage index is the actual wage index paid to these hospitals in FY 2020, the FAH requests that CMS apply the 5 percent reduction from the wage index being paid in FY 2020 rather than the one that was included in the FY 2020 IPPS final rule.***

#### **III.A.2.d. Proposed Transition Budget Neutrality**

CMS proposes to invoke its exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to apply budget neutrality for the 5 percent cap on reductions to the IPPS wage index. CMS states that it “has used its exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to budget neutralize transition wage index policies when such policies allow for the application of a transitional wage index only when it benefits the hospital.”<sup>6</sup>

However, as we argue above, 42 U.S.C. § 1395ww(d)(5)(I)(i) neither authorizes nor requires budget neutrality. Further, to the extent the policy CMS proposes is intended only to benefit hospitals, not applying budget neutrality for the wage index transition would be both consistent with the statute and CMS's logic for invoking § 1395ww(d)(5)(I)(i). ***The FAH strongly recommends, therefore, that CMS not apply budget neutrality to offset the costs of the sound transition policy that applies a 5 percent cap on reductions to the IPPS wage index values.***

#### **III.E.2. Deadline for Submitting the 2019 Medicare Wage Index Occupational Mix Survey for Use Beginning with the FY 2022 Wage Index**

Hospitals were required to submit their completed 2019 surveys to their MACs by July 1, 2020. CMS granted hospitals nationwide an extension until August 3, 2020 due to the COVID-19 public health emergency. In *COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers* on the CMS website, CMS notes that “if hospitals encounter difficulty meeting this extended deadline date, hospitals should communicate their concerns to CMS via their MAC, and CMS may consider an additional extension if CMS determines it is warranted.”<sup>7</sup>

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<sup>6</sup> 85 Fed. Reg. at 32,706-07.

<sup>7</sup> CMS, COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers (June 25, 2020), at <https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf>.

Given the ongoing public health emergency, *the FAH requests that CMS extend the deadline for submitting occupational mix data from the 2019 survey until at least November 1, 2020.* We believe this later deadline will assist hospitals while still allowing sufficient time for CMS to incorporate 2019 occupational mix data, which CMS should not abandon, into the FY 2022 IPPS rates. As the FY 2021 IPPS final rule will not be published until after the August 3, 2020 extended deadline, CMS must use another vehicle to extend the deadline for submitting 2019 occupational mix survey data. The FAH requests that CMS update *Emergency Declaration Blanket Waivers* to establish the later deadline. We further request that CMS publicize the deadline extension through listserve messages and an announcement on its regular Tuesday “Office Hours” national teleconference.

### **III.G.3 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 25<sup>th</sup> percentile by half of the difference between the hospital’s wage index value and the 25<sup>th</sup> percentile wage index value. CMS 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 2021 IPPS Proposed Rule, CMS proposes to continue this policy for the 2<sup>nd</sup> of four consecutive fiscal years.

While 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.<sup>8</sup> 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 faced by rural hospitals and ensure that Medicare reimbursement formulas do not operate to magnify the stress on the rural health delivery system and access issues faced by rural Medicare beneficiaries. Therefore, the FAH supports CMS’s 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

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<sup>8</sup> MedPAC June 2018 Data Book, Section 2: Medicare Beneficiary Demographics (July 20, 2018).

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's 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.***

In the FY 2020 IPPS final rule, CMS invokes 42 U.S.C. § 1395ww(d)(3)(E) of the Act and its exceptions and adjustments authority under § 1395ww(d)(5)(I)(i) as the basis for raising low wage index values.<sup>9</sup> It then makes this policy budget neutral for FY 2020 and proposes to make this policy budget neutral for FY 2021 through adjustments to the IPPS standardized amounts.

If CMS could adopt this policy under 42 U.S.C. § 1395ww(d)(3)(E) of the Act, budget neutrality would be required. However, section 1886(d)(3)(E) of the Act 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.” While CMS intervenes to override the result produced by 42 U.S.C. § 1395ww(d)(3)(E) for sound policy reasons, it can only do so under a different statutory authority. For this reason, CMS also cites the exceptions and adjustments authority under section 1886(d)(5)(I)(i) as the statutory basis for its low wage index policy.

Clause (i) of § 1395ww(d)(5)(I), however, does not authorize budget neutrality. This clause allows for 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's 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.

As 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's assertion in the FY 2020 IPPS final

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<sup>9</sup> 84 Fed. Reg. 42,044, 42,329 (Aug. 16, 2019).



rule,<sup>10</sup> it is inappropriate to mitigate the wage index's impact on low wage index hospitals in a budget neutral manner. ***For this reason, CMS's 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.***

### **III.H. Revisions to the Wage Index Based on Hospital Reclassifications**

In the FY 2021 IPPS Proposed Rule, CMS is waiving the 60-day delay in the effective date of the final rule and replacing it with a 30-day delay as a result of the COVID-19 public health emergency. This means that rather than the final rule being available on public display by August 1 as it is traditionally, CMS may make the final FY 2021 IPPS rule available as late as September 1, 2020. Under section 1886(d)(10)(C)(ii), geographic reclassification applications for FY 2022 are due to the Medicare Geographic Classification Review Board (MGCRB) by September 1, 2020. Under 42 CFR section 412.230(d)(2), the 3-year average hourly wage provided in the FY 2021 IPPS final rule is used for FY 2022 geographic reclassification applications. **If CMS does not publish the IPPS final rule until September 1, 2020, the 3-year average hourly wage information that hospitals will need to submit an FY 2022 MGCRB application will be unavailable by the statutory deadline. The FAH urges CMS to take steps to ensure that data is available and the deadline extended to allow sufficient time to review the data for timely submission. The FAH urges CMS to notify providers no later than August 1 of its decision.**

While the MGCRB deadline is statutory, we believe there are several options available to CMS to accommodate this situation. During a public health emergency, section 1135(b)(5) of the Social Security Act (the Act) allows the Secretary “to waive deadlines and timetables for performance of required activities, except that such deadlines and timetables may only be modified, not waived.” In MLN Matter SE 19019, CMS provided hospitals in Georgia and South Carolina until October 1, 2019 to submit geographic reclassification applications as a result of the public health emergency declared in these states due to Hurricane Dorian. In 2006, CMS lost a case on the occupational mix adjustment that required the agency to conduct a new occupational mix survey. Final wage data was not available timely for the September 1 MGCRB deadline. In the May 17, 2006 occupational mix Proposed Rule, CMS allowed hospitals to submit incomplete applications to the MGCRB by September 1 that could be supplemented later when the final 3-year average hourly wage data was available. We believe CMS should use its section 1135 of the Act authority as it did last year in Georgia and South Carolina to extend the deadline for hospitals to submit geographic reclassification applications.

Whatever CMS decides to do, hospitals must be notified well in advance of the September 1, 2020 deadline for submitting MGCRB applications. If the IPPS final rule is not published until September 1, 2020, the final rule cannot be the vehicle for communicating to hospitals how to handle the deadline for FY 2022 MGCRB applications. As was done for Hurricane Dorian, we suggest CMS provide an MLN Matters article informing the hospitals that

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<sup>10</sup> *Id.* at 42,331 (“[W]e would consider it inappropriate to sue the wage index to increase or decrease overall IPPS spending.”).

the application deadline for FY 2022 MGCRB applications has been delayed under your section 1135 of the Act authority due to the COVID-19 public health emergency. As noted above, the FAH urges CMS provide this guidance as soon as possible but no later than August 1, 2020.

### **III.I.2.c. Effects of Implementation of Revised OMB Labor Market Area Delineations on Reclassified Hospitals**

Hospitals applied for reclassification based on the prior OMB delineations, not the revised delineations proposed for FY 2021. Following past practice, CMS assigned a hospital or group of hospitals a new geographic reclassification based on the new OMB delineations. For individual hospital reclassifications, CMS assigned the reclassified hospital to a CBSA that would contain the most proximate county that: (1) is located outside of the hospital's proposed FY 2021 geographic labor market area, and (2) is part of the original FY 2020 CBSA to which the hospital is reclassified. For county group reclassifications, CMS reassigned hospitals to the CBSA under the revised OMB delineations that contains the county to which the majority of hospitals in the group reclassification are geographically closest. CMS permitted hospitals to withdraw or terminate their FY 2021 reclassifications assigned by CMS in the Proposed Rule or request an alternative one if the hospital or county group qualifies for reclassification to the alternative area. *The FAH agrees with these proposed policies.*

## **DISPROPORTIONATE SHARE HOSPITAL PAYMENTS**

### **IV.G. Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2021**

The ongoing COVID-19 public health emergency is expected to have profound impacts on the key factors undergirding calculation of Medicare DSH payments for FY 2021, but the Proposed Rule does not address or mention COVID-19 in the context of Medicare DSH or address the appropriateness of extrapolating from prior fiscal years and pre- or early-COVID-19 economic estimates. Because of the COVID-19 pandemic and associated State stay-at-home orders, the unemployment rate rose to 14.7 in April 2020. Although it has fallen slightly in the ensuing months, it remains well above the 4.0 percent projection set forth in the President's Budget. This significant and unexpected nationwide spike in the unemployment rate is already having associated impacts on coverage as large numbers of Americans lose access to employer-sponsored coverage (ESI) and either gain coverage largely under the Medicaid program or ACA marketplaces, or become uninsured. Meanwhile, the proportion of inpatient admissions among Medicare and Medicaid beneficiaries is expected to remain high during the course of the pandemic due to the disproportionate impact of COVID-19 among these communities and the delay or cancellation of elective inpatient admissions.

In light of the profound, ongoing consequences of COVID-19, the FAH and economic observers expect that hospitals' disproportionate patient percentages will largely increase nationwide in FY 2021, increasing the projected, aggregate amount of traditional Medicare DSH payments (*i.e.*, those Medicare DSH payments that would be paid under subsection (d)(5)(F) in the absence of 42 U.S.C. § 1395ww(r)) well above levels projected based on FY 2017 data and the economic assumptions and actuarial analysis used to develop the President's Budget

estimates in February 2020.<sup>11</sup> Likewise, the percentage of individuals expected to be uninsured in FY 2021 is expected to significantly surpass the CMS’s Office of the Actuary’s (OACT) projections, which expressly “do not take into account the impacts of COVID-19 because of the timing of the report and the highly uncertain nature of the pandemic.”<sup>12</sup> The FAH therefore strongly urges CMS to revisit its calculation of Factor One and Factor Two in order to ensure that its uncompensated care (UC) DSH payments are sufficient and grounded in reasonable, supportable estimates that appropriately address the ongoing impact of COVID-19 and healthcare, coverage, and the economy.

### **UC Calculation of Proposed Factor 1 FY 2021**

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’s Factor 1 calculation begins with 100 percent of empirically justified Medicare DSH payments in a baseline year (FY 2017 for FY 2021 UC payments), and this number is then adjusted based on increase factors applied by the OACT to determine estimated FY 2021 empirically justified Medicare DSH payments. Factor 1 equals 75 percent of this amount.

OACT began with a baseline figure of \$14.004 billion for Medicare DSH expenditures for FY 2017. The following table shows the factors applied to update this baseline to determine the Factor 1 estimate for FY 2021:

<b>FY</b>	<b>Update</b>	<b>Discharge</b>	<b>Case-Mix</b>	<b>Other</b>	<b>Total</b>	<b>Estimated DSH Payment (in billions)</b>
2018	1.018088	0.983	1.018	1.03145	1.0508	14.716
2019	1.0185	0.9549	1.01	1.02025	1.0022	14.748
2020	1.031	0.9756	1.005	0.9961	1.0069	14.85
2021	1.031	0.9959	1.005	1.00225	1.0342	15.359

OACT estimates that 100 percent of DSH in FY 2021 would be \$15.359 billion. Factor 1 would equal 75 percent of this amount or \$11.519 billion. This figure is \$919 million or 7.4 percent less than factor 1 for FY 2020. The Proposed Rule indicates that the Factor 1 estimates

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<sup>11</sup> In light of the economic volatility resulting from COVID-19 and the resulting economic downturn, the Midsession Review of the President’s Budget “does not report updated economic assumptions or provide updated revenue and deficit estimates” for FY 2021. Office of Management and Budget, Mid-Session Review (July 2020), at <https://www.whitehouse.gov/wp-content/uploads/2020/07/21msr.pdf>.

<sup>12</sup> CMS, National Health Expenditure Data, Projected, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected>.

for proposed rules are generally consistent with the economic assumptions and actuarial analyses used to develop the President’s Budget estimates under current law, and the Factor 1 estimates for the final rule are generally consistent with those used for the Midsession Review of the President’s Budget.<sup>13</sup> The President’s Budget was released to the public before COVID-19 became widespread in the United States and, therefore, does not include the impact of the public health emergency beginning in March of 2020 (or for the second half of FY 2020) on the above estimates. Moreover, although the Midsession Review of the President’s Budget acknowledged that the “public health emergency . . . resulting from the COVID-19 pandemic, along with the economic contraction resulting from many State-level stay-at-home and social distancing orders, has transformed the Federal fiscal outlook in the near and immediate term,” this year’s Midsession Review “does not report updated economic assumptions or provide updated revenue and deficit estimates for the budget window.”<sup>14</sup> Thus, restricting the estimate to economic assumptions and actuarial analyses undergirding the President’s Budget wholly fails to account for the profound impact of COVID-19 on empirically justified Medicare DSH payments.

Of particular concern in the above estimates is the “other” factor for FY 2020 and FY 2021. This factor accounts for all other variables that may affect Medicare expenditures for DSH that are not explicitly accounted for in the prior columns. According to the Proposed Rule, the “other” factor incorporates the effects of the difference between total hospital discharges and IPPS discharges, the change in rates for the 2-midnight rule, and Medicaid expansion due to the ACA. The first two of these “other” factors have remained and are expected to remain relatively stable: IPPS discharges continue to comprise a significant, and arguably growing share of total hospital discharges, and the 2-midnight rule has been in place for several years. As such, we believe the most important variable in the “other” factor that accounts for changes in the later years of this table is Medicaid enrollment.

The “other” factor shows a 0.39 percent reduction and a 0.22 percent increase for FY 2020 and FY 2021 respectively implying a small reduction in Medicaid enrollment for FY 2020 and a small increase for FY 2021. The FAH believes these figures vastly understate what is actually happening with Medicaid enrollment in FY 2020 and what will likely happen in FY 2021. According to the Urban Institute, between 12 and 21 million people will gain Medicaid coverage as a result of losing ESI due to the COVID-19 public health emergency.<sup>15</sup> The Kaiser Family Foundation estimates that of the 27 million people losing ESI as of May 2, 2020, nearly half (12.7 million) are eligible for Medicaid.<sup>16</sup> These sources suggested that the “other” factor should reflect a significant increase in Medicaid enrollment for FY 2020, well beyond OACT

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<sup>13</sup> 85 Fed. Reg. at 32748.

<sup>14</sup> Office of Management and Budget, Mid-Session Review (July 2020), at <https://www.whitehouse.gov/wp-content/uploads/2020/07/21msr.pdf>.

<sup>15</sup> Bowen Garrett and Anuj Gangopadhyaya, How the COVID-19 Recession Could Affect Health Insurance Coverage, Urban Institute, May 2020.

<sup>16</sup> Rachel Garfield, Gary Claxton, Anthony Damico and Larry Levitt, *Eligibility for ACA Health Coverage Following Job Loss*, Kaiser Family Foundation, May 13, 2020.

estimates. Further, Federal Reserve Chair Jerome Powell expects the economic dislocation resulting from the COVID-19 public health emergency to continue well into the FY 2021.<sup>17</sup>

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 2021 IPPS/LTCH PPS final rule.” (85 FR 32748). As indicated above, projections used for the midsession review of the President’s Budget would normally be used to forecast Factor 1 for the final rule, but the recently released Midsession Review “does not report updated economic assumptions or provide updated revenue and deficit estimates” for FY 2021.<sup>18</sup> In the absence of these projections, OACT continues to be obligated to account for COVID-19 in projecting empirically justified Medicare DSH payments by using the latest economic forecasts from reliable sources. Based on reliable, public data, Medicaid enrollment has already increased substantially in FY 2020 and that further enrollment increases will continue into FY 2021. In updating the Factor 1 estimates for the final rule, ***the FAH strongly urges OACT to update its Medicaid enrollment estimates and account for the impact of the COVID-19 public health emergency to determine Factor 1.***

### UC Calculation of Proposed Factor 2 FY 2021

Factor 2 of the UC DSH calculation adjusts Factor 1 for the change in the number of uninsured individuals in the United States since 2013, the last year before the ACA’s coverage expansion. The higher the uninsured rate, the larger the aggregate dollar amount of UC DSH payments that are distributed to IPPS hospitals under Factor 3. Because Factor 2 turns exclusively on the uninsured rate, it is critical that CMS’s estimate accurately accounts for significant factors that are expected to fuel the uninsured rate. For FY 2021, OACT estimates the uninsured rate as 9.5 percent, the same percentage OACT estimated one year ago for FY 2020. The 2013 uninsured rate is calculated at 14 percent. Based on this difference, OACT estimates that Factor 2 is equal to 0.6786. When multiplied by Factor 1 (\$11.519 billion), proposed Factor 2 produces a UC DSH pool of \$7.816 billion. This amount is \$534 million or 6.4 percent less than the amount of UC DSH payments in FY 2020. This proposed reduction to aggregate UC DSH payments fails to account for the significant loss of coverage resulting from COVID-19, relying on pre-COVID-19 economic indicators to produce an unsupportable and depressed uninsured rate that does not capture the current and projected economic outlook.

Factor 2 is determined using estimates of the uninsured from the National Health Expenditure Accounts (NHEA) with the latest historical data through 2018.<sup>19</sup> In an explanatory document on CMS’s website dated March 24, 2020, OACT indicates:

The models used to project trends in health care spending are estimated based on historical relationships within the health sector, and between the health sector and

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<sup>17</sup> Federal Reserve Chairman Jerome Powell, *60 Minutes Interview*, May 17, 2020.

<sup>18</sup> Office of Management and Budget, Mid-Session Review (July 2020), at <https://www.whitehouse.gov/wp-content/uploads/2020/07/21msr.pdf>.

<sup>19</sup> 85 Fed. Reg. 32751.

macroeconomic variables. Accordingly, the spending projections assume that these relationships will remain consistent with history, except in those cases in which adjustments are explicitly specified.<sup>20</sup>

At the time of this OACT statement, the United States was in the early stages of the COVID-19 public health emergency. The nation's economy was just beginning to undergo an unprecedented, sudden, and severe contraction due to the pandemic. Tens of millions of Americans have since lost and continue to lose their jobs, with many losing access to employer-sponsored insurance (ESI). Many economists, including Chairman Powell, believe that economic trends in FY 2020 and FY 2021 will not be consistent with the sustained economic growth that the country experienced from the end of the Great Recession in 2008 until earlier this year.

In selecting use of the NHEA to determine Factor 2, OACT states:

Timeliness and continuity are important considerations because of our need to be able to update this estimate annually. Accuracy is also a very important consideration and, all things being equal, we would choose the most accurate data source that sufficiently meets our other criteria.<sup>21</sup>

Further, OACT states “we may also consider the use of more recent data that may become available for purposes of estimating the rates of uninsurance used in the calculation of the final Factor 2 for FY 2021.”<sup>22</sup> The FAH agrees that timeliness and accuracy are of critical importance to estimates of Factor 2 of the UC determination. Given the large economic dislocation and the documented loss of ESI, the FAH believes we can expect there will be large increases in the uninsured rate in FY 2020 and FY 2021. Data and projections from the Urban Institute indicate that between 5 and 10 million individuals under age 65 are expected to become uninsured due to the loss of employment sponsored coverage associated with the COVID-19 pandemic, with non-expansion states being disproportionately impacted.<sup>23</sup> These figures equate to an increase in the unemployment rate of between 1.9% to 3.5%.

Although Medicaid and subsidized ACA coverage are options for some people losing ESI, many people may not know about these options or may not take advantage of them. For example, estimates indicate that only 43% of those eligible for subsidized ACA coverage are enrolled in such coverage.<sup>24</sup> In addition, over 20 percent of those that become uninsured due to loss of ESI may be ineligible for Medicaid or ACA subsidies due to their income or other

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<sup>20</sup> Office of the Actuary, Projections of National Health Expenditures and Health Insurance Enrollment: Methodology and Model Specification, page 1.

<sup>21</sup> 85 Fed. Reg. at 32,751.

<sup>22</sup> *Id.*

<sup>23</sup> Bowen Garrett and Anuj Gangopadhyaya, How the COVID-19 Recession Could Affect Health Insurance Coverage, Urban Institute, May 2020.

<sup>24</sup> Kaiser Family Foundation, Marketplace Enrollees Receiving Financial Assistance as a Share of the Subsidy-Eligible Population, 2019, available at <https://www.kff.org/health-reform/state-indicator/marketplace-enrollees-eligible-for-financial-assistance-as-a-share-of-subsidy-eligible-population/>.

factors.<sup>25</sup> Medicaid eligibility is also limited in non-expansion states that are currently experiencing significant increases in COVID-19 cases, including Texas, Florida, Georgia, and Mississippi. All of these factors combined with the loss of ESI due to economic contraction make increases in the uninsured rate a certainty that must be accounted for by OACT in Factor 2 of the UC DSH determination. ***The FAH strongly urges OACT to broaden its data sources to reflect current estimates of the uninsured rate in FY 2021. Accurately projecting the uninsured rate in FY 2021 as part of Factor 2 necessitates consideration of the profound economic changes and losses of ESI attributable to the COVID-19 pandemic.***

### UC-DSH Calculation of Proposed Factor 3 for FFY 2020

The FAH commends CMS for its efforts over the past several years to: (1) better define the costs of UC, 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 WS S-10 so that costs are more accurately and consistently reported by hospitals; (3) allow providers to amend their WS S-10s to comply with CMS’s revised instructions; and (4) develop, engage in, and improve an audit process aimed at more accurately allocating and disbursing the UC fund to providers. Given the relative weights Factor 3 assigns to hospitals, the FAH appreciates CMS’s recent efforts to rigorously audit hospitals’ reported data to ensure hospitals are reporting costs consistently and accurately.

The audit process has improved the data nationally and specifically by hospital. A comparison of the UC cost information for 2017 cost reports reveal the significant impact that the audits have had. The comparison was made using CMS’s “Medicare DSH Supplemental Data File for 2021 Proposed Rule” and comparing it with CMS 2020 DSH file Alternative information. Both sets of information used 2017 cost reports. The following table summarizes the changes on a hospital-by-hospital basis for hospitals expected to receive DSH:

Category	Number	% of DSH Hospitals
Total DSH Hospitals	2,410	
Some Change	1,363	57%
Change >5%	683	28%
Change > 10%	534	22%

Overall, the change in UC costs for all DSH hospitals was a decline of 3.2% between the two files. This overall decline will increase to 3.7% when the UC cost is updated to reflect data from the March 31, 2020 HCRIS file. These findings suggest that the audit process has improved the reliability of UC costs that are used to distribute the aggregate UC payments in Factor 3.

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<sup>25</sup> Rachel Garfield, Gary Claxton, Anthony Damico and Larry Levitt, *Eligibility for ACA Health Coverage Following Job Loss*, Kaiser Family Foundation, May 13, 2020.

***We again encourage CMS to utilize an audit process similar to the wage index audit process to capture and improve the data for all UC-DSH hospitals.*** As part of the wage index audit process, CMS builds into the schedule a period of time for hospitals to review the data after it has been processed by CMS or the MAC. Hospitals are then permitted to notify CMS of issues related to mergers and/or to report potential upload discrepancies due to MAC mishandling of the WS-10 data during the report submission process. The FAH recommends that CMS provide at least a 14-day period to submit corrections for MAC and /or CMS mishandling of data. In the past we have seen a few cases of the MACs overwriting amended and/or audited data with older data. While this has occurred infrequently, a sufficient timeframe, no less than 14 days, to review and correct UC costs that result from MAC or CMS mishandling of the data would be equitable and improve the cost allocation. Such a policy would be conceptually consistent with the 14-day time period that CMS allows to submit corrections in the merger listing.

The wage index process was developed over many years and it has now become a routine part of CMS and hospital processes with clear expectations of schedules and obligations over a period of more than a year. Advantages of that process that would also apply to UC audits include: (1) an announced schedule so that hospitals can plan to have the resources available when the audits will occur; and (2) an informal appeals and correction process to CMS (not the Provider Review Reimbursement Board (PRRB)) if the provider disagrees with an audit adjustment.

While CMS may argue that the statute precludes administrative and judicial review, the appeals process here that is also used for the wage index would be an informal one through the MACs and CMS, and not the PRRB. The informal process CMS uses for the wage index is clear that if any step in the process is missed, the provider is foreclosed from appealing that item at any later point. CMS only evaluates policy issues, not the adequacy of documentation. A similar process for UC would require diligence on the part of the provider to respond to deadlines knowing that failure to do so would permanently disadvantage the provider just as it does for the wage index.

***The FAH requests that CMS develop an abbreviated appeals and correction process for UC audits for the FY 2022 IPPS rule.*** The deadline on the FY 2018 cost reports is scheduled to be completed and entered into HCRIS by December 31, 2020. For the FY 2022 UC process, CMS could create a process that is analogous to the following deadlines in the wage index development process:

- March 19, 2021. MACs transmit final revised wage index data to CMS. A similar deadline would be imposed for the WS S-10 on MACs to provide UC data to CMS that becomes publicly available. As audits are scheduled to be completed by December 31, 2020, this deadline could be earlier than for the wage index development process.
- April 2, 2021. Deadline for hospitals to appeal MAC determinations and request CMS's intervention in cases where the hospital disagrees with the MAC's determination. In limited circumstances where the MAC has mishandled data or not applied CMS policy



correctly, there would be an analogous deadline for hospitals to appeal WS S-10. Any decision by CMS would be final and not subject to further review by the PRRB. Again, as the UC audits are scheduled to be completed by December 31, 2020, this date could be earlier than for the wage index development process.

Just as it does for the wage index, CMS could provide the MAC with analytical processes to identify hospitals and areas the audits need to focus on. The results from the 2018 audits currently underway will provide audited results for all DSH hospitals. Now that a baseline has been established for UC audits, comparisons to the prior year can provide information where the MACs can do more focused audits. Patient detail for charity write-offs are now required to be submitted for FY 2019 and later cost reports. Review on this data could be used in place of some audits steps currently being performed.

### **The Change to Use of a Single Year of Data**

While the FAH supports using audited WS S-10 data for allocating UC-DSH payments, and thus supports CMS's proposal to use the single available year of audited data (FY 2017 cost report data) for FY 2021, the FAH notes that the use of multiple years of audited data would tend to smooth over any remaining anomalies in the data and thus result in more accurate allocation of UC-DSH payments in future years. We therefore recommend that CMS not finalize its proposal to only use one year of audited data beyond FY 2021 so that CMS can appropriately consider using two or three years of audited data in future fiscal years. The Proposed Rule indicates that CMS used a HCRIS extract updated through February 19, 2020 and intends to use the March 2020 update of HCRIS for the FY 2021 final rule and the March updates for all future years. CMS requests comment on use of more recent data that may become available after March. ***The FAH believes that CMS should use the June 30 update to HCRIS for the FY 2021 IPPS final rule.***

### **Mergers**

In situations where hospitals merge after the fiscal year for which CMS is using the hospitals' cost report data to determine the UC costs, CMS's policy is generally to combine the merged hospitals' UC costs to determine its UC payment. While this policy works well in situations where both hospitals have coinciding cost reporting periods and the merger occurs without any short period cost reports, it creates complexity when the merger occurs partway through the surviving hospital's cost reporting period. CMS's past policy has been to annualize the acquired hospital's data before determining a merged hospital's UC share. However, this process can overstate the acquired hospital's UC share. In its place, CMS proposes to incorporate a prorated unannualized UC share for the acquired hospital based on the number of days in its cost reporting.

Similarly, CMS outlines a method for how hospital mergers would be treated where the merger occurs after the final rule and CMS does not have cost report data for the merged hospital. In this circumstance, CMS would treat the newly merged hospital similar to how it treats a new hospital eligible for DSH and UC. Interim UC payments would be based on the

surviving hospital's cost report data, and the final settled cost report would reflect the surviving hospital's data that also includes the acquired hospital's UC information. ***The FAH supports both of these methodological changes for merged hospitals.***

#### **IV.N. Payments for Indirect and Direct Graduate Medical Education Costs**

The FAH supports CMS's proposal to temporarily increase the cap on a hospital's number of full-time equivalent (FTE) residents when the hospital is training residents displaced from their original program due to the program or hospital's closure. Modifying these policies will remove the currently overly restrictive requirements on a resident's physical location on the day their original training program or hospital closes.<sup>26</sup> To further ensure that these changes will be beneficial for both displaced residents and the hospitals that continue their training, the FAH urges CMS to allow the date of notification of the closure to be the earliest of the date the program or hospital gives notice of its impending closure to either the public or the accrediting body.

#### **IV.P. Market-Based MS-DRG Data Collection and Relative Weighting Calculation Methodology**

**The FAH strongly opposes CMS's proposal to require the disclosure of median payer-specific negotiated rate data for MA plans and third-party payers, as well as the incorporation of such data into the MS-DRG weighting methodology.** At its core, the proposal pursues an impermissible goal—shifting from a relative resource-based MS-DRG weighting system to one based on market rates. CMS lacks any authority to adopt a “market-based” MS-DRG weighting methodology because Congress has explicitly instructed CMS to weight MS-DRGs based on “relative hospital resources used with respect to discharges” for each MS-DRG in 42 U.S.C. § 1395ww(d)(4)(B). Moreover, although CMS has authority to collect certain information through annual cost reports, this authority only reaches that data that is necessary to determine appropriate payment amounts and does not permit the collection of market data that is wholly irrelevant to Medicare payment. Moreover, the Proposed Rule severely underestimates the operational burdens and costs of compliance and overestimates the value and utility of median payer-specific negotiated rate data. Although the FAH supports continued efforts to improve upon the accuracy and appropriateness of relative weight calculations, we oppose upending the current cost-based methodology through the use of payer-specific negotiated rate data. **Therefore, the FAH strongly urges CMS to abandon the proposed market-based MS-DRG data collection and relative weighting calculation methodology as unlawful and inappropriate.**

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<sup>26</sup> Current requirements do not permit an adjustment of the FTE cap for hospitals training displaced residents who: 1) departed their previous program between the day of closure; 2) are undertaking a previously planned rotation at another hospital or facility on the day of the closure; and 3) were matched to but had not yet begun training at the program on the date of the closure.

**A. CMS Lacks Authority to Require the Disclosure of Median Payer-Specific Negotiated Rate Data or to Make Changes to the MS-DRG Weight Methodology Based on Such Data**

The Proposed Rule erroneously suggests that CMS has authority to require providers to submit median payer-specific negotiated rate data under 42 U.S.C. §§ 1395l(e) and 1395g(a) and to then reweight MS-DRGs based on this third-party payer rate data. As a preliminary matter, Congress has specifically mandated that CMS use resource-based MS-DRG relative weights rather than any market-based approach. Thus, the data that CMS proposes to collect cannot be used to update the relative weights of MS-DRGs. Separately, the cost reporting statutes cited only permit the collection of data for purposes of determining the amount of payment. Because CMS has no authority to alter MS-DRG weights based on payer-specific negotiated rates or otherwise base payment on these rates, CMS also does not have authority to require the submission of this data from providers.

***1. The Requirement that MS-DRG Weights be Based on Relative Resource Utilization***

Under 42 U.S.C. § 1395ww(d)(4)(B), CMS is required to assign an “appropriate weighting factor” to each MS-DRG, and that weighting factor must reflect “the relative hospital resources” used with respect to discharges classified in that MS-DRG compared to discharges classified within other MS-DRGs. Likewise, CMS is required to adjust the MS-DRG weighting factors annually to reflect “factors which may change the relative use of hospital resources,” including changes in treatment patterns and technology.<sup>27</sup> As such, Congress mandated that CMS establish and update MS-DRG weights based on “relative hospital resources used.”<sup>28</sup> Because CMS is required to use a resource-based weighting system, it is precluded from adopting a “market-based” system or otherwise incorporating data on payer-specific negotiated rates into the MS-DRG weighting methodology.

Consistent with this statutory mandate, CMS has spent decades creating and refining an MS-DRG weighting system in which “[e]ach DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat

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<sup>27</sup> 42 U.S.C. § 1395ww(d)(4)(C)(i). The emphasis on resource-based weighting for MS-DRGs is also evident from the new technology add-on payment statute, which requires that, after the new technology add-on payment period expires, discharges involving the new service or technology be “classified within a new or existing [MS-DRG] *with a weighting factor* under paragraph (4)(B) that is *derived from cost data* collected with respect to discharges occurring during such period.” 42 U.S.C. § 1395ww(d)(5)(K)(ii)(IV). This provision again confers no latitude for CMS to adopt a market-based weighting system or to otherwise incorporate median payer-specific negotiated weight data into the MS-DRG weighting methodology.

<sup>28</sup> *Id.* § 1395ww(d)(4)(B).

cases in all DRGs.”<sup>29</sup> As the Proposed Rule notes, CMS currently uses a cost-based methodology to determine the relative hospital resources used for each discharge and adjusts MS-DRG relative weights based on these relative costs. This process involves reducing hospital charges to costs using hospital cost-to-charge ratios. The cost-based methodology for MS-DRG weighting has been in place for over a decade, beginning with fiscal year (FY) 2007. Prior to the FY 2007 IPPS Final Rule, CMS used a charge-based system for estimating relative hospital resources utilization by MS-DRG. Under this charge-based system, DRG weights were calibrated using standardized relative charges. This system was developed based on the observed correlation between charge-based and cost-based weights. In FY 2007, however, CMS transitioned to a cost-based MS-DRG weighting system in order to address distortions under the previous charge-based system and better capture relative hospital resource utilization.<sup>30</sup> Separately, CMS has refined its process for reducing charges to costs over the years as issues have arisen. The most notable example of this is CMS’s much needed 2003 change in the methodology for outlier payments, which addressed the adjustment of cost-to-charge ratios by a subset of providers to maximize outlier payments.<sup>31</sup> The FAH has frequently commented over the decades on ways in which cost-based methodologies can be refined and improved, and we strongly urge CMS to continue along this well-worn path, rather than radically shifting toward an untested and unpredictable new system.

Unlike the current cost-based system for weighting MS-DRGs, which appropriately seeks to quantify the relative hospital resources used in each discharge, the proposed market-based weighting system would be wholly untethered from the relative hospital resources used. The Proposed Rule does not provide any basis for concluding that median payer-specific negotiated rates could represent the relative hospital resources used in discharges. Rather, the Proposed Rule identifies studies concerning differences in Medicare FFS payment amounts and payer-specific negotiated rates and posits that payer-specific negotiated rates “may reflect the relative hospital resources used within an MS-DRG differently than [the] current cost-based methodology.”<sup>32</sup> This is not, however, the conclusion of any of the cited studies. Nor could it be—none of the cited studies even purport to address the relative hospital resources involved in various discharges.

By way of example, the Proposed Rule relies substantially on the evaluation of 2013 claims data by Jared Lane K. Maeda and Lyle Nelson to suggest that payer-specific negotiated rates “may reflect the relative hospital resources used,” but the study made no conclusions

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<sup>29</sup> Proposed Rule, 85 Fed. Reg. at 32,470. Similar statements have appeared annually in IPPS rulemaking since at least the FY 1997 IPPS Proposed Rule. E.g., 61 Fed. Reg. 27,444, 27,445 (May 31, 1996).

<sup>30</sup> 71 Fed. Reg. at 47,882.

<sup>31</sup> 68 Fed. Reg. 34,494, 34497 - 34504 (June 9, 2003).

<sup>32</sup> 85 Fed. Reg. at 32,793. It is unclear what it would mean to reflect relative hospital resource utilization “differently” than the current cost-based methodology. The only relevant question should be whether an MS-DRG weighting methodology accurately captures relative resource utilization. A cost-based methodology clearly does so, but there is no basis for viewing median payer-specific negotiated rates as representing relative hospital resource utilization.

regarding relative resource utilization.<sup>33</sup> In fact, the study does not even use the word “resource” or discuss hospital costs involved in the delivery of care. In addition, the limitations of the study call into question whether the observed differences in payment reflect other factors, such as relative patient acuity. The authors expressly noted that they “would not be able to capture” differences in acuity between a Medicare Advantage (MA) patient within a particular DRG and a Medicare fee-for-service patient assigned to the same DRG.<sup>34</sup> This study also did not endeavor to account for the impact of managed care on the observed payment data. For example, a payer’s prior authorization requirement for inpatient admissions may result in certain short stays being treated as observation stays such that inpatient discharges skew to higher acuities and higher payment.<sup>35</sup> The impact of these payer behaviors on the data was not evaluated in this study or even acknowledged by the authors. In short, this study and the other cited studies do not include any suggestion—let alone evidence—that either payer-specific negotiated rate or payment data is probative of relative hospital resource utilization.

**Overall, there is no reason to suspect that median payer-specific negotiated rates for discharges in an MS-DRG would represent relative hospital resource utilization, and the Proposed Rule fails to articulate any basis for determining that any such correlation exists. In contrast, the current cost-based system for weighting MS-DRGs measures hospitals’ relative resource utilization, as is required by statute.**

## ***2. CMS Cannot Require the Submission of Data that is Immaterial to Payment***

Because the weighting factor methodology required under 42 U.S.C. § 1395ww(d)(4)(B) requires the use of hospital resource utilization data rather than payer-specific negotiated rate data, it follows that neither 42 U.S.C. § 1395g(a) nor § 1395l(e) authorizes CMS to gather data concerning median payer-specific negotiated rates through hospital cost reports. The Proposed Rule suggests that CMS is authorized to require submission of this data under 42 U.S.C. §§ 1395g(a) and 1395l(e), but these statutes are expressly confined to the submission of data necessary to determine payment. For example, the latter statute bars payment to a provider unless the provider has “furnished such information as may be necessary *in order to determine the amounts due* such provider . . . under this part for the period with respect to which the amounts are being paid or for any prior period.” The language of 42 U.S.C. § 1395g(a) is

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<sup>33</sup> Maeda JLK & Nelson L, How Do the Hospital Prices Paid by Medicare Advantage Plans and Commercial Plans Compare With Medicare Fee-for-Service Prices?, *The Journal of Health Care Organization, Provision and Financing*, 2018;55(1-8).

<sup>34</sup> *Id.* at p.3.

<sup>35</sup> Notably, this study focused on claims *payments*, rather than payer-specific negotiated rates. The payment methodologies in managed care agreements may result in variable payment amounts for stays classified to a particular DRG based on factors such as the length of stay or the applicability of a stoploss provision. Because Maeda and Nelson focused on payment amounts, their results may reflect acuity differences and their study is generally inapplicable to CMS’s MS-DRG reweighting proposal.

virtually identical, again requiring that the data be connected to the determination of the amount of payment to the provider.<sup>36</sup>

**The Proposed Rule cites to no other statutory authority for the collection of data on median payer-specific negotiated rates, and the cited statutes are inapplicable to the data collection proposed because median payer-specific negotiated rates simply cannot be used as the basis for IPPS payments.** As discussed above, Congress requires that MS-DRGs be weighted based on relative hospital resource utilization, barring the use of the market data CMS proposes to collect. The Proposed Rule also suggests that median payer-specific negotiated rates could be used for determining outlier payments or new technology add-on payments, but again, these options are statutorily barred. With respect to outlier payments, the statute explicitly provides that outlier payments are available “where *charges adjusted to cost*” exceed the outlier threshold.<sup>37</sup> Similarly, Congress requires that the payment for new technology add-on payments be made “in an amount that adequately reflects *the estimated average cost* of such service or technology.”<sup>38</sup> Moreover, CMS is required to collect data “with respect to the costs” of the new technology or medical service and, after the new technology add-on payment period expires, must use “cost data collected with respect to discharges during such period” to assign an appropriate weighting factor to the new or existing MS-DRG in accordance with 42 U.S.C. § 1395ww(d)(4)(B).<sup>39</sup> Because CMS cannot use median payer-specific negotiated rate data to assign relative weights to MS-DRGs, determine outlier payments, or determine new technology add-on payments, the data collection proposed is unconnected with payment and cannot be adopted under the cost reporting statutes, 42 U.S.C. § 1395g(a) and § 1395l(e).

Finally, CMS’s proposed amendment to 42 C.F.R. § 413.20(d)(3) is likewise impermissible and cannot be finalized because CMS lacks the statutory authority to require the proposed data collection.

### **3. *The President’s Executive Order Cannot and Does Not Authorize the Collection of Median Payer-Specific Negotiated Rate Data or the Adoption of a Market-Based MS-DRG Weighting System***

The Proposed Rule extensively relies on Executive Orders as the basis for the proposed collection of median payer-specific negotiated rates and adoption of a market-based MS-DRG weighting system. In particular, the Proposed Rule discusses Executive Order 13813 of October 12, 2017, entitled “Promoting Healthcare Choice and Competition Across the United States;” the resulting report entitled “Reforming America’s Healthcare System Through Choice and Competition;” and Executive Order 13890 of October 3, 2019, entitled “Promoting Healthcare

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<sup>36</sup> Under 42 U.S.C. § 1395g(a), a provider must “furnish[] such information as the Secretary may request *in order to determine the amounts due* such provider under this part for the period with respect to which the amounts are being paid or any prior period” in order to receive payment.

<sup>37</sup> 42 U.S.C. § 1395ww(d)(5)(A)(ii) (emphasis added).

<sup>38</sup> *Id.* § 1395ww(d)(5)(K)(ii)(III) (emphasis added).

<sup>39</sup> *Id.* at § 1395ww(d)(5)(K)(ii)(II), (IV).

Choice and Competition Across the United States.” In particular, the Proposed Rule explicitly states that the proposed market-based data collection and MS-DRG weighting is designed to “address the directives in [Executive Orders] 13813 and 13890.”<sup>40</sup> An Executive Order, however, cannot expand CMS’s authority or alter the instruction of Congress.<sup>41</sup> Rather, the legislative authority remains with Congress, and Congress has only authorized the Secretary to craft a relative resource-based MS-DRG weighting methodology that is fundamentally incompatible with the market-based weighting methodology proposed here.

**In sum, CMS does not have the authority to implement its proposal to collect hospitals’ median payer-specific negotiated rate data for MA organizations or for any other third-party payer, and it does not have the authority to develop an MS-DRG weighting methodology using such data or otherwise shift from a resource-based weighting methodology to a market-based weighting methodology.**

**B. The Proposed “Market-Based MS-DRG Relative Weight” Data Collection and Methodology Would Introduce Data Distortions**

The absence of statutory authority supporting the proposed data collection and methodology change alone necessitates abandonment of CMS’s proposal. **Even putting the question of authority aside, however, the proposal is simply inappropriate because the shift to relying on median payer-specific negotiated rates for each DRG would (1) provide no insight into DRGs that ought to be reclassified and (2) produce skewed or distorted data.**

The Proposed Rule provides a cursory explanation of the goals behind the proposed “market-based MS-DRG relative weight” data collection and methodology, none of which suffices to justify the proposal. First, the Proposed Rule notes that “by reducing our reliance on the hospital chargemaster, we can adjust Medicare payment rates so that they reflect the relative market value for inpatient items and services.”<sup>42</sup> This observation, however, wrongly suggests that such an adjustment is permissible and desirable, when in fact CMS is statutorily precluded from adopting a market-based methodology for inpatient payments. Instead, the goal of any methodology for updating the relative weights of MS-DRGs must be to accurately capture the

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<sup>40</sup> 85 Fed. Reg. at 32,791.

<sup>41</sup> Recently, the Secretary took great pains to argue that “nothing in [Executive Order 13877, entitled “Improving Price and Quality Transparency in American Health Care to Put Patients First”] prejudged the contours of the Final Rule [on Price Transparency Requirements for Hospitals to Make Standard Charges Public], and indeed, HHS did not rely on the Executive Order in justifying its interpretation of ‘standard charges.’” Def.’s Mot. for Summ. J. at 32 (ECF No. 19), *Am. Hosp. Ass’n v. Azar*, No. 1:19-CV-03619 (June 23, 2020). Likewise, the district court emphasized its conclusion that the Executive Order at issue only required “that the agency *propose* a rule that included standard charges” and did not direct the adoption of the standard charges rule. *Am. Hosp. Ass’n v. Azar*, No. 1:19-CV-03619 (June 23, 2020). Here, however, the Proposed Rule expressly states that it was crafted to respond to a “directive” in two Executive Orders.

<sup>42</sup> 85 Fed. Reg. at 32,790.

relative utilization of hospital resources. And along similar lines, outlier and new technology add-on payments are required to be based on hospital *costs*, necessitating reliance on cost-based data and methodologies.<sup>43</sup>

Second, the Proposed Rule identifies public feedback suggesting that “the Medicare program’s uses of hospital gross charges for some payments in rate setting has served as the most significant barrier to hospitals’ efforts to rebase their chargemasters.”<sup>44</sup> However, CMS concedes that these concerns are “adequately address[ed]” by “existing administrative mechanisms for hospitals to voluntarily lower their charges.”<sup>45</sup> In addition, barriers to rebasing charges will continue to exist regardless of any Medicare changes because charges continue to be relevant outside the Medicare program, including payment methodologies used by certain Medicaid fee-for-service programs, Medicaid managed care payers, and commercial payers. For example, many commercial governmental managed care payer agreements include stoploss or outlier provisions that convert to a cost-based payment methodology for certain high-cost cases. In light of the many varied purposes served by the hospital chargemaster, there does not appear to be a readily available or preferable path to move away from the maintenance and use of the hospital chargemaster, and the Proposed Rule does not provide any such opportunity.

Against this backdrop, the proposed data collection and change to the MS-DRG weighting methodology would be problematic in terms of data quality and usability issues, some of which are described briefly below.<sup>46</sup>

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<sup>43</sup> 42 U.S.C. § 1395ww(d)(5)(A)(ii), (K)(ii)(III).

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* at 32,791; *see also* 42 C.F.R. § 412.84(i)(1), 84 Fed. Reg. 42,630.

<sup>46</sup> In addition, the proposed data collection would risk significant market disruption and unforeseen anticompetitive effects because median payer-specific negotiated rates for each subsection (d) hospital would be made publicly available to other hospitals and payers on the hospital’s cost report. As one payer observed in comments to the HHS Office of the National Coordinator for Health Information Technology (ONC) on the proposed information blocking rule, dominant health plans in local and regional markets can use disclosed rate information “to deter and punish hospitals that lower rates or enter into value-based arrangements with the dominant plan’s competitors, thus maintaining their dominance and fostering higher costs of care.” Unitedhealth Group to HHS ONC, RIN 0955-AA01 (June 3, 2019), *available at* <https://www.regulations.gov/document?D=HHS-ONC-2019-0002-1855>. Likewise, the Federal Trade Commission (FTC) has explicitly warned against the disclosure of pricing information among competing plans and providers because making such information public may “inadvertently distort competition.” FTC to HHS Office of the National Coordinator for Health Information Technology, RIN 0955-AA01, *available at* [https://www.ftc.gov/system/files/documents/advocacy\\_documents/ftc-staff-comment-departmenthealth-human-services-regarding-21st-century-cures-actinteroperability/v190002\\_hhs\\_onc\\_info\\_blocking\\_staff\\_comment\\_5-30-19.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-departmenthealth-human-services-regarding-21st-century-cures-actinteroperability/v190002_hhs_onc_info_blocking_staff_comment_5-30-19.pdf); *see also* Koslov T & Jex E, FTC, “Price Transparency or TMI?” (July 2015), *available at* <https://www.ftc.gov/newsevents/blogs/competition-matters/2015/07/price-transparency-or-tmi>; Lao M, Feinstein D, & Lafontaine F letter to Hoppe J. and McCrery J. (June 29, 2015), *available at* [https://www.ftc.gov/system/files/documents/advocacy\\_documents/ftc-staff-comment-regarding-amendmentsminnesota-government-data-practices-act-regarding-health-care/150702minnhealthcare.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-regarding-amendmentsminnesota-government-data-practices-act-regarding-health-care/150702minnhealthcare.pdf).



***Impeding Changes to MS-DRG Classifications.*** Under the present system, CMS uses claims data to detect situations where treatment patterns or technology evolves such that changes to the MS-DRG classification system are appropriate. For example, claims in an MS-DRG might conform to a bimodal curve and data analysis may disclose that the MS-DRG has come to encompass two distinct types of cases with differing resource consumptions that necessitates the creation of a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS-DRG.<sup>47</sup> Median payer-specific negotiated rate data, however, would not provide data concerning variation among cases assigned to a particular MS-DRG, and thus could not assist CMS with classification changes necessitated by changes in treatment patterns, technology, or other factors.

***Confounding Variables.*** The median payer-specific negotiated rate data that CMS proposes to collect would reflect a number of factors, including the patient population served, local market conditions, the impact of prior authorization and utilization management activities, and other confounding factors. As a result, the rate data would be skewed by factors that do not reflect national market rates, let alone relative hospital resource utilization. By way of example, heavy MA penetration in a market may depress median payer-specific negotiated rates, so data from hospitals in that market would be skewed to reflect MA penetration. With respect to median payer-specific negotiated charge data for all third-party payers, differences in the mix of payer types (MA, Medicaid managed care, large group, small group, qualified health plans, etc.) may significantly skew the median reported rate data. For example, providers in states with high Medicaid managed care penetration would have their median payer-specific negotiated rates skewed downward for services that are more heavily utilized among the Medicaid population. If this median rate data were then used for purposes of weighting MS-DRGs, the weights of services that are more heavily utilized by Medicaid beneficiaries would be depressed by Medicaid managed care utilization alone. These are just some examples of the many anticipated and unanticipated ways in which median payer-specific negotiated rates would be skewed by factors that are not reflective of market rates or hospital resource consumption.

***Varying Assumptions in Determining Payer-Specific Negotiated Rates.*** There will be many cases where the payment rates agreed to between the payer and the provider do not lend themselves to ready calculation of a set dollar amount for each MS-DRG, and because hospitals will need to build various assumptions into their calculation of payer-specific negotiated rates for each MS-DRG, the resulting median rate data will reflect differences in the assumptions and methodologies applied by different hospitals. Variability in assumptions and methodologies could also result in unanticipated manipulation of the median rate data, making it unreliable for any purpose. The Proposed Rule assumes that providers will be able to assign a payer-specific negotiated rate to each MS-DRG for each third-party payer and that this process will occur in a predictable, consistent manner between hospitals and discharge types. But this assumption is inconsistent with hospitals' managed care agreements, which may impose varying payment obligations for discharges that would be classified to the same MS-DRG. These differences would be most marked where the agreement contemplates payment based on a methodology that is not tied to any MS-DRG classification. The following discussion provides a few examples of common negotiated payment methodologies that payers frequently include in managed care

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<sup>47</sup> E.g., 85 Fed. Reg at 32,472.

agreements, but that would preclude a hospital from directly mapping a dollar amount to an MS-DRG for the payer:

- ***Per Diem Rates, Percent of Charges, or Alternative DRG Methodologies.*** As CMS observes in the Proposed Rule, “not all third party payers use the MS-DRG patient classification system.”<sup>48</sup> Many third party payers negotiate rate on a per diem basis, as a percentage discount off of charges, or under an alternative classification system (e.g., all patient refined DRGs (APR-DRGs)). The Proposed Rule suggests that, in such a case, the hospitals would “determine and report the median payer-specific negotiated charges by MS-DRG using its payer-specific negotiated charges for the same or similar package of services that can be crosswalked to an MS-DRG.”<sup>49</sup> The Proposed Rule, however, provides no guidance on the methodology that would be used to determine whether there is the requisite similarity in a package of services and to crosswalk to an MS-DRG. The variability in provider methodologies for this crosswalking process would risk manipulation or skewing of the data. On the other hand, narrowing the data collection to exclude rates not based on an MS-DRG classification would suppress data in a non-random fashion, skewing the collected rate data to overrepresent the activity of payers, plan types, and hospitals that negotiate MS-DRG rates and away from other payers, plan types, and hospitals.
- ***DRG Tied to Days.*** Even where a managed care agreement applies a DRG-based payment system, there may be particular admissions where the payment amount is based on both the DRG as well as the length of stay. For example, for an inpatient stay classified to a particular MS-DRG, the hospital might receive \$10,000 for days one through three, \$5,000 for days four through six, and \$2,000 for any additional days. Assigning a payer-specific negotiated rate to that MS-DRG would necessitate assumptions concerning the length of stay. Thus, two hypothetical hospitals with the exact same rate structure might calculate different payer-specific negotiated charges for this MS-DRG, reflecting the typical acuity of their patients or varying assumptions regarding the typical length of stay.
- ***Stoploss.*** Many managed care agreements (including those that adopt DRG-based rates) contain a stoploss provision, under which the payment methodology shifts to a percentage of charges after a particular threshold (e.g., total charges or number of days) is met. Some procedures may be more likely than others to exceed the threshold for stoploss payment, and for certain MS-DRGs, stoploss may be triggered in the majority of cases. In addition, because payers vary in their prior authorization requirements, for some payers, admissions with certain MS-DRGs will skew toward higher acuity patients that are more likely to trigger stoploss. It is unclear how the payer-specific negotiated rate would be determined for these payers and MS-DRGs, and variation in provider methodologies to account for stoploss provisions and the typical acuity of a hospitals’ patients would again distort the data.

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<sup>48</sup> 85 Fed. Reg. at 32,791.

<sup>49</sup> *Id.*

- ***Capitation, Value Based Payment, and Risk Sharing.*** Finally, there are numerous hospital reimbursement methodologies that cannot be readily translated into a set payer-specific negotiated rate for each MS-DRG, including, but certainly not limited to, reimbursement based on capitation arrangements, complex value-based reimbursement methodologies, incentive payment arrangements, and other risk-sharing arrangements, including risk pools. If reimbursement under these systems is excluded from the data collection on payer-specific negotiated rates, then the data will skew away from hospitals that increasingly take on and manage risk and markets where capitation is more prevalent. On the other hand, the Proposed Rule provides no information as to how a hospital could go about calculating a coherent payer-specific negotiated rate for such lines of business, and it does not appear that there is a rational method by which a hospital could do so. Additional problems would arise in hybrid reimbursement systems that combine DRG-based payment with risk-sharing or value-based payment methodologies (e.g., a quarterly value-based add-on payment). It is unclear how a hospital could go about determining the payer-specific negotiated rate for an MS-DRG under such an agreement. If the payer-specific negotiated rate were calculated only based on the portion of the payment that is based on the DRG, then the rate data would misleadingly understate the negotiated rates, which could then chill value-based arrangements and risk sharing arrangements. On the other hand, there is no clear way to accurately capture the entire arrangement in a single payer-specific negotiated rate value. And, if data from such arrangements were simply excluded, this would again skew the data to the exclusion of hospitals that take on greater levels of risk in their managed care contracting.

Recognizing some of the limitations of payer-specific negotiated rate data, the Proposed Rule also seeks comment on the submission of median negotiated reimbursement (payment) amounts for each MS-DRG.<sup>50</sup> This alternative, which is wholly divorced from the standard charges Final Rule,<sup>51</sup> would still result in data that is skewed by payers' managed care practices (e.g., prior authorization activities that increase the acuity of inpatients and length of stay restrictions that limit payment), payer mix, Medicaid managed care penetration, denials, underpayments and other conflating factors. Moreover, the suggestion in the Proposed Rule that this data "may also provide a reasonable market-based estimate of relative resources used to provide services for an MS-DRG,"<sup>52</sup> is wholly unsupported by any evidence. Payers do not contract to reimburse providers on a reasonable cost basis or otherwise seek to reflect hospital resource utilization in their reimbursement amounts. Moreover, hospitals and payers evaluate the entirety of a rate structure when entering into a managed care agreement, without regard for whether the payment amounts on an MS-DRG by MS-DRG basis will appropriately reflect relative hospital resource utilization. In short, this alternative suffers from many of the same

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<sup>50</sup> 85 Fed. Reg. at 32,795.

<sup>51</sup> Price Transparency Requirements for Hospitals to Make Standard Charges Public, 84 Fed. Reg. 65,524 (Nov. 27, 2019).

<sup>52</sup> 85 Fed. Reg. at 32,795.

weaknesses as reporting median payer-specific negotiated rates, and it is likewise unlawful as it is untethered from relative hospital resource utilization.

**C. The Proposed Rule Understates the Burdens Associated with Collecting Median Payer-Specific Negotiated Rates**

In order to support its development of a market-based MS-DRG weighting methodology, CMS proposes to collect median payer-specific negotiated rate data on cost reports for reporting periods ending on or after January 1, 2021. **The Proposed Rule relies on the erroneous assumption that it is not only feasible for hospitals to determine median payer-specific negotiated rates for each MS-DRG, but also that the burden of making such a determination merely involves the rote extraction of existing data that the Hospital Price Transparency final rule already requires to be submitted. These assumptions are incorrect.**

Section 3506(c)(1)(A)(iv) of the Paperwork Reduction Act of 1995 requires HHS to evaluate fairly whether proposed collections of information should be approved and to review “a specific, objectively supported estimate of burden.” The Proposed Rule, however, provides no objective support for its assumption that each hospital would, on average, only require 5 hours for record keeping and 10 hours for reporting for the proposed Worksheet S-12. This assessment is based on key mistaken assumptions: that payer-specific negotiated rate data is already compiled and maintained as part of hospitals’ management practices and electronic accounting and billing systems and can readily be updated with each rate change; that each payer’s rate methodology can be reliably crosswalked to an appropriate MS-DRG; that non-Medicare and non-MA discharges can be readily accurately assigned to an MS-DRG despite known disparities in coding diagnoses; that each discharge can be crosswalked to the “payer-specific negotiated rate” for the applicable MS-DRG such that the median payer-specific negotiated rate for each MS-DRG can be identified. As explained in Part B, above, these processes are far more complex than described in the Proposed Rule. Even for hospitals with robust data systems, endeavoring to reduce these payment methodologies to a set dollar amount for each MS-DRG would require significant resources beyond those required under the Hospital Price Transparency Rule and well in excess of the 15 hours described in the Proposed Rule.

**The burden of complying with the Proposed Rule would be particularly acute in the first year because the Proposed Rule suggests an implementation date that would require the calculation of payer-specific negotiated rates crosswalked to MS-DRGs for periods prior to the effective date of the Hospital Price Transparency Final Rule.** At present, the Hospital Price Transparency Final Rule is slated to take effect on January 1, 2021, although the FAH would strongly urge HHS to delay the effective date of that rule until the matter is settled by the courts so that hospitals can continue to prioritize their efforts to contain and combat COVID-19.<sup>53</sup> CMS, however, proposes that the collection of median payer-specific negotiated

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<sup>53</sup> The Proposed Rule notes the extraordinary burdens that COVID-19 has placed on health care regulators, and, in light of CMS’s prioritization of efforts in support of containing and combatting the COVID-19 public health emergency, waives the 60-day delay in the effective date of the IPPS and LTCH PPS final rule. 85 Fed. Reg. 32,889. This same rationale supports delay of the effective date of the Hospital Price Transparency Final Rule in light of the extraordinary burdens hospitals face on the front lines of the COVID-19 pandemic.

rates begin for cost-reporting periods ending on or after January 1, 2021. If finalized, this would mean that a provider with a February-to-January cost reporting period would be required to go back through the managed care agreements and rate sheets that were in place from February 1, 2020 through January 31, 2021 and map *historic* payer-specific negotiated rates to each MS-DRG. **This would impose a significant additional burden that is wholly unaddressed in the Proposed Rule, and it would do so at a time when hospitals are committing significant resources to the front-line response to COVID-19.**

## **VII. LONG-TERM CARE HOSPITAL PPS**

The FAH appreciates that the scope of CMS's LTCH PPS rulemaking is more limited this year in recognition of the ongoing COVID-19 pandemic. We expect that it will be some time before LTCHs return to normal operations. We further appreciate CMS's continued willingness to engage with stakeholders on an ongoing basis as it assesses the impact of COVID-19 on operations and implications for rate setting and payment policy. Going forward, we encourage CMS to continue to limit the number of payment and policy changes it proposes in future years to allow providers time to adjust to what has been a significant and prolonged period of operational and financial volatility. And, as previously discussed, due to the unprecedented effect the COVID-19 pandemic is having on LTCH utilization, CMS should carefully consider and address the impact of COVID-19 on Medicare data for FY 2020 and FY 2021 in advance of LTCH rulemaking for FY 2022 and subsequent years. Along the same lines, as discussed further below, the far-reaching impact of the pandemic on post-acute care delivery amplifies calls for a reset of the timelines for a unified post-acute care payment system established six years ago under the 2014 Improving Medicare Post-Acute Care Transformation (IMPACT) Act.

### *CMS Response to the COVID-19 Pandemic*

The COVID-19 pandemic has significantly disrupted the country's healthcare delivery system. In areas with high rates of COVID-19 cases, LTCHs and other hospitals have been overwhelmed as they provide care to patients suffering with COVID-19. In the Fact Sheet accompanying the release of the proposed rule, CMS explains that it is limiting this year's annual rulemaking to essential policies because of the COVID-19 pandemic. CMS recognizes that due to the COVID-19 pandemic, hospitals may have a limited capacity to review and comment on proposed policy changes.

The FAH appreciates that CMS is limiting the scope of this year's rulemaking due to the COVID-19 pandemic. LTCHs are demonstrating the value they provide to their communities and the Medicare program during this pandemic. LTCHs have always been capable of providing hospital care for the most vulnerable patient populations, including patients with respiratory and cardiac issues. These structural and operational capacities, including ventilators, pulmonologists, critical care nurses, and established ventilator and infection control protocols, among others, are essential to treat the most severe COVID-19 cases. LTCHs are not only the post-acute care provider type best positioned to treat COVID-19 patients, but as acute care hospitals, they have also created additional capacity for acute care hospitals to treat COVID-19 patients by accepting transfers of many types of non-COVID-19 patients.

While we appreciate the quick actions CMS took to assist providers, including LTCHs, in responding to the COVID- 19 pandemic, we believe CMS must begin accounting for the longer-term effects that the COVID-19 pandemic will have on the LTCH PPS, beginning with a careful examination, and possible exclusion, of data collected from the COVID- 19 public health emergency (“PHE”) period when CMS is setting the payment rates for the LTCH PPS. The data that CMS collects during the PHE is not representative of typical LTCH PPS data. For example, as required by section 3711(b)(2) of the Coronavirus Aid, Relief, and Economic Security Act, (Pub. L. 116-136) (the “CARES Act”), CMS is not currently applying the LTCH site neutral payment rate to discharges that do not meet the LTCH patient criteria. In addition, the LTCH length of stay data during the PHE are not representative of the typical LTCH length of stays. CMS properly anticipated this when it issued a waiver under section 1135 of the SSA of the LTCH average length of stay (“ALOS”) requirement during the PHE. Further, LTCH cost-to-charge ratios (“CCRs”) will be skewed because there are greater costs associated with treating COVID-19 patients (e.g., staffing, PPE, etc.). **These and other payment policy ramifications of the data distortions resulting from the pandemic must be carefully considered and addressed in collaboration with stakeholders in advance of rulemaking for FY 2022 and subsequent years.**

#### *Development of a Post-Acute Care Payment System Technical Prototype*

The COVID-19 pandemic has raised numerous issues and questions around the operational and clinical capabilities of America’s post-acute care (PAC) providers (inpatient rehabilitation facilities (IRFs) and long-term care hospitals (LTCHs), skilled nursing facilities (SNFs), and home health agencies (HHAs)), including patient outcomes and safety. A significant aspect of the IMPACT Act was the mandate to design a Unified Post-Acute Care (PAC) Prospective Payment System (PPS). The law laid out a timeline for the collection and reporting of substantial amounts of quality and patient data, followed by an eventual report from CMS to Congress on a technical PAC PPS prototype.

This timeline, however, must now be revisited and updated in order to reflect the reality that IMPACT Act data from 2017-2019 is no longer an accurate depiction of the post-acute care landscape. In the six years since the enactment of the IMPACT Act, significant changes in each of the four PAC setting payment systems have occurred, including CMS’s concerted shift towards patient-driven reimbursement, and now the unprecedented impacts of the COVID-19 pandemic. Together, these dynamics have created important shifts in the way post-acute care is delivered and paid for, shifts that are not sufficiently captured in the data CMS is currently relying on from 2017-2019 to inform its development work on the PAC PPS technical model. **Given these changes, the FAH urges CMS to work with Congress to immediately refresh the Unified PAC PPS mandate outlined in the IMPACT Act as part of the next COVID-19 relief package.**

The design of a unified payment system that spans multiple care settings is no small undertaking, even in the absence of far-ranging exogenous shocks to the health care system like COVID-19. All PAC settings are currently in the midst of adapting to setting-specific overhauls (the Patient Driven Groupings Model in HHAs, the Patient Driven Payment Model in SNFs, a fundamentally changed case-mix system in IRFs, and the adjustment to fully site-neutral

payments for non-qualifying cases for LTCHs), while a pandemic continues to radically change the ways in which patients interact with the health care system and the evolving technology available to providers, such as telehealth. With these additional challenges, building an accurate PAC PPS to produce desirable expected outcomes becomes all but impossible due to forces that complicate the collection, completeness, and representativeness of underlying claims and assessment data.

Furthermore, there remains a lack of robust, standardized patient data across all settings from which to base the model's development. CMS recently announced its delay in the release of new or revised Standardized Patient Assessment Data Elements (SPADEs) in all four PAC settings<sup>54,55,56</sup> to allow providers maximum flexibility in responding to the COVID-19 public health emergency. While this decision alleviates burden on providers in the short term, it hinders efforts to build a Unified PAC PPS which requires standardized, established data inputs across settings. As part of the revised timeline for IMPACT Act implementation, it is crucial that CMS build in time for a public release of any and all data that could inform the model's development to allow for independent analysis that can then inform future work.

Now is not the time to risk patient care and rush ahead with the design of a Unified PAC PPS that relies on pre-COVID-19, pre-PAC setting PPS overhaul data. Instead, it would be prudent to wait until the health care system stabilizes following the end of the pandemic, then gather data that reflects the adjustments made to address COVID-19. These adjustments are likely to be very different from one PAC setting to another, meaning that as of now there is no clear understanding as to how PAC settings will differentiate from one another in the future, how patient "overlap" between the settings might evolve, and which new diagnostic and treatment technologies will move forward more permanently.

Ultimately, a comprehensive understanding of the evolving differences across PAC settings will be necessary so that, in the course of modelling a unified PAC PPS, decisions on which aspects should be preserved and which should not can be made on an informed basis. A Unified PAC PPS put in place prematurely could well produce significant unintended consequences with unknowable opportunity costs and patient consequences. We should take a fresh look at what the normalized data are telling us as we move through and beyond the COVID-19 pandemic response and become more familiar with the new payment systems.

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<sup>54</sup> CMS, Delayed: Release of Updated Versions of IRF and LTCH Assessment Instruments (and Supporting Training), May 2020, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Training>.

<sup>55</sup> CMS, Delayed: Release of Updated Version of the Home Health Assessment Instrument (and Supporting Training), May 2020, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Training>.

<sup>56</sup> CMS, Delayed: Release of Updated Versions of SNF Assessment Instrument (and Supporting Training), May 2020, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Training>.

A thoughtfully designed, Unified PAC PPS founded on accurate, reliable data from each PAC setting is important for the sustainability of our health care system and the assurance that seniors will get the right care, at the right time, in the right post-acute setting. **That is why the FAH strongly supports a careful reset of the IMPACT Act’s PAC PPS timeline in the next COVID-19 relief package – to expand the mandated Unified PAC PPS timeframe and to allow for consideration of how PAC will adjust to the new PAC PPS systems and COVID-19 pandemic. The FAH urges CMS to work with Congress to immediately enact these changes to give the agency the time it needs to appropriately consider all of the implications and to engage stakeholders on next steps in this process.**

## QUALITY PROGRAMS

### **VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers**

#### **A. Hospital Inpatient Quality Reporting (IQR) Program**

##### *Changes to Requirements for Electronic Clinical Quality Measures (eCQMs)*

CMS proposes to expand reporting of eCQMs for both the Inpatient Quality Reporting Program and the Promoting Interoperability Program and to begin public reporting of hospital performance on eCQMs. Instead of reporting data on eCQMs for one self-selected calendar quarter, hospitals would report data for two self-selected calendar quarters in 2021, three quarters in 2022, and increasing to all four calendar quarters beginning in 2023. Public reporting would begin with the data submitted for 2021, and CMS expects these data would be posted as early as the fall of 2022.

***The FAH does not support the proposed expansion of eCQM reporting or public reporting until problems with validation of eCQM data are addressed.*** FAH members that have participated in eCQM data validation continue to report unresolved concerns. They have not been able to authenticate validation results provided for 2017 and 2018 because mismatches on the validation reports were not specifically identified. As a result, the hospital cannot determine whether the mismatches are caused by data capture, the Quality Reporting Document Architecture (QRDA) data submission format, or other technical issues. It is unclear whether mismatches occur because the validation process compares the eCQM data against PDF versions of patient medical records, which can include free text that is not part of the data extracted from the electronic health record for purposes of the eCQM. Hospitals and vendors need a better understanding of the cause of mismatches and how to correct them in advance of any public reporting. The proposal to expand the data validation educational review process to include hospital queries regarding eCQM validation is welcome, but we believe CMS should broadly review and clarify the eCQM data validation procedures and reports to provide more clarity. The value to hospitals that CMS perceives from reviewing eCQM performance for multiple quarters of data and taking action to investigate and make improvements is not possible without improvements to the validation reports. ***CMS should postpone expanding reporting and public reporting of eCQMs until issues around the accuracy of the data validation are resolved.***



***Further, in considering its proposals to require additional quarters of reporting for eCQMs, CMS should consider the timing of data submissions and the updating of electronic health record (EHR) systems by EHR vendors.*** Currently, eCQM specifications are updated by CMS annually and vendors must update EHR systems to accommodate those changes. Our members report that these vendor updates generally do not occur until mid-year. The deadline for eCQM reporting for a year occurs during the first calendar quarter of the subsequent year, and the FAH believes that to avoid confusion vendor updates to the eCQM specifications should not take place prior to that data submission. For that reason, reporting data on all four calendar quarters would be problematic. As part of its vision for full-year reporting and public reporting of eCQMs, what expectations does CMS have for the timeliness of vendor updates? Does CMS plan to increase the frequency of updates to eCQM specifications to maintain clinical relevance and account for changes in applicable ICD codes as they occur? If eCQM specifications are changed over the course of a year, how will that be taken into account in eCQM validation?

***Finally, before instituting public reporting of eCQMs, CMS should provide assurances that the data reported are sufficient to reliably capture hospital performance.*** Under the Proposed Rule, public reporting would begin with the two calendar quarters of data reported for 2021. A hospital must report data for a selected eCQM unless it has 5 or fewer applicable cases in a quarter. This could result in display of performance for a hospital based on as few as 12 cases. Data should only be publicly reported on quality measures if consumers are able to reliably compare performance across hospitals. Before proceeding with public reporting, CMS should consider whether the number of quarters of eCQM data reported by hospitals and the applicable case thresholds are sufficient to result in reliable comparisons of hospital performance.

#### *Consolidation of Quality Program Data Validation*

CMS proposes to streamline the process for selection of hospitals for data validation by combining the validation processes for chart-abstracted data and eCQM data. This includes selecting one pool of hospitals for validation of both types of measures, modifying the criteria for targeted selection and exclusion of hospitals, and combining the validation scoring in a way that would weigh validation scores for chart-abstracted measures at 100 percent. The pool of hospitals randomly selected for validation would be reduced from 400 to 200 hospitals. Hospitals selected for validation would be required to submit PDF copies of medical records using direct electronic files submission via a CMS-approved secure file transmission process; other forms of medical record submission would no longer be allowed.

***The FAH supports the proposed changes to data validation processes and appreciates the reduced burden that would result from a smaller validation pool. We note the concerns discussed earlier with respect to the lack of clarity and specificity in the reports currently provided to hospitals under the eCQM data validation process.***

## **Impact of COVID-19 on Quality Reporting and Pay for Performance Programs**

The FAH appreciates the steps that CMS took in March 2020 to provide relief under the hospital quality reporting programs and the three pay-for-performance programs (Hospital Readmissions Reduction Program (HRRP), Value-based Purchasing (VBP) Program, and the Hospital-Acquired Condition (HAC) Reduction Program) in light of the COVID-19 national public health emergency. Hospital reporting of data for the fourth quarter of 2019 is optional, and data for the period from January 1, 2020 through June 20, 2020 has been excluded from these programs, including for measures calculated by CMS using hospital claims as well as data that would otherwise have been submitted by hospitals for this period.

***CMS should now consider the impact of these COVID-19 related data exclusions on the reliability of measures used for the hospital quality programs. The FAH believes that performance periods for measures that include this reporting gap should not be included in the HRRP, VBP and HAC program scoring calculations and should not be publicly reported on Hospital Compare.***

## **Hospital Star Ratings**

CMS updated the overall quality star ratings at *Hospital Compare* and [data.medicare.gov](https://data.medicare.gov) on January 2020 with the quarterly refresh of data. ***The FAH urges CMS to suspend all future overall star ratings data refreshes while improvements to the methodology are proposed and implemented as these ratings are misleading.***

The FAH appreciates CMS's consideration in postponing the proposals for methodological changes to overall star ratings in view of COVID-19 and we look forward to proposals for changes in the methodology in the near future.

## **Social Determinants of Health**

The FAH supports the efforts that CMS has undertaken in recent years to eliminate measures that do not meet quality program goals, and we encourage further streamlining of quality measures to focus on those that provide the most valuable information to patients and providers. Further efforts that contribute to provider burden reduction, such as targeting a smaller number of the most meaningful quality measures, allows providers to focus reporting efforts such as on reporting data that improve risk adjustment of measures to account for clinical risk and social determinants of health as well as to account for social risk factors in value-based payment programs. ***The FAH urges CMS to create standards for capturing social risk data in electronic health records (EHRs) and to develop better approaches to adjust measures and define hospital risk pools in value-based payment programs beyond the use of dual eligibility status for Medicare and Medicaid.*** This will improve the accuracy of measures, improve our value-based programs, and provide valuable data necessary for health disparities research. The achievement of these three goals is necessary and indispensable to eliminate health disparities and assist with efforts aimed at improving quality of care for vulnerable populations.

#### **VIII.D. Medicare and Medicaid Promoting Interoperability Programs**

Health information technology (HIT) holds enormous potential to improve the quality and efficiency of care provided to patients, reduce provider burden, and advance population health management and breakthroughs in health care research. The FAH offers the below comments in response to proposed changes to the Promoting Interoperability Program (PIP).

##### *Electronic Health Record (EHR) Reporting Period*

The FAH supports the proposed EHR reporting period of a minimum of any continuous 90-day period for CY2022 for both new and returning eligible hospitals and Critical Access Hospitals (CAHs). The FAH agrees with CMS that this proposal provides stability for eligible hospitals and CAHs as they implement the ONC and CMS interoperability, information blocking, and patient access final rules and also address the COVID-19 pandemic.

##### *Query of a Prescription Drug Monitoring Program (PDMP) Measure*

The FAH supports CMS's proposal to continue the Query of a PDMP measure as voluntary for the CY 2021 reporting period with a "yes" response for this measure earning five bonus points. As the FAH has noted in previous comments, PDMPs are still maturing and there remains significant platform variation across states. This measure should remain voluntary until these reporting barriers are addressed, including ensuring that vendors integrate PDMPs into EHRs and that hospitals have sufficient time to effectively implement the systems.

The FAH also supports the continuation of the current PIP measure values and scoring methodology for the CY 2021 reporting period.

##### *Proposed eCQM Reporting Periods and Criteria for the Medicare and Medicaid Promoting Interoperability Programs in CY 2021, 2022, and 2023*

The FAH continues to support the alignment of the PIPs with the Hospital IQR Program but does not support the proposed expansion of eCQM reporting or public reporting until problems with validation of eCQM data are addressed.<sup>57</sup> Additional information regarding the FAH's concerns on these proposals can be found above in Section VIII.A. (Hospital IQR Program).

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<sup>57</sup> CMS proposes to expand reporting of eQMs for both the Inpatient Quality Reporting Program and the PIP and to begin public reporting of hospital performance on eQMs. Instead of reporting data on eQMs for one self-selected calendar quarter, hospitals would report data for two self-selected calendar quarters in 2021, three quarters in 2022, and increasing to all four calendar quarters beginning in 2023. Public reporting would begin with the data submitted for 2021, and CMS expects these data would be posted as early as the fall of 2022.

### *Future Direction of the Promoting Interoperability Program*

The FAH supports CMS's desire to reduce administration burden associated with the PIP and further align the PIP with the Quality Payment Program (QPP) and the goals of the CMS and Office of the National Coordinator for Health Information Technology (ONC) final rules under the 21<sup>st</sup> Century Cures Act.

Hospitals and physicians have been inundated with a myriad of HIT-related upgrades, new implementations (including testing and training), and workflow changes in the last several years and face significant costly and time-consuming changes in the years ahead to comply with the CMS and ONC information blocking and patient data access final rules, as well as appropriate use criteria (AUC); the recently finalized admission, discharge, and transfer (ADT) notification Condition of Participation; new e-prescribing requirements; and disclosure of negotiated rates, among others. In addition to the volume and enormity of these requirements, many have inadequate effective dates that do not appropriately account for the time needed for EHR vendors to build the systems and hospitals to implement them, particularly when hospitals are using significant resources to address the ongoing COVID-19 pandemic. There is also often confusion about the overlap of various programs. For example, health care providers are currently unsure how the PIP information blocking attestations and the ONC final rule information blocking requirements relate to one another.

To truly create alignment between the programs and reduce the administrative burden on health care providers, the FAH strongly urges CMS to assess the full breadth and depth of these requirements and view them as a whole rather than as individual programs or policies. This includes examining definitions and requirements across the programs and simplifying and removing duplicative or contradictory requirements. It also includes examining effective dates across all the technology-related programs and delaying them where needed to avoid overlap and appropriately account for the time and resources needed for design, build, and implementation. The FAH also urges CMS, ONC, and HHS to utilize enforcement discretion and not penalize health care providers who are unable to comply with the information blocking and other requirements in the recently finalized CMS and ONC rules. This enforcement discretion should last until at least six months to one year after the end of the public health emergency. Lastly, the FAH specifically urges clarification regarding the relationship between the PIP attestations and the ONC information blocking requirements.

### **IX.B. PRRB Electronic Filing**

The FAH appreciates the August 15, 2018 release of the Office of Hearings Case and Document Management System (OH CDMS) for Provider Reimbursement Review Board (PRRB) appeals. This electronic filing system improves the efficient management of PRRB appeals, and the proposed regulatory changes addressing paper-focused definitions and the use of terms like "mail" and "hand delivery" in the Proposed Rule are sensible and appropriate modifications to support electronic filing. The FAH supports these technical changes and the continued development and expansion of electronic filings through OH CDMS.

The FAH, however, is concerned that there are additional technical issues that need to be addressed within OH CDMS before the electronic submission of PRRB appeals becomes mandatory and that the premature shift to mandatory filing will unduly burden providers. Significant improvements have been made to OH CDMS since its release, and the FAH applauds the efforts to expand OH CDMS's functionality for different types of appeals over the years. However, continued refinements should be made before electronic submission through OH CDMS becomes mandatory. For example, OH CDMS does not currently include a batch upload functionality. As a result, users must manually enter data for each provider through a painstaking process that increases the risk of human error. Deploying a batch upload functionality is critical for large common issue related party appeals that can involve dozens or over a hundred providers in a single submission. At present, paper filing still provides a distinct advantage for these large group appeals because data can be compiled, organized, and error-checked using spreadsheets before submission. Once provider information can be uploaded to OH CDMS as structured data (*e.g.*, a CSV file), we expect that electronic submission will become feasible and reliable even for large group appeals. At that time, it may be appropriate to require mandatory electronic submissions, but at present, shifting toward mandatory electronic submission would unduly burden providers and increase the likelihood of burdensome data-entry errors.

Further, the PRRB currently requires providers to generate a schedule of providers and jurisdictional documentation in hard copy. The FAH requests that a move toward mandatory electronic filing include upgrades to OH CDMS that enable providers to automatically generate electronic schedules of providers and jurisdictional documentation. We appreciate and applaud the PRRB's efforts to add these critical features to OH CDMS, and urge the PRRB to continue expanding OH CDMS's features and functionality as it moves toward mandatory electronic filing.

### **IX.C. Proposed Revisions of Medicare Bad Debt Policy**

The Proposed Rule includes amendments to 42 C.F.R. § 413.89(b), (c), (e), and (f) that would revise the reasonable collection efforts requirement and the standards for bad debt accounting. Although some of the proposed amendments to § 413.89 represent appropriate clarifications and policies supported by the FAH, the FAH is concerned with CMS's overly expansive use of retroactive rulemaking and proposal that contractual allowances cannot be treated as bad debt amounts. On the other hand, the FAH strongly supports adoption of the alternative approaches for providers to comply with the must-bill policy and evidence a State's cost-sharing liability (or absence thereof) for dual eligible beneficiaries when a State does not process a Medicare crossover claim and issue a Medicaid remittance advice (RA) because this alternative proposal represents a pragmatic and equitable approach to holding providers harmless for a State's non-compliance with the Federal statutory requirements concerning the processing of crossover claims and issuance of the Medicaid RA.

#### **1. Issuance of a Bill (Proposed 42 C.F.R. § 413.89(e)(2)(i)(A)(3))**

The FAH is supportive of CMS's proposal to amend § 413.89(e)(2) to add subparagraph (i)(A)(3), providing a 120-day timeframe for the issuance of a bill during cost reporting periods

beginning on or after October 1, 2020, but recommends modifying this provision to state that the benchmark event for this 120-day period is the later of: (1) the date of the Medicare RA; or (2) the date of the RA or *the determination of non-coverage* from the beneficiary's secondary payer, if any. As modified, this proposed amendment would create a concrete deadline for issuance of the bill, thereby addressing inconsistent approaches applied by Medicare contractors, and would also appropriately tie the timing of the bill to payer activity rather than the "discharge or death of the beneficiary."<sup>58</sup> In addition, the proposed amendment appropriately identifies a reasonable timeframe—120 days—for issuance of the beneficiary bill following the benchmark event.

In the Proposed Rule, CMS correctly recognizes that it is appropriate to use payer activity (e.g., issuance of an RA) as the benchmark event for issuance of the bill rather than treating the Medicare beneficiary's date of discharge or death as the benchmark event. Providers typically have 12 months to submit a Medicare claim following the furnishing of services, and it would be inappropriate to issue a bill to the beneficiary unless and until the Medicare RA is received and any claim to a secondary payer is processed. Where there is a secondary payer, the Proposed Rule would use the secondary payer's RA as the benchmark event for issuance of the bill. Although this approach will suffice where the services are ultimately covered by the secondary payer, there are situations where the secondary payer will instead issue a determination of non-coverage. For example, this may occur where the beneficiary's coverage with the secondary payer is ultimately determined by the payer to be invalid. In order to address situations where a secondary payer is billed but determines the care is not covered, the FAH supports the use of the determination of non-coverage as the benchmark event for the 120-day deadline for issuance of a bill. To this end, the FAH urges CMS to revise proposed subsection (e)(2)(A)(3)(ii) to read as follows: "The date of the remittance advice or the determination of non-coverage from the beneficiary's secondary payer, if any."

## **2. Partial Payments and Proposed 42 C.F.R. § 413.89(e)(2)(i)(A)(5)**

The FAH opposes CMS's proposal to require—prospectively and retroactively—that reasonable collection efforts be extended by another 120 days for each partial payment. The Proposed Rule states that proposed § 413.89(e)(2)(i)(A)(5) is consistent with CMS's longstanding intention and PRM section 310.2.<sup>59</sup> The actual language of PRM section 310.2, however, suggests instead that the 120-day collection period runs from the date of the first bill and does not restart following partial payment. It reads in full as follows, "If after reasonable and customary attempts to collect a bill, the debt *remains unpaid* more than 120 days *from the date the first bill is mailed* to the beneficiary, the debt may be deemed uncollectible."<sup>60</sup> This existing guidance is markedly different from proposed § 413.89(e)(2)(i)(A)(5), which would require that the provider restart the 120-day collection period upon any partial payment on the account.

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<sup>58</sup> Provider Reimbursement Manual, Ch. 3, § 310 (CMS Pub. 15-1) (PRM).

<sup>59</sup> 85 Fed. Reg. at 32,869 (quoting PRM section 310.2 as saying "if, after 120 days, a payment is not received, the unpaid amount can be written off")

<sup>60</sup> PRM section 310.2 (emphasis added).

The Proposed Rule—aside from being a new rule rather than a clarification or codification of an existing policy—is also inappropriate because it would result in an unnecessary and significant aggregate increase in provider collection costs and burdens. Under the Proposed Rule, even a token partial payment (*e.g.*, a payment of \$5.00 on the 110<sup>th</sup> day after issuance of the bill) would restart the collection period based on the unsupported assertion that a partial payment always “evidences the beneficiary’s willingness to pay the debt, at least in part.”<sup>61</sup> To the contrary, there are circumstances where a partial payment (particularly of a nominal amount) does not indicate any likelihood of recovery based on sound business judgment and where the provider would therefore not pursue further collection efforts for amounts owed by non-Medicare patients. Because the Proposed Rule for partial payments would override sound business judgment, the proposal would produce an undue burden for providers and would improperly subject Medicare beneficiaries to more extraordinary collection efforts compared to those to which non-Medicare patients are subjected.

Current CMS policy instead allows an uncollected amount to be “deemed uncollectible” if “the debt remains unpaid more than 120 days from the date the first bill is mailed to the beneficiary,”<sup>62</sup> as long as the provider’s collection effort is “similar to the effort the provider puts forth to collect comparable amounts from non-Medicare patients,”<sup>63</sup> and “[s]ound business judgment established that there was no likelihood of recovery at any time in the future.”<sup>64</sup> These rules create a temporal threshold, but then ensure that providers engage in more robust efforts insofar as such efforts are warranted based on sound business judgment and the provider’s collection efforts for non-Medicare patients. Extending the collection period based on partial payment, where sound business judgment and the provider’s process for handling similar partial payments for other patients does not so require, would result in significant, aggregate additional collection costs for providers. The Proposed Rule assumes, without support, that restarting the collection period due to partial payment “is not burdensome to the provider and requires little additional resources from the provider because the account is still open . . . and has not yet been written off as a bad debt.”<sup>65</sup> Collection efforts, however, can be costly to providers because they can include subsequent billings, collection letters, telephone calls, or personal contacts with the responsible party, and the costs of these efforts over an additional 120-day period would be significant and unwarranted, particularly where “sound business judgment” establishes that there’s no likelihood of future recovery. In fact, there may be cases where these collection efforts are more costly than the partial payment that resulted in the 120-collection period restarting.

Moreover, it is unnecessary for CMS to impose these additional collection burdens on providers because there is an established process for addressing recoveries of amounts included

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<sup>61</sup> 85 Fed. Reg. at 32,869.

<sup>62</sup> PRM section 310.2.

<sup>63</sup> PRM section 310. The Proposed Rule would codify this requirement at 42 C.F.R. § 413.89(e)(2)(i)(A)(I).

<sup>64</sup> 42 C.F.R. § 413.89(e)(4); *see also* PRM section 308.

<sup>65</sup> 85 Fed. Reg. at 32,869.

in allowable bad debts in a prior period. Where a provider recovers an amount written off as bad debt in a prior cost reporting period after receiving Medicare reimbursement associated with that bad debt amount, the recovered amount reduces the provider's reimbursable costs in the period in which the amount is recovered by an amount that does not exceed the actual amount reimbursed by Medicare for the related bad debt in the applicable prior cost reporting period.<sup>66</sup> This rule for recoveries appropriately recognizes that sound business judgment is not perfectly predictive, and there will be situations where a provider appropriately writes off an amount as an allowable bad debt but subsequently receives a recovery of part or all of that amount. Furthermore, this process ensures that the program is made whole for such recoveries. The Proposed Rule, however, would require providers to undertake onerous collection efforts that are contrary to sound business judgment in cases where further collection would not be pursued from non-Medicare patients in order to virtually eliminate the possibility that recoveries in subsequent cost-reporting periods will occur.

Because proposed § 413.89(e)(2)(i)(A)(5) would impose excessive costs that are unnecessary for the efficient administration of the program in light of other rules assuring reasonable collection efforts and the appropriate handling of recoveries, the FAH urges CMS to not finalize this proposed provision concerning partial payments.

### **3. Documentation of Reasonable Collection Effort for Non-Indigent Beneficiaries (Proposed 42 C.F.R. § 413.89(e)(2)(i)(A)(6))**

Although the FAH largely supports the proposed requirements for documenting reasonable collection efforts for non-indigent beneficiaries, the FAH requests that CMS confirm that the requirement for documentation in the "beneficiary's file" does not require additional recordkeeping beyond prevailing industry standards for electronic recordkeeping of collection efforts. Providers typically use standard form letters, and when a letter or notice is sent to a beneficiary, a collection note is added to the electronic beneficiary file referencing the form letter that was used by an identifying number or other identifier. An actual copy of the letter that was sent to the beneficiary is not typically kept in the beneficiary file, but the collection notes combined with the standard form letters allows an auditor to determine what letters or notices were sent to the beneficiary on what days. This practice allows for efficient electronic recordkeeping while retaining sufficient documentation for audit purposes. To the extent that proposed § 413.89(e)(2)(i)(A)(6) might be read as suggesting that a physical copy of any collection notice must be retained in the beneficiary file, the FAH requests that CMS clarify that providers may reference form letters in electronic beneficiary files without the need to retain a copy of the actual letter that was sent.

Moreover, to the extent that CMS intends to require that actual copies of such letters and notices be maintained in beneficiary files, the FAH strongly opposes this proposal. This requirement would necessitate significant and costly changes to electronic recordkeeping for collection activities that are not accounted for in CMS's impact estimate. Moreover, because standard electronic recordkeeping practices permit an auditor to clearly identify which letters and notices were sent on which dates, the additional and significant burden of maintaining actual

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<sup>66</sup> 42 C.F.R. § 413.89(f); PRM section 316; *see also* proposed 42 C.F.R. § 413.89(f)(2).



copies of each such letter and notice would far exceed the minimal (if any) benefit of requiring recordkeeping in this fashion. Therefore, the FAH strongly opposes the adoption of any such requirement as unduly burdensome and inconsistent with industry standards.

#### **4. Documentation of Reasonable Collection Efforts for Indigent Dual-Eligible Beneficiaries (Proposed 42 C.F.R. § 413.89(e)(2)(iii)(C))**

The FAH strongly urges CMS to adopt the alternative approaches for providers to comply with the “must bill” policy and still evidence a State’s cost sharing liability (or absence thereof) for dual eligible beneficiaries when a State does not process a Medicare crossover claim and issue a Medicaid RA to providers.<sup>67</sup> As the Proposed Rule notes, there are States that do not comply with the Federal statutory requirements to process Medicare crossover claims and produce a Medicaid RA. This failure on the part of certain States results in provider appeals, and some States have persisted in their non-compliance notwithstanding CMS efforts to clarify State obligations with respect to crossover claims. Permitting a provider to rely on documentation other than the Medicaid RA when the State does not process a Medicare crossover claim and issue a Medicaid RA would provide pragmatic flexibility to providers that would otherwise be disadvantaged by a State’s failure to issue a Medicaid RA.

In particular, the FAH recommends that CMS permit providers to rely on the following types of documentation as alternatives to the Medicaid RA where a State does not process the Medicare crossover claim and issue a Medicaid RA: (1) State Medicaid notification where the State has no legal obligation to pay the beneficiary’s cost-sharing, (2) documentation setting forth the State’s Medicare cost-sharing liability, and (3) documentation verifying the beneficiary’s eligibility for Medicaid for the date of service.

In addition, the FAH requests that CMS revise proposed § 413.89(e)(2)(iii)(C) to clarify that the Medicaid RA or alternative documentation need only be obtained and maintained by the provider and need not be submitted to the MAC, except upon request at audit. Although proposed § 413.89(e)(2)(iii)(C) refers to the submission of the Medicaid RA to the provider’s MAC, it is the FAH’s understanding that, consistent with current practice, CMS only intends to require that the provider submit such documentation for select beneficiary accounts upon request by the MAC and does not intend to require that the provider submit such documentation with its cost report. Requiring submission of the Medicaid RA (or alternative supporting documentation) with the cost report would be administratively impractical, highly burdensome for the provider, and unnecessary to the efficient administration of the program. The Proposed Rule fails to set forth any rationale that would support the submission of this documentation with the cost report, and such a requirement would also be inconsistent with other cost reporting regulations that make clear that providers are to submit *cost data* rather than actual records. For example, 42 C.F.R. § 413.24(a) states that providers must “provide adequate cost data” that is based on “financial and statistical records” that are “capable of verification by qualified auditors,” indicating that records like the Medicaid RA or similar documentation are to be retained for presentation at audit rather than submitted with the cost report.

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<sup>67</sup> 85 Fed. Reg. at 32,874.

In light of the absence of any rationale for requiring *submission* of the Medicaid RA with the cost report in the Proposed Rule, the inconsistency between proposed § 413.89(e)(2)(iii)(C) and existing cost reporting regulations, and the extraordinary burden on providers and MACs if Medicaid RAs were required to be submitted with cost reports, it is the FAH’s understanding that CMS only intends for Medicaid RAs or alternative documentation to be submitted upon request by the MAC. Therefore, the FAH urges CMS to revise proposed § 413.89(e)(2)(iii)(C) to read as follows: “(C) Must submit the Medicaid remittance advice received from the State or appropriate, alternative documentation to its Medicare contractor upon request at audit.”

## **5. Indigent Non-Dual Eligible Beneficiaries and Worksheet S-10**

The FAH opposes CMS’s proposal to require providers to undertake extensive asset tests before determining that a non-dual eligible beneficiary is indigent such that the beneficiary’s coinsurance or deductible obligations can be deemed uncollectible without first applying a collection effort. Although CMS states in the preamble that the provider “must apply its customary methods for determining whether the beneficiary is indigent,”<sup>68</sup> the particular requirements set forth in proposed 42 C.F.R. § 413.89(e)(2)(A)(ii) go far beyond the customary methods by which providers determine indigence under any program. In particular, CMS has devoted substantial efforts to clarify requirements for determining when uncompensated care can be included on worksheet S-10 due to application of financial assistance policies, creating an opportunity to use the more refined process developed in the UC DSH context for bad debt purposes as well. The FAH therefore urges CMS to instead provide that, where a Medicare beneficiary’s coinsurance or deductible obligation qualifies as charity care for purposes of UC DSH and worksheet S-10, such coinsurance or deductible obligation may be deemed uncollectible without applying a collection effort. This approach would promote the interests of paperwork reduction and cost reporting simplification because a single process would be deployed for both rules. Considerable effort has gone into refining and clarifying the instructions for worksheet S-10 and auditing worksheet S-10 data, enabling the ready application of the settled UC DSH charity care rules to the determination of a non-dual eligible beneficiary’s indigency for bad debt purposes. The FAH therefore strongly urges CMS to simply clarify that where a Medicare coinsurance or deductible amount is written off as charity care for UC DSH purposes, that amount also qualifies as a bad debt amount without applying a collection effort.

## **6. Medicare Bad Debt and Contractual Allowances**

The FAH strongly opposes CMS’s proposed amendment to § 413.89(c), which would require that Medicare bad debts be treated as “implicit price concessions” rather than “contractual allowance amounts” for cost reporting periods beginning on or after October 1, 2020, and the proposed amendment to § 413.89(b)(1)(ii), which would likewise define bad debts to require that the bad debt amounts be “categorized as implicit price concessions.” This new requirement would unnecessarily elevate form over substance, requiring some providers to change their financial statements even though their current processes appropriately ensure that bad debt amounts are written off from accounts receivable.

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<sup>68</sup> 85 Fed. Reg. at 32,872.

The Proposed Rule correctly notes that Medicare-Medicaid crossover claim amounts are sometimes written off as contractual allowances, whether because the provider is unable to bill the beneficiary for the remaining deductible or coinsurance amounts or because the Medicaid remittance advice explicitly refers to the unpaid deductible or coinsurance amounts as a “Medicaid contractual allowance.”<sup>69</sup> Although the Proposed Rule indicates that amounts so classified would not be considered bad debt amounts, it does not present any programmatic concerns with permitting providers to categorize bad debt amounts as contractual allowances. Rather, the Proposed Rule only provides the circular assertion that the contractual allowances could not be considered bad debt amounts “because these amounts were written off to a contractual adjustment or allowance account instead of a bad debt expense account.”<sup>70</sup> In addition, the Proposed Rule fails to address other types of bad debts that would not constitute implicit price concessions. For example, where patient deductible and coinsurance obligations are handled in bankruptcy, these bad debt amounts may be written off from accounts receivable but would not be categorized as implicit price concessions in the provider’s financial records.

The FAH urges CMS to decline to finalize the proposed amendments to § 413.89(b)(1)(ii) and (c), and instead to continue treating uncollected Medicare and coinsurance amounts as bad debt amounts as long as the provider can show that (1) the account is no longer part of its patient accounts receivable on its financial statements, (2) the criteria for allowable bad debt under § 413.89(e) are satisfied, and (3) the provider treats the amount as a reduction in revenue rather than as part of the costs of providing the services, in accordance with existing § 413.89(c).

## **7. Retroactive Rulemaking**

The Proposed Rule characterizes many of the proposed amendments to 42 C.F.R. § 413.89 as “the clarification and codification of our longstanding Medicare bad debt policies,” and proposes that the amendments would have retroactive as well as prospective effect, except for a handful of changes that are proposed to be prospective only. In some cases, however, the “longstanding Medicare bad debt policies” described in the Proposed Rule are in fact areas that have been hotly disputed in litigation or where MACs have applied different standards when auditing bad debt claims, indicating that the claimed policy may in fact be new rather than “longstanding.” By way of example, as explained above, proposed § 413.89(e)(2)(i)(A)(5) is inconsistent with PRM section 310.2, and the Proposed Rule actually misquotes PRM section 310.2 when characterizing the proposed regulatory amendment as consistent with CMS’s longstanding policy concerning partial payments and reasonable collection efforts.

The Proposed Rule suggests that retroactive rulemaking under 42 U.S.C. § 1395hh(e)(1)(A)(ii) is permissible and appropriate for most of the amendments to § 413.89 because “failure to apply the change retroactively would be contrary to the public interest.” In support of this assertion, CMS characterizes the retroactive rules as the “clarification and codification of longstanding Medicare bad debt policies,” but as is noted above, some of the proposed retroactive rules are in fact new policies or policies that have only been inconsistently

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<sup>69</sup> 85 Fed. Reg at 32,876.

<sup>70</sup> *Id.*

applied. The Proposed Rule provides no rationale as to why or how retroactive application of the *new* bad debt rules could serve any important public interest. In addressing the “public interest” CMS focuses on concerns that non-retroactive application of the proposed bad debt rules “might cause [certain] providers to resubmit previously submitted cost reports.”<sup>71</sup> But, retroactive application raises more compelling risks that are contrary to the public interest—namely the potential reopening of cost reports or the application of new rules to submitted cost reports that remain open. Retroactive application of the proposed amendments to 42 C.F.R. § 413.89(e)(2)(i)(A)(5) would be administratively burdensome for Medicare contractors and providers and create substantial uncertainty if retrospective disallowances are permitted based on the final rule. In order to address this significant concern, if any of the rules are given a retrospective application, the FAH strongly urges CMS to mitigate these risks by, at a minimum, instructing Medicare contractors that any finalized amendments to the bad debt regulation do not provide the basis for reopening any cost report and cannot be applied to disallow bad debt amounts reported in any open cost report submitted before October 1, 2020.

Finally, although the Proposed Rule suggests that the public interest may be furthered by retroactive application of the bad debt rules, it does not establish that failing to apply the rules retroactively would be “*contrary to the public interest*,” as would be required under § 1395hh(3)(1)(A)(ii). The existence of public interest concerns favoring retroactive application is not equivalent to a determination that it would actually be contrary to the public interest to follow the normal course and only apply a rule prospectively. The FAH is concerned that the Proposed Rule suggests an overly expansive view of the Secretary’s authority for retroactive rulemaking and urges CMS to properly focus on prospective rulemaking, except in extraordinary circumstances where doing so would be contrary to the public interest.

## **8. Joint Education**

Lastly, the FAH urges CMS to conduct joint provider and Medicare contractor education concerning the final rule in order to ensure that CMS, Medicare contractors, and providers can come to a common understanding of the new, clarified, or codified bad debt rules. Joint education assists stakeholders and contractors in developing shared vocabulary and expectations and provides the opportunity to proactively address questions and requests for clarifications that will arise early on. In light of the substantial nature of the proposed bad debt rules, the FAH strongly supports such joint education in order to both assure a smoother roll-out of the final rule and to reduce the likelihood that the finalized bad debt rules will be inconsistently applied or will result in unnecessary disputes or litigation.

## **OUTLIER PAYMENTS**

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

For FY 2021, 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

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<sup>71</sup> 85 Fed. Reg. at 32,867.

payment, and any add-on payments for new technology, plus the proposed fixed loss threshold of \$30,006. The present threshold, which has been in effect since October 1, 2019, is \$26,552. This proposed increase of more than \$3,450 is on top of an increase of more than \$2,900 in the threshold between FYs 2017 and 2020. CMS indicates that it has used the same methodology to calculate the fixed loss threshold as it has since FY 2014, with limited exceptions (beginning in FY 2020, CMS's methodology accounts for the estimated impact of outlier reconciliation, and it uses public, FY data to calculate the charge inflation factor). Just as with last year's rule-making, 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 2021 represents an increase of more than \$6,400 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**

CMS proposes to again apply key methodological refinements that were first applied in the FY 2020 IPPS rulemaking. First, CMS proposes to again account for outlier reconciliation in the FY 2021 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 2021 fixed-loss threshold.

Second, the Proposed Rule charge inflation factor calculation methodology mirrors the FY 2020 final rule, relying on charge data from FYs 2018 and 2019. We believe the decision to move to this publicly available data continues to be a thoughtful choice for the Proposed Rule. We do not believe that less current data should be used for the final rule. Rather, 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. Watson Policy Analysis (WPA) conducted various examinations and probing of data to understand the factors that drove CMS to increase the threshold over \$2,900 between FY 2017 and FY 2020, and to propose to increase the threshold an additional \$3,500 in FY 2021, and observed that the

inclusion of extreme cases in the calculation of the threshold significantly impacts CMS's determination of the fixed-loss threshold.<sup>72</sup>

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 2021 Proposed Rule Table**

<b>Trim threshold</b>	<b>Number of cases removed</b>	<b>Calculated FLT</b>	<b>Percentage of cases trim removes</b>
None	-	\$ 30,111	0.0000%
\$2,000,000	1,330	\$ 27,994	0.0163%
\$1,750,000	1,967	\$ 27,529	0.0241%
\$1,500,000	3,065	\$ 26,851	0.0376%
\$1,250,000	5,016	\$ 25,982	0.0615%
\$1,000,000	9,318	\$ 24,606	0.1143%
\$750,000	20,222	\$ 22,472	0.2481%
\$500,000	57,471	\$ 18,745	0.7051%

The FY 2021 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 (1,330 cases) drives the threshold down over \$2,100. 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 (9,318 cases) drives the threshold down approximately \$5,500, and removing all cases with charges above \$500,000 (57,471 cases) drives the threshold down over \$11,300. A comparison of the two tables indicates 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:

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<sup>72</sup> See the attached WPA report *Summary of Research Modeling FY 2021 Proposed Inpatient Prospective Payment System Outlier Payments* (Attachment A). All the tables contained in this comment are set forth in and derived from the WPA Report.

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	3,062	0.0342%	437

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 it is absolutely critical to the process for setting the outlier threshold that CMS accurately calculate prior year actual payment comparisons to the 5.1% target. It is impossible for CMS to appropriately modify its methodology to achieve an accurate result if it is not aware of, or is misinformed about, the magnitude of inaccuracies resulting from prior year methodology. CMS's estimate of 5.38% of outlier payments as a percentage of MS-DRG payments for FY 2019 deviates from WPA's actual estimate (WPA Report at p. 5) of the outlier payment level using the most recently updated MedPAR file by about 0.13%:

<b>Data Source</b>	<b>Operating IPPS Payments Net of IME, DSH and Outlier Amounts (\$) (Does not include Capital)</b>	<b>Outlier Payments (\$)</b>	<b>Outlier Payment Level (%)</b>	<b>Total Medicare Payment (\$)</b>
MedPAR 2019 Actual Outlier Payments, FY 2019 Final Rule Impact File Adjustment Factors. Correction Notice version	\$ 101,315,392,964	\$ 5,213,397,145	5.15%	\$ 114,552,455,071

As demonstrated in the following table from WPA Report at p. 6, 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:

<b>Federal Fiscal Year (Month of HCRIS release)</b>	<b>Number of cost reports</b>	<b>IPPS Payments Net of IME, DSH and Outlier amounts</b>	<b>Outlier Payments</b>	<b>Outlier Payment Level (%)</b>	<b>Target Outlier Payments (5.1%)</b>	<b>Shortfall in Outlier Payments</b>
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 2019 (March)	589	\$15,751,055,199	\$701,144,065	4.26%	\$830,753,000	(\$830,753,000)

Note: 2019 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 since at least 2013, 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 WPA Report at p. 7 shows this trend of regular, significant variances between proposed and final fixed-loss thresholds:

<b>FY</b>	<b>Proposed</b>	<b>Final</b>	<b>Variance</b>	<b>% of Variance</b>
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			

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 use the most recent data in order to appropriately calculate the outlier threshold.

With regard to the current rule-making WPA was able to replicate the threshold within \$105. Thus, we have high confidence that WPA understands CMS's methodology and has accurately modeled that methodology such that inputting more current data will yield a threshold that will be more likely to meet the target percentage of 5.1%.

The FAH is not proposing a threshold for FY 2021. While we have confidence in the work of WPA, its work is dependent on large variables in the outlier calculation. We also note that the impact of the inclusion of extreme cases in the calculation of the fixed loss threshold is significant and we urge CMS to carefully study this trend and whether outlier payment policy should be adjusted so that it is fair to all hospitals that fund outlier payments. Finally, we recognize that with the release of the MedPAR final data with additional claims, which will lead to new weights being calculated, and with updated cost to charge ratios, it is appropriate to recalculate the fixed loss threshold from the data that will be released with the final rule.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Steve Speil", with a stylized flourish at the end.

**Summary of research modeling****FY 2021 Proposed Inpatient Prospective Payment System****Outlier Payments**

Date: June 29, 2020

*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) 2021 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 32908 of the Federal Register.<sup>1</sup> We attempted to replicate the CMS logic and then compared our results and made a variety of adjustments to assess the impact of using different parameters. This report summarizes our findings.

*Summary*

A summary of findings is as follows:

- WPA was able to come close to the CMS calculation of the Fixed Loss Threshold (FLT). CMS published \$30,006. Using the weights reported by CMS, WPA calculated \$30,111.
- 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 calculated an actual outlier payment proportion of 5.15% versus the 5.38% reported in the rule for FY 2019. As a part of the rate-setting, the target percentage is intended to be 5.1%
- WPA was able to come close to the estimate of charge inflation. CMS reported a charge inflation of 6.353% while WPA has calculated 6.404%.

*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

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<sup>1</sup> "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 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals. Published in Federal Register, Vol. 85, No. 104, Friday, May 29, 2020.

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 2021 outlier payment from the FY 2021 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 2021 proposed file: contains inpatient hospital claims from FY 2019 that were used by CMS to model proposed FY 2021 payments,
- Table 5 – Weight file: contains the proposed weights for FY 2021,
- Impact file: contains hospital specific characteristics and payment factors,
- DSH Supplemental File: contains uncompensated care per claim payment amounts for providers,
- The FY2021 Proposed IPPS rule, in particular information on cost and charge inflation factors, and
- Inpatient Provider of Services File: contains provider specific information.
- Hospital Cost Reporting Information System (HCRIS) data containing cost reports from providers. This information was used to calculate the adjustment to the outlier target based on the historical outlier reconciliation.

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

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

WPA calculated a fixed loss threshold of: \$30,111 versus the published number of \$30,006, a difference of \$105 or about 0.35%.

WPA did update the replication to account for the payment of clinical trial CAR-T cases at 15% of the normal payment rate.

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 2021 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).

Comparing the 3,273 providers listed in the impact file and a simulated December 2019 PSF file, we had a match rate of 97.49% (3,191 providers) for operating CCRs. When comparing the impact file provider list and the March 2020 PSF, we had a match rate of 70.12%.<sup>2</sup>

For the December 2019 comparison, the average difference in operating CCRs between the impact file and the PSF file (weighted by the number of discharges) was -0.027% if all providers were used, and -1.8% if just those providers with differences were used.

For the March 2020 comparison, the average difference in operating CCRs between the impact file and the PSF file (weighted by the number of discharges) was 0.209% if all providers were used and 0.647% if just those providers with differences were used.

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

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<sup>2</sup> Note: The PSF file for December 2019 was removed before the IPPS rule was released and not downloaded. So as an approximation, we took the March 2020 and restricted it to records in the PSF file prior to 1/1/20, to simulate a December 2019 PSF file. This is consistent with prior years.

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

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

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

### Analysis 3: FY 2019 Outlier payment using FY 2019 MedPAR data

In order to examine the actual outlier payments, WPA modeled payments and combined outlier payment information to estimate the actual payments. CMS published an estimate that outlier payments were 5.38%.<sup>3</sup> The chart below shows operating payments and the outlier payments that we calculated. The operating payments and the total payments are based on the modeling simulation. The outlier payment amount is from the reported outlier payments from the MedPAR 2019 Proposed File. In the simulation using the CMS FLT we estimate that outlier payments are 5.15%.

<b>Data Source</b>	<b>Operating IPPS Payments Net of IME, DSH and Outlier Amounts (\$) (Does not include Capital</b>	<b>Outlier Payments (\$)</b>	<b>Outlier Payment Level (%)</b>	<b>Total Medicare Payment (\$)</b>
MedPAR 2019 Actual Outlier Payments, FY 2019 Final Rule Impact File Adjustment Factors. Correction Notice version	\$ 101,315,392,964	\$ 5,213,397,145	5.15%	\$ 114,552,455,071

### Analysis 4: Outlier payments from Medicare cost reports

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

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<sup>3</sup> P. 32910 of the Federal Register version of the rule.

<b>Federal Fiscal Year (Month of HCRIS release)</b>	<b>Number of cost reports</b>	<b>IPPS Payments Net of IME, DSH and Outlier amounts</b>	<b>Outlier Payments</b>	<b>Outlier Payment Level (%)</b>	<b>Target Outlier Payments (5.1%)</b>	<b>Shortfall in Outlier Payments</b>
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 2019 (March)	589	\$15,751,055,199	\$701,144,065	4.26%	\$830,753,000	(\$830,753,000)

Note: 2019 data does not have all providers' cost report yet.

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

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

### **Analysis 5: Fixed Loss Threshold over time**

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



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

### **Analysis 6: Modeling of FY2020 outlier percentage**

WPA was asked to examine if it would be possible to provide any estimates of the proportion of outlier payments for FY2020. WPA has made some estimates, but they are subject to significant assumptions. The difficulty is that the FY2020 MedPAR data has not been released and the year is still ongoing.

However, CMS has started releasing quarterly updates for the Standard Analytic Files (SAF) and the Calendar Year 2019 Q4, which is the same as Fiscal Year 2020 Q1 data has been released.

Using claims from this actual claims data, WPA is currently calculating an outlier percentage of 4.95% for the first quarter of FY2020. However, this will be changing with additional data as it becomes available.

### **Analysis 7: Outlier Reconciliation**

In the FY2020 IPPS rule, CMS finalized a new methodology to adjust the outlier target percentage to account for outlier reconciliation. WPA was successful in replicating the CMS calculations exactly given the logic described. WPA also found that no adjustment should be made for FY2021 based on the data to be used this year.

### **Analysis 8: Explorations on high charge cases**

As evidenced in Analysis 5, the Fixed Loss Threshold has been adjusting over time, and the FY 2021 Proposed Rule Fixed Loss Threshold is nearly \$3,500 higher than the FY 2020 Final Fixed Loss Threshold. 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.

Trim Threshold	Number of cases removed	Calculated FLT	Percentage of cases trim removes
None	-	\$ 30,111	0.0000%
\$ 2,000,000	1,330	\$ 27,994	0.0163%
\$ 1,750,000	1,967	\$ 27,529	0.0241%
\$ 1,500,000	3,065	\$ 26,851	0.0376%
\$ 1,250,000	5,016	\$ 25,982	0.0615%
\$ 1,000,000	9,318	\$ 24,606	0.1143%
\$ 750,000	20,222	\$ 22,472	0.2481%
\$ 500,000	57,471	\$ 18,745	0.7051%

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 FY2019 data, this trend continued. There is an increase at a much faster rate than previous years for this 2019 data. (Note: 2018 data has also been updated to the final rule.)

<b>Year</b>	<b>Number of cases over \$1.5 million</b>	<b>Percentage of total cases</b>	<b>Number of unique providers</b>
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	3,062	0.0342%	437