Charles N. Kahn III
President & CEO

June 25, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

***RE: CMS-1694-P, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims; Proposed Rule (Vol. 83, No. 88), May 7, 2018***

Dear Administrator Verma:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching hospitals in urban and rural America, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. The FAH appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) about the 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 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and

Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims; Proposed Rule (Vol. 83, No. 88), May 7, 2018.

## EXECUTIVE SUMMARY

Medicare Disproportionate Share Hospital (DSH) Payments

The FAH and its members support CMS's proposed policies and commend the Agency for its efforts over the past year to: (1) better define the costs of uncompensated care, consistent with Congress' focus on the uncompensated care costs of uninsured patients, by including the cost of uninsured patient discounts into the definition of charity care for Worksheet S-10 (WS S-10) purposes; (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 2014 and 2015 WS S-10s to comply with CMS's revised instructions; (4) fix its policy for annualizing data from long and short period cost reports so that providers in those situations will not be disadvantaged; and (5) push providers receiving large distributions from the uncompensated care fund to restate erroneously reported data in time for it to be used to better disburse the UC-DSH fund for FY 2019. CMS's progress in improving both the processes and data for UC-DSH disbursements were exceptional.

However, while CMS has done much in the last year to cause the data in WS S-10 to be more usable to distribute UC-DSH payments, CMS still needs to take steps to cause hospitals to more accurately report that data. This includes further educating providers about the correct way to report each line item relevant to the UC-DSH calculation on WS S-10, and actually auditing the data rather than just preparing edits to identify gross aberrations in reported data.

CAR T-Cell Therapy

The FAH recommends that CMS provide for the applicable MS–DRG payment plus the blended average sales price (ASP) for substantially similar Chimeric Antigen Receptor (CAR) T-cell therapies T-cell therapy, starting with YESCARTA™ and KYMRIAH™. CAR T-cell therapy represents a significant medical advancement for beneficiaries who previously had limited to no treatment alternatives. But, because of the extraordinary drug costs, CAR T-cell therapy also threatens to disrupt IPPS reimbursement through underpayment of CAR T-cell therapy cases (particularly in rural markets) and/or the redistribution of payment from basic hospital services to CAR T-cell therapy drugs unless an adequate add-on payment is provided. In order to preserve access to care while also maximizing price-based competition among CAR T-cell therapy drug manufacturers, the FAH recommends adoption of an alternative new-technology add-on payment that is set based on the blended ASP for substantially similar CAR T-cell therapy drugs. Applying this add-on payment in FY 2019 will provide an opportunity for competition to reduce current prices, for CMS to develop experience with CAR T-cell therapy claims, and for Congress to explore any appropriate legislative approaches to CAR T-cell therapy payment, if appropriate and necessary.

Quality Payment and Reporting Programs

The FAH commends CMS for its proposed application of the Meaningful Measures initiative to the hospital inpatient quality reporting and pay-for-performance programs. Prioritizing and reducing the number of quality measures across these programs addresses our previously expressed concerns about the burden of managing many measures and the unnecessary duplication of measures across programs. The FAH supports a focus on measures designed for improving patient care and working towards outcomes that are meaningful to patients. It is appropriate that in its review of the hospital quality programs, CMS takes a holistic approach to evaluate each of the pay-for-performance program measures in the context of all three programs (readmissions reduction, hospital-acquired conditions reduction, and value-based purchasing).

Promoting Interoperability Programs

The FAH appreciates that the proposed modifications to the requirements that eligible hospitals and CAHs must meet to demonstrate meaningful use of certified electronic health record technology (CEHRT) in the Proposed address concerns raised by the field about the feasibility of operationalizing current requirements. These concerns include reducing the number of objectives and measures, maintaining the minimum 90-day reporting period in 2019 and 2020, providing additional flexibility for Program scoring, and removing the Coordination of Care Through Patient Engagement objective and associated measures.

The FAH also appreciates CMS's desire to provide additional flexibility for eligible hospitals and CAHs and the focus on interoperability. The proposed scoring changes are an improvement over retaining the current Stage 3 scoring requirements but will take time to implement. Thus, we believe providers should be given more flexibility to select measures, and the points required for meeting meaningful use should be adjusted to reflect these implementation issues. Additionally, while the FAH supports the attention to measures involving opioids as an important topic area, we do not believe that they are ready for implementation until the specifications and operational aspects are more fully developed. Lastly, while we recognize the potential value of API functionality, there are concerns across stakeholders about API readiness, as well as the security of APIs and third-party applications. We urge CMS to work with the Office of the National Coordinator for Health Information Technology (ONC) to establish a trust framework for third party applications, including security standards, terms of use, and an overall validation process. Hospitals must be empowered to protect their systems – and their patients' *Health Insurance Portability and Accountability Act* (HIPAA)-covered protected health information – from unproven and potentially harmful applications.

Price Transparency

The FAH supports CMS's efforts to require hospitals to make available a list of their current standard charges via the internet in a machine-readable format and to update this information at least annually, or more often as appropriate. Many hospitals already comply with this requirement, either voluntarily or because it is required under state law.

The FAH is also supportive of efforts to ensure that consumers have clear, accessible, and actionable information concerning their cost-sharing obligations, but is concerned that CMS is considering avenues for providing this information that focus exclusively on hospitals when payers—insurers, group health plans, Medicare, Medicare Advantage organizations, and others—are best suited to provide actionable coverage and cost-sharing information for all providers and suppliers involved in an episode of care. Payers understand the full range of benefits under a patient's applicable health coverage and cost-sharing obligations (including out-of-pocket spending limits, deductibles, coinsurances, and any reference-based pricing strategies used by the plan) and, because an episode of care typically involves multiple providers and suppliers, the payer is the only entity that is capable of providing a patient with an accurate and actionable estimate of their potential financial exposure for the entire episode of care. Hospitals are simply not the appropriate entity to be tasked with interpreting and explaining a patient's cost-sharing obligations under a particular plan. As such, the publication of average or median hospital rates or discounts as some sort of proxy for an individual's cost-sharing obligations would be misleading to individual consumers, contrary to Congress's express direction that hospitals publish information on standard "charges," and counterproductive to a competitive marketplace for hospital services.

In addition, the FAH continues to recommend that CMS adopt the "surprise billing" section of the National Association of Insurance Commissioners' (NAIC) Health Benefit Plan Network Access and Adequacy Model Act (Model Act) as a robust way to address the issue of surprise billing. The FAH believes this policy provides real protection for patients and strikes the right balance between the roles and responsibilities of hospitals, providers, and plans in situations in which a patient seeks care at an in-network hospital and may be treated by a provider who is not covered by the patient's plan.

Request for Information on Promoting Interoperability

The FAH has long supported efforts to achieve comprehensive interoperability and data liquidity. As the largest purchasers and consumers of health information technology (HIT), hospitals and health systems have a vested interest in data flow to improve patient care, workflow efficiencies and clinician satisfaction, population health and payment models, and research. However, the FAH does not support the proposed revision of the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) related to interoperability and the exchange of health information. The current ecosystem is simply not mature enough to facilitate the movement of this information, as evidenced by the obstacles that currently prevent seamless information exchange and would make it exceedingly difficult for hospitals and other providers to comply with the requirements. Additionally, post-acute providers and behavioral health providers have not been able to adopt HIT to the extent of hospitals and critical access hospitals (CAHs) because they were ineligible for the EHR Incentive Programs under the *Health Information Technology for Economic and Clinical Health (HITECH) Act*.

The FAH appreciates CMS's focus on interoperability and shares CMS's frustrations regarding the lack of actionable, accessible electronic information, as well as the desire to accelerate an interoperable health system that improves the safety and quality of care, enables

innovations, and achieves the best possible outcomes for patients. To continue to address these concerns, the FAH recommends that CMS permit the numerous public and private initiatives in this area, some of which are nascent, time to mature and advance our shared goals.

Long-Term Care Hospitals (LTCHs)

The FAH supports CMS's proposal to eliminate the 25% Rule. The 25% Rule deters the admission of patients who are otherwise appropriate for the LTCH level of care, arbitrarily caps the number of patients an LTCH can admit from any hospital yet still receive a full payment, and thus interferes with the normal LTCH admissions process. In addition, it has been rendered obsolete by the new system of LTCH patient criteria.

By the same token, the FAH strongly opposes the application of a 0.9% permanent budget neutrality adjustment. The LTCH patient criteria and site neutral payment rate already serve as a true functional replacement for the 25% Rule, and CMS has not previously applied such an adjustment in connection with multiple statutory and regulatory moratoria on the rule.

In addition, the FAH strongly disagrees with CMS's proposal to apply a budget neutrality factor to LTCH site neutral cases that qualify for high cost outlier payments. As the FAH explained in previous years' comments, this BNA is duplicative and unwarranted because CMS has already applied budget neutrality adjustments to reduce the operating and capital portions of the IPPS standard Federal payment rate before using that rate to determine the IPPS comparable per diem amount for site neutral payment cases.

Finally, the FAH remains concerned about the sustained rapid rise in the high-cost outlier fixed loss threshold. Among the issues that CMS must address is the influence of one provider's aberrant data that is driving the threshold higher: 76 of its 87 LTCH standard rate cases were outlier cases, representing only 0.116% of all such cases but consuming 2.65% of all outlier payments.

## MS-DRG CLASSIFICATIONS

### II.F. Proposed Changes to Specific MS-DRG Classifications

For this proposed rule, CMS's MS-DRG change analysis is based on ICD-10-CM claims data from the ICD-10 claims data from the September 2017 update of the FY 2017 MedPAR file, which contains hospital bills received through September 30, 2017, for discharges occurring through September 30, 2017. Based on the review of the rule, the FAH agrees overall with the proposed changes being recommended for MS-DRG and/or ICD-10 code classification changes for FY 2019 other than the items noted below.

## CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL THERAPY: DRG CLASSIFICATION, APPLICATION FOR NEW TECHNOLOGY ADD-ON PAYMENT, AND PAYMENT ALTERNATIVES

### II.F.2.d., II.H.5.a., & Addendum II.A.4.g.3. Proposed FY 2019 Payment for CAR T-Cell Therapy

The FAH appreciates CMS's request for comments concerning the appropriate MS–DRG assignment and the pending new technology payment applications for CAR T-cell therapy, and more importantly, CMS's request for comments concerning the use of alternative approaches to establish payment for CAR T-cell therapies in FY 2019. The significant costs of CAR T-cell therapy—which are beyond the control of individual hospitals—risk disrupting the IPPS as a whole, including Medicare's MS–DRG payments and inpatient outlier payments, while also creating a barrier to access. And, if IPPS reimbursement for CAR T-cell therapy is inadequate, it creates a perverse incentive for care to be provided on an outpatient basis when inpatient care would be more clinically appropriate. ***In order to mitigate these risks and maximize price-based competition between existing and emerging CAR T-cell therapy manufacturers, the FAH recommends that CMS provide for the applicable MS–DRG payment plus the blended average sales price (ASP) for substantially similar CAR T-cell therapies T-cell therapy, starting with YESCARTA™ and KYMRIAH™.*** For FY 2019, CMS has the authority to adopt an appropriate payment system for CAR T-cell therapy in the form of a novel add-on payment under section 1886(d)(5)(K) of the Social Security Act. Applying a temporary, ASP-based payment in addition to the MS-DRG-based payment amount will support price-based competition among CAR T-cell therapy manufacturers (including any new entrants), provide the necessary data for CMS to project Medicare CAR T-cell therapy utilization and costs, roughly harmonize OPPS and IPPS payment for CAR T-cell therapy in the first years of its availability, and permit stakeholders to seek a legislative solution if needed.

CMS first requested comments in the FY 2019 IPPS proposed rule concerning the appropriate MS–DRG assignment for procedures involving CAR T-cell therapy. For FY 2019, the FAH supports CMS's proposed approach of assigning ICD–10–PCS procedure codes XW033C3 and XW043C3 to Pre-MDC MS–DRG 016 but only for non-CAR T-cell therapy product costs. As CMS observes, the requirement that any new MS–DRG be established in a budget neutral manner makes the creation of a new MS–DRG that includes payment for the CAR T-cell therapy product problematic. Once CMS has data on the cost of CAR T-cell therapy from inpatient hospital claims, the recalibration of relative weights that would result from the creation of a new MS–DRG for CAR T-cell therapy would be primarily driven by the extraordinary cost of the CAR T-cell therapy drugs. The redistributive effect of this process would depress payment for core services in order to provide for payment of CAR T-cell therapy services. In addition, if a new MS–DRG was created for the CAR T-cell therapy procedure codes, the resulting payment amount would vary significantly based on the applicable wage index even though labor costs are a relatively insignificant component of the costs of CAR T-cell therapy care. Significant wage-based variation in IPPS payment amounts for CAR T-cell therapy are simply unsupported where it is drug costs, not wages, that drive the vast majority of CAR T-cell therapy payment. In fact, any MS–DRG payment methodology for CAR T-cell therapy would create a significant patient access problem in rural markets because the use of a wage-adjusted

standardized amount would depress CAR T-cell therapy reimbursement in low wage markets even though CAR T-cell therapy drug costs remain the same across markets. If hospitals in low wage markets are acutely underpaid for CAR T-cell therapy drugs, it would not be financially feasible to offer CAR T-cell therapy in these markets, and patients with relapsed or refractory B-cell lymphomas living in low-wage markets would be left without access to a critical therapy. If the CAR T-cell therapy procedure codes are assigned to MS–DRG 016 and the MS–DRG is appropriately retitled, the redistributive effect from recalibration of the relative weights is mitigated but not eliminated.[1] Further, the problem with adjusting non-labor related costs for the wage index would continue.

Prior to having inpatient charges and costs for setting an MS–DRG relative weight for CAR T-cell therapy, the resulting payment will be inadequate under CMS's typical approach to new technology add-on payments given the extraordinary cost of CAR T-cell therapy drugs. In our modeling of various payment approaches, payment of the MS–DRG amount, a new technology add-on payment under the formula in 42 C.F.R. § 412.88, and an outlier payment could still generate a loss of over $330,000 per case for a hospital. Even applying a CCR of 1.0 for the CAR T-cell therapy drugs for purposes of both the new technology add-on payment and the outlier payment, a hospital would still lose approximately $60,000 per case. Financial losses at these levels will reduce hospitals' ability to offer CAR T-cell therapy, thereby diminishing patient access to a novel therapy.

Under the OPPS, payment for CAR T-cell therapy drugs is made at ASP plus 6%. The extraordinarily high cost of the CAR T-cell therapy drugs creates the risk that the ASP plus 6% payment methodology will far outstrip IPPS payment based on the MS–DRG amount and additional payment amounts based on charges reduced to costs (*i.e.*, a new technology add-on payment and outlier payment). Such asymmetry between OPPS and IPPS reimbursement for CAR T-cell therapy might create a financial incentive for providers to shift CAR T-cell therapy cases to the outpatient setting, even where inpatient care would be clinically appropriate.

Payment of an ASP-based amount in addition to the MS-DRG amount is preferable to other alternatives, including the use of a CCR of 1.0 for charges associated with ICD–10–PCS procedure codes XW033C3 and XW043C3. First, an ASP-based system has the distinct advantage of encouraging price-based competition among CAR T-cell therapy drug manufacturers as long as the ASP is set using the weighted average sales price of substantially similar CAR T-cell therapy drugs. At this time, the two CAR T-cell therapy drugs (YESCARTA™ and KYMRIAH™) are substantially similar in terms of their mechanisms and

[1] The annual recalibration process uses more recent cost report and utilization data to reset the MS–DRG relative weights. An MS–DRG's relative weight will equal average costs of all cases in the MS–DRG divided by the average costs of all cases. If average cost for an MS–DRG increases less than the average cost of all cases, its relative weight will go down and vice versa. Given the extraordinarily high cost of CAR T-cell therapy, it will raise the average cost per case across all cases by more than the average cost per case in any individual MS–DRG that does not include CAR T-cell therapy thereby causing the relative weights for all MS–DRGs that do not include CAR T-cell therapy to decline. Including CAR T-cell therapy in its own MS–DRG will maximize the redistributive impact while including CAR T-cell therapy in an MS–DRG with other lower cost cases will lower the average MS–DRG cost for the MS–DRG that includes CAR T-cell therapy mitigating some of the redistributive impact but resulting in underpayment of CAR T-cell cases. The redistributive impact will be more significant to the extent there are more CAR T-cell cases affecting the average cost per case.

indications, despite having been assigned separate HCPCS codes. Using a blended ASP for substantially similar CAR T-cell therapy drugs (*i.e.*, the weighted average sales price of YESCARTA™ and KYMRIAH™) for payment purposes would maximize price-based competition between manufacturers of substantially similar CAR T-cell therapy drugs. Each manufacturer would have a strong incentive to adjust its price to just at or below the blended ASP. Thus, whenever the blended ASP for CAR T-cell therapy drugs declined in a quarterly ASP update, the manufacturer of the higher-priced CAR T-cell therapy drug would likely compete for market share by reducing its CAR T-cell therapy price to or below the blended ASP price. Because each price reduction would prompt a quarterly reduction to the blended ASP, and reductions in the blended ASP would incentivize further price-reductions, a blended ASP-based payment methodology has the distinct advantage of accelerating price-based competition. A payment system based on charges reduced to costs, in contrast, does not maximize price-based competition among drug manufacturers because a higher charge for a product will result in a higher cost, regardless of whether the drug charges are reduced to costs by applying the hospital's average CCR or a CCR of 1.0. Further, using a CCR of 1.0 for expensive drugs sets an important policy precedent that CMS will equate charges with costs when a product is very expensive. Such a policy could lead to drug and device manufacturers raising their prices to hospitals for other products in order to make the same argument that a special CCR should be applied to their products. These are all reasons why the FAH has significant concerns about the idea of using a CCR of 1.0 for CAR T-cell products.

Incorporating an ASP-based payment would also roughly harmonize IPPS and OPPS reimbursement for CAR T-cell therapy. Payment of the MS–DRG amount plus ASP for inpatient CAR T-cell therapy, on the other hand, would mitigate the risk that insufficient inpatient reimbursement would improperly or prematurely push CAR T-cell therapy cases to the outpatient setting.

CMS has the authority to provide for additional payment at the ASP amount in FY 2019, and the FAH strongly urges CMS to exercise this authority. Under section 1886(d)(5)(K) of the Social Security Act, CMS is required to "establish a mechanism to recognize the costs of new medical services and technologies" in a manner that provides for "additional payment . . . in an amount that adequately reflects the estimated average cost of such service or technology." To date, CMS has implemented subparagraph (d)(5)(k) through its new technology add-on payment regulations at 42 C.F.R. §§ 412.87 through 412.88. In the context of CAR T-cell therapy drugs, however, CMS's new technology add-on payment mechanism fails to "adequately reflect[] the estimated average cost of such service or technology" as required by the applicable statute. Payment based on a portion of charges reduced to costs under section 412.88 would result in significant financial losses for providers, as described above. Therefore, the FAH recommends that CMS instead establish an alternative mechanism that recognizes the costs of CAR T-cell therapy drugs through an ASP methodology. ***In particular, the FAH urges CMS to create an alternative mechanism under section 1886(d)(5)(K) for CAR T-cell therapy that provides for payment of the entire ASP amount as an add-on payment to the standard DRG payment.*** Alternatively, CMS could establish a mechanism under section 1886(d)(5)(K) that provides for the use of ASP as a proxy for costs for CAR T-cell therapy drugs. In order to ensure that this alternative mechanism adequately reflects the estimated average cost of CAR T-cell therapy, the amount of the add-on payment would also need to be increased to 100% of the amount by which

the costs of the case (including the ASP for CAR T-cell therapy drugs) exceed the standard DRG payment. In either case, CMS could consider temporarily restricting access to the CAR T-cell therapy add-on payment to cases involving specified diagnostic codes until such time as the National Coverage Analysis process for CAR T-cell therapy drugs is complete.

One question that CMS may face is whether these options could be adopted in the final rule without them having been specifically proposed by CMS in the FY 2019 IPPS proposed rule as required by the Administrative Procedure Act (APA). In the 2019 IPPS proposed rule, CMS did not make a specific proposal but requested public comment on:

> "Alternative approaches [to] new technology add-on payment applications, and the most appropriate way to establish payment for FY 2019 under any alternative approaches… These payment alternatives, including payment under any potential new MS–DRG, also could take into account an appropriate portion of the average sales price (ASP) for these drugs, including in the context of the pending new technology add-on payment applications." (83 Fed. Reg. 20189)

In our view, this statement effectively placed the public on notice that CMS was considering a policy change for how it prices CAR T-cell products. Further, the implication of CMS's comment solicitation was that it did not know specifically what policy to adopt but was looking for public input on that question in the FY 2019 IPPS final rule so that policy could be put in place as CAR T-cell products are now on the market. For this comment solicitation to have meaning, CMS must adopt a policy in the final rule based on these the comments rather than wait a year to undergo notice and comment rulemaking on a specific policy proposal. Finally, CMS specifically requests using an "appropriate portion of average sales price (ASP) for these drugs"—the exact policy that the FAH is suggesting that CMS use in the FY 2019 IPPS final rule to price CAR T-cell products. Thus, a final rule adopting this method, or some modification of this method, would be a logical outgrowth of the proposed rule, permissible under notice and comment rule-making.

The FAH believes that CMS has constructively met the requirements for notice and comment rulemaking required by the APA. Nevertheless, if CMS believes that those requirements have not been met, the APA provides that notice and comment rulemaking can be waived if the agency finds good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and the agency incorporates a statement of its finding and the reasons for those findings when adopting the policy. In this circumstance, the FAH believes it would be contrary to the public interest to go through a full notice and comment procedure after soliciting comments in the FY 2019 IPPS proposed rule on alternative ways than CMS's typically uses to price CAR T-cell products. As noted above, the FAH believes CMS's traditional pricing mechanisms have the potential to result in significant underpayment to hospitals for this innovative therapy. Waiting a full year to go through a full notice and comment rulemaking procedure to develop an ASP-based CAR T-cell therapy payment would be contrary to the public interest because underpayment for CAR T-cell therapy could impede access to this life-saving therapy. CMS has been in situations such as this frequently and has finalized a rule on an interim basis and provided an additional comment period. While we believe a final rule consistent with the CMS proposed rule here satisfies the logical outgrowth test, CMS also could

choose to issue this part of the rule as an interim final rule with comment period on the specific method CMS adopted, and those it rejected.

In conclusion, CAR T-cell therapy represents both a significant medical advancement for beneficiaries who previously had limited to no treatment alternatives. But, because of the extraordinary drug costs, CAR T-cell therapy also threatens to disrupt IPPS reimbursement through underpayment of CAR T-cell therapy cases (particularly in rural markets) and/or the redistribution of payment from basic hospital services to CAR T-cell therapy drugs unless an adequate add-on payment is provided. In order to preserve access to care while also maximizing price-based competition among CAR T-cell therapy drug manufacturers, the FAH recommends adoption of an alternative new-technology add-on payment that is set based on the blended ASP for substantially similar CAR T-cell therapy drugs. Applying this add-on payment in FY 2019 will provide an opportunity for competition to reduce current prices, for CMS to develop experience with CAR T-cell therapy claims, and for Congress to explore any appropriate legislative approaches to CAR T-cell therapy payment, if appropriate and necessary.

**II.F.5. MDC 6 (Diseases and Disorders of the Digestive System) Updates to Bowel Procedures, MS-DRGs 329 – 331 and MS-DRGs 344-346**

CMS's data analysis included two distinct sections of ICD-10 PCS procedure codes for bowel procedures in MDC 6. CMS received a request to reassign 8 ICD-10 PCS procedure codes describing reposition colon/takedown colostomy from MS DRGs 344-346 to MS DRGs 329-331. CMS proposes to maintain the current MS DRG assignment to MS DRGs 344-346. CMS additionally reviewed and proposes that 12 ICD-10 PCS procedure codes for repair of ascending colon, transverse colon, descending colon and sigmoid colon (open and percutaneous endoscopic approach) and reposition of ileum and large intestine (open and percutaneous endoscopic approach) be reassigned from MS-DRGs 329, 330 and 331 to MS-DRGs 344, 345 and 346 when reporting a bowel procedure as the only OR procedure performed.

The FAH respectfully asks CMS to consider additional data analysis with a more complete and current two-year set of data that incorporates appropriate coding guidance. Specifically, CMS should examine the impact of cases in which one of these procedures performed that have principal diagnoses associated with attention to stomas (colostomy vs ileostomy) vs specific conditions (e.g. obstruction, disruption wound, colostomy, sepsis, etc.) or complications in order to determine whether differences in the resources, LOS, and charges would warrant a change in MS DRG assignment. In addition, despite the fact there is two years of ICD-10 data available for analysis, the coding guidance from AHA Coding Clinic for ostomy closures was released in 3Q 2016 (effective with discharges 9/23/2016); guidance on root operation for "reposition" was released in 3Q 2017 pg. 9 (effective with discharges 7/27/2017), and, guidance on reposition of intestine was released in 4Q 2017 (effective with discharges 10/1/2017). The dates of these specific coding guidance references results in only one year of data to base the analysis on.

Based on the above considerations, the FAH supports maintaining the MS-DRG assignment for the 12 procedure codes for repair of ascending colon, transverse colon, descending colon and sigmoid colon (open and percutaneous endoscopic approach) and

reposition of ileum and large intestine (open and percutaneous endoscopic approach) to MS-DRGs 329, 330 and 331. Additionally, the FAH supports maintaining the 8 procedure codes describing reposition colon/takedown colostomy to MS DRGs 344-346. We recommend that CMS revisit these two proposals in future rulemaking when more complete and current ICD-10 data is available.

**II.F.13 Medicare Code Editor (MCE) Changes**

The FAH agrees in general with all proposed MCE changes. However, we recommend that CMS does not add ICD-10-CM diagnosis Z49.01 "Encounter for fitting and adjustment of extracorporeal dialysis catheter" to the unacceptable principal diagnosis edit code list. Although this code is more likely to be assigned in an outpatient setting, it seems to conflict with what is outlined in section II.F.9 for MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) of this proposed rule. In this section, CMS proposes to reassign admission for renal dialysis as 3 of 4 ICD-9-CM equivalent codes of V56.0 are unacceptable principal diagnoses (Z49.02, Z49.31, and Z49.32). CMS notes to only use ICD-10-CM diagnosis code of Z49.01 as principal diagnosis as part of the proposal to delete MS DRG 685 and reassign this principal diagnosis code to MS-DRGs 698, 699, 700.

**II.F.15.c. Principal Diagnosis Is its Own CC or MCC**

CMS is proposing to remove the special logic in the GROUPER for processing claims containing a diagnosis code from the "Principal Diagnosis Is Its Own CC or MCC Lists," and CMS is proposing to delete the tables containing the lists of principal diagnosis codes, Table 6L.--Principal Diagnosis Is Its Own MCC List (82 ICD-10-CM diagnosis codes and Table 6M.--Principal Diagnosis Is Its Own CC List (253 ICD-10-CM diagnosis codes), from the ICD-10 MS-DRG Definitions Manual for FY 2019.

These tables are those conditions (designated MCCs or CCs) that act as their own MCC/CC when assigned as a principal diagnosis in a given case. CMS noted its internal comprehensive review and analysis that was completed and which provided some level of insight for this proposal. However, CMS's overarching comment noted that they "believed that there were more effective indicators of resource utilization that the Principal Diagnosis as its on MCC or CC."

It is important to note that during the ICD-9-CM Coordination & Maintenance Committee, September 16, 2009, CMS presented the ICD-10-CM/PCS MS-DRG Conversion Project. The conditions that were present in 2009 seem to still be in place that could result in MS-DRG variance. The project identified discrepancies with conversion of MCC and CC lists attributed to translating ICD-9-CM codes in which two codes are needed, and in ICD-10 they were replaced by one ICD-10-CM combination code. In ICD-9-CM, the secondary diagnosis codes were designated as CC or MCC. This secondary diagnosis code is now combined into one principal diagnosis within ICD-10, which resulted in the creation of the ICD-10-CM code acting as its own MCC/CC. An example included was 414.0* (5 codes) (Coronary Atherosclerosis) with secondary CC of 411.1 (Unstable Angina) becoming I25.7*0 (8 codes) (Atherosclerosis of coronary artery with unstable angina) in ICD-10. In the CMS C&M presentation, under

cardiovascular MS-DRG Issues resolved, it was stated "Therefore, when I27.710 is the principal diagnosis, the MS-DRG assignment logic will be modified to assign it to the appropriate 'with CC' MS-DRG."

The FAH ***strongly disagrees*** with the proposal to globally eliminate tables 6L and 6M. The FAH asks that CMS revisit this topic and consider a more detailed analysis. This analysis should be consistent with the approach that CMS conducts when proposing severity level changes (MCC/CC) for conditions. The logic described as part of the MS-DRG Conversion Project with the MCC and CC lists translation from ICD-9-CM to ICD-10-CM should also be considered.

**II.F.16.b.1. Human Immunodeficiency Virus (HIV) Disease – Requested Change to Severity Levels**

Based in part on the internal CMS data analysis noted in the proposed rule as well as the advice of its clinical advisors, CMS is proposing to change the severity level of ICD-10-CM diagnosis code B20 from an MCC to a CC.

CMS's data in the proposed rule did not strongly suggest that the categorization of HIV as an MCC was inaccurate. CMS additionally noted that its clinical advisors indicated that, for many patients with HIV disease, symptoms are well controlled by medication, and, that if these patients have an HIV-related complicating disease, that complicating disease would serve as a CC or an MCC.

The FAH respectfully disagrees with the proposal to reassign ICD-10-CM diagnosis code B20 from an MCC to a CC. Such a change should not be made absent strong supporting empirical data, and as noted in the proposed rule, CMS's data analysis did not strongly support this recategorization.

**II.H.4.a-g. Proposed FY 2019 Status of Technologies Approved for FY 2018 Add-On Payments**

There were 7 add-on payment categories approved for FY 2018 that were discussed in the FY 2019 proposed rule. The FAH agrees with CMS's proposal for the below 7 add-on payment categories based on rationale provided by CMS for each in which determination to continue or discontinue is based on the anniversary date of entry on the market. Per notation in the proposed rule, CMS only extends add-on payments for an additional year only if the 3-year anniversary date of the product's entry into the U.S. market occurs in the latter half of the fiscal year.

- Defitelio (Defibrotide) – CMS proposes to continue for fiscal year (FY) 2019
- Edwards Intuity and LivaNova Perceval Valve – CMS proposes to discontinue FY 2019
- GORE EXCLUDER Iliac Branch Endoprosthesis (Gore IBE Device) – CMS proposes to discontinue for FY 2019
- Praxbind Idarucizumab – CMS proposes to discontinue for FY 2019
- Stelara – CMS proposes to continue for FY 2019
- Vistogard (Uridine Triacetate) – CMS proposes to discontinue for FY 2019

- ZINPLAVA – CMS proposes to continue for FY 2019

## WAGE INDEX

### III.D.2. Proposed Update of Policies Related to Other Wage Related Cost Clarification of the Calculation of Other Wage-Related Costs, and Proposals for FY 2020 and Subsequent Years

CMS has invited public comments on their proposal to eliminate other wage-related costs from the calculation of the wage index for FY 2020 wage index and subsequent years. CMS states in their comments that only 8 hospitals out of over 3,000 IPPS hospitals in the proposed 2019 wage index calculation had cost on this line. The FAH supports the elimination of this cost for FY 2020 and after.

### III.D.3. Proposals to Codify Policies Regarding Multicampus Hospitals

The FAH appreciates CMS's proposal to provide greater clarity concerning the treatment of multicampus hospitals by amending its regulations for sole community hospitals (SCHs), rural referral centers (RRC), rural reclassification, and Medicare-dependent small rural hospitals (MDHs) to expressly address the situation of multicampus hospitals. ***The FAH, however, requests that CMS clarify that IPPS-excluded remote locations are not required to satisfy the SCH, RRC, MDH, or rural reclassification requirements in order for the hospital to qualify as an SCH, RRC, or MDH or to reclassify as rural.*** The proposed amendments to the regulations are confined to hospitals with one or more remote locations that provide and bill services under the IPPS. 83 Fed. Reg. at 20566-67 (proposed 42 C.F.R. §§ 412.92(a)(4), 412.96(d), 412,103(a)(7), 412.108(a)(3)). Each proposed regulation, however, goes on to specify that the requirements apply to "the main campus and its remote location(s)." *Id.* In context, it appears that CMS's intent is to make the pertinent requirements applicable to the main campus as well as any remote locations that provide and bill services under the IPPS. But references to the hospital's "remote location(s)" in the regulations could be broadly read as encompassing IPPS-exempt remote locations. The FAH therefore urges CMS to confirm and clarify that data from an IPPS-excluded remote location (e.g., an off-campus inpatient psychiatric unit) would not be combined with the main campus data and the IPPS-excluded remote location would not be required to independently satisfy the location, mileage, travel time, and distance requirements in order for the hospital to qualify as an SCH, RRC, or MDH or to reclassify as rural.

### III.G.2. Proposed Application of the Rural, Imputed, and Frontier Floors

In recognition that the application of the imputed floors transfers payments from hospitals in States with rural hospitals and all rural hospitals to hospitals in all-urban states, CMS is proposing not to apply an imputed floor to wage index calculations and payments for hospitals in all-urban States for FY 2019 and subsequent years. Consistent with prior comments submitted when the imputed floor was first adopted and in the comments to the proposed 2008 and 2009 IPPS regulation, the FAH strongly supports discontinuing the use of the imputed floor after FY 2018. We agreed with CMS's assessment in the FY 2008 IPPS proposed rule that this type of

floor should apply only when required by statute and also agreed with CMS's decision in the final 2008 IPPS rule to end the use of the imputed rural floor in FY 2009.

**III.I.2.b. Proposed Revision of Reclassification Requirements for a Provider That Is the Sole Hospital in the MSA**

Under current policy, a hospital in a single hospital MSA must contact its CMS Regional Office or Medicare Administrative Contractor for a statement certifying that it is the only hospital in its labor market area to receive a waiver from the wage comparison criteria to be able to do a geographic reclassification. Hospitals have complained that this process is administratively burdensome and unnecessary. CMS is proposing that, for reclassification applications for FY 2021 and subsequent fiscal years, a hospital would provide the wage index data from the current year's IPPS final rule to demonstrate that it is the only hospital in its labor market area with wage data listed within the 3-year period considered by the MGCRB. The FAH supports this proposal and agrees this reduces the administrative burden on the provider and CMS.

**III.N. Request for Public Comments on Wage Index Disparities**

The hospital wage index has its origins in the Social Security Act, Section 1886(d)(3)(E). In creating the Medicare inpatient prospective payment system (PPS) for hospitals, Congress required that the Secretary adjust the standardized payment amounts "for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level." CMS has applied a wage index to adjust the "labor-related" portion of hospital payments since the inception of the short-stay acute hospital inpatient PPS in 1983, and in subsequent years to other hospital PPS payment systems as these sectors moved to prospective payments as well as other health care providers.

Hospital wage index policy has been dynamic and has evolved over time through various changes initiated by CMS exercising its regulatory authority and in response to periodic specific statutory changes mandated by Congress. One constant is that throughout its history, the wage index has presented a range of policy challenges, both macro and micro, that can frustrate providers because of its complexity and the administrative burdens it imposes, but more importantly, because of its significant effects on institutional payment amounts as well as its perceived impact on the geographic distribution of Medicare payments.

***Notwithstanding these concerns, the FAH acknowledges and applauds CMS for its sustained diligence and focus on, and for working with, hospitals to maintain and improve the wage index system.***

While the wage index may appear to be ripe for reform, the FAH urges CMS to exercise great care and caution in recommending legislative or proposing regulatory changes and to consider seriously whether specific and tailored modifications to the current system, consistent with past practice, could achieve a reasonable and acceptable level of improvement and instill

confidence among hospitals that the wage index operates fairly and equitably in achieving its intended purpose.

Governing Policy Principles

As CMS reviews and considers a range of reforms for the hospital wage index, the FAH asks that it pay particular attention to the following key governing principles.

• *Transparent data sources subject to review and correction.*

Hospitals must have an opportunity to review, validate, and, as appropriate, correct the source data used to derive a wage index adjustment.

• *Hospital wages and benefits only, including contract labor.*

As a payment adjustment for hospitals, the wage index should accurately reflect the unique characteristics of the labor marketplace for hospitals. The best way to achieve this is through the exclusive use of hospital wage and benefit data. It should be noted that Bureau of Labor Statistics (BLS) data does not satisfy those core principles. Therefore, at this time, the FAH opposes using BLS data as a surrogate for the current source of data – the hospital cost report, which, among other attributes, is transparent, subject to scrutiny and correction among other safeguards, hospital-specific, and reasonably accurate in reflecting a hospital's labor costs.

Among its limitations, BLS data are collected by occupation and include non-hospital personnel. In addition, the data are confidential preventing CMS from learning which hospitals or other entities had submitted or not submitted data, and eliminating external data review and verification. This conceivably could create an incentive for lower paying providers to refrain from submitting information thus skewing the data and undermining its accuracy and fairness. Further, BLS is empowered to impute data; does not distinguish between full and part-time employees; uses sample data for only two pay periods per year, which would not capture seasonality that occurs in certain markets; and uses the wages paid to contract employees, not the amount paid to the agency by the hospital, which would understate actual hospital costs in areas where contract labor is more prevalent, such as areas that may suffer from a shortage of nursing staff.

• *Preserve exceptions process permitting hospital reclassification*.

While examining and potentially redefining appropriate hospital labor markets within which hospitals would be classified is a critical element of reform, it is undoubtedly one of the most difficult, complicated by the patchwork of political jurisdictions and boundaries. Regardless of the outcome of this review or any new approach adopted, some hospitals, perhaps a significant number, will be unfairly disadvantaged when comparing their labor costs with those of the area within which they have been arbitrarily assigned. There must be a fair and robust process to remedy these situations and provide the hospital with an appropriate wage index adjustment through reclassification.

• *Consistent national application of wage index policy.*

There should be uniformity in all aspects of wage index data development and application, especially in light of the budget neutral nature of the wage index. Much of the body of CMS's wage index regulations and rules are administered regionally by Medicare contractors, and it is not uncommon for there to be inconsistent interpretation and application of the rules regarding data collection resulting in regional inequities.

In addition, all hospitals, including inpatient rehabilitation facilities (IRF), long-term acute care, and inpatient psychiatric facilities should have the ability to obtain geographic reclassifications. Further, the IRF wage index should be based on the same current year pre-classified wage index values as acute care hospitals rather than prior year values.

• *Stability and predictability.*

The FAH recommends that CMS evaluate the use of a stop-loss floor to reduce year to year volatility. Such a policy would not penalize areas that experience rapidly increasing wages and would offer downside protection to areas with significant declines in wages. Another option to consider is the application of a multi-year rolling average of wages, though this policy tends to compromise the objective of using more current data.

• *Balance burden and benefit.*

While there are many criticisms of the current hospital wage index – its complexity, administrative burden, data timeliness, redistributive effects – effective, consensus, solutions are elusive. While a policy response may be conceptually appealing and appear to provide a clear benefit, when implemented, there will undoubtedly be an associated burden and cost, with likely redistributive effects, and the possibility of an unintended consequence, which must be carefully weighed.

From the FAH perspective, the occupational mix adjustment is a case in point. However well-intentioned, the substantial administrative burden imposed by the occupational mix adjustment has far exceeded whatever benefit it might have conferred. The result of this policy has been a significant payment redistribution that can appear random rather than directed towards addressing a policy goal.

The FAH appreciates this periodic call for comments on the hospital wage index and stands ready to work with CMS to explore potential reforms that address identified disparities.

## HOSPITAL-SPECIFIC PAYMENT RATE

### IV.B. Proposed Changes in the Inpatient Hospital Updates for FY 2019

The FAH believes that CMS has errored in determining the hospital-specific payment (HSP) rates for Sole Community and Medicare Dependent Hospitals resulting in rates that are much too low. As part of our examination of the posted rates, the FAH arrayed the hospital-specific amounts from the FY 2018 final rule impact file and the FY 2019 proposed rule where there was an HSP in both files for the hospital. There were 438 hospitals with an HSP in both years. Of these, there were 373 hospitals with a drop in the update between 0.5% and 0.6%, and all of those appear to have declined 0.59%. However, the IPPS standardized amounts increased 1.5%. Of the adjustments that apply to the IPPS standardized amounts, it is our understanding that the only one that does not apply to the HSP rate is the +0.5% for documentation and coding. That would imply that the most common change to the HSP should be an approximately 1.0% increase. Instead, most hospitals show a 0.59% decline in their HSP rate. That figure does not appear to correlate to any other adjustments to which a hospital might be subject, such as a 2.1 percentage point penalty for failure to demonstrate meaningful use or a 0.7 percentage point reduction under the Inpatient Quality Reporting program.

We urge CMS to carefully reexamine its calculations and correct what would appear to be an error in the determination of hospital-specific payment rates.

## DISPROPORTIONATE SHARE HOSPITAL PAYMENT

### IV.F. Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2019

#### UC-DSH Calculation of Proposed Factor 3 for FY 2019

The FAH and its members support CMS's proposed policies and commend the Agency for its efforts over the past year to: (1) better define the costs of uncompensated care, consistent with Congress' focus on the uncompensated care costs of uninsured patients, by including the cost of uninsured patient discounts into the definition of charity care for Worksheet S-10 (WS S-10) purposes; (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 2014 and 2015 WS S-10s to comply with CMS's revised instructions; (4) fix its policy for annualizing data from long and short period cost reports so that providers in those situations will not be disadvantaged; and (5) push providers receiving large distributions from the uncompensated care fund to restate erroneously reported data in time for it to be used to better disburse the UC-DSH fund for FY 2019. CMS's progress in improving both the processes and data for UC-DSH disbursements were exceptional.

Consequently, we have much less to offer through this year's comment by way of critique on the use of WS S-10 to allocate and disburse the uncompensated care fund to providers. The FAH appreciates CMS's proposed approximately $1.5 billion increase in the UC-

DSH pool. Hospitals will need these funds to respond to an expected increase in the uninsured rate and as uncompensated care costs continue to rise. Otherwise, we have no specific comments to offer on CMS's calculation of Factors 1 and 2. Instead, for Factor 3 we offer below our review of the FY 2014 and 2015 WS S-10 data to help CMS identify how its efforts over the last year improved the quality of that data and to help CMS focus on where work still needs to be done. After our review of the data we make some additional recommendations about audit focus going forward and process improvements in an effort to further refine the quality of the data and the accuracy of provider payments for UC-DSH.

## A. An Analysis of Changes in Reported WS S-10 Data for FYs 2014 and 2015

In the early fall of 2017 CMS, at the urging of the hospital industry, amended its instructions for the preparation of WS S-10 in significant ways. The amendments were so significant that CMS appropriately allowed providers to amend their WS S-10s for FYs 2014 and 2015 to account for the changes. The deadlines for these amendments varied and expanded through the fall of 2017, until early 2018. The FAH and its members began assessing the quality and impact of the amended data beginning with the availability of the December 2017 update to HCRIS. As we became aware of continued and significant problems with the amended data apparently so did CMS, which began contacting many hospitals with deadlines to correct data by March 23, 2018 and then contacted additional hospitals in April. Some, but apparently not all of these corrections to WS S-10 data began to appear by the March 31, 2018 update to HCRIS. Below we set forth several data tables that array key data elements as they have changed in response to WS S-10 instruction amendments over time.

Table 1

**Summary of Charity Information from Worksheet S-10**
**Cost Reports beginning in FY 2014**
**Limited to Hospitals expected to received DSH in FY 2019**
**and that were not an IHS, PR or AIRP**

| HCRIS Data | Insured Charity Charges Line 20 Col 2 | Medicaid Charges in Insured Charges | Insured Charity Charges (1) | Total Charity Charges | Insured as a % of Total Charity |
|---|---|---|---|---|---|
| 3/31/17 | 9,797,628,036 | 739,670,725 | 9,154,780,565 | 64,763,052,812 | 14.1% |
| 12/31/17 | 10,289,450,080 | 755,587,195 | 9,602,670,624 | 77,922,423,270 | 12.3% |
| Change 3/31 to 12/31/17 | 491,822,044 | 15,916,470 | 447,890,059 | 13,159,370,458 | -1.8% |
| % Change 3/31 to 12/31/17 | 5% | 2% | 5% | 20% | |
| | | | | | |
| 3/31/18 | 6,670,416,693 | 794,352,041 | 5,876,064,652 | 80,112,188,375 | 7.3% |
| Change 3/31/17 to 3/31/18 | (3,127,211,343) | 54,681,316 | (3,278,715,913) | 15,349,135,563 | -6.8% |
| % Change 3/31/17 to 3/31/18 | -32% | 7% | -36% | 24% | |

(1) Insured charges was developed by subtracting Line 25 from worksheet S-10 from Line 20 Column 2 from Worksheet S-10

Table 1 above provides an analysis of changes to insured charity charges from the FY 2014 HCRIS data set as it appeared at three different updates, March 31, 2017, December 31, 2017 and March 31, 2018. These updates represent a view of the data before CMS made significant changes to the WS S-10 instructions, after hospitals were allowed to amend their reports to accommodate changes to the instructions, and finally after hospitals were individually contacted by CMS because those hospitals appeared to have significantly anomalous reported data in WS S-10. With the first amendment of the data, hospitals appeared to have continued to misinterpret the instructions and increased their insured charity charges (these represent insurance copayments discounted under charity care policies), along with adding the new category of uninsured discounts to total charity charges. But after CMS contacted certain hospitals in March of 2018, insured charity charges dropped by 36% from March 31, 2017, after initially rising 5% in the December 31, 2017 update. While we were surprised by that 36% decrease in a previously reported insured charity charge statistic, we were not surprised by the 20% and 24% increase respectively in total charity charges because of the new category of uninsured discounts that now factors in to total charity charges.

In Table 2 below we review the detail associated with the FY 2014 WS S-10 charity charge data associated with the reduction in insured charity charges between the December 2017 and March 2018 HCRIS updates to get a sense for where the large decrease in reported increased charity charges originated.

Table 2

**Comparision of Insured Charges between 12-31-17 and 3-31-18 HCRIS Files**

**Hospitals Limited to Hospitals Expected to receive DSH in 2019, HCRIS Data from 2014 Cost Report mad not an IHS, PR or AIRP Hospital**

| Prov # | Hospital Name | Insured Chgs 3-18 | Insured Charges 12-17 | Change | Hospitals | % Change | Latest HCRIS Update |
|---|---|---|---|---|---|---|---|
| 100001 | UF HEALTH JACKSONVILLE | 4,611,974 | 657,713,181 | (653,101,207) | 1 | -99% | 1/31/18 |
| 490009 | UNIVERSITY OF VIRGINIA MEDICAL CENTER | 15,996,695 | 611,623,181 | (595,626,486) | 1 | -97% | 3/30/18 |
| 340030 | DUKE UNIVERSITY HOSPITAL | 6,023,927 | 232,062,563 | (226,038,636) | 1 | -97% | 3/30/18 |
| 390115 | ARIA HEALTH | 11,676,843 | 206,249,014 | (194,572,171) | 1 | -94% | 3/22/18 |
| 450289 | HARRIS HEALTH SYSTEM | 21,450,823 | 169,728,289 | (148,277,466) | 1 | -87% | 3/29/18 |
| 220071 | MASSACHUSETTS GENERAL HOSPITAL | 76,970 | 130,776,088 | (130,699,118) | 1 | -100% | 1/23/18 |
| 050599 | UNIVERSITY OF CALIFORNIA DAVIS MEDICAL CENTER | 782,795 | 112,721,229 | (111,938,434) | 1 | -99% | 2/1/18 |
| 450040 | COVENANT MEDICAL CENTER | 7,982,815 | 116,177,122 | (108,194,307) | 1 | -93% | 1/19/18 |
| 110087 | GWINNETT MEDICAL CENTER | 5,494,358 | 99,772,143 | (94,277,785) | 1 | -94% | 1/18/18 |
| 310001 | HACKENSACK UNIVERSITY MEDICAL CENTER | 1,319,299 | 91,469,622 | (90,150,323) | 1 | -99% | 1/31/18 |
| 520098 | UNIVERSITY OF WI HOSPITALS & CLINICS AUTHORITY | 9,806,954 | 94,728,594 | (84,921,640) | 1 | -90% | 3/29/18 |
| 140242 | CENTRAL DUPAGE HOSPITAL | 31,246,496 | 114,994,478 | (83,747,982) | 1 | -73% | 1/18/18 |
| 140091 | THE CARLE FOUNDATION HOSPITAL | 9,409,301 | 92,803,042 | (83,393,741) | 1 | -90% | 1/18/18 |
| 340040 | VIDANT MEDICAL CENTER | 1,718,021 | 66,684,682 | (64,966,661) | 1 | -97% | 3/30/18 |
| 450209 | NORTHWEST TEXAS HOSPITAL | 43,517,426 | 106,917,391 | (63,399,965) | 1 | -59% | 1/31/18 |
| 340155 | DUKE REGIONAL HOSPITAL | 2,767,083 | 63,476,420 | (60,709,337) | 1 | -96% | 3/30/18 |
| 100135 | TALLAHASSEE MEMORIAL HOSPITAL | 3,209,307 | 58,895,833 | (55,686,526) | 1 | -95% | 3/15/18 |
| 060028 | SAINT JOSEPH HOSPITAL | 1,112,375 | 49,001,307 | (47,888,932) | 1 | -98% | 1/31/18 |
| 330191 | GLENS FALLS HOSPITAL | 1,673,887 | 48,349,386 | (46,675,499) | 1 | -97% | 3/9/18 |
| 050327 | LOMA LINDA UNIVERSITY MEDICAL CENTER | 92,369 | 46,355,060 | (46,262,691) | 1 | -100% | 3/29/18 |
| **Grand Total** | | **179,969,718** | **3,170,498,625** | **(2,990,528,907)** | **20** | **-94%** | |
| | Total all other Hospitals with Changes | 1,626,427,349 | 2,362,504,414 | (736,077,065) | 651 | -31% | |
| | Hospitals without Changes | 4,069,667,585 | 4,069,667,585 | 0 | 1,689 | 0% | |
| | All Hospitals | 5,876,064,652 | 9,602,670,624 | (3,726,605,972) | 2,360 | -39% | |

Table 2 above indicates that of $3.7 billion in insured charity charge reductions between the two HCRIS updates for FY 2014, almost $3 billion originates from 20 hospitals. The group of hospitals is similar but not identical for FY 2015 WS S-10 data, and the totals are almost identical; where of $3.7 billion in insured charity charge reductions, $2.85 billion came from the top 20 hospitals, and the rest of the reduction came from all others. See Table 3 below. This indicates to us that CMS's special initiative in March of 2018 was very effective in reducing misreported charity charges that otherwise would have inappropriately shifted a large share of the UC-DSH pool of funds to these 20 providers.

Table 3

**Comparision of Insured Charges between 12-31-17 and 3-31-18 HCRIS Files for FY 2015 Cost Reports**

**Hospitals Limited to Hospitals Expected to receive DSH in 2019, HCRIS Data from 2015 Cost Report and not an IHS, PR or AIRP Hospital**

| Prov # | Hospital Name | Insured Charges 3-2018 | Insured Charges 12-2017 | Change | Hospitals | % Change | Latest HCRIS Update |
|---|---|---|---|---|---|---|---|
| **Top 20 Reductions in Insured Charges** | | | | | | | |
| 100001 | SHANDS JACKSONVILLE MEDICAL CENTER | 4,966,422 | 657,713,181 | (652,746,759) | 1 | -99% | 1/18/18 |
| 490009 | UNIVERSITY OF VIRGINIA MEDICAL CENTE | 19,491,482 | 485,417,493 | (465,926,011) | 1 | -96% | 3/30/18 |
| 450124 | UNIVERSITY MED CENTER BRACKENRIDGE | 11,455,982 | 256,748,112 | (245,292,130) | 1 | -96% | 1/19/18 |
| 140114 | SWEDISH COVENANT HOSPITAL | 1,479,419 | 171,748,399 | (170,268,980) | 1 | -99% | 1/18/18 |
| 520098 | UNIVERSITY OF WI HOSPITALS & CLINICS | 10,639,712 | 151,239,205 | (140,599,493) | 1 | -93% | 3/29/18 |
| 050283 | VALLEY MEMORIAL HOSPITAL | 1,875,172 | 119,153,368 | (117,278,196) | 1 | -98% | 3/29/18 |
| 110087 | GWINNETT HOSPITAL SYSTEM INC | 4,908,536 | 116,664,481 | (111,755,945) | 1 | -96% | 1/18/18 |
| 340040 | PITT COUNTY MEMORIAL HOSPITAL | 1,455,170 | 104,709,238 | (103,254,068) | 1 | -99% | 3/30/18 |
| 390115 | ARIA HEALTH | 10,309,509 | 97,759,190 | (87,449,681) | 1 | -89% | 1/23/18 |
| 450102 | CHRISTUS MOTHER FRANCES HOSP-TYLER | 35,943,367 | 121,454,857 | (85,511,490) | 1 | -70% | 1/18/18 |
| 260065 | MERCY HOSPITAL SPRINGFIELD | 16,348,810 | 91,359,394 | (75,010,584) | 1 | -82% | 1/18/18 |
| 310001 | HACKENSACK UNIVERSITY MEDICAL CENTER | 110,784 | 70,185,154 | (70,074,370) | 1 | -100% | 2/1/18 |
| 450135 | TEXAS HEALTH FORT WORTH | 5,544,584 | 73,677,459 | (68,132,875) | 1 | -92% | 1/25/18 |
| 330191 | GLENS FALLS HOSPITAL | 2,180,002 | 69,966,468 | (67,786,466) | 1 | -97% | 3/9/18 |
| 100135 | TALLAHASSEE MEMORIAL HOSPITAL | 4,134,747 | 70,795,219 | (66,660,472) | 1 | -94% | 3/15/18 |
| 140067 | SAINT FRANCIS MEDICAL CENTER | 1,482,655 | 67,448,291 | (65,965,636) | 1 | -98% | 3/23/18 |
| 050231 | POMONA VALLEY HOSPITAL MED CTR | 361,850 | 66,227,413 | (65,865,563) | 1 | -99% | 3/29/18 |
| 050169 | PRESBYTERIAN INTERCOMMUNITY HOSPITAL | 1,650,132 | 67,203,862 | (65,553,730) | 1 | -98% | 1/31/18 |
| 100044 | MARTIN MEMORIAL MEDICAL CENTER | 2,759,758 | 67,149,411 | (64,389,653) | 1 | -96% | 3/28/18 |
| 450801 | CHRISTUS ST MICHAEL | 5,722,668 | 66,868,430 | (61,145,762) | 1 | -91% | 1/18/18 |
| Grand Total | | 142,820,761 | 2,993,488,625 | (2,850,667,864) | 20 | -95% | |
| | Total all other Hospitals with Changes | 1,758,163,544 | 2,638,185,605 | (880,022,061) | 744 | -33% | |
| | Hospitals without Changes | 4,351,672,630 | 4,351,672,630 | 0 | 1,626 | 0% | |
| | All Hospitals | 6,252,656,935 | 9,983,346,860 | (3,730,689,925) | 2,390 | -37% | |

We also reviewed bad debts reported on WS S-10 because that category of cost has been misunderstood and misreported in prior years. We focused our efforts on hospitals with the largest change in reimbursement for UC-DSH between the FY 2018 final and the FY 2019 proposed rules. That data is set forth in Table 4 below.

Table 4

**Top 10 Hospitals Bad Debt Trend**

**Sorted by Change in UC DSH Payments**

| | |
|---|---|
| Projected to Receive DSH in FY 2019 | YES |
| IHS,PR, or AIRP | NO |
| Data in 2014 | Yes |

| RANK | Medicare CCN | Hospital Name | Proposed 19 UC DSH Pmts | Final 2018 UC DSH Payments | Payment Change | 2013 Bad Debts | 2014 Bad Debts | 2015 Bad Debts |
|---|---|---|---|---|---|---|---|---|
| 1 | 490009 | UNIVERSITY OF VIRGINIA MEDICAL CENTER | 82,180,458 | 7,989,029 | 74,191,429 | 41,609,366 | 39,087,743 | 44,901,206 |
| 2 | 450289 | HARRIS HEALTH SYSTEM | 141,324,729 | 67,527,761 | 73,796,968 | 126,285,036 | 16,926,728 | 50,195,828 |
| 3 | 340030 | DUKE UNIVERSITY HOSPITAL | 51,724,278 | 16,954,669 | 34,769,609 | 34,681,115 | 48,471,219 | 42,804,235 |
| 4 | 450015 | PARKLAND HEALTH AND HOSPITAL SYSTEM | 86,829,828 | 55,322,661 | 31,507,167 | 371,106,723 | 217,047,539 | 233,689,859 |
| 5 | 100022 | JACKSON MEMORIAL HOSPITAL | 82,374,122 | 58,562,541 | 23,811,581 | 442,284,502 | 471,553,884 | 553,482,653 |
| 6 | 140124 | JOHN H STROGER JR HOSPITAL | 49,263,420 | 28,048,507 | 21,214,912 | 326,845,888 | 182,089,957 | 172,692,948 |
| 7 | 520098 | UNIVERSITY OF WI HOSPITALS & CLINICS AUTHORITY | 27,245,707 | 7,296,255 | 19,949,452 | 34,563,000 | 20,324,000 | 36,483,644 |
| 8 | 390115 | ARIA HEALTH | 20,564,012 | 6,950,119 | 13,613,894 | 16,918,571 | 14,217,542 | 12,325,094 |
| 9 | 340155 | DUKE REGIONAL HOSPITAL | 15,392,824 | 4,498,606 | 10,894,218 | 11,115,765 | 13,669,276 | 10,007,663 |
| 10 | 490022 | MARY WASHINGTON HOSPITAL, INC | 17,555,814 | 6,954,436 | 10,601,379 | 39,648,971 | 50,482,324 | 46,345,936 |
| **Grand Total** | | | **574,455,193** | **260,104,584** | **314,350,609** | **1,445,058,937** | **1,073,870,212** | **1,202,929,066** |

Data Sources:
FY 2019 IPPS Proposed Rule: Medicare DSH Supplemental Data File
CMS 3/31/2018 HCRIS File
Only includes hospitals expected to receive DSH payments in FY 2019, has HCRIS data in FY 2014 and is not a HIS, All Inclusive Rate or PR Hospitals.

In reviewing the trend in reported bad debt over a three-year period for each of these facilities, we noticed anomalies in the FY 2014 and 2015 periods for Provider Nos. 45-0289, 10-0022, and 52-0098 that bare further consideration by CMS. The bad debt component of the UC-DSH share equation can have a significant impact on a hospital's share of the pool.

In Tables 5 through 7 below we review edits of the WS S-10 data to identify areas of continued concern. In Table 5 below we reviewed the change in the number of providers with high charity charges in relation to total hospitals charges.

Table 5

**Summary of Charity Information from Worksheet S-10**
**Cost Reports beginning in FY 2014**
**Limited to Hospitals expected to received DSH in FY 2019**
**and that were not an IHS, PR or AIRP**

| HCRIS Data | Hospitals with S-10 Charges > 100% of C | Hospitals with S-10 Charges > 70% of C | Hospitals with S-10 Charges > 50% of C |
|---|---|---|---|
| 3/31/17 | 2 | 22 | 97 |
| 12/31/17 | 1 | 26 | 104 |
| Change 3/31 to 12/31/17 | (1) | 4 | 7 |
| % Change 3/31 to 12/31/17 | -100% | 15% | 7% |
| | | | |
| 3/31/18 | 1 | 25 | 103 |
| Change 3/31/17 to 13/31/18 | (1) | 3 | 6 |
| % Change 3/31/17 to 13/31/18 | -100% | 12% | 6% |

There has been an increase between the HCRIS updates from March 2017 to 2018 in hospitals with WS S-10 charity charges that are greater than 50% and 70% of charity charges. Hospitals with such high ratios merit further and detailed review.

In Table 6 below we consider hospitals reporting very high WS S-10 costs in relation to total costs, focusing on hospitals reporting WS S-10 costs at 50% and 25% of total costs. We

were surprised to find a large number of hospitals reporting WS S-10 costs at 25% of total costs, and that the number of such hospitals increased between the December 31 and March 31 updates for FY 2014 data.

Table 6

| Summary of Charity Information from Worksheet S-10<br>Cost Reports beginning in FY 2014<br>Limited to Hospitals expected to received DSH in FY 2019<br>and that were not an IHS, PR or AIRP | | | |
|---|---|---|---|
| HCRIS Data | Hospitals with Calc S-10 Cost > 50% of Total | Hospitals with Calc S-10 Cost > 25% of Total | |
| 3/31/17 | 7 | 44 | |
| 12/31/17 | 7 | 38 | |
| Change 3/31 to 12/31/17 | 0 | (6) | |
| % Change 3/31 to 12/31/17 | 0% | -16% | |
| | | | |
| 3/31/18 | 3 | 41 | |
| Change 3/31/17 to 13/31/18 | (4) | (3) | |
| % Change 3/31/17 to 13/31/18 | -57% | -8% | |

In Table 7 below we examine the change in the number of hospitals reporting very high cost to charge ratios for FY 2014 over the three HCRIS updates. We were pleased to see that no hospitals reported a cost to charge ratio equal to or in excess of 1 by the March 31, 2018 update, but are still skeptical of the quality of the data for hospitals reporting cost to charge ratios in excess of 0.6%.

Table 7

| Summary of Charity Information from Worksheet S-10<br>Cost Reports beginning in FY 2014<br>Limited to Hospitals expected to received DSH in FY 2019<br>and that were not an IHS, PR or AIRP | | | |
|---|---|---|---|
| HCRIS Data | Hospitals with CCR =1 | Hospitals with CCR=>1 | Hospitals with CCR >.6 |
| 3/31/17 | 0 | 5 | 33 |
| 12/31/17 | 0 | 3 | 31 |
| Change 3/31 to 12/31/17 | 0 | (2) | (2) |
| % Change 3/31 to 12/31/17 | #DIV/0! | -67% | -6% |
| | | | |
| 3/31/18 | 0 | 0 | 28 |
| Change 3/31/17 to 13/31/18 | 0 | (5) | (5) |
| % Change 3/31/17 to 13/31/18 | #DIV/0! | -167% | -16% |

Based on the above apparent aberrational relationships, we next looked for providers that typified aberrational characteristics by rank from the last available HCRIS update, March 2018. In Tables 8-10 below for FY 2014 WS S-10 data we examine the top 20 providers by total WS S-10 charges to total Worksheet C charges, total WS S-10 costs to Worksheet C costs, and total insured charges less Medicaid charges to total charity charges. In many respects the results are problematic to an accurate distribution of UC-DSH payments given that these problems should have been addressed by these providers through CMS's special efforts to contact hospitals in March of 2018.

Table 8

**Summary of UC Cost to Total Cost per Worksheet C**

Hospitals Expected to Receive UC DSH Payments in FY 2019

Sorted by the % of S-10 to Total Charges

Sources:

3/31/2018 HCRIS File for cost reports beginning in FY 2014

Proposed Rule Supplemental DSH File

Hospitals Limited to Hospitals Expected to receive DSH in 2019, HCRIS Data from 2014 Cost Report mad not an HIS, PR or AIRP Hospital

| | |
|---|---|
| IHS,PR, or AIRP | NO |
| New Hospital | (All) |
| Data in 2014 | 1 |
| Projected to Receive DSH in FY 2019 | YES |

| Prov # | Hospital Name | Total 19 UC DSH Payments | Total Charges S-10 | Worksheet C Charges | S-10 Charges % of Total Charges |
|---|---|---|---|---|---|
| 260048 | TRUMAN MEDICAL CENTER HOSPITAL HILL | 17,223,620 | 563,655,572 | 537,163,384 | 105% |
| 050113 | SAN MATEO MEDICAL CENTER | 1,869,064 | 397,798,568 | 415,948,605 | 96% |
| 140089 | MC DONOUGH DISTRICT HOSPITAL | 1,043,087 | 131,552,828 | 139,004,575 | 95% |
| 050668 | LAGUNA HONDA HOSPITAL & REHABILITATION CENTER | 229,956 | 283,474,977 | 302,950,660 | 94% |
| 450024 | UNIVERSITY MEDICAL CENTER OF EL PASO | 17,650,163 | 807,047,449 | 870,481,273 | 93% |
| 190006 | UNIVERSITY HOSPITAL & CLINICS | 9,712,630 | 207,449,223 | 230,495,286 | 90% |
| 050159 | VENTURA COUNTY MEDICAL CENTER | 4,289,678 | 739,262,138 | 889,170,006 | 83% |
| 450289 | HARRIS HEALTH SYSTEM | 141,324,729 | 2,591,984,147 | 3,130,849,937 | 83% |
| 190005 | UNIVERSITY MEDICAL CENTER NEW ORLEANS | 23,986,114 | 712,829,834 | 886,261,889 | 80% |
| 050543 | COLLEGE HOSPITAL COSTA MESA | 2,430,628 | 83,335,727 | 104,355,253 | 80% |
| 050089 | COMMUNITY HOSPITAL OF SAN BERNARDINO | 2,275,810 | 688,995,533 | 905,095,622 | 76% |
| 050149 | CALIFORNIA HOSPITAL MEDICAL CENTER LA | 6,418,968 | 976,623,705 | 1,285,260,891 | 76% |
| 190011 | UNIVERSITY HEALTH CONWAY | 3,427,281 | 102,948,264 | 137,563,409 | 75% |
| 330009 | BRONX-LEBANON HOSPITAL CENTER | 15,663,529 | 604,660,367 | 809,907,312 | 75% |
| 050738 | GREATER EL MONTE COMMUNITY HOSPITAL | 1,028,846 | 222,123,494 | 301,469,256 | 74% |
| 140124 | JOHN H STROGER JR HOSPITAL | 49,263,420 | 860,006,958 | 1,168,152,685 | 74% |
| 170194 | DOCTORS HOSPITAL LLC | 42,794 | 66,717,232 | 91,697,120 | 73% |
| 140077 | TOUCHETTE REGIONAL HOSPITAL INC | 1,043,143 | 40,200,915 | 55,346,974 | 73% |
| 450015 | PARKLAND HEALTH AND HOSPITAL SYSTEM | 86,829,828 | 3,174,040,748 | 4,383,019,743 | 72% |
| 050608 | DELANO REGIONAL MEDICAL CENTER | 1,410,695 | 151,732,074 | 210,250,191 | 72% |
| **Grand Total** | | **387,163,983** | **13,406,439,753** | **16,854,444,071** | **80%** |

Across these 20 hospitals on average, total WS S-10 charges averaged 80% of total hospital charges. No hospital could survive that situation for a year. Thus, we expect there is still significant over reporting of WS S-10 charges that need to be examined for these hospitals in advance of using this information to determine their share of UC-DSH payments.

Table 9 below identifies a relationship similar to Table 8, but uses costs instead of charges. Interestingly, the top 20 providers in this comparison are similar to but not identical with the providers identified in Table 8. We have the same concerns with the providers represented in this table as above.

Table 9

**Summary of UC Cost to Total Cost per Worksheet C**

Hospitals Expected to Receive UC DSH Payments in FY 2019

Sorted by the % of UC Cost to Total Cost

Sources:

3/31/2018 HCRIS File for cost reports beginning in FY 2014

Proposed Rule Supplemental DSH File

Hospitals Limited to Hospitals Expected to receive DSH in 2019, HCRIS Data from 2014 Cost Report mad not an HIS, PR or AIRP Hospital

| | |
|---|---|
| IHS,PR, or AIRP | NO |
| New Hospital | (All) |
| Data in 2014 | 1 |
| Projected to Receive DSH in FY 2019 | YES |

| Prov # | Hospital Name | Total 19 UC DSH Payments | Total Cost New Calc | Total Cost Worksheet C | UC Cost of W/S C Cost |
|---|---|---|---|---|---|
| 190006 | UNIVERSITY HOSPITAL & CLINICS | 9,712,630 | 61,262,308 | 94,924,807 | 64.5% |
| 450289 | HARRIS HEALTH SYSTEM | 141,324,729 | 669,072,616 | 1,056,611,978 | 63.3% |
| 100026 | BAY MEDICAL CENTER SACRED HEART HEALTH SYSTEM | 5,677,364 | 108,466,359 | 203,878,347 | 53.2% |
| 190183 | LEONARD J CHABERT MEDICAL CENTER | 5,868,190 | 34,928,075 | 74,606,819 | 46.8% |
| 110111 | UNIVERSITY HOSPITAL MCDUFFIE | 748,264 | 6,424,999 | 13,824,601 | 46.5% |
| 190011 | UNIVERSITY HEALTH CONWAY | 3,427,281 | 33,658,638 | 72,584,613 | 46.4% |
| 450015 | PARKLAND HEALTH AND HOSPITAL SYSTEM | 86,829,828 | 455,085,742 | 984,690,038 | 46.2% |
| 010008 | CRENSHAW COMMUNITY HOSPITAL | 425,844 | 4,923,225 | 11,371,256 | 43.3% |
| 190005 | UNIVERSITY MEDICAL CENTER NEW ORLEANS | 23,986,114 | 115,262,843 | 267,643,495 | 43.1% |
| 490022 | MARY WASHINGTON HOSPITAL, INC | 17,555,814 | 166,330,722 | 390,752,664 | 42.6% |
| 450209 | NORTHWEST TEXAS HOSPITAL | 13,331,870 | 74,184,741 | 202,408,558 | 36.7% |
| 440111 | METRO NASHVILLE GENERAL HOSPITAL | 7,012,264 | 30,434,310 | 83,373,338 | 36.5% |
| 150024 | ESKENAZI HEALTH | 27,287,348 | 159,392,883 | 440,097,059 | 36.2% |
| 190208 | EAST CARROLL PARISH HOSPITAL | 414,823 | 3,463,347 | 9,568,637 | 36.2% |
| 450024 | UNIVERSITY MEDICAL CENTER OF EL PASO | 17,650,163 | 94,791,904 | 265,455,516 | 35.7% |
| 190312 | OUR LADY OF THE ANGELS HOSPITAL | 4,212,029 | 15,800,470 | 44,720,489 | 35.3% |
| 360361 | KINGS DAUGHTERS MEDICAL CENTER OHIO | 588,710 | 6,625,996 | 18,837,241 | 35.2% |
| 140124 | JOHN H STROGER JR HOSPITAL | 49,263,420 | 235,313,277 | 669,756,526 | 35.1% |
| 450092 | FORT DUNCAN MEDICAL CENTER | 3,383,147 | 16,679,425 | 47,671,677 | 35.0% |
| 450124 | DELL SETON MED CENTER AT THE UNIVERSITY OF TX | 17,835,644 | 100,721,565 | 293,901,614 | 34.3% |
| **Grand Total** | | **436,535,477** | **2,392,823,444** | **5,246,679,273** | **42.6%** |

Table 10 below compares for each provider the reported total insured charity charges from WS S-10 with total charges reported on WS S-10. It is an interesting relationship because for these providers, almost all of the charity charges are equal to copayments forgiven under charity care policies. These providers are either under reporting other than uninsured charity charges or are misreporting such charges in insured charity charges.

Table 10

**Summary of Insured Charity Charges to total Charity Charges - Top 20**

Hospitals Expected to Receive UC DSH Payments in FY 2019

Sorted by the % of Insured Charity Charges to Total Charges

Sources:

3/31/2018 HCRIS File for cost reports beginning in FY 2014

Proposed Rule Supplemental DSH File

Hospitals Limited to Hospitals Expected to receive DSH in 2019, HCRIS Data from 2014 Cost Report mad not an HIS, PR or AIRP Hospital

| | |
|---|---|
| IHS,PR, or AIRP | NO |
| New Hospital | (All) |
| Data in 2014 | 1 |
| Projected to Receive DSH in FY 2019 | YES |

| Prov # | Hospital Name | Total 19 UC DSH Payments | Insured Charges Less Medicaid | Total Charity Charges | % Insured Charity Chgs to Total |
|---|---|---|---|---|---|
| 180106 | THE MEDICAL CENTER AT ALBANY | 225,401 | 54,832 | 54,832 | 100.0% |
| 390194 | BLUE MOUNTAIN HOSPITAL-GNADEN HUETTEN CAMPUS | 545,421 | 944,929 | 944,929 | 100.0% |
| 270003 | ST PETER'S HOSPITAL | 1,951,783 | 11,848,196 | 11,848,196 | 100.0% |
| 030069 | HAVASU REGIONAL MEDICAL CENTER | 787,027 | 16,044 | 16,044 | 100.0% |
| 180101 | GEORGETOWN COMMUNITY HOSPITAL | 473,113 | 134 | 134 | 100.0% |
| 080004 | BAYHEALTH - KENT GENERAL HOSPITAL | 3,931,244 | 8,729,150 | 8,729,150 | 100.0% |
| 220024 | HOLYOKE MEDICAL CENTER | 866,528 | 346,631 | 346,631 | 100.0% |
| 080009 | BAYHEALTH - MILFORD MEMORIAL HOSPITAL | 1,358,643 | 2,687,857 | 2,687,857 | 100.0% |
| 180021 | PINEVILLE COMMUNITY HOSPITAL | 285,170 | 171,309 | 171,309 | 100.0% |
| 180024 | SPRING VIEW HOSPITAL | 310,376 | 22,733 | 22,733 | 100.0% |
| 010008 | CRENSHAW COMMUNITY HOSPITAL | 425,844 | 3,210,659 | 3,213,863 | 99.9% |
| 360072 | FAIRFIELD MEDICAL CENTER | 6,166,781 | 44,496,707 | 45,361,442 | 98.1% |
| 230216 | MCLAREN PORT HURON | 1,168,008 | 78,071 | 79,591 | 98.1% |
| 160058 | UNIVERSITY OF IOWA HOSPITAL & CLINICS | 10,869,990 | 30,480,447 | 31,095,969 | 98.0% |
| 180053 | FLEMING COUNTY HOSPITAL | 191,489 | 133,185 | 136,587 | 97.5% |
| 500001 | NORTHWEST HOSPITAL | 1,839,996 | 7,072,634 | 7,341,359 | 96.3% |
| 500008 | UNIVERSITY OF WASHINGTON MEDICAL CTR | 6,463,247 | 17,174,384 | 18,046,234 | 95.2% |
| 050257 | GOOD SAMARITAN HOSPITAL | 568,365 | 170,849 | 184,032 | 92.8% |
| 190045 | ST TAMMANY PARISH HOSPITAL | 5,959,883 | 27,055,682 | 29,221,697 | 92.6% |
| 100026 | BAY MEDICAL CENTER SACRED HEART HEALTH SYSTEM | 5,677,364 | 92,015,555 | 99,978,980 | 92.0% |
| **Grand Total** | | **50,065,672** | **246,709,988** | **259,481,569** | **95.1%** |

All of the above indicates that CMS still has work to do to (1) audit reported WS S-10 data, and (2) educate providers about the correct way to report each line item relevant to the UC-DSH calculation on WS S-10. Some of that work should be done before CMS publishes the final rule for this year using this data for payment purposes.

## B. A Proposed Process to Correct and Apply Worksheet S-10 Data

While CMS has done much in the last year to cause the data in WS S-10 to be more usable to distribute UC-DSH payments, CMS still needs to take steps to cause hospitals to more accurately report that data and to actually audit the data rather than just prepare edits to identify gross aberrations in reported data. We propose a plan to address each of these steps below.

### 1. *CMS Should Identify Clarifying Instructions to WS S-10 in the Final Rule and Provide an Opportunity to Amend all Outstanding WS S-10s that Could be Used for Future UC-DSH Calculations*

Our members view the current instructions to WS S-10 to be reasonably clear. But data from the above Tables 4-10 suggest providers need further clarity in these instructions or education by CMS. We think the IPPS rulemaking process is a good place to begin to work through such issues as CMS has invited providers to do this year. Thus, we think the IPPS final rule this year is a good place to announce revised instructions that should be implemented by allowing providers to amend all outstanding WS S-10s to comply with those revisions. But CMS

is under no obligation to issue sub-regulatory guidance in the final rule. We simply believe that a process that announces possible changes in the instructions in the proposed rule, to elicit discussion, is a valuable tool for CMS moving forward. Other options could include an expert industry panel to advise CMS on instruction changes. We are not suggesting such instructions should be subject to rulemaking, just that the proposed and final rules are good vehicles to work through issues with the instructions and such vehicle for discussion is not available by simply publishing them in a manual. We also believe the process that CMS used this year to contact hospitals with data aberrations and provide a short timeline to fix such aberrations is valuable and should continue.

CMS should set a deadline of October 1, 2018 for providers to submit such amendments to their MACs. This would give CMS time to run edits or audit the data before the December HCRIS update. Providers could then see the results of such edits and audits in that update, and they would have time to work with their MACs to clean up issues with changes in their reported data before the March update, which can be used to prepare the UC-DSH calculations for the proposed rule.

*2. CMS Needs to Establish an Audit Protocol for Worksheet S-10 Data*

It is critical that CMS subject the WS S-10 data that would be utilized to distribute the UC-DSH payments to an audit review. Beginning for FY 2020, the most efficient method to do this would be a process similar to the annual wage index development process. This will likely take more effort in the initial years since charity charges have only rarely been audited for any hospitals (and only for EHR payment purposes) and the auditors have no experience with (a) non-Medicare bad debts or (b) insured charity charges or (c) uninsured discounts. In addition, individual hospitals would be directly impacted by their specific S-10 data versus the overall market level impact that occurs with the wage index. Because hospitals have an even greater interest in the correctness of such an audit than for the wage index, the process for hospital feedback in such audits should at least equal the process for the wage index.

We suggest CMS focus on FYs 2014 through 2016 data and identify at a high level, as we did in Part A of this comment, highly aberrant data reported by hospitals. In particular, just as we noted in Part A, as it did this year, CMS should focus on the major items that skew the Factor 3 calculation heavily in a provider's favor that are well out of normal ranges such as insured charity charges as a percentage of total charity charges, charity charges in relation to total charges, cost to charge ratios or claimed bad debt. But unlike this year, CMS should focus on the extent of the aberration and not, as we believe it did this year, on hospitals just at the top of the disbursements list. Hospitals reporting such aberrant data should be given a reasonable period of time to justify or replace their reported data with the understanding that if they cannot satisfy CMS with a reliable data element, for example, the amount of their non-Medicare bad debt, such data may be rejected entirely in the Factor 3 calculation, or subject to some local average replacement. As there is no administrative or judicial review of a hospital's UC-DSH payment, we believe the policy decision CMS makes on this issue – whether to reject the hospital's data entirely or substitute alternative data in its place – should be addressed through rulemaking.

### C. Problems with Proposed Rule Calculations

Our review also found there are over 200 hospitals expected to receive UC-DSH payments that had no change in the WS S-10 cost calculations for insured charity charges and bad debts applied to their FY 2014 cost reports. We are unclear why this happened, but CMS should ensure that this policy is applied to all such charge data whether or not it has been amended, in the final rule. This could be done by calculations outside of the cost report if necessary.

Finally, we think CMS should use the most recent HCRIS update, even if it entails a special run for CMS, when it finalizes the UC-DSH calculation for the final rule. We note that some amended data requested by CMS and timely provided by hospitals did not make its way into the March 2018 update. Consequently, CMS should use the May or later HCRIS update to ensure that the best data is used in the final rule. We also ask CMS to allow revisions to the WS S-10 data where the MAC mishandled the amendments submitted by the deadlines in CMS instructions. In a few cases the MACs have replaced the amended information that was included in the December 31, 2017 HCRIS file with older data in the March 31, 2018 HCRIS file. We are concerned this may occur after March 31st. A deadline of August 31st could be established to submit these changes.

## QUALITY PAYMENT PROGRAMS

### Meaningful Measures

The FAH commends CMS for its proposed application of the Meaningful Measures initiative to the hospital inpatient quality reporting and pay-for-performance programs. Prioritizing and reducing the number of quality measures across these programs addresses our previously expressed concerns about the burden of managing many measures and the unnecessary duplication of measures across programs. The FAH supports a focus on measures designed for improving patient care and working towards outcomes that are meaningful to patients. It is appropriate that in its review of the hospital quality programs CMS takes a holistic approach to evaluate each of the pay-for-performance program measures in the context of all three programs (readmissions reduction, hospital-acquired conditions reduction, and value-based purchasing).

In the proposed rule CMS proposed to adopt an eighth quality measure removal factor for the Value-Based Purchasing (VBP) Program, the Hospital Inpatient Quality Reporting (IQR) Program, and the Long Term Care Hospital Quality Reporting Program (LTCH QRP). This new quality removal factor aligns across both programs and would serve to remove measures where "the costs associated with a measure outweigh the benefit of its continued use in the program." The FAH supports the proposal to add an eighth factor, identified as the cost associated with a measure outweighing the benefit of its continued use in the program, to the lists of factors used for considering removal of measures from the Hospital VBP Program and the Inpatient Quality IQR Program and the LTCH QRP. This proposed new factor is appropriate for moving toward measure sets that meet the goal of streamlining measures with a focus on those that will work

toward the best outcomes for patients. The FAH appreciates that CMS has identified costs beyond those associated with data collection and submission. However, the costs associated with tracking performance and investing resources for quality improvement should be considered as well. It would be useful for CMS to clarify in the final rule the nature of the burden that the removal of a measure relieves, and methods or criteria used to assess when the measure cost or burden outweighs the benefits of retaining it.

Hospitals must have timely performance data for measures to be useful to informing and prioritizing quality improvement activities, which should be the primary goal of the various quality payment programs. Providing annual data on claims-based measure performance is insufficient for these needs and impedes hospitals' ability to improve care to patients. As CMS works to streamline measure sets to target those measures most meaningful for improving patient care, the availability of timely and actionable information should be considered. The FAH urges that CMS provide quarterly performance reports on claims-based measures so that hospitals can undergo self-assessments and take more timely action to address areas of concern.

**IV.H. Hospital Readmissions Reduction Program (HRRP)**

FY 2019 marks the implementation of a new readmission formula under which hospitals will be stratified into peer groups based on the percentage of patients who are Medicare-Medicaid dual eligibles for purposes of determining the HRRP payment adjustment. As previously finalized, CMS will use five peer groups and adjust the readmission formula to reflect the difference between the hospital's excess readmissions ratio and the median ratio for its peer group instead of a comparison with the national average.

FAH members have a long-standing belief that additional risk adjustment should be used to address social risk factors, in particular for readmissions and other outcome measures used in payment programs. The FAH believes the stratification approach that will begin in FY 2019 for the HRRP is a reasonable first step for addressing social risk factors. However, our members urge CMS to continue to analyze the impact of social risk factors on hospital readmission rates and to improve the risk adjustment of the readmission measures to account for social risk factors beyond dual eligibility status. While dual eligibility status is a reasonable initial proxy, CMS should undertake a more direct assessment of the effects of social risk factors through risk adjustment of the readmission measures to account for specific factors that are known to affect readmission rates and that are beyond the hospital's control. These may include community characteristics such as availability of healthcare providers and access to pharmacies and transportation as well as patient-level information such as education and language proficiency.

The presence of State Certificate of Need laws and regulations should also be considered. The current readmission measures are not easily used for purposes of continuous quality improvement, a critical element if the readmission reduction program is to be a quality improvement program and not simply a tool for implementing payment penalties. Annual release of hospital performance on these measures does not provide hospitals with sufficient information to track quality improvement, and the data and algorithms needed to self-assess performance on readmissions is not available. Routine quarterly reports, even if they are a rolling multi-year measure, would be a significant improvement over the annual only release of this information.

Even semi-annual reports would be an improvement and offer hospitals greater opportunity to develop specific interventions when readmission rates are higher than desired.

**IV.I. Hospital Value-Based Purchasing Program**

The FAH supports the proposed removal of ten measures from the VBP Program. Six of the measures proposed for removal also form the complete set of six measures used in the HAC Reduction Program. We agree that their removal from the VBP Program will eliminate unnecessary duplication and the risk of penalizing hospitals twice for the same measure. As the FAH has commented in the past, measures should be used in only one quality program. In addition, the FAH supports removal of the remaining Safety Domain measure, Elective Delivery (NQF #0469) as CMS has noted that performance on the measure no longer meaningfully differentiates hospitals for purposes of VBP Program scoring.

Removal of the three condition-specific episode payment measures (for AMI, heart failure, and pneumonia), all of which were previously finalized for future implementation, is appropriate because these conditions are included in the overall Medicare Spending per Beneficiary (MSPB) measure. If CMS does not finalize removal of these condition-specific episode payment measures as proposed, the MSPB measure should be modified to exclude these conditions. The FAH has expressed concerns in the past about the duplication of these measures within the VBP Program.

Further, the FAH continues to strongly encourage CMS to revisit the MSPB measure to address questions and concerns raised by the FAH and others during the last National Quality Forum (NQF) endorsement review. Specifically, it is critical to better understand how the measure performs given that the biggest driver for the measure is post-discharge costs. Currently, it is not clear how hospitals can substantially influence the total costs associated with a hospitalization given that 84% of all costs attributed to a hospital are in the 30 days following discharge. In addition, the previous testing found that there was a weak association between MSPB and the readmission measures. In light of these ongoing questions, the FAH remains concerned that the measure as currently specified could yield data that is not actionable or have unintended negative consequences on hospitals, particularly when used in VBP.

The FAH is also extremely concerned with the measure's risk adjustment approach. During the NQF review, the developer provided results that demonstrated a clear difference in costs between rural and urban hospitals, which may indicate that the current set of risk factors is insufficient. In addition, the FAH strongly believes that the conceptual basis and empirical analysis lacked rigor as several studies demonstrate other social risk factors that could potentially drive costs such as living alone, having unmet functional needs, lacking self-management skills, having limited education, inadequate health literacy, education levels, occupation, renting vs. owning their homes, and poor access to medical care were not addressed in the risk model. The FAH believes that the steps taken by NQF on ensuring that the measure was adequately assessed for inclusion of social risk factors in the risk adjustment approach were inadequate.

With the VBP Safety domain empty of measures under the CMS proposals in this proposed rule, the FAH supports removal of the safety domain and reweighting of the remaining

three domains for purposes of VBP Program scoring. The FAH supports the proposal to weight the Clinical Outcomes domain at 50% of the total score and the Patient Engagement and Efficiency domains retaining a weight of 25% each. The higher weight is justified because the Clinical Outcomes domain has multiple measures and improving clinical outcomes is the underlying goal of the VBP Program.

Improving the Hospitals Consumer Assessment of Healthcare Providers and Systems (HCAHPS)

The FAH strongly urges CMS to incorporate electronic deployment, for instance, through email, apps or web-based applications, of the HCAHPS survey as additional modes of administration. Hospitals struggle to increase low levels of response rates, which result, in part, from limitations of the current outmoded forms of deploying surveys.

**IV.J. Hospital-Acquired Condition (HAC) Reduction Program**

The FAH supports the proposed elimination of measure domains in the HAC Reduction Program, with assignment of an equal weight to all six performance measures. The FAH also believes that the variable domain weight alternative described in the proposed rule would be preferable to the current fixed domain weighting approach. While in the past the FAH has supported giving a greater weight to Domain 2 because the CDC NSHN infection measures are stronger measures than the claims-based patient safety composite, we agree with CMS that the current construct of two domains with disparate weighting results in anomalous weighting of measures for those hospitals that report on only a small subset of the Domain 2 measures.

The FAH understands the need to establish data reporting and validation requirements within the HAC Reduction Program if the proposed removal of the hospital-associated infection (HAI) measures from the IQR Program is finalized. However, the FAH is concerned about 1) the implications of hospitals potentially being separately selected for data validation for the IQR Program and HAC Reduction Program in the same year and 2) the implicit increase in burden for hospitals now needing to track two separate validation programs. CMS has previously adopted a policy under which a hospital that is selected for data validation under the IQR Program for a year is ineligible for selection for eCQM validation in that year. As part of the efforts to reduce provider burden, the FAH encourages CMS to finalize a policy under which a hospital selected for data validation under the IQR Program is not eligible for selection in that year for data validation in the HAC Reduction Program. In addition, the FAH encourages CMS to reduce hospital burden by ensuring that notices of inclusion and validation of results be located in a single interface and posted at the same time.

The FAH has serious concerns about the penalty applied to hospitals failing validation under the HAC Reduction Program. The Hospital HAC Reduction Program seeks to encourage hospitals to reduce HACs by penalizing the worst-performing 25% of hospitals. Under the proposed validation penalty method, a hospital failing validation may incur a penalty of 1% reduction to payments if it falls into the worst-performing 25% as a result of the failed validation; which is excessive especially when viewed against what is currently incurred for failing validation under IQR. Paradoxically, it is technically possible to fail validation for reporting HAC numbers that are higher than those the hospital actually has, suggesting that

failing validation does not necessarily imply being a worse performer. While the FAH understands the need to impose a separate validation process under the HAC Reduction Program because of the removal of these measures from the Hospital IQR program, the FAH requests that any validation failure penalty be no more than the penalty for failing validation under IQR. In addition. the FAH strongly requests that a validation failure not incorrectly apply the title of 'worst performer' to hospitals, which may be at fault for failing data quality submission rather than for having performance issues.

Finally, a recent report from the Agency for Healthcare Research and Quality (AHRQ) indicates that between 2014 and 2016, hospital acquired conditions were reduced nationwide by 8%. AHRQ calculated that this reduction of 350,000 hospital-acquired conditions helped prevent an estimated 8,000 deaths and saved $2.9 billion over a period of two years. This is a testament to the efforts of community hospitals in making care safer. Hospitals are dedicated to providing safe care to the communities they serve. They have been working tirelessly to make patients safer by reducing hospital-acquired infections and it is paying off. But despite the success, some hospitals are still being penalized by a system that does not recognize trends in improvement. The FAH continues to oppose the structure of the HAC Reduction Program in which facilities in the bottom 25th percentile receive penalties, regardless of their levels of performance or improvement.

## GRADUATE MEDICAL EDUCATION

### IV.K.2. Proposed Changes to Medicare GME Affiliated Groups for New Urban Teaching Hospitals

The FAH supports CMS's proposed revision to 42 C.F.R. § 413.79(e), which would provide additional flexibility for new urban teaching hospitals entering into Medicare graduate medical education (GME) affiliation agreements. Under current law, a new urban teaching hospital may enter into a Medicare GME affiliation agreement only if the resulting adjustment is an increase to its direct GME and indirect medical education (IME) full-time equivalent (FTE) caps. CMS is proposing to allow two or more new urban teaching hospitals to form a Medicare GME affiliated group, even where at least one will experience a decrease to its direct GME and IME FTE caps due to the affiliation. The FAH supports the proposal and agrees that flexibility with regard to Medicare GME affiliation agreements is warranted to promote cross-training of residents consistent with the intent of the Medicare GME affiliation agreement provision.

<u>The FAH Urges CMS to Issue Formal Guidance Concerning Rotating Residents</u>

The FAH urges CMS to also expand program flexibility by addressing the so-called "resident rotator" situation. It is the FAH's position that a small number of rotating residents should not trigger a non-teaching hospital's per-resident amount (PRA) for direct GME (DGME) reimbursement nor its DGME and IME FTE caps under the regulations for new programs at 42 C.F.R. § 413.79(e). CMS has broad statutory discretion to confirm that a hospital has not established a new medical residency training program by virtue of having a limited number of resident rotators and that the PRA and FTE caps are therefore not inadvertently triggered in these

situations. *See* 42 U.S.C. § 1395ww(h)(2)(F), (h)(4)(H)(i) (providing CMS with discretion to adopt PRA and FTE cap rules that it "determines to be appropriate" for new medical residency training "programs"). Doing so would not contravene existing statutes and regulations, and it would both foster residency program development and fair reimbursement to providers. To date, CMS has not issued formal guidance on the resident rotator situation. However, the FAH is aware of occasions on which CMS staff members have informally opined that the FTE cap and/or PRA is triggered in resident rotator circumstances.

The application of this informal interpretation prevents new teaching hospitals from developing robust new programs, simply because they previously allowed a small number of residents to rotate to their hospital. The FAH strongly urges CMS to issue formal guidance confirming that PRA and FTE caps are not triggered in resident rotator situations. This would avoid the imposition of artificially low caps or low PRA that might result when a small number of residents rotate to a non-teaching hospital.

## HOSPITAL INPATIENT ADMISSION ORDERS

### IV.M. Proposed Revision of Hospital Inpatient Admission Orders Documentation Requirements Under Medicare Part A

Hospital providers have had considerable confusion and significant concerns with the physician admission order requirements of 42 C.F.R. § 412.3 since their inception as part of the two-midnight rulemaking for IPPS 2014. The FAH and its members are therefore pleased that CMS is proposing to eliminate the requirement for an admission order in the patient medical record as part of this rulemaking. 83 Fed. Reg. at 20447-8.

In the FY 2014 IPPS final rule (83 Fed. Reg, at 20447), CMS adopted in regulation the requirement that a beneficiary becomes a hospital inpatient if formally admitted pursuant to the order of a physician (or other qualified practitioner as provided in the regulations) in accordance with the hospital conditions of participation (CoPs). That regulation also contained a subsection (c) that provided: "[t]he physician order also constitutes a required component of physician certification of the medical necessity of inpatient hospital services under subpart B of Part 424 of this Chapter." The regulatory cross reference is to 42 C.F.R. § 424.13, which at the time required the certification be completed for all inpatient stays before discharge. As a result, a new regulatory link was created that required completion of the inpatient physician order by discharge, because it was a necessary component of the physician certification.

However, as part of the CY 2015 OPPS final rule, CMS eliminated the physician certification requirement for the majority of inpatient stays, those under 20 days. (*See* 79 Fed. Reg. 66770, 66999 (Nov. 14, 2014).) To effectuate this change, CMS deleted then existing subsection (c) from section 412.3. Thus, the regulatory linkage that required the completion of the physician admission order (signature or authentication) at the same time as certification also was eliminated. Thus, the regulatory text clearly no longer required a completed admission order by discharge as of January 1, 2015. CMS never engaged in rulemaking to fill the gap resulting from that rule change.

Around the same time, CMS provided informal guidance as part of its two-midnight FAQs that allowed MACs to ignore the signed order requirement by exercising discretion to assess whether the patient medical record as a whole exhibited an intent to admit a patient as an inpatient. CMS acknowledges this discretion to disregard the signed admission order requirement in this proposed rule. 83 Fed. Reg. at 20447-8. CMS also acknowledges now that: "It was not our intent when we finalized the admission order documentation requirements that they should by themselves lead to the denial of payment for otherwise medically reasonable necessary inpatient stay, even if such denials occur infrequently." *Id.* at 20448. Our view is that CMS never imposed the written order requirement as a condition of payment after January 1, 2015, because conditions of payment are bright lines that do not have discretionary exceptions exercisable by private parties, especially when CMS acknowledges that it never intended the signed admission order requirement to be the sole determinant of whether a claim is paid. There was still a somewhat now less clear admission order requirement to be present in the medical record, but the nature of the evidence for that order is unclear from the regulation.

Whether CMS offers this change as a clarification of policy or a new policy is important because literally hundreds of thousands of claims may be or likely are in some stage of disclosure, denial or appeal, where the claim was denied solely because of the lack of, or a defect that resulted in the absence of, a signed admission order. All of these ultimately will end up in the appeal process unless CMS makes clear that this clarification of the rules is to effect CMS's original intent that the absence of a written physician order will not be the sole basis for the denial of a claim, which is nothing more than what CMS has stated in the proposed rule. This clarification is also consistent with 42 C.F.R § 482.24(c), which requires that the medical record as a whole should support an inpatient admission.

We therefore request that in the preamble language accompanying the final rule for this provision, CMS make clear the change clarifies CMS's original intent that solely the absence of a signed admission order is not intended to result in the denial of an otherwise supported and necessary inpatient claim.

In addition, the FAH requests further clarification of CMS's policy regarding documentation of the order in determining whether a patient is an inpatient. The proposed rule indicates that its proposal regarding the inpatient admission order "does not change the requirement that an individual is considered an inpatient if formally admitted as an inpatient under an order for inpatient admission." *Id.* at 20448. The FAH believes this statement could be viewed as being in conflict with the proposal that inpatient admission order is not required as a condition of Medicare payment. We believe that CMS is intending to indicate that its policy is the same with respect to determining when a patient becomes an inpatient (*e.g.*, formally admitted to the hospital pursuant to an inpatient admission order) but that documentation of that requirement will be flexible (*e.g.*, the hospital can use an inpatient order, progress notes, the medical record as a whole or other documentation that supports inpatient medical necessity is met and the hospital is operating in accordance with the hospital CoPs). Under such a policy, it would still be advisable for the hospital to retain an inpatient admission order as documentation of the intent to admit the patient, but it would not be the sole documentation that would provide support for an admission in the event the order is missing, defective, or not properly authenticated.

The FAH also requests that CMS clarify application of its sub-regulatory guidance to the inpatient order requirements. In guidance on the CMS website from January 30, 2014, CMS provides detailed requirements regarding the content of the inpatient admission order, the qualifications of the ordering/admitting practitioner, knowledge of the patient's treatment in the hospital, timing, and specificity of the order. (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/IP-Certification-and-Order-01-30-14.pdf). This guidance has also been incorporated into the Medicare Benefit Policy Manual, Chapter 1, section 10.2. Given the specificity of this guidance, the FAH is uncertain how it will apply if documentation of an inpatient order is not required. Again, we believe CMS is intending to indicate that if an inpatient order is used to document that a patient was admitted, CMS's sub-regulatory guidance will apply. However, the lack of order is not sufficient to deny an inpatient claim if other information in the medical record supports that an inpatient admission was medically reasonable and necessary.

## LONG-TERM CARE HOSPITAL PPS

### VII.C. Proposed Modifications to the Application of the Site Neutral Payment Rate

In December 2013, Congress significantly changed the LTCH PPS by establishing a second rate of payment that approximates what Medicare pays short-stay acute care hospitals (STACHs) under the IPPS.[2] This site neutral payment rate applies to all LTCH discharges under Medicare Part A that do not meet one of two patient criteria (*i.e.*, the ICU criterion or the ventilator criterion).[3] Congress provided a two-year transition period during which site neutral discharges are paid a blended rate between the site neutral payment rate and the standard LTCH Federal payment rate.[4] This initial transition period applied to LTCH discharges in cost reporting periods that began in FYs 2016 and 2017.[5]

In February 2018, Congress extended the transition period to the LTCH site neutral payment rate by two years under section 51005 of the *Bipartisan Budget Act of 2018*.[6] To pay for this extension, the same provision of the BBA included a 4.6% payment cut to the most common basis to calculate the site neutral payment rate—the IPPS comparable per diem amount.

The FAH supports CMS's proposal to implement section 51005(a) of the BBA by extending the transition period to site neutral payment for two more years, until discharges in LTCH cost reporting periods commencing on or before September 30, 2019. ***As discussed below, however, the FAH opposes CMS's proposal to implement the 4.6% payment cut to site neutral payments effective for discharges on or after October 1, 2017 for all LTCHs. The cut should only be effective for discharges in LTCH cost reporting periods that begin on or after October 1, 2017. The FAH also expresses its concern that CMS already began implementing these changes in early April 2018, based upon guidance issued in March that was not publicly available.***

---

[2] PSRA § 1206(a)(1).
[3] *Social Security Act* (SSA) § 1886(m)(6)(b)(ii).
[4] *Id.* at § 1886(m)(6)(b)(iii).
[5] *Id.* at § 1886(m)(6)(B)(i)(I); *see also* 42 C.F.R. § 412.522(c)(3).
[6] BBA § 51005.

## A. The Two Related Provisions of BBA Section 51005 Must be Read Together and Interpreted in that Context

Section 51005 of the BBA reads as follows:

> **SEC. 51005. EXTENSION OF BLENDED SITE NEUTRAL PAYMENT RATE FOR CERTAIN LONG-TERM CARE HOSPITAL DISCHARGES; TEMPORARY ADJUSTMENT TO SITE NEUTRAL PAYMENT RATES.**
>
> (a) EXTENSION.—Section 1886(m)(6)(B)(i) of the Social Security Act (42 U.S.C. 1395ww(m)(6)(B)(i)) is amended—
>
> (1) in subclause (I), by striking "fiscal year 2016 or fiscal year 2017" and inserting "fiscal years 2016 through 2019"; and
>
> (2) in subclause (II), by striking "2018" and inserting "2020".
>
> (b) TEMPORARY ADJUSTMENT TO SITE NEUTRAL PAYMENT RATES.—Section 1886(m)(6)(B) of the Social Security Act (42 U.S.C. 1395ww(m)(6)(B)) is amended—
>
> (1) in clause (ii), in the matter preceding subclause (I), by striking "In this paragraph" and inserting "Subject to clause (iv), in this paragraph"; and
>
> (2) by adding at the end the following new clause:
>
> "(iv) ADJUSTMENT.—For each of fiscal years 2018 through 2026, the amount that would otherwise apply under clause (ii)(I) for the year (determined without regard to this clause) shall be reduced by 4.6 percent.".

Both subsection (a) and subsection (b) use the term "fiscal year" without specifying hospital fiscal year or federal fiscal year. However, by reading each change along with the part of the Medicare statute it amends (Section 1886(m)(6)(B)(i)), it is clear that this subsection extended the blended rate of 50% site neutral payment and 50% LTCH PPS standard Federal payment rate to site neutral payment case discharges in *cost reporting periods* beginning in FY 2016 through FY 2019. Specifically, BBA section 51005(a)(1) extended the blended payment rate simply by striking from the Medicare statute the existing years in which the blended payment rate applied (*i.e.*, FY 2016 and FY 2017) and inserting the new years in which the blended payment rate applies (*i.e.*, FYs 2016 through 2019). Prior to the BBA, section 1886(m)(6)(B)(i)(I) of the Social Security Act stated that the blended payment rate applied "for discharges in cost reporting periods beginning during fiscal year 2016 or fiscal year 2017." The text of the complete SSA provision at issue, both before and after the BBA, states that the blended payment rate applies based on "discharges in cost reporting periods."[7]

Subsection (b) adds a new paragraph to the same part of the Medicare statute (Section 1886(m)(6)(B)) that reduces the IPPS comparable per diem amount for LTCH site neutral cases by 4.6% to pay for the extension of the blended rate. The BBA states that the cut applies to

[7] SSA § 1886(m)(6)(B)(i)(I).

"fiscal years 2018 through 2026."[8] In this context, the "fiscal years" for applying the 4.6% payment cut must mean cost reporting periods because the entire section 1886(m)(6)(B) of the Medicare statute defines the applicable site neutral payment rate by cost reporting periods, and that is the only way to harmonize Section 51005 with the previously codified section it amends.

Congress included only these two provisions in BBA section 51005. The first provides additional relief to LTCHs, the second provision pays for that relief. Accordingly, both provisions should be implemented consistently.

CMS inconsistently interprets these provisions in the FY 2019 IPPS/LTCH PPS proposed rule. Regarding the 4.6% payment cut to the IPPS comparable per diem amount for site neutral cases, CMS states only that "[i]n order to implement section 51005(b) of Pub. L. 115-123, we are proposing to revise § 412.522(c)(1) by adding new paragraph (iii) to specify that, for discharges occurring in FYs 2018 through 2026, the amount payable under § 412.522(c)(1)(i) (that is, the IPPS comparable amount) will be reduced by 4.6 percent."[9]

CMS provides no further explanation in the preamble to the proposed rule or in the transmittal, so it is unclear whether the Agency ever considered the inconsistency between the effective dates of the payment cut and the transition period extension. The FAH submits these comments in the hope that CMS will correct this inconsistency in the final rule.

### B. The Legislative Intent of BBA Section 51005 Supports Using Hospital Fiscal Year for the Effective Date of the Cut to the IPPS Comparable Per Diem Amount

Congress expressly enacted the 4.6% payment cut to the IPPS comparable per diem amount in BBA section 51005 to pay for the additional two years that LTCHs would benefit from the extension of the blended payment rate for site neutral cases. This legislative intent compels use of consistent effective dates for the extension of the rate and the cut so that they are implemented simultaneously based on the hospital's fiscal year, not the federal fiscal year. This intent is confirmed by the CBO score for the BBA and by the CRS analysis of the BBA.

The CBO's analysis of the BBA scored both provisions of section 51005 together because the 4.6% payment cut pays for the extension of the transition period with the blended payment rate.[10] They are intertwined. The CRS analysis of the BBA reached the same conclusion. CRS stated that the cost of the transition period extension is offset by the 4.6% cut to the IPPS comparable per diem amount.[11]

---

[8] BBA § 51005(b)(2).

[9] Transmittal 4046, Change Request 10547 (May 10, 2018), replacing Transmittal 3986 (March 2, 2018). The MACs were not allowed to share the original transmittal with providers because it was marked "Sensitive and Controversial." *Id.* at 1. The MACs began repricing LTCH claims in accordance with the original transmittal on April 2, 2018. *Id.* The FAH does not understand the basis for withholding this guidance from LTCHs for more than two months. CMS has to date not provided any explanation for the delay.

[10] *See* Congressional Budget Office, Estimated Direct Spending and Revenue Effects of Division E of Senate Amendment 1930, the Bipartisan Budget Act of 2018 3 (2018).

[11] *See* Paulette C. Morgan, Cong. Research Serv., R45126, Bipartisan Budget Act of 2018 (P.L. 115-123): Brief Summary of Division E—The Advancing Chronic Care, Extenders, and Social Services (ACCESS) Act 23 (2018)

Accordingly, it is clear that Congress intended for the 4.6% cut to the IPPS comparable per diem amount to pay for the extension of the transition period for site neutral payments, which is effective for LTCH cost reporting periods that begin in FY 2018**.** CMS's proposal to implement the 4.6% payment cut based on the federal fiscal year is not consistent with this intent.

It also would be inconsistent and inequitable for CMS to implement the extension of the blended payment rate and the 4.6% cut to the IPPS comparable per diem amount at different times. If the federal fiscal year is deemed the effective date of the 4.6% cut, many LTCHs will see their site neutral payments cut long before (in fact, in some up to 11 months earlier) they are entitled to the extension of the blended payment rate, whereas other LTCHs will suffer no premature reduction at all. Such incongruity and inequity could not have been Congress' intent. CMS can easily resolve these issues by implementing the 4.6% payment cut based on hospital fiscal years, not the federal fiscal year.

CMS's proposed interpretation is also inconsistent with the rest of the site neutral payment statute and regulation. The site neutral statute at SSA section 1886(m)(6) consistently uses cost reporting period start dates as the effective dates for changes in site neutral payments.[12] The existing regulation for site neutral payments implementing SSA section 1886(m) also uses cost reporting periods as the effective dates for all aspects of the site neutral payment rate.[13]

**VII.E. Proposed Elimination of the "25-Percent Threshold Policy" Adjustment**

CMS applies the 25% Rule to LTCH discharges of patients in excess of an applicable percentage threshold, which is 25% (or up to 50% for rural LTCHs and referring hospitals that are urban single or MSA-dominant). Under the 25% Rule, discharges in excess of the threshold (25% or 50%) are paid at the lesser of the applicable LTCH PPS payment amount or an ''IPPS equivalent'' amount. The 25% Rule's full implementation has been frozen for most of its history pursuant to moratoria established under the *Medicare, Medicaid and SCHIP Extension Act of 2007* (MMSEA), and, as amended, under section 15006 of the *21st Century Cures Act.* CMS also extended the relief period under section 412.538 by an additional year through regulation.

CMS now proposes to terminate the 25% Rule. CMS states that the site neutral payment rate created a "financial incentive for LTCHs to limit admissions according to the criteria for payment at the LTCH PPS standard Federal payment rate." Accordingly, CMS now "recognize[s] that the policy concerns that led to the 25-percent threshold policy may have been ameliorated, and that implementation of the 25-percent threshold policy would place a regulatory burden on providers."

CMS also proposes, however, that a one-time budget neutrality adjustment of 0.990535 be applied to the FY 2019 LTCH PPS standard Federal payment rate, to avoid an increase in

("The cost of the extended phase-in period is offset by reducing the applicable Inpatient Prospective Payment System-comparable per diem amount by 4.6% for FY 2018 through FY 2026.").

[12] *See* SSA § 1886(m)(6)(A)(i) ("For a discharge in cost reporting periods beginning on or after October 1, 2015 . . . ."); *Id*. at § 1886(m)(6)(B)(i)(I) ("[F]or discharges in cost reporting periods beginning during fiscal years 2016 through 2019 . . . ."); *Id.* at § 1886(m)(6)(C)(i) ("For cost reporting periods beginning during or after fiscal year 2016 . . . .").

[13] *See* 42 C.F.R. § 412.522.

aggregate LTCH PPS payments. This additional BNA would only be applied to the LTCH PPS standard Federal payment rate, or such portion of a blended payment during the extended transition period to site neutral payment, but not to the site neutral payment rate.

## A. The 25% Rule Should be Eliminated

***The FAH supports CMS's proposal to eliminate the 25% Rule at 42 C.F.R. § 412.438 (previously 42 C.F.R. §§ 412.534 and 412.536).*** The 25% Rule deters the admission of patients who are otherwise appropriate for the LTCH level of care, arbitrarily caps the number of patients an LTCH can admit from any hospital yet still receive a full payment, and thus interferes with the normal LTCH admissions process.[14]

The 25% Rule is not a statutory requirement. Rather, CMS developed the 25% Rule entirely through regulations in 2004, 2006 and 2016. CMS created the 25% Rule principally based on its assertion of the need to: (1) limit patient shifting driven by financial considerations from STACHs to LTCHs, (2) address the statutory prohibition under section 1886(d)(1)(B) of the Act that LTCHs cannot be units of another hospital, and (3) limit non-co-located LTCH discharges in Section 412.536 based upon concerns about discharge patterns among commonly owned hospitals. The 25% Rule policies thus can be modified or retired by CMS action alone.

As noted earlier, Congress has on several occasions frozen the 25% Rule to give CMS time to reconsider the need for this policy. Both of the statutes that established moratoria, MMSEA, as amended, and the *Pathway for SGR Reform Act of 2013* (PSRA), also required CMS to reevaluate the 25% Rule payment adjustment policies and explain to Congress why these policies would still be needed after the adoption of LTCH patient and facility criteria that would distinguish between payment rates. Now that CMS has done so, it is time to eliminate the 25% Rule policies once and for all.

***The FAH contends the 25% Rule regulations should be eliminated because they are not consistent with the new system of LTCH patient criteria and thus are no longer needed – the new LTCH patient criteria address the same policy concerns that led CMS to establish the 25% Rule in the first place***.

Congress stated in the PSRA that patient discharges meeting the LTCH patient criteria are to be paid at the standard LTCH PPS standard payment amount—not some amount that approximates the IPPS payment amount. The 25% Rule, thus is facially inconsistent with this statutory requirement because the 25% Rule would still reduce payments for discharges above the 25% threshold, even though they meet the new patient criteria, to an IPPS equivalent amount.

The FAH further contends that merely delaying the effective date of the new 25% Rule regulation again will not resolve any of the concerns about the 25% Rule. CMS has already had ample time during the many statutory and regulatory moratoria on the 25% Rule regulations to reevaluate this policy. Since CMS proposes to formally eliminate the policy, the FAH asks that CMS retire the regulations in the FY 2019 final rule.

[14] Notably, MedPAC has characterized the 25% Rule as a "blunt" and "flawed" policy for this reason. Report to the Congress: Medicare Payment Policy, MedPAC, Ch. 10, at 237 (March 2011).

For the reasons discussed above, CMS also should not allow Section 412.538 to go into effect in October 2018 as CMS has suggested is an alternative. LTCH providers nationwide are just now learning how to work within the framework of the new dual-rate payment system. If Section 412.538 takes effect, all Medicare patients could be harmed by the artificial admission limits under this policy, as it is likely to affect providers' choices in accepting patients.

## B. CMS Should Not Apply a Budget Neutrality Adjustment (BNA) when Retiring the 25% Rule

***The FAH believes that CMS should not adopt the 25% Rule BNA. The LTCH patient criteria and site neutral payment rate already serve as a true functional replacement for the 25% Rule, as CMS envisioned.*** 82 Fed. Reg. 37990, 38319 (Aug. 14, 2017). CMS apparently agrees since CMS now states that the site neutral payment rate "likely results in LTCH providers closely considering the appropriateness of admitting a potential transfer to an LTCH setting, regardless of the referral source, thereby lessening the concerns that led to the introduction of the 25-percent threshold policy."

A budget neutrality adjustment with the repeal of the 25% Rule also is inconsistent with how prior moratoria on the 25% Rule were implemented. In the case of each prior statutory moratorium, no BNA was adopted by CMS...[15] Likewise, CMS adopted no BNA when it adopted either of the two prior regulatory moratoria of the 25% Rule, the most recent being only in 2017. Yet, in the current proposed rule, CMS states that the full repeal of the 25% Rule "would be expected to result in an increase in aggregate LTCH PPS payments." But CMS offers no explanation in the proposed rule as to why there is suddenly a need for a BNA in FY 2019 given that no prior moratoria on the 25% Rule included a BNA.

The FAH agrees that the LTCH patient criteria and site neutral payment rate fully address whatever concerns CMS had that led to the creation of the 25% Rule. Discharges that meet one of the two narrow categories under LTCH patient criteria have been expressly determined by Congress to be appropriate for care in LTCHs and paid for at the standard Federal rate. Accordingly, there would be no inappropriately added costs to the Medicare program as a result of the repeal of the 25% Rule, since all patients not meeting LTCH criteria are paid at the site neutral rate (or a blended rate during the transition period), based on the IPPS rate.

Moreover, the FAH contends that finalizing a BNA for the repeal of the 25% Rule will have the same effect as permanently applying the 25% Rule. CMS is proposing a 0.990535 BNA that will reduce the FY 2019 standard federal payment rate by approximately 1%. According to CMS, this adjustment is supposed to reduce aggregate payments to LTCHs by the amount that the repeal of the 25% Rule allegedly increases costs to the Medicare program in FY 2019. However, because CMS is not simultaneously proposing to increase Medicare payments by the same 1% amount in FY 2020, the effect of this "one-time" adjustment actually constitutes a permanent reduction to all LTCH payments for standard rate cases.

[15] CMS did not include a BNA in connection with the adoption of any of the 25% Rule regulations at 42 C.F.R §§ 412.534, 412.536 and 412.538, even though these regulations are not budget neutral because they cause a reduction in Medicare payments for discharges in excess of the applicable percentage thresholds.

If CMS finalizes the proposed 25% Rule BNA, providers' LTCH payments will be permanently reduced by an amount equal to the estimated effect of the 25% Rule in FY 2019, had the regulation at section 412.538 gone into effect. This means that the BNA will reduce aggregate LTCH payments by roughly $36 million next year, *and each and every year that follows*. Moreover, this reduction will affect *all* LTCHs, not just those previously impacted by the 25% Rule. The FAH objects to such a policy. This is neither fair to LTCH providers nor consistent with Congressional intent.

The FAH contends further that if CMS continues to include the proposed BNA in the final rule, the BNA will be significantly overstated given that CMS has not accounted for likely behavioral changes by providers with respect to admissions and discharges. There are a number of behavioral differences between FY 2016 discharges that CMS evaluated for the BNA and the FY 2019 discharges that will occur if the 25% Rule at section 412.538 actually were to go into effect. CMS did not account for these behavioral differences when calculating the BNA factor in the proposed rule. Such differences include, but are not limited to: adjustments for prior moratoria that lessened the expected impact of the 25% Rule, the fact that during most or all of 2016, freestanding LTCHs were not subject to the 25% Rule at all, and more lenient thresholds for HwHs and rural providers.

These behavioral differences stem from the fact that whenever the 25% Rule was in effect, LTCHs changed their behavior by trying to limit admissions of patients from the same referral source when the LTCH was at risk of exceeding the applicable percentage threshold. Accordingly, if the 25% Rule were still effective in FY 2019, LTCHs would be expected to continue to make these behavioral changes to limit the number of discharges subject to payment adjustment. CMS fails to account for this phenomenon in the proposed rule. 82 Fed. Reg. 37990, 38316 (Aug. 14, 2017).

The FAH contends that, at a minimum, if CMS decides to include a behavioral adjustment when calculating any BNA for the repeal of the 25% Rule, any such BNA would need to account for the decrease in LTCH admissions over the applicable threshold percentage that would have occurred if the 25% Rule was in effect. As a result of such behavior changes, there would be far fewer LTCH admissions exceeding LTCHs' applicable threshold percentages in FY 2016 MedPAR files that CMS is using to calculate this BNA, and the BNA should be reduced significantly.

**Addendum IV.D. Proposed Adjustment for LTCH PPS High Cost Outlier (HCO) Cases**

CMS is proposing to continue to use the current high-cost outlier policies for standard Federal payment rate cases and site neutral payment rate cases, as initially modified in the FY 2016 IPPS/LTCH PPS final rule. Specifically, CMS has indicated it plans to maintain separate HCO targets, one for LTCH PPS standard Federal payment rate cases and one for cases paid at the site neutral payment rate. CMS is modifying the current LTCH PPS HCO payment methodology for LTCH PPS standard Federal payment rate cases in FY 2019, reducing the 8% outlier "pool" to 7.975% pursuant to section 15004 of the *21st Century Cures Act*. CMS also is proposing to continue to use the target that is used for IPPS HCO payment of 5.1% for HCO payments to cases paid at the site neutral payment rate.

CMS is proposing an FY 2019 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $30,639, based upon only cases that meet the new patient criteria; this represents a very significant increase from $27,381 in FY 2018, and even sharper increases from $21,943 in FY 2017 and $16,423 in FY 2016. CMS is proposing a $27,545 FY 2019 fixed-loss amount for cases paid at the site neutral payment rate, which is an increase from proposed FY 2018 IPPS fixed-loss amount of $26,537.

While the FAH generally supports using a target amount of 8% (now 7.975%) for HCOs paid using the LTCH PPS standard Federal payment rate, the FAH is once again concerned about another significant increase in the proposed FY 2019 fixed-loss amount of $30,639 for LTCH PPS standard Federal payment rate cases. This represents a 12% increase from FY 2018 and a 40% increase from the FY 2017 fixed-loss amount of $21,943. These large increases from year to year are concerning and not consistent with CMS's policy goal of mitigating instability in the HCO fixed-loss amounts for LTCH PPS standard Federal payment rate cases. ***CMS should provide more information in the proposed rule for the annual payment update to the LTCH PPS about how it calculates the outlier threshold for LTCH standard rate cases. In particular, CMS should provide the charge inflation factor and an explanation of how it was calculated, as CMS already does for the IPPS.***

In addition, some of the instability is traceable to an anomaly impacting only one provider and should be corrected for. In attempting to understand the cause or causes for the $3,258 increase in the outlier threshold for LTCH Standard Rate cases from $27,381 for FY 2018 to $30,639, the FAH is aware that Watson Policy Analysis (WPA) undertook a comprehensive review of outlier claims in the data CMS used to set the outlier thresholds for FYs 2018 and 2019 by provider. The review for each provider included total outlier payments, the cost to charge ratio used to pay outlier claims, the number of such claims and the average reimbursement for each claim compared to national averages.

WPA's review discovered a significant anomaly in the data that caused the threshold to increase by $1,096 of the $3,258 increase. A new provider appeared in the data that was not present in the FY 2018 claims data used to calculate the threshold for that year. That provider, Carolinas Continuecare Hospital, Provider No. 34-2021, appears for the first time in the FY 2019 impact file. This provider received $7.5 million in outlier payments, which is 2.65% of all outlier payments. Yet, the provider had only 87 cases out of 74,878 (0.116%) standard rate cases according to CMS, and 76 of its 87 standard rate cases were outlier cases. Across all of their cases, outlier and non-outlier, the outlier payments averaged $86,000 per case. The cost to charge ratio used by its MAC to pay the outlier claims was 1.029%.

Given the very high cost to charge ratio used to pay the provider, and the fact that the provider was not in the impact file in the prior year, the provider either is a new provider and had a CCR assigned to it for outlier payment purposes, or an erroneous CCR was assigned to the provider for outlier payment purposes. In either event, that CCR was so high that the provider's outlier payments will be reconciled when the provider's cost report is settled. Indeed, the next highest CCR in the impact file is 0.7 and that provider received only $543,000 in outlier payments, Provider No. 23-2029. The majority of provider cost to charge ratios in the impact file fall below 0.4. The most recent HCRIS update indicates that Provider No. 34-2021 has an

actual cost to charge ration of .323 from its filed June 30, 2017 year-end cost report, which shows $14,625,758 of total charges and $4,727,723 of total costs.

Therefore, CMS is setting the outlier threshold for FY 2019 based on an erroneous data element that significantly influences the calculation of the threshold. ***CMS can and should eliminate the influence of Provider No. 34-2021's data in the outlier threshold calculation either by using the above actual CCR to determine what if any outlier payments the provider would have received for this year or by eliminating the provider's data entirely.*** Either approach would have the same effect, reducing the threshold by about $1,096. CMS has used this approach most recently in calculating provider UC-DSH Factor 3 percentages, by requiring providers with anomalous data to correct or normalize their data before it could be used to calculate their Factor 3 percentages.

Budget Neutrality Adjustment (BNA) for Site Neutral HCO Cases

CMS also proposes to continue to apply a BNA reduction factor of 5.1% under section 412.522(c)(2)(i) to all cases paid at the site neutral payment rate (including the site neutral payment rate portion of blended rate payments during the transition period) so that HCO payments for site neutral cases will not result in any change in estimated aggregate LTCH PPS payments.

***The FAH strongly disagrees with CMS's proposal to apply an additional 5.1% BNA for site neutral cases that qualify as high-cost outliers. As the FAH explained in previous years' comments, this BNA is duplicative and unwarranted because CMS has already applied budget neutrality adjustments to reduce the operating and capital portions of the IPPS standard Federal payment rate by the same 5.1%, before using that rate to determine the IPPS comparable per diem amount for site neutral payment cases.***

The IPPS comparable per diem amount, as determined under section 412.529(d)(4), is "based on the sum of the applicable operating inpatient prospective payment system standardized amount and the capital inpatient prospective payment system Federal rate in effect at the time of the LTCH discharge."[16] CMS claims that a separate BNA for LTCH site neutral HCO cases will "reduce differences between HCO payments for similar cases under the IPPS and site neutral payment rate cases under the LTCH PPS and promote fairness between the two systems." 83 Fed. Reg. at 20596. However, by aligning this proposed policy with the IPPS payment system—and making the IPPS comparable per diem amount and the IPPS fixed-loss amount the primary components—CMS also is required to consider the adjustments that it has *already* made to the proposed IPPS and capital PPS payment rates to account for outlier payments. And, as noted earlier, CMS already reduced the operating standardized payment amount under the IPPS and the capital federal rate under the capital PPS for outliers. As CMS explains, these 5.1% (IPPS) and 5.06% (capital) outlier adjustment factors, respectively, already reduce the IPPS and capital PPS payment rates. *Id.* at 20582-84.

MedPAC's prior May 31, 2016 comment letter states that CMS should not apply a separate budget neutrality adjustment to site neutral high-cost outliers because "the IPPS

[16] 42 C.F.R. § 412.529(d)(4)(i)(A).

standard payment amount is already adjusted to account for HCO payments."[17] The FAH agrees with MedPAC that this BNA is duplicative and should not be applied. CMS should only adjust LTCH site neutral payments once for outlier budget neutrality.

CMS's unwillingness to address these issues directly the past two years requires that we raise them again for further consideration this year. The FAH asks that CMS acknowledge these concerns, as it appears incorrect for CMS to have applied the 5.1% (0.949) site neutral HCO BNA to FY 2016, FY 2017 and FY 2018 site neutral payments for the same reasons that CMS should not apply this BNA to FY 2019 site neutral payments. Accordingly, ***CMS should reverse this adjustment to all FY 2016, FY 2017, and FY 2018 payments, or make an equivalent prospective increase in payments to FY 2019 site neutral rate cases to account for this continuing underpayment.***

## QUALITY DATA REPORTING

### VIII.A. Hospital Inpatient Quality Reporting Program

Removal of Measures

The FAH strongly supports the proposed removal of 39 measures from the IQR Program. We agree that the IQR Program measure set should be streamlined to focus on those measures, which are not addressed in one of the three pay-for-performance programs, and meet the goal of improving patient care and outcomes that are most meaningful to patients.

Performance on 19 of the 39 measures proposed for removal will continue to be reported on the Hospital Compare website because these measures will continue to be part of one of the three acute hospital pay-for-performance programs. As noted in the proposed rule, eliminating duplication of measures across programs will prevent situations in which hospitals must track performance on the same measures for different performance periods. For example, for the CDC NSHN infection measures, the IQR Program reporting period is one calendar year (e.g., 2016 performance for FY 2018 payment), and for the HAC Reduction Program, it is two consecutive calendar years (2015 and 2016 performance for FY 2018 payment). We appreciate that CMS understands that the burden of quality measurement is not limited to data collection and submission; hospitals must track performance and develop quality improvement strategies for all measures, even those that are calculated by CMS based on claims data.

Of the remaining 20 measures proposed for removal, seven are electronic clinical quality measures (eCQMs). The FAH agrees with CMS that reducing the number of eCQMs would create a streamlined measure set and make it easier for vendors to maintain specifications for the

[17] MedPAC Comment Letter to CMS re: File Code CMS-1655-P at 16 (May 31, 2016). The letter states further: "MedPAC urges CMS to eliminate the proposed payment adjustment for discharges paid the site-neutral rate to account for outlier payments under this payment methodology. Given that the IPPS standard payment amount is already adjusted to account for HCO payments, CMS's proposal to reduce the site-neutral portion of the LTCH payment by a budget neutrality adjustment of 0.949 is duplicative and exaggerates the disparity in payment rates across provider settings. Given this duplication, CMS should not adjust the site-neutral rate further." *Id*. @ 16-17 (emphasis added).

available eCQMs. If the proposal is adopted, hospitals would choose to report on 4 out of 8 available eCQMs instead of the current 4 out of 15 measures for both the IQR Program and the Medicare Promoting Interoperability Program. The rationales offered by CMS for removing the specific measures proposed for removal are appropriate: only one hospital reporting (AMI-8a); measures that are based on documentation without evaluation of clinical quality (STK-8, STK-10 and CAC-3); retention of the chart-abstracted version (PC-01); little benefit to measuring widely practice standard of care (EDHI-1a); and another measure offers more actionable information (ED-1).

In addition, CMS is proposing to remove the seven eCQMs for CY 2020 collection period/FY 2022 payment determination period. The FAH does not think there is benefit in waiting a year to remove these measures and proposes removal of these measures be made effective for the CY 2019 collection period/FY 2021 payment determination period.

Another six of the measures proposed for removal are condition-specific episode payment measures, and the FAH supports removal of these measures because there are no associated clinical quality measures for these conditions in the IQR Program measure set. The FAH agrees with CMS that information on episode payment is not useful to Medicare beneficiaries in choosing and comparing providers absent information on clinical quality as well.

Finally, four chart-abstracted clinical quality measures are proposed for removal from the IQR Program. The FAH has long believed that the measures used in any of the quality reporting or pay-for-performance programs should provide value in the data generated in proportion to the intensity of the data-collection effort. While chart-abstraction data collection may be necessary to develop some measures that are beneficial in advancing clinical quality improvement and guiding consumer choices, the FAH supports removal of the specific measures as proposed. As CMS has noted, the measure of patient influenza immunization (IMM-2) is topped out. The two emergency department throughput measures (ED-1 and ED-2) proposed for removal are duplicated by the available reporting of the eCQM version of ED-2, and the similar outpatient quality reporting program measure (OP-18, Median Time from ED Arrival to ED Departure for Discharged ED Patients). Finally, the preventable venous thromboembolism measure (VTE-6) overlaps with two related eCQMs (VTE-1 and VTE-2).

Modified PSI-90

The FAH welcomes the removal of the PSI 90 patient safety composite measure from the Hospital VBP Program and requests that it also be removed from the IQR Program. Given the changes made to the composite, the FAH does not yet know how a hospital's performance will shift when used in this program nor does the FAH believe that these population-based measures are appropriate for hospital accountability. The potential differences in performance and ranking should be explored and education should be provided before it is implemented in the program.

Impact to Hospital Overall Star Ratings

The removal of some measures from the IQR program raises the question of the impact to the Hospital Overall Star Ratings. The FAH requests clarification on whether these measures

will remain in Hospital Compare and Hospital Overall Star Ratings through some other mechanism or if the intention is to remove these measures from the star ratings methodology. Along those lines, the FAH requests that analysis of the impact to star ratings as a result of the removal of these measures be conducted.

Data Submission for eCQMs

Regarding the proposals for data submission of eCQMs, the FAH supports continuation of the 90-day reporting period for the 2019 reporting year (2021 payment determination). However, we urge CMS to also finalize the same 90-day reporting period for 2020 reporting year, as this policy is proposed with respect to 2020 reporting of eCQMs in the Promoting Interoperability Programs. We appreciate that CMS has aligned the eCQM requirements between the two programs and encourage CMS to continue this in the future as long as there is an eCQM reporting element in both.

Hospital-Wide Mortality Measures

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

As we noted during the last comment period in February 2017, we do not believe that the rationale for this measure provides sufficient evidence that a death in the 30 days following an inpatient admission is an indicator of the quality of care provided by a hospital and may well be due to other factors outside of a hospital's control. The articles and research cited to demonstrate the importance and underlying evidence to support the measure continue to be solely focused on mortality while in the hospital. The FAH does not believe that adequate justification has been made for these measures.

It was the FAH's understanding that while the developer did not believe that social risk factors should be included in the risk model, testing would be completed to determine whether adjustment of these risk factors was warranted. Regrettably, it appears that this testing was not done. The FAH believes that some clinical diagnoses and outcomes will be impacted more significantly by social risk factors (e.g., availability of services such as pharmacies and transportation). Measures must be specified to ensure that they produce results that are reliable and valid and enable fair comparisons. By not examining whether any one of these community-level factors should be included, there is increased risk that a hospital's true performance will be misrepresented and could provide inaccurate information to patients and their families. The FAH strongly urges CMS to complete additional testing to determine whether social risk factors should be included.

The FAH also questions the usefulness of the measure given the limited variation in performance scores with only six hospitals identified as statistically worse than the national average and the majority of the hospitals (92.4%) were no different than the national average. We do not believe that this measure provides any new information that would be useful to hospitals and patients. The proposed approach to report the probability that a hospital is

statistically different than average is potentially worth exploring but examples on how this information would be displayed and whether it would be understandable to a patient and their family or useful to a hospital for quality improvement must be examined further prior to its implementation.

The FAH has several concerns related to the lack of evidence to support the measures' focus, lack of testing for social risk factors in the risk adjustment approach, and limited usefulness of the results for quality improvement and accountability purposes. As a result, the FAH strongly urges CMS to complete additional testing to address many of these questions and concerns prior to implementation of the measure in a federal program.

Hospital Harm – Opioid-Related Adverse Events eCQM

The FAH recognizes the need to address these important patient safety events. However, if CMS proceeds with further development and testing of this measure, the degree to which this measure yields sufficient variation in performance scores across all hospitals must be determined. While the eCQM addresses events that are useful to be tracked for quality improvement, the FAH is concerned that the differences in scores may be minimal and may not yield reliable and valid representations of performance across the hospitals. This question should be examined to ensure that comparisons in the quality of care can be made and are useful to allow patients and families to distinguish higher quality of care, and by hospitals for quality improvement.

The FAH also strongly encourages CMS to assess the feasibility of collecting the required data elements from electronic health record systems (EHRs) for each of the four measures. The FAH is concerned that the complexity of the measure and, particularly the complexity of the numerator, may significantly impact an individual hospital's ability to successfully collect and report on each measure. Thorough assessments of each data element and the required calculations and logic must be vetted across several hospitals and vendor systems to truly understand whether the measure is ready to be implemented in EHRs. If the measure is not determined to be feasible in the majority of vendor systems currently used, then it would be prudent for CMS to delay further testing and implementation of the measures until these gaps in EHRs data capture and reporting can be addressed.

In addition to thorough feasibility assessments, determinations on whether this measure is reliable and valid must be completed. As noted above, the numerator of this measure is complex and as a result, there is increased risk for missing data and errors in data capture and calculation that could distort results and misrepresent the truly quality of care provided by hospitals. Comprehensive testing for reliability and validity, including at the individual data element level, and NQF endorsement must be completed prior to implementation in any federal program.
In conclusion, the FAH urges CMS to carefully assess the feasibility, reliability, and validity of each of these eCQMs prior to implementation in a federal program. Misrepresenting the quality of care must be avoided and careful evaluations of each testing area must be completed to ensure that it does not occur. We also request that CMS determine whether additional work is needed on the Hospital Harm – Hypoglycemic measures or if the existing NQF-endorsed measure should be considered instead.

**VIII.C. Long-Term Care Hospital Quality Reporting Program**

The FAH supports the proposed removal of three measures from the LTCH Quality Reporting Program; two measures beginning with the FY 202 LTCH QRP and one measure beginning with the FY 2021 LTCH QRP. The FAH supports removal of (1) National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716); and (2) National Healthcare Safety Network (NHSN) Ventilator- Associated Event (VAE) Outcome Measure (NQF #1716).

The NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716) is duplicative with NHSN Central line-associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139) which is a better measure as it is more strongly associated with the desired patient outcome for bloodstream infections than the NHSN Facility-wide Inpatient Hospital-Onset MRSA Bacteremia Outcome Measure (NQF #1716). The FAH supports the removal of the NHSN VAE Outcome Measure (NQF #1716) as other measures in the program have the same focus and are more strongly associated with desired patient outcomes than the NHSN VAE Outcome Measure.

The FAH supports removal of Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) beginning with the FY 2021 LTCH QRP as most patients are vaccinated prior to admission outside of the LTCH.

The proposed rule notes that CMS is considering multiple methods of notification of non-compliance with the LTCH QRP. The FAH appreciates CMS's attempt to accommodate multiple methods of notification to help ensure receipt of these notifications. However, the FAH requests that CMS send notices to a single designated representative through a pre-selected single method of notification to ensure that noncompliance notices be received.

## PROMOTING INTEROPERABILITY PROGRAMS

**VIII.D. Proposed Changes to the Medicare and Medicaid EHR Incentive Programs (Now Referred to as the Medicare and Medicaid Promoting Interoperability Programs)**

CMS proposes many modifications to the requirements that eligible hospitals and CAHs must meet to demonstrate meaningful use of certified electronic health record technology (CEHRT). ***The FAH appreciates that the proposals address concerns raised by the field about the feasibility of operationalizing current requirements, including reducing the number of objectives and measures, maintaining the minimum 90-day reporting period in 2019 and 2020, providing additional flexibility for Program scoring, and removing the Coordination of Care Through Patient Engagement objective and associated measures.*** We continue to believe that interoperable CEHRT can be a conduit for having the right information in the right place at the right time, resulting in better care for patients and empowering patients (and their caregivers) to assume a more active role in their own care. The comments and suggestions offered below are

intended to support the goals of advancing interoperability and increasing the use of health information technology.

### VIII.D.3. Certification Requirements

The proposed rule reaffirms the previously adopted requirement that for the 2019 reporting year, all hospitals and CAHs must use technology certified to the 2015 Edition in order to meet the meaningful use requirement. The FAH understands CMS's desire to move to the 2015 Edition to advance interoperability. However, CMS is also proposing changes to the objectives and measures that would require numerous updates to current EHR systems. If the proposed rule is finalized, even providers that have previously implemented the 2015 Edition will have limited time to work with vendors to make the significant modifications needed in order meet all the meaningful use requirements. CMS notes in the proposed rule that, "As of the beginning of the first quarter of CY 2018, ONC confirmed that at least 66 percent of eligible clinicians and 90 percent of eligible hospitals and CAHs have 2015 Edition available...." 83 Fed. Reg 20517. However, availability does not necessarily equate to delivery and implementation. Based on experience, it can take up to 15-18 months to implement such changes, which could make it difficult for some providers to meet even the 90-day reporting requirement. ***Given these operational concerns, should CMS move forward with requiring the 2015 Edition in 2019, we believe providers should be given more flexibility to select measures, and the points required for meeting meaningful use should be adjusted to reflect these implementation issues.*** These are discussed in further detail below.

### VIII.D.4. EHR Reporting Period in 2019 and 2020

The FAH thanks CMS for its proposal to maintain a minimum 90-day reporting period for the 2019 and 2020 reporting years. In light of the requirement to use the 2015 Edition only and the many other changes in meaningful use requirements proposed in the rule, we appreciate the flexibility provided in maintaining the 90-day reporting period for 2019 and 2020. As noted above, the many changes in objectives and measures will require adjustments to EHR software that cannot be quickly implemented by vendors, so allowing hospitals to continue to choose a 90-day reporting period is essential.

### VIII.D.5. Proposed Scoring Methodology Under the Medicare Promoting Interoperability Program

The proposed rule would revamp the scoring of objectives and measures for purposes of determining whether an eligible hospital or CAH is a meaningful user of CEHRT, including: reducing the number of objectives and measures; calculating a performance score for most measures; assigning points based on the performance score, with a minimum of 50 points total across all objectives and measures required for a hospital or CAH to be considered a meaningful user of CEHRT. These changes would replace the current system, which requires performance to a predetermined threshold for every measure, with failure to meet a single threshold resulting in failure to meet meaningful use.

***The FAH appreciates CMS's desire to provide additional flexibility for eligible hospitals and CAHs and the focus on interoperability. The proposed scoring changes are an improvement over retaining the current Stage 3 scoring requirements but are also fresh changes to the Program that will take time to implement.*** As discussed above, the 15-18 months needed to operationalize these new requirements may make it difficult for some providers to meet even the 90-day reporting requirement, and the FAH encourages CMS to be mindful of these timelines when proposing Program adjustments. Given these operational concerns, we urge CMS to monitor this transition closely for unanticipated implementation issues. CMS should also build additional flexibility into the methodology for the final rule to further address provider burden and keep the focus on information sharing, including:

- Hospitals and CAHs should be able to choose which measures to report across objectives to meet the minimum points threshold. This would permit them to identify the measures that are best suited to their EHR technology and experience.

- The proposed minimum number of points required to be considered a meaningful user should be phased in. Even with the proposed shortened 90-day reporting period, adapting to the new objectives and measures and achieving a level of performance needed to meet 50 points may prove difficult for some hospitals. We recommend that for the initial implementation, the minimum threshold be set at 30 points. The threshold could be adjusted up to 50 points in the future as hospitals gain experience with the 2015 Edition objectives and measures.

In addition to these flexibilities, we are interested in understanding how the proposed changes to the Medicare Promoting Interoperability Program would align with the objectives and measures for the Merit-based Incentive Payment System (MIPS) for physicians and other clinicians. All providers participating in these programs should be working toward the same ends, and many hospitals engage in MIPS reporting on behalf of their clinicians. For these reasons, to the greatest extent possible the objectives and measures of these programs should be aligned.

**VIII.D.6. Proposed Measures Under the Medicare Promoting Interoperability Program**

***The FAH thanks CMS for proposing to simplify the Program measures and objectives, in particular, removal of the Coordination of Care Through Patient Engagement objective and associated measures.*** This removal is a relief to our members because hospitals should not be assessed on the extent to which patients chose to engage with their electronic health record, something over which providers have little to no control. The FAH appreciates CMS's continued commitment to reevaluating measures on an ongoing basis to ensure they are achieving their intended outcome and offers additional recommendations regarding Program measures below.

<u>E-prescribing</u>

The FAH supports continuation of the existing e-prescribing measure, although we request clarification that hospitals continue to have the flexibility to include or exclude controlled substances from the measure calculation as long as they do so uniformly across

patients and all available schedules and in accordance with applicable law. Our members found the discussion in the preamble to be confusing in this regard.

The proposed rule proposes to add two new measures involving opioids to this objective, first as voluntary measures with bonus points available in 2019, and then as mandatory measures in 2020. The FAH supports initially introducing all new measures that CMS may propose to add to the Program as voluntary measures eligible for bonus points. Regarding these specific measures, while the FAH supports the attention to measures involving opioids as an important topic area, we do not believe that they are ready for implementation and instead recommends that CMS not finalize a mandatory implementation date for either of these measures until the specifications and operational aspects are more fully developed. Further, as discussed below, we recommend that the opioid treatment agreement measure not be implemented at all – not even voluntarily – at this time.

One proposed new measure, "Query of Prescription Drug Monitoring Program (PDMP)," assesses the number of Schedule II opioid prescriptions for which CEHRT data are used to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law. Our members cite current challenges associated with querying PDMPs, most notably the lack of integration of this feature into CEHRT. In addition, PDMPs maintain and exchange data differently, which poses problems when a provider must query multiple state PDMPs. We urge CMS to work with the ONC to ensure interoperability between and among PDMPs (i.e., data movement across states), as this will improve the usefulness of PDMP queries to fight opioid addiction. Finally, the FAH urges CMS to further refine the measure to limit queries of the PDMP to once during the stay regardless of whether multiple medications are prescribed during that time. As the patient would be in the same facility during the stay and is unlikely to be receiving prescriptions from other providers during that time, this refinement makes sense and would reduce provider burden associated with multiple PDMP queries.

The FAH does not believe the second proposed new measure, "Verify Opioid Treatment Agreement," is appropriate for implementation – even voluntarily – at this time. This measure would require hospitals to identify whether the patient has an active signed opioid treatment agreement and incorporate it into the patient's electronic medical record using CEHRT. While we understand and applaud the goal behind this proposal, the questions asked by CMS in the proposed rule underscore that no definition exists for such treatment agreements, and no processes exist for incorporating them into a medical record using CEHRT. As a result, providers will be burdened with attempting to locate and determine what qualifies as a treatment agreement, and the measure will produce information that is inconsistent and not useful to physicians in preventing and treating opioid addiction and abuse. Additionally, 2019 (or 2020) is too soon to implement this measure as none of the elements are clear, and vendors will need more than a few months to modify and incorporate it into CEHRT. Instead, CMS could address the desire for this information by working with ONC and standards development organizations to establish a data class that would allow providers to exchange treatment agreement information as part of the Continuity of Care Document (CCD) or other routine data currently exchanged. This would obviate the need for a separate action to track down and incorporate treatment agreements, reducing both provider and patient burden. As to the latter, if providers are unable to locate

and/or determine what constitutes a treatment agreement, they may resort to asking the patient to sign a new one, burdening the patient and leading to multiple, potentially conflicting documents.

Additionally, the FAH requests that CMS clarify that the term "electronically prescribed," which is used in the denominators of the two proposed new measures, delineates prescriptions that are electronically documented within a patient's medical record from those that are "electronically transmitted," as referenced in the numerator of the current e-prescribing measure. We believe this distinction is appropriate and want to be sure this understanding is what CMS intends.

Health Information Exchange

The FAH generally supports the new combined measure proposed in this objective, "Support Electronic Referral Loops by Receiving and Incorporating Health Information," as well as the exclusion that would apply to any hospital that could not implement the measure for the 2019 reporting period. This measure would build on and replace two measures previously adopted for Stage 3, and vendors will need sufficient time to make these features functional, and then hospitals will need time to implement them. Even if the medical record system is modified to provide hospitals the ability to satisfy this measure, it would represent considerable effort for hospitals to perform all the elements of reconciling medication, medication allergy, and current problem lists.

To address these operational concerns, the FAH suggests that CMS consider phasing in elements of this measure or scoring it in such a way that a hospital meeting some of the elements would receive points. For example, CMS could greatly reduce the provider burden associated with the proposed measure by requiring only that the medication, allergy, and problem information be in the record and available for provider review. The audit logging capabilities of the EHR could be leveraged to show that a provider reviewed the patient's medications, allergies, and problem list rather than requiring that the provider formally "reconcile" the information by checking a box or providing a signature within the EHR. Alternatively, if CMS finalizes a requirement for a formal reconciliation action, the measure should initially focus only on medication and allergy reconciliation. If problem lists are later added to the measure, CMS should require only that these lists be incorporated into the record and available to the clinician rather than requiring problem list reconciliation.

The FAH also urges CMS to permit hospitals to be credited with providing shared access to the medical record in addition to sending and receiving information. The goal of the measure is for other providers to view patient medical records, and this should include contracted physicians or others located elsewhere in the hospital's system who view the record without having to formally "send" and "receive" the information.

The FAH also seeks clarity on what information would increment in the numerator of the measure. Specifically, we request that CMS clarify that the reconciliation process can involve manual updates to the electronic record and not rely solely on information that is received electronically. This flexibility would be consistent with what CMS has indicated in past

rulemaking and allow the receiving provider to utilize both information received electronically and information received directly from the patient.

Provider to Patient Exchange

The FAH supports removal of the Patient Specific Education measure, but we continue to have deep concerns about the measure that would be renamed "Provide Patients Electronic Access to Their Health Information." This measure requires hospitals to ensure that the patient's health information is available to them using any application of their choice that meets the API technical specifications. While we recognize the potential value of API functionality, it is new in the 2015 Edition, there are concerns about API readiness across stakeholders, and our members are only just beginning to test the API feature. Importantly, because applications are proprietary, this proposal would require hospitals to interact with a wide range of products with whom they have no relationship or agreement. Our members are very concerned about the security of APIs and various applications from multiple standpoints, including lack of security of patient data (e.g., smartphone applications are not generally subject to HIPAA), as well as making their electronic health records vulnerable to malware, hacking, and data mining. Hospitals must be empowered to protect their systems – and their patients' HIPAA-covered protected health information – from unproven and potentially harmful applications and, as such, should not be considered "information blocking" for forgoing relationships with questionable applications.

We urge CMS to work with ONC to establish a trust framework for third party applications, including security standards, terms of use, and an overall validation process, as well as an agency-led (e.g., CMS, ONC, OCR, FTC) hotline for stakeholders to report inappropriate application security or data usage. In developing this framework, it is imperative that third party application developers be held accountable for any inappropriate use of patients' health information and liable in the event of breach of such information. And, similarly, we encourage CMS and its agency partners to ensure that providers that comply with a patient request to share data with a third-party application are not liable for any breach or inappropriate data usage on the part of that application. While the FAH stands ready to work with CMS and the other agencies to help develop this trust framework, it is unrealistic and burdensome to expect individual providers to vet the security of third-party applications.

It is also unrealistic and burdensome to expect individuals to understand the difference between HIPAA-covered entities, such as hospitals, and non-HIPAA-covered entities, such as most smartphone applications. CMS, ONC, OCR, and FTC should undertake a joint campaign to educate patients about the differences between HIPAA and non-HIPAA-covered entities, and how that may affect the ways in which their data is used, stored, and shared with others. Given these uncertainties, the FAH recommends that, until there is more robust infrastructure to vet applications – or patients can access their data under the Draft Trusted Exchange Framework and Common Agreement (TEFCA), CMS should allow providers to begin with an application of their choice instead of being required to interact with any application a patient may choose. This recommendation carefully balances patient access to data with providers' need to protect their systems and patient health information. Additionally, as mentioned above, the FAH believes the infrastructure envisioned under the TEFCA could provide patients with the access to their medical records that CMS envisions. Specifically, providers could direct patients seeking their

electronic health information to the Qualified Health Information Network (HIN) and ensure HINs are appropriately situated to respond to and fulfill these patient inquiries as a condition of becoming a Qualified HIN.

Public Health and Clinical Data Exchange

The FAH supports the proposal to reduce the number of public health measures on which eligible hospitals and CAHs must report, down from three measures in Stage 3. The proposal for measures in the Public Health and Clinical Data Exchange objective would be improved, however, if hospitals could report on any two measures in the category instead of being required to report the Syndromic Surveillance measure and one other. Syndromic surveillance is not available in some states, including California, Iowa, and Oklahoma, so it is not appropriate as a mandatory measure. While the choice of any two measures is preferable, at a minimum, if the Syndromic Surveillance measure is made mandatory in the final rule, hospitals meeting the exclusion for this measure should be able to choose an alternative measure to report instead of having the ten points for this objective reassigned to the Provider to Patient Exchange objective. In addition, we recommend that hospitals be eligible for bonus points (e.g., five points) for reporting on a third measure in this objective.

Participating in public health data exchange can be burdensome to multistate health systems because there is a lack of uniformity across states in formats and other features. Instituting uniformity across states would reduce these costs and administrative burden. In addition, as the Administration moves forward with developing the Draft TEFCA, CMS might consider using that infrastructure to enable Qualified HINs to report these data to states rather than individual providers. Lastly, to help support development of APIs, CMS should offer bonus points to hospitals willing to participate in emerging standards pilots for API-based public health reporting.

**VIII.D.8. Promoting Interoperability Program Future Direction**

The FAH appreciates CMS's commitment to continually reevaluating the Promoting Interoperability Program to reduce burden, support alignment with the Quality Payment Program, advance interoperability, and promote innovative uses of health information technology (HIT). The FAH supports the idea of developing and/or designating some "priority health IT activities" as alternatives to the current measures-based Program. FAH members participate in regional and state health information exchanges, and the Draft TEFCA offers potential for enhanced interoperability through voluntary engagement with Qualified HINs. For example, CMS suggests the possibility that a hospital participating in TEFCA would be deemed to meet the Health Information Exchange objective. The FAH generally supports such an approach and recommends that – until the TEFCA is further revised and becomes operational – CMS provide full credit for the Health Information Exchange objective to providers who participate in a HIN. The FAH provided detailed comments on the Draft TEFCA (Attachment A), including the need: 1) for a second version of the TEFCA (Draft TEFCA 2.0) on which stakeholders would again be invited to comment; and 2) to align the TEFCA with the Promoting Interoperability Programs to the fullest extent possible (e.g., allowing providers to implement one open API to satisfy both participation in the TEFCA and requirements under the Promoting

Interoperability Programs). This and other steps to align these initiatives would result in greater electronic data exchange and promote interoperability.

### VIII.D.9. Clinical Quality Measurement in the Promoting Interoperability Programs

The FAH appreciates the continued alignment between the IQR Program and the Interoperability Program requirements for reporting of eCQMs. For both programs, the proposed rule would continue to require that hospitals report on 4 self-selected measures, and the available measures would be reduced to 8 from the current 16 measures beginning with the 2020 reporting period.

The FAH agrees with CMS that reducing the number of eCQMs would create a streamlined measure set, help reduce the workflow interferences caused by eCQMs, and make it easier for vendors to maintain specifications for the available eCQMs. Regarding the burden of eCQM reporting, our members note the high costs of upgrading eCQM mapping tools each year, including vendor fees and employee time. CMS should take these costs into account and strive to minimize annual changes to the eCQMs. For additional comments related to eCQMs, please see section VIII. A. of this letter.

## MEDICARE COST REPORTS

### IX. Proposed Revisions of the Supporting Documentation Required for Submission of an Acceptable Medicare Cost Report

The FAH supports several of the proposed revisions to the supporting documentation requirements for filed cost reports. However, the requirements for the following two proposed revisions would complicate and increase the cost reporting burden, without improving the accuracy of the cost reporting process.

<u>Home Office Allocations</u>

The FAH is in agreement that completing a Home Office Cost Statement (HOCS) is necessary to support the costs a home office allocates to provider cost reports. However, the FAH disagrees that having a HOCS submitted with each provider cost report would facilitate a contractor's review and verification of the cost report without needing to request additional data. Our member companies have (1) individual HOCS(s) that support a very large number of providers, e.g., over 150 providers across 10 MACs for one member, and (2) many providers within our member companies have varying year ends that also differ from the year end of the HOCS. Both of these circumstances make this an impractical requirement. In the case of providers that have a different year end from the HOCS, the HOCS correlating to the providers' year ends may not even be filed yet. For example, in the case of a provider's cost report year end that is 9/30/17 with a HOCS year-end that is 12/31/17, the provider's cost report would have been filed was on 2/28/18, while the HOCS covering nine months (1/1/17-9/30/17) of the provider's filed cost report won't be filed until 5/31/18, and therefore home office costs must be

estimated for the provider. For these numerous situations, the contractors will still have to request additional information from the providers to support the home office (HO) allocations.

The FAH encourages CMS to continue to utilize the existing system, in which the HOCS is filed with the Home Office (HO) MAC, and is readily available to provider MACS through the HO MAC. It is our understanding that the HO MACs provide a copy of the accepted HOCS(s) to each of the MACs that are included on the HOCS assignment of hospitals, FORM CMS-287-05, Worksheet A2, and Part III – Listing of Chain Healthcare Facility Components. The distribution of the filed and accepted HOCS through the HO MACs facilitates accurate and consistent reporting of HO allocations across contractors that would be more difficult to achieve if all the many individual providers provided them separately. For the many providers whose cost report periods will not correlate to a filed HOCS, the HO MAC providing a copy of the HOCS allows each MAC to provide consistent communication to their staff regarding receipt and application of HOCS(s) across their organization.

Intern and Resident Information System (IRIS) Data

The FAH also has concerns with the requirement that the count of total FTEs in the IRIS data must equal the count of total FTEs in the cost report, for cost reporting periods filed on or after October 1, 2018. There are various situations in which the IRIS data FTE total count will not agree with the total FTEs in the cost report. For example, if the number of residents trained exceeds the number of accredited FTE slots, the IRIS FTE count would be greater than the cost report FTE count. These inconsistencies may be resolved by incorporating changes into the Extensible Markup Language (XML)-based IRIS file format or by adding a line to the cost report. The proposed IRIS file should consider that different categories of residents are placed on different cost report lines, e.g., residents from new programs and residents from existing programs.

The FAH strongly encourages CMS to delay implementation of this requirement until the necessary changes are made to the IRIS data and/or cost report form, and the changes are incorporated and tested. The FAH also recommends that CMS release a draft of the IRIS instructions and proposed file format for comment prior to implementation.

## PRICE TRANSPARENCY

### X. Requirements for Hospitals to Make Public a List of Their Standard Charges via the Internet

The FAH supports CMS updating its guidelines to require hospitals to make available a list of their current standard charges via the internet in a machine-readable format and to update this information at least annually, or more often as appropriate. Many hospitals already comply with this requirement, either voluntarily or because it is required under state law.

The FAH is also supportive of efforts to ensure that consumers have clear, accessible, and actionable information concerning their cost-sharing obligations, but is concerned that CMS is

considering avenues for providing this information that focus exclusively on hospitals when payers—insurers, group health plans, Medicare, Medicare Advantage organizations, and others—are best suited to provide actionable coverage and cost-sharing information for all providers and suppliers involved in an episode of care.

CMS should give careful consideration to the best method and data needed to provide patients with the information required to understand potential cost-sharing obligations. Requiring hospitals to disclose competitively sensitive information, including average or median contracted rates or discounts, would not enable patients to better understand their potential financial liability for services or to accurately compare their likely cost-sharing exposure between hospitals. A patient's cost-sharing obligation is determined based on benefits and coverage under her plan, the plan's provider network and cost-sharing structure, and the plan's specific negotiated rates with each provider and supplier involved in an episode of care. As a result, average or median contracted rates or discounts do not help patients to accurately compare their potential financial liability for an episode of care. In fact, by consulting with her plan, a patient might discover that her actual projected financial liability for an episode of care would be lower at a hospital with "higher" average or median contracted rates. Meanwhile, disclosing information concerning contracted rates or discounts would ultimately be counterproductive to a competitive marketplace. Economists and antitrust enforcers have recognized that the disclosure of negotiated provider network rates could lead to inflation of prices by discouraging private negotiations that can result in lower prices for some buyers. In fact, the Department of Justice and Federal Trade Commission's antitrust safety zone for pricing surveys requires that the source data be at least three months old. Department of Justice and Federal Trade Commission, Statement on Provider Participation in Exchanges of Price and Cost Information (Aug. 1996).

Payers, on the other hand, can provide clear, accurate and actionable cost-sharing information to members and beneficiaries without jeopardizing price-based competition among providers. Payers are uniquely qualified to provide patients with precise information concerning any limitations on their coverage, the scope of patient cost-sharing obligations (including out-of-pocket spending limits, deductibles, coinsurances, and any reference-based pricing strategies used by the plan), any network tiering used by the plan, and the applicable allowed amount for each provider or supplier involved in an episode of care. CMS's Office of the Actuary estimates that approximately 90% of individuals will have health coverage in 2019 (an uninsured rate of 9.6%). 83 Fed. Reg. at 20392. Thus, for the vast majority of patients, payers are in the best position to provide the most relevant information. Payers understand the full range of benefits under a patient's applicable health coverage and cost-sharing obligations and, because an episode of care typically involves multiple providers and suppliers, the payer is the only entity that is capable of providing a patient with an accurate and actionable estimate of their potential financial exposure for the entire episode of care.[18] Seeking this information from each provider and supplier involved in an episode of care is not only inefficient, but it is also error-prone

[18] This is also true with regard to Medigap coverage. CMS asked who is best situated to provide patients with Medigap coverage clear information on their out-of-pocket costs prior to receipt of care. 83 Fed. Reg. at 20549. Responsibility to provide this information should fall on the Medigap plan itself, which is the entity in a position to provide enrollees with accurate and actionable information regarding their cost-sharing obligations for an entire episode of care.

because the cost-sharing picture is fragmented among the providers and suppliers and may not accurately reflect the details of the patient's coverage.

With regard to patients who are uninsured, hospitals and other providers may be the preferred source of pricing information, but it is the FAH's belief that uninsured patients are best served by receiving individualized information through a provider's financial counselors. Most uninsured patients receive substantially discounted or even free care under a hospital's charity care policy or receive other generous discounts that limit their financial obligations. Moreover, a sizeable number of uninsured patients are actually eligible for free or subsidized health coverage. By meeting with a hospital's financial counselor, these individuals can access individualized and actionable pricing information and make informed choices concerning their medical care. Overemphasizing a hospital's typical or average rates, discounts, or charges, on the other hand, may dissuade individuals that may be entitled to free or low-cost care from speaking with a financial counselor and, in some circumstances, may cause an individual to forego needed care.

For these reasons, the FAH believes requiring hospitals to publish median contracted rates or discounts or to provide an estimate of the patient's out-of-pocket costs before furnishing a service is not an appropriate avenue to address concerns about transparency. Hospitals will always provide patients with assistance in understanding their obligations and with available programs and policies such as eligibility for charity care and discounts. But as stated earlier, it is far more appropriate for covered individuals to receive cost-sharing estimates from the applicable payer, whereas uninsured individuals should consult with the provider's financial counselor to obtain an individualized assessment of her eligibility for charity care, discounts, or free or subsidized health coverage. Along similar lines, the FAH believes that information concerning "what Medicare pays" for a service is not a useful reference point and does not help patients to understand their potential financial liability. Medicare rates are not negotiated in arm's-length transactions and provide little to no information about the rates negotiated with or established by other payers, let alone the cost-sharing obligation borne by the patient. In addition, the provision of Medicare-specific pricing information by providers would likely create confusion among patients who are either not enrolled in Medicare or who receive their Medicare benefits through a Medicare Advantage plan that pays a different, negotiated rate. However, should CMS desire for patients to have that information, it is in the best position to provide it.

The FAH also opposes any effort to expand section 2718(e) of the Public Health Service Act (PHSA) to require disclosure of median rates, discounts, or competitively sensitive information. Section 2718(e) requires each hospital to establish, update, and make public "a list of the hospital's standard ***charges*** for items and services provided by the hospital" (emphasis added). Critically, Congress chose to use the word "charges" in lieu of "price," "rate," "cost," or any other similar term. CMS should not ignore Congress' clear intent to address dissemination of charge information by redefining "standard charges" as rate information, discounts, or other pricing information that is simply unrelated to charges.

Finally, the FAH opposes the creation of a federal enforcement mechanism for section 2718(e) of the Public Health Service Act. Based on the plain text of the Public Health Service Act, Congress declined to provide *any* penalties or enforcement authority with regard to section 2718(e). In addition, the enforcement provisions for Part A of title XXVII of the Public Health

Service Act, which apply only to health insurers, emphasize the overriding importance of state-level enforcement of insurance market requirements. States are far better suited than CMS to experiment with price transparency measures and to enforce these measures as appropriate under their general police powers. Meanwhile, Congress specifically did not grant CMS statutory authority to enforce the requirement that hospitals publish their standard charges.

***The FAH supports CMS's goal of ensuring that patients have access to clear, accurate, and actionable cost-sharing information, and urges CMS to pursue this goal through payer-side regulations.*** Hospitals are simply not the appropriate entity to be tasked with interpreting and explaining a patient's cost-sharing obligations under a particular plan. Payers, on the other hand, are in a position to offer this important information. As such, the publication of average or median hospital rates or discounts as some sort of proxy for an individual's cost-sharing obligations would be misleading to individual consumers, contrary to Congress's express direction that hospitals publish information on standard "charges," and counterproductive to a competitive marketplace for hospital services.

Related to ensuring patients have access to clear, accurate, and actionable cost-sharing information is the opportunity for CMS to take action to negate negative outcomes from instances where consumers are subject to a "surprise bill" when they receive services in an in-network hospital, but some of those services are delivered by an out-of-network physician. This is another example of how consumers may not have accurate information from their insurance plan about in-network providers and are not adequately protected against unexpected out-of-pocket costs. CMS finalized a policy in the Final Notice of Benefit and Payment Parameters for 2017 to address surprise bills to consumers. Under this policy, beginning in 2018, Qualified Health Plans (QHP) sold on the Marketplace must count the cost-sharing amount associated with an essential health benefit provided by an out-of-network provider in an in-network facility (e.g., hospital) toward an enrollee's annual cost-sharing limit. This requirement does not apply if the QHP provides written notice to the beneficiary (a non-customized form letter would suffice) that the provider might be out-of-network and the beneficiary could be subject to additional cost-sharing obligations. The QHP has the longer of 48 hours prior to the service or the time in which the plan would typically respond to a prior authorization request to provide the notice.

Unfortunately, the CMS policy falls short of the mark as it provides more protection for plans than it does for consumers. It is reasonable to assume that QHPs will routinely issue the form letter, in which case the consumer remains exposed to the additional cost-sharing, while the plan keeps the consumer that much further away from reaching the annual cost-sharing limit, the point at which the plan becomes fully responsible for the cost of care. ***Instead, the FAH continues to recommend that CMS adopt the surprise billing section of the National Association of Insurance Commissioners' (NAIC) Health Benefit Plan Network Access and Adequacy Model Act (Model Act) as a more robust way to address the issue of surprise billing.*** The FAH believes this policy provides real protection for patients by providing an important measure of transparency combined with reasonable protections of patients' financial interests. In addition, the NAIC provision strikes the right balance between the roles and responsibilities of hospitals, providers, and plans in situations in which a patient seeks care at an in-network hospital and may be treated by a provider who is not covered by the patient's plan.

Under the NAIC's Model Act, if a patient receives emergency treatment from an out-of-network provider (e.g., anesthesiologist, pathologist, radiologist) at an in-network facility, the patient's out-of-pocket costs would be limited to those of an in-network provider. If the billed amount from the out-of-network provider is at least $500 more than the allowed amount under the patient's plan, the proposal offers a mediation process between the out-of-network physician and the insurance company when they cannot agree on a payment amount – essentially holding the patient harmless. Additionally, before any non-emergency treatment is scheduled, the Model Act would require the in-network hospital to provide the patient a written notice stating, among other items, that the patient might be treated by a provider who the patient's plan determines is out-of-network, as well as a range of what the charges could be for such treatment. The notice also would include a statement telling the patient that she can obtain from her plan a list of providers who are covered by her plan, and request treatment from one.

Finally, for information to be meaningful, accessible, and actionable, it must be readily available for all types of consumers. Health plans should use effective and innovative communication methods and convey the information as simply and directly as possible. Insurers should continually communicate price and other information in multiple ways using a variety of methods to be most effective and have the broadest reach.

## CLAIM CERTIFICATION

### XI. Proposed Revisions Regarding Physician Certification and Recertification of Claims

We applaud CMS for its proposed changes to the Medicare regulations at 42 CFR 424.11(c) regarding physician certification and recertification as to the medical necessity of certain types of covered services provided to Medicare beneficiaries. The current regulations provide that when supporting information for the required physician certification statement is available elsewhere in the records (for example, in the physician's progress notes), the information need not be repeated in the statement itself. Further, the regulations specify that it will suffice for the statement to indicate where the information is to be found. We appreciate that CMS has identified this latter provision as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers and may be resulting in unnecessary denials of Medicare claims. Therefore, we support CMS's proposal to delete the last sentence of § 424.11(c) and to relocate the second sentence of § 424.11(c) (indicating that supporting information contained elsewhere in the provider's records need not be repeated in the certification or recertification statement itself) to the end of the immediately preceding paragraph (b), which describes similar kinds of flexibility that are currently afforded in terms of completing the required statement.

## PROMOTING INTEROPERABILITY AND ELECTRONIC INFORMATION EXCHANGE

### XII. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

CMS is seeking feedback in the proposed rule on how it could advance the electronic exchange of information in support of care transitions between hospitals and community providers using: CoPs, CfCs, and RfPs for Long-Term Care Facilities. Specifically, CMS is considering revising these to require providers to electronically perform a variety of activities, including: transfer of medically necessary information from a hospital to another facility upon a patient transfer or discharge; transfer of discharge information from a hospital to a community provider, if possible; and providing patients access to certain information via electronic means, if requested, including directing that information to a third-party application.

The FAH has long supported efforts to achieve comprehensive interoperability and data liquidity – the free flow of meaningful, actionable information that supports and enhances patient care within and across settings. As the largest purchasers and consumers of health information technology (HIT), hospitals and health systems, have a vested interest in data flow to improve patient care, workflow efficiencies and clinician satisfaction, population health and payment models, and research. ***However, the FAH does not support the proposed revision of the CoPs, CfCs, and RfPs related to interoperability and the exchange of health information.*** The current ecosystem is simply not mature enough to facilitate the movement of this information, as evidenced by the obstacles that currently prevent seamless information exchange and would make it exceedingly difficult for hospitals and other providers to comply with the requirements. The FAH appreciates CMS's acknowledgement of this in the proposed rule, noting that, "While both adoption of EHRs and electronic exchange of information have grown substantially among hospitals, significant obstacles to exchanging electronic health information across the continuum of care persist. Routine electronic transfer of information post-discharge has not been achieved by providers and suppliers in many localities and regions throughout the Nation." 83 Fed. Reg. 20550.

These obstacles are amplified in the patient discharge and transfer arenas because post-acute providers and behavioral health providers were ineligible for the EHR Incentive Programs under the *Health Information Technology for Economic and Clinical Health (HITECH) Act*, which have been instrumental in enabling acute care hospitals to achieve so much of the potential that EHRs specifically and HIT generally offer. As such, post-acute providers and behavioral health providers have not been able to adopt HIT to the extent of hospitals and CAHs. Thus, were CMS to move forward with revisions to the CoPs, CfCs, and RfPs, hospitals and CAHs would be unable to meet these requirements because of the lack of providers available to accept that information electronically. And, for post-acute care and behavioral health providers, it would be unfair, and tantamount to an unfunded mandate, to require that these providers adopt and maintain expensive EHRs and other HIT through CoPs, CfCs, and RfPs when they receive no corresponding financial assistance to do so.

The lack of providers in a position to accept this information electronically raises questions regarding how providers would be deemed in compliance with such requirements. How would providers prove during a survey process that they are "interoperable?" Would they need to send information to other providers electronically? Ensure those providers ultimately received the information? Receive information from other providers? And/or receive information and incorporate it into an actionable format in the EHR? These are just a sampling of the multitude of questions that would arise in determining compliance – and many of them would hinge not on the individual provider's action, but the actions of HIT vendors and other providers over whom the hospital has virtually no control. For example, a hospital may be able to send the information electronically, but the receiving hospital or post-acute care provider is unable to accept it. Or, a provider may be unable to incorporate the information it receives into its EHR in a format acceptable to the surveyors due to the limitations of the EHR itself, for example, the misaligned standards, semantics, and specifications that currently hinder data flow and useable data across vendor platforms. Additionally, the CoPs, CfCs, and RfPs are infrequently updated relative to the annual Medicare payment rules and rules related to the Promoting Interoperability Programs. As such, it is possible that the proposed revisions to these requirements could quickly become outdated and hinder future HIT-related innovation, and in many cases even before they are finalized.

Failure to comply with CoPs, CfCs, or RfPs, carries serious penalties for health care providers, including the potential inability to treat Medicare and Medicaid beneficiaries. Such penalties also have profound consequences for patients as well, as they may lose the ability to receive treatment in their communities. ***Imposing these penalties on providers and patients in the face of an immature health information ecosystem – and the significant implementation issues raised above – would only restrict rather than facilitate patients' access to care and information exchange.***

The FAH appreciates CMS's focus on interoperability and shares CMS's frustrations regarding the lack of actionable, accessible electronic information, as well as the desire to accelerate an interoperable health system that improves the safety and quality of care, enables innovations, and achieves the best possible outcomes for patients. ***To continue to address these concerns, the FAH recommends that CMS permit the numerous public and private initiatives in this area, some of which are nascent, time to mature and advance our shared goals. CMS and ONC should also continue to work to improve the capabilities of EHRs and other HIT, including: simplifying information exchange across HIT vendor platforms; identifying patients across vendor platforms; and simplifying clinician workflow related to sending, receiving, incorporating, and utilizing information.***

As CMS states in the proposed rule, there are "several important initiatives that will be implemented over the next several years to provide hospitals and other participating providers and suppliers with access to robust infrastructure that will enable routine electronic exchange of health information." *Id.* These initiatives include the TEFCA, which is still in draft form; the revamped and refocused Promoting Interoperability Program, which was recently proposed; the Prevention of Information Blocking Attestation;[19] and the MyHealthEData initiative, which was

[19] Eligible hospitals, eligible professionals, and CAHs participating in the Promoting Interoperability Programs must attest to the Prevention of Information Blocking Attestation. *The Medicare and Medicaid EHR Incentive Programs*

announced earlier this year, among others. There are also private-sector led efforts underway to advance other components of the interoperability puzzle, such as plug-and-play interoperability among devices and systems.[20] The FAH provided feedback on these and other initiatives and looks forward to continuing to work with CMS, ONC, and other private-sector partners to realize the promise of HIT to improve our nation's health care system.

## OUTLIER PAYMENTS

### Addendum II.A.4.g. Proposed Outlier Payments

For FY 2019, CMS has proposed a case be eligible for high cost outlier payments when the cost of the case exceeds the sum of the of the prospective payment rate for the diagnosis related group (DRG), any indirect medical education (IME) and disproportionate share hospital (DSH) and Uncompensated Care payments, any add-on payments for new technology and the proposed fixed loss threshold of $27,545. The present threshold, which has been in effect since October 1, 2017, is $26,537. This more than $1,000 increase is on top of an increase of more than $3,000 in the threshold between FYs 2017 and 2018. CMS indicates that it has used the same methodology to calculate the fixed loss threshold as it has since FY 2014 (we address in a separate comment how the Agency proposes to address new treatments such as CAR-T with regard to outlier payments). Just as with last year's rule-making, we are concerned with the lack of transparency associated with the Agency's assessment of the charge inflation component of the fixed loss threshold calculation, as we explain below.

The proposed threshold for FY 2019 represents an increase of more than $4,000 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. We are particularly concerned about the magnitude of the increase given that (a) for FY 2016, when the threshold was set at $22,544, Watson Policy Analysis (WPA), see the attached report *Summary of Research Modeling FY 2019 Proposed Inpatient Prospective Payment System Outlier Payments* (Attachment B) at p. 5[21], indicates that outlier payments as a proportion of DRG payments will be about 5.08%, which is still lower than CMS's target of 5.1%, and (b) for FY 2017, when the threshold was set at $$23,573, WPA Report at p.1 indicates that outlier payments as a proportion of DRG payments will be about 5.3%, only nominally above the target. Given that the thresholds applied in FYs 2016 and 2017 appear to result in total outlier payments very close to the 5.1% target,[22] it is particularly questionable whether such a significant increase in the threshold is warranted.

---

*Prevention of Information Blocking Attestation Fact Sheet*, October 2017, available at: https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EHR_InformationBlockingFact-Sheet20171106.pdf.

[20] Center for Medical Interoperability, *Fact Sheet*, available at: http://medicalinteroperability.org/wp-content/uploads/2017/01/CMI-Overview-Jan2017.pdf.

[21] All of the tables herein appear in the WPA report except for the table in section D of the comment, also prepared by WPA, but supplemental to the WPA report.

[22] CMS calculates an estimate of the actual outlier payments for FY 2017 in the proposed rule at 5.53%. WPA cannot reconcile that amount from the most recent HCRIS update. Rather that most recent data indicate actual

## A. CMS's Charge Inflation Calculation Lacks Transparency and Prevents Adequate Notice and Comment

Telling for the FAH and problematic for purposes of our comments last year, we noted that though CMS provided a new table with quarterly total charges and claims data for the eight quarters that CMS used to calculate the charge inflation factor, the data was only provided in totals and the source of the data was not identified. In particular, the figures in the table could not be matched with publicly available data sources, and since CMS did not provide any guidance that described whether and how it edited the data to arrive at the total of quarterly charges and charges per case, the table was not useful in assessing the accuracy of the charge inflation figure. In the FY 2019 proposed rule, CMS again offers a table with quarterly total charges and claims data for the eight quarters used to calculate the charge inflation factor. In addition, this year, like last year, CMS offers a more detailed summary table by provider with the monthly charges that were used to compute the charge inflation factor. The FAH appreciates the additional data, but maintains that CMS has not provided enough specific information and data to allow the underlying numbers used in CMS's calculation of the charge inflation factor to be replicated and/or tested for accuracy. CMS acknowledges it is working through internal issues with providing such data, as it has stated in prior years. 83 Feg. Reg. at 20581. But its efforts ring a bit hollow over the several year period. In the absence of more specific data and information about how it was edited by CMS to arrive at the totals used in its charge inflation calculation, CMS has not provided adequate notice to allow for meaningful comment.

## B. 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. For example, in the FY 2017 proposed rule, CMS estimated that its "current estimate, using available FY 2015 claims data, is that actual outlier payments for FY 2015 were approximately 4.68 percent of actual total MS-DRG payments." *See* 81 Fed. Reg. at 25273, col.3 (Apr. 27, 2016). We are concerned that CMS believed it would hit its 5.1% target amount for FY 2015, only to learn later that its original estimate was overstated, and, notwithstanding, still raise the threshold for the subsequent year.

In this year's proposed rule, CMS states that its "current estimate, using available FY 2017 claims data, is that actual outlier payments for FY 2017 were approximately 5.53 percent of actual total MS-DRG payments." See 82 Fed. Reg. 20175 at col. 1 (Apr. 28, 2017). However, WPA's analysis concludes this figure is overstated. See WPA Report at Analysis 3, pp. 4-5. Specifically, WPA concluded that the outlier payments for FY 2017 amount to 5.3% of total DRG payments, as illustrated below:

---

outlier payments at 5.3% of total DRG payments. CMS provides no data for actual or estimated outlier payments for FY 2018 in the proposed rule.

| Data Source | Operating IPPS Payments Net of IME, DSH and Outlier Amounts ($) (Does not include Capital) | Outlier Payments ($) | Outlier Payment Level (%) | Total Medicare Payment ($) |
|---|---|---|---|---|
| MedPAR 2017 Actual Outlier Payments, FY 2017 Final Rule Impact File Adjustment Factors | $83,278,767,052 | $4,414,651,611 | 5.30% | $110,546,869,819 |

While WPA's estimate still puts outlier payments above the 5.1% target, albeit nominally, the FAH finds it concerning that CMS's estimate is, yet again, overstated.

As demonstrated by the following table, the use of more recent data (i.e., the March file versus the December file) also has a significant impact on the calculation of the actual outlier payment level:

| Federal Fiscal Year (Month of HCRIS release) | Number of cost reports | IPPS Payments Net of IME, DSH and Outlier amounts | Outlier Payments | Outlier Payment Level (%) | Target Outlier Payments (5.1%) | Shortfall in Outlier Payments |
|---|---|---|---|---|---|---|
| FY 2013 (Dec) | 2,875 | $75,513,803,937 | $3,820,292,807 | 4.82% | $4,058,170,707 | ($237,877,900) |
| FY 2013 (Mar) | 3,047 | $80,760,714,604 | $4,270,125,578 | 5.02% | $4,340,143,777 | ($70,018,199) |
| FY 2014 (Dec) | 2,388 | $63,505,784,324 | $3,085,415,408 | 4.63% | $3,412,850,369 | ($327,434,961) |
| FY 2014 (Mar) | 3,054 | $82,479,662,313 | $4,343,131,876 | 5.00% | $4,432,521,368 | ($89,389,492) |
| FY 2015 (Dec) | 2,850 | $78,849,610,927 | $3,847,264,205 | 4.65% | $4,238,185,938 | ($390,921,733) |
| FY 2015 (Mar) | 3,036 | $84,552,076,553 | $4,283,484,754 | 4.82% | $4,543,853,974 | ($260,369,220) |
| FY 2016 (Dec) | 2,852 | $81,185,256,122 | $4,223,366,030 | 4.94% | $4,362,921,000 | ($139,554,970) |
| FY 2016 (Mar) | 3,048 | $87,553,087,944 | $4,689,098,313 | 5.08% | $4,705,190,000 | ($16,091,687) |

The FAH emphasizes the importance of CMS using the most recent data available to more accurately assess the outlier payment level.

## C. Using Most Recent Data to Calculate the Threshold

We also note that with each rulemaking, until FY 2017, the final outlier threshold established by CMS is always significantly lower that the threshold set forth in the proposed rule. The table below expresses this trend graphically.

| FY | Final | Proposed | Variance | % Variance |
|---|---|---|---|---|
| 2009 | $20,045 | $21,025 | $(980) | -4.66% |
| 2010 | $23,140 | $24,240 | $(1,100) | -4.54% |
| 2011 | $23,075 | $24,165 | $(1,090) | -4.51% |
| 2012 | $22,385 | $23,375 | $(990) | -4.24% |
| 2013 | $21,821 | $23,630[23] | $(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% |

While 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 revised, additional or other data in calculating the final threshold. We are concerned this was not done for FY 2018 and will not be done for FY 2019. 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, we note, for example, that CMS has used data from the December 2017 PSF file, but that at the time the proposed rule was issued, the March 2017 PSF file was available. We had WPA attempt to replicate CMS's methodology in setting the threshold using the same data CMS indicates it used for the proposed threshold. Correcting for the revised transfer weights, WPA was able to replicate the threshold within $4, accepting CMS's charge inflation factor as accurate only because it could not replicate that factor due to a lack of supporting information for CMS's calculation. 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%.

We are particularly interested in whether, for the FYs 2017 and 2018 proposed rule, CMS used more updated data than it had used in prior years to calculate the proposed threshold. If that

[23] CMS issued a corrected proposed outlier threshold of $26,337 in 77 Fed. Reg. at 34328 (Jun. 11, 2012) but references the noted lower figure in the FY 2013 final rule as its corrected proposed outlier threshold in the FY 2013 Final Rule, 77 Fed. Reg. at 53696 (Aug. 31, 2012).

is the case, then CMS's use of more updated data to calculate the proposed threshold may explain why the variance between the proposed and final threshold for FYs 2017 and 2018 was much smaller than the variance we had seen in prior years, and why we may see a significantly smaller variance between the proposed and final threshold for FY 2019 as well.

## D. Accounting for Outlier Reconciliation

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. In the Proposed Rule, CMS addresses its decision not to consider the impact of outlier reconciliation in its determination of the outlier threshold as follows:

> "As we did in establishing the FY 2009 outlier threshold (73 FR 57891), in our projection of FY 2018 outlier payments, we are not proposing to make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement. We continue to believe that, due to the policy implemented in the June 9, 2003 Outlier Final Rule (68 FR 34494), CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict the specific hospitals that will have CCRs and outlier payments reconciled in any given year." 83 Fed. Reg. at 20582, col. 2.

The FAH has concerns regarding CMS's decision not to consider outlier reconciliation in developing the outlier threshold and its failure to provide any objective data concerning the number of hospitals that have been subjected to reconciliation and the amounts recovered during this process. We are certainly aware that in February 2003, the Secretary signed an emergency interim final regulation that would have corrected the outlier threshold to account for reconciliation, but that the rule was not issued because of objections from the Office of Management and Budget. If it was possible to correct the outlier threshold at the time reconciliation was first being proposed, it is difficult to understand why, with fourteen years of reconciliation experience, that cannot be accomplished. We are particularly concerned with CMS's failure to consider adjusting for reconciliation this year given CMS's projected charge inflation factor of 9.5% over two years, which, if costs were held constant, would suggest that a significant number of hospitals could be subject to reconciliation.

**Historical Outlier Reconciliation Payments Using the 1996 and 2010 HCRIS File[24]**

| Summary by year Year | Net Total reconciliation (Operating and Capital) |
|---|---|
| 2004 | $(6,111,318) |
| 2005 | $(8,498,329) |
| 2006 | $(34,483,808) |
| 2007 | $(9,462,780) |
| 2008 | $(8,924,446) |
| 2009 | $(10,781,254) |
| 2010 | $(25,357,945) |
| 2011 | $(2,148,212) |
| 2012 | $(230,535) |
| 2013 | $- |
| 2014 | $57,659 |
| Total | $(105,940,968) |

The FAH again requests that CMS disclose in the final IPPS rule and future proposed and final IPPS rule making the amount CMS has recovered through reconciliation by year. Historical information that provides the total amounts recovered by the program through reconciliation each year since the inception of reconciliation would provide a baseline and trend information to assess whether reconciliation is a significant factor to be considered in the development of the outlier threshold. The information will allow the FAH and others to comment specifically on how this provision would impact the threshold. Absent the disclosure of data showing that the recoveries obtained through the reconciliation process are immaterial, the FAH requests that CMS consider these recoveries in its determination of the outlier threshold in the final and future rule making and to be transparent about the amounts involved in that process.

## E. Extreme Cases Significantly Skew the Fixed Loss Threshold

The FAH also asks CMS to consider whether it is appropriate to include extreme cases when calculating the threshold and whether recent volume increase in such cases points to a larger problem that CMS should investigate. WPA conducted various examinations and probing of data to understand the factors that drove CMS to increase the threshold over $4,000 between FY 2017 and FY 2019 and observed that the inclusion of extreme cases in the calculation of the threshold significantly impacts its determination.

[24] Outlier reconciliation from 1996 and 2010 format HCRIS cost reports Using Worksheet E, Part A. Operating outlier reconciliation from line 52, capital from line 53 from 1996 file and for the 2010 format data, using line 92 for operating and 93 for capital. Reconciliation data has been missing from HCRIS since FY 2014. We request CMS restore this information to the HCRIS data set.

In the IPPS rate-setting process, 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 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 for FYs 2019 and 2018, using 2017 and 2016 data, respectively:

**FY 2019 Proposed Rule Table**

| Trim threshold | Number of cases removed | Calculated FLT | Percentage of cases trim removes |
|---|---|---|---|
| None | - | $27,549 | 0.000% |
| $2,000,000 | 1,024 | $26,029 | 0.011% |
| $1,750,000 | 1,476 | $25,676 | 0.016% |
| $1,500,000 | 2,334 | $25,161 | 0.025% |
| $1,250,000 | 3,874 | $24,437 | 0.041% |
| $1,000,000 | 7,237 | $23,312 | 0.077% |
| $750,000 | 15,832 | $21,525 | 0.168% |
| $500,000 | 45,897 | $18,285 | 0.487% |

**FY 2018 Proposed Rule Table**

| Trim threshold | Number of cases removed | Calculated FLT | Percentage of cases trim removes |
|---|---|---|---|
| None | - | $26,788 | 0.000% |
| $2,000,000 | 738 | $25,585 | 0.008% |
| $1,750,000 | 1,076 | $25,327 | 0.011% |
| $1,500,000 | 1,733 | $24,890 | 0.018% |
| $1,250,000 | 2,942 | $24,294 | 0.031% |
| $1,000,000 | 5,679 | $23,317 | 0.060% |
| $750,000 | 13,039 | $21,595 | 0.139% |
| $500,000 | 38,637 | $18,561 | 0.411% |

The FY 2019 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 (1,024 cases) drives the threshold down over $1,500. 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 (7,237 cases) drives the threshold down over $4,000, and removing all cases with charges above $500,000 (45,897 cases) drives the threshold down over $9,000. 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*[25] above $1.5 million for each of the past several years:

| Year | Number of cases over $1.5 million | Percentage of total cases | Number of unique providers |
|---|---|---|---|
| 2011 | 926 | 0.0088% | 272 |
| 2012 | 994 | 0.0098% | 272 |
| 2013 | 1,092 | 0.0111% | 283 |
| 2014 | 1,329 | 0.0141% | 306 |
| 2015 | 1,539 | 0.0161% | 320 |
| 2016 | 1,733 | 0.0185% | 334 |
| 2017 | 2,291 | 0.0250% | 403 |

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. We are particularly concerned that these very high charge cases may be related to the practices identified in the DHHS Office of the Inspector General Report, Medicare Hospital Outlier Payments Warrant Increased Scrutiny, OEI-06-10-00520 (November 2013) and we have never found any indication that CMS studied the OIG's concerns and responded to this report. We urge CMS to address these issues in response to this comment.

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 case

The FAH is not proposing a threshold for FY 2019. While we have confidence in the work of WPA, its work is dependent on a large variable in the outlier calculation, charge inflation, that we cannot verify from the limited information that CMS has provided. 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 needs to 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 and revised 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.

[25] This is a slightly different comparison from the tables above that look at total charges instead of covered charges.

**********

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

Sincerely

**ATTACHMENT A**

**Charles N. Kahn III**
**President & CEO**

February 18, 2018

Electronically Submitted at exchangeframework@hhs.gov

Donald Rucker, MD
National Coordinator for Health Information Technology
Department of Health and Human Services
330 C Street, SW, Floor 7
Washington, DC 20201

**Re: Draft Trusted Exchange Framework and Common Agreement**

Dear Dr. Rucker:

The Federation of American Hospitals (FAH) appreciates the opportunity to comment on the Office of the National Coordinator for Health Information Technology's (ONC) Draft Trusted Exchange Framework and Common Agreement (Draft TEFCA). The FAH is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay, rehabilitation, long-term acute care, psychiatric, and cancer hospitals in urban and rural America, and they provide a wide range of acute, post-acute, and ambulatory services.

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. While the *Health Information Technology for Economic and Clinical Health (HITECH) Act* catalyzed broad adoption of electronic health records (EHRs), the use of such technology has not yet achieved the quality and efficiency goals desired by stakeholders across the health care sector. The inability of various forms of HIT – from EHRs to devices – to both exchange and use information is a significant barrier to achieving these goals. Congress recognized this barrier at it relates to EHRs in directing ONC to develop a Trusted Exchange Framework in the *21st Century Cures Act*. The FAH appreciates ONC's efforts to further the exchange and use of information and offers the below comments in response to the Draft Framework.

Scope of the Draft TEFCA

In the *21st Century Cures Act*, Congress directed ONC to focus on exchange and use of information between health information networks (HINs), which, if implemented appropriately, can advance the exchange of meaningful health information. However, while network-to-network exchange is an important piece of the interoperability puzzle, it is not sufficient to achieve comprehensive interoperability, which involves HIT beyond EHRs and HINs. The FAH appreciates ONC's recognition of this in the Draft TEFCA, which notes that "an individual's health information is not limited to what is stored in electronic health records (EHRs), but includes information from many different sources."[1] This vision – that there should be information exchange throughout the health care system, including during an episode of care to care transitions to an applications-based marketplace – is shared by the health care community. Private-sector led efforts are underway to advance other components of the interoperability puzzle, such as plug-and-play interoperability among devices and systems.[2] **The FAH supports these private-sector-led endeavors and urges ONC to look beyond the Draft TEFCA to align the with those efforts.** Only when all stakeholders in the health care system focus on comprehensive interoperability will we achieve the progress to which we have long aspired.

TEFCA Timeline

The Draft TEFCA is meant to support four important outcomes, including patient and provider access to information, availability of population level data, and support of user-focused innovation.[3] The FAH believes the likelihood of achieving these goals would be improved by revising the timeline for the TEFCA. As discussed in more detail below, the Draft TEFCA raises several questions that should be answered – and on which stakeholders should have the opportunity to comment – before being finalized. **Specifically, the FAH recommends that ONC use the feedback on this version of the Draft TEFCA to release a second version of the Draft TEFCA (Draft TEFCA 2.0) on which stakeholders would again be invited to comment. In addition, the Draft TEFCA 2.0 should be released *before* ONC issues a Funding Opportunity Announcement (FOA) for the Recognized Coordinating Entity (RCE).** Lastly, the statute requires ONC to consult "with the National Institute of Standards and Technology [NIST]…for the pilot testing of the trusted exchange framework and common agreement."[4] ONC should build this pilot testing into the revised timeline for finalizing the TEFCA.

**Additionally, the FAH believes the likelihood of success would improve by phasing in the supported purposes and use cases over time.** The permitted purposes outlined in the Draft TEFCA will require considerable time and resources to implement and may initially be out of reach for some HINs and Participants. Prioritization coupled with a manageable timeline for implementation will best serve the stakeholders participating under the TEFCA.

---

[1] Office of the National Coordinator for Health Information Technology, *Draft Trusted Exchange Framework*, p. 3 (January 5, 2018).
[2] Center for Medical Interoperability, *Fact Sheet*, available at: http://medicalinteroperability.org/wp-content/uploads/2017/01/CMI-Overview-Jan2017.pdf.
[3] Office of the National Coordinator for Health Information Technology, *Draft Trusted Exchange Framework*, p. 7 (January 5, 2018).
[4] P.L. 114-255, Section 4003 (December 13, 2016).

Recognized Coordinating Entity (RCE)

As described by ONC, the RCE will be the linchpin for the success or failure of implementation of the TEFCA. The FAH agrees with ONC's assessment "that a private-sector organization would be best positioned to serve as the RCE" and that the RCE "will need to have experience with building multi-stakeholder collaborations and implementing governance principles."[5] **The FAH further believes that the RCE should be a sector-neutral group that is able to represent the end-users of health information – first and foremost providers and patients – to ensure that all viewpoints are included in the Common Agreement and implementation of the Framework. Specifically, the RCE should *not* be an HIT developer or developer-affiliated entity.** In order to achieve the necessary balance of viewpoints among the health care sector, ONC may need to consider a conglomerate RCE model, such as one organization to serve as the multi-stakeholder arm that further fleshes out and updates the TEFCA and another organization to ensure compliance with the TEFCA. Another factor for consideration in selecting the RCE is whether the entity can also participate as a Qualified HIN. The FAH urges ONC to clarify that the RCE (or RCEs) *cannot* also be a Qualified HIN.

Additionally, the FAH questions whether a cooperative agreement is the most appropriate structure for the relationship between the RCE and ONC. The ideal structure should maximize transparency in the process and place stakeholders on at least equal footing as compared to ONC. Lastly, the FAH has concerns about the sustainability of the model laid out in the TEFCA, including the availability of adequate funding for the RCE over time. This concern is heightened by the recently released President's FY19 Budget in which the Administration lays out plans for further reductions to ONC's budget. As noted above, the FAH strongly recommends that ONC address these concerns in a Draft TEFCA 2.0 and prior to releasing the FOA for the RCE.

Questions Raised by the TEFCA

The Draft TEFCA raises several important questions that should be addressed prior to finalization. **The FAH again strongly recommends the release of a Draft TEFCA 2.0 with comment period, as well as ample time for pilot testing in collaboration with NIST.** Some specific questions that the FAH encourages ONC to address in the Draft TEFCA 2.0 involve the voluntary nature of the agreement and associated enforcement, the sustainability of the model and fees, patient access to data, and provider burden.

*Voluntary Participation*

The Draft TEFCA lays out some of the requirements by which Qualified HINs and Participants must abide, while also noting that participation is voluntary. This presents a unique challenge for the RCE when implementing and enforcing the TEFCA. The FAH's members currently participate in regional health information exchanges (HIEs) across the country and have found various levels of sophistication regarding the ability to quickly update standards or accurately perform patient matching. How will the RCE ensure Qualified HINs are complying with the TEFCA, including staying current with standards, performing updates within a

[5] Office of the National Coordinator for Health Information Technology, *Draft Trusted Exchange Framework*, p. 9 (January 5, 2018).

reasonable timeframe, or accurate patient matching? Should the RCE find a deficiency, what are the mechanisms by which the RCE can enforce the terms of the TEFCA?

Another question that arises when evaluating the Draft TEFCA is whether ONC is planning for overlap between the TEFCA and the information blocking rulemaking the agency expects to release in the spring. **The FAH urges ONC to maintain the voluntary nature of the TEFCA, specifically that hospitals and other health care providers cannot be deemed "information blockers" if they determine that participation under the TEFCA is not optimally serving their patients or that such participation is not possible due to EHR limitations.** Such a requirement – de facto mandatory participation by health care providers – would place providers at a distinct disadvantage relative to Qualified HINs should they determine, for example, that there are deficiencies with the Qualified HIN network, including information security or even fees for membership or queries. A de facto mandatory requirement also would be counter to the Administration's intent to simplify the current burdensome regulatory structure by unnecessarily applying a regulatory standard that could unintentionally thwart the end goals of TEFCA.

*Sustainability of the TEFCA Model / Fees*

A network of Qualified HINs naturally raises questions about the sustainability of the TEFCA model, including the fees associated with participating in or making queries via a Qualified HIN and the viability of Qualified HINs over time. The Draft TEFCA states that Qualified HINs must make their fees[6] public within 15 days of signing the Common Agreement.[7] **The FAH appreciates and supports this requirement and also believes that the fees – and any fee increases – should be reasonable and relatively consistent across Qualified HINs.** If a Qualified HIN uses a transaction fee or similar model, the entity should be required to provide the associated fee after the End User inputs the query and before the Qualified HIN completes the query. This will ensure Participants and/or End Users are not hit with surprise fees. Additionally, should a Qualified HIN's fees grow rapidly or the quality of the Qualified HIN's product decreases, it is unclear what sort of authority either ONC or the RCE would have to ameliorate such concerns. At the very least, health care providers should have the ability to: 1) quickly and easily switch to another Qualified HIN; and 2) stop participation without penalty if there are no suitable Qualified HINs available.

As health care providers switch Qualified HINs based on fees or performance, it seems there is a risk that some Qualified HINs could exit the marketplace over time, resulting in gaps in available information and/or consolidation in the market. A diminishing number of Qualified HINs could lead to higher prices for Participants, even as their access to patient information dwindles. This is especially problematic if health care providers find that belonging to a Qualified HIN advances better patient care, yet participation is not feasible, or, alternatively, providers feel they may risk regulatory consequences for lack of participation. **The FAH**

[6] *Id.* at p. 25. "Fees: all fees and other amounts charged by a person or entity with respect to the services provided by the person or entity in connection with the Common Agreement. Fees may include but not limited to, one-time membership fees, ongoing membership fees, testing fees, ongoing usage fees, transaction fees, data analytics fees, and any other present or future obligation to pay money or provide any other thing of value."
[7] *Id.* p. 34.

**recommends that ONC thoroughly and fairly address these concerns by requiring and policing reasonable and consistent fees across Qualified HINs and by reassuring health care providers that participation under the TEFCA is not a requirement to avoid potential penalties associated with information blocking.**

*Patient Access to Data / HIPAA Protections*

The FAH has long supported patients' rights to access their health care information under HIPAA. The Draft TEFCA notes that the "terms and conditions for trusted exchange [of electronic health information (EHI)] align with all of the requirements of and sit on the foundation of the HIPAA Rules."[8] Health care providers are familiar with the HIPAA Rules and believe they provide important protections for both patients and providers regarding the exchange of protected health information (PHI). However, the requirements in the Draft TEFCA for information sharing and privacy (e.g., breach notification requirements) differ from those with which covered entities much comply under HIPAA, which could lead to confusion and increased burden. **Additionally, ONC should further clarify that Participants and End Users are not responsible for data breaches either by a Qualified HIN or an application (app) or other third-party product to which a patient has directed their EHI. A certification process should be used to determine that apps or third-party products are appropriately requesting EHI and meet the necessary security standards.** The FAH also urges ONC to clarify the parameters of access to information shared via the Common Agreement by Qualified HIN Participants that are not themselves Covered Entities or Business Associates.

An important part of using patient information is ensuring the patient has provided his or her consent. The "Consent" requirements in the Draft TEFCA state that "Each Qualified HIN shall require its Participants to provide the Qualified HIN with a copy of each consent of a Qualified HIN's consenting individual."[9] **While health care providers currently routinely obtain consent from individuals in the course of providing services, the FAH is concerned about the burden associated with providing the Qualified HIN with a copy of each consent – or withdrawal of consent – signed by a patient during the course of business.** It also remains unclear what mechanism would be available to allow providers to electronically track consent (and changes in consent) and enable this information to move swiftly and efficiently from the Participant to the Qualified HIN.

**The FAH also encourages ONC to clarify that providing a patient with access to EHI that is not directly maintained by the Participant entity is the responsibility of the Qualified HIN.** To do otherwise would place an extraordinary burden – of both time and associated fees – on health care providers to query and provide access to multiple records that do not exist in their systems. In providing this clarification, ONC should permit health care providers to direct patients to the Qualified HIN for access to their EHI and ensure HINs are appropriately situated to respond to and fulfill these patient inquiries as a condition of becoming a Qualified HIN.

[8] *Id.* at p. 22.
[9] *Id.* at p. 37.

**Lastly, the FAH recommends that ONC work closely with the Centers for Medicare & Medicaid Services (CMS) to ensure any requirements for patient access to data are in synch with requirements for eligible hospitals under the EHR Meaningful Use Program.**

*Participant Requirements*

The FAH has concerns about Participant responsibilities related to housing EHI and updating clinical records. The Draft TEFCA is currently unclear as to whether the Qualified HIN (either itself or through a connectivity broker) or the Participant will be responsible for storing the EHI and maintaining the infrastructure necessary to facilitate information exchange. In one scenario, Participants respond to requests for EHI from the Qualified HIN and supplies only the information requested; in another scenario, Participants are continually sending EHI to the Qualified HIN, which is responsible for storing the information and fulfilling any queries. **The FAH urges clarification regarding whether the TEFCA will prescribe a required model or whether each Qualified HIN will choose based on its preferences, recognizing that the burden of operating under the different scenarios will vary among health care providers.** The latter model may be too burdensome for some Participants, while the first model may also impose unnecessary burdens depending on the resources (e.g., time, staff, costs) required to reply to queries.

Additionally, the discussion surrounding Principle 4A in the document notes that, as part of ensuring information integrity, "Qualified HIN participants need to update individuals' clinical records to ensure that medications, allergies, and problems are up to date prior to exchanging such data with another healthcare organization."[10] **This requirement is not only over-burdensome for health care providers but also potentially dangerous, as the clinician may not have seen the patient in months or even years and has no way of knowing the patient's status or medications. The FAH strongly recommends that ONC remove this requirement.**

The FAH appreciates the opportunity to comment on the Draft TEFCA. We look forward to continued partnership with ONC as we strive to advance the use of HIT to improve our nation's health care system. If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1500.

Sincerely,

[10] *Id.* at p. 19.

**Summary of research modeling**

**FY 2019 Proposed Inpatient Prospective Payment System**

**Outlier Payments**

Date: June 15, 2018

*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) 2019 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 20580 of the Federal Register.[1] We attempted to replicate the CMS logic and then compared our results and made a variety of adjustments to assess the impact of using different parameters. This report summarizes our findings.

*Summary*

A summary of findings is as follows:

- WPA was able to come reasonably close to the CMS calculation of the Fixed Loss Threshold (FLT). CMS published $27,545. Using the weights reported by CMS, WPA calculated $27,622. However, WPA believes there is a minor error in the weight calculation due to incorrect national average CCRs being used. When WPA uses weights calculated by WPA correcting this error, WPA calculated $27,549 as the fixed loss threshold.
- WPA analyzed CMS' charge inflation calculation and did not identify any issues or concerns in the calculation based on the data presented. However, there is not clear information or data provided to allow the underlying numbers used in the calculation to be able to be replicated and/or tested for accuracy.
- WPA calculated an actual outlier payment proportion of 5.30% versus the 5.53% reported in the rule for FY 2017. As a part of the rate-setting, the target percentage is intended to be 5.1%. However, in some years the target may be met while in other years the target is not met.

[1] "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Records (EHR) Incentive Program (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professions; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims". *Federal Register* Vol. 83, No. 88, Monday, May 7, 2018

*Background on outlier payments*

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

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

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

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

**Analysis 1: Replication of the CMS estimated FY 2019 outlier payment from the FY 2019 IPPS proposed rule**

WPA estimated payments, including outlier payments from the FY 2017 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 2017 proposed file: contains inpatient hospital claims from FY 2017 that were used by CMS to model proposed FY 2019 payments,
- Table 5 – Weight file: contains the proposed weights for FY 2019,
- Impact file: contains hospital specific characteristics and payment factors,
- DSH Supplemental File: contains uncompensated care per claim payment amounts for providers,
- The FY2019 Proposed IPPS rule, in particular information on cost and charge inflation factors, and
- Inpatient Provider of Services File: contains provider specific information.

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: $27,622 versus the published number of $27,545, a difference of $77 or about 0.28%. However, that was using the CMS published weights which WPA believes to be slightly off. Using the WPA calculated weights, correcting for the incorrect national average CCRs, WPA calculates $27,549.

As a part of this replication, there are some methodological notes:

- Although we have been able to replicate the final calculation for the charge inflation factor with the data presented in the rule, it is not possible to replicate the underlying numbers that are presented in the rule. CMS published numbers without releasing the full underlying data that went into those numbers or detail on their methodology (such as what data was included in the numbers, or the data cleaning that may have taken place.) CMS has released summary data by month and by provider to address this issue.
- CMS appears to provide potentially different descriptions of the charge inflation calculation, but this does not appear to make any material difference.

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 2019 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 3,333 providers listed in the impact file and a simulated December 2016 PSF file, we had a match rate of 97.33% (3,244 providers). When comparing the impact file provider list and the March 2018 PSF, we had a match rate of 67.69%.[2]

For the December 2017 comparison, the average difference in operating CCRs between the impact file and the PSF file (weighted by the number of discharges) was -0.002% if all providers were used, and -0.192% if just those providers with differences were used.

For the March 2017 comparison, the average difference in operating CCRs between the impact file and the PSF file (weighted by the number of discharges) was 0.240% if all providers were used and 0.677% 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:

[2] Note: The PSF file for December 2017 was removed before the IPPS rule was released and not downloaded. So as an approximation, we took the March 2018 and restricted it to records in the PSF file prior to 1/1/18, to simulate a December 2017 PSF file. This is consistent with prior years.

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

* 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 2017 Outlier payment using FY 2017 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 5.53%.[3] The chart below shows operating payments and the outlier payments that we calculated. The operating payments and the total are based on the modeling simulation. The outlier payment amount is from the reported outlier payments from the MedPAR 2017

[3] P. 20584 of the Federal Register version of the rule.

Proposed File. In the simulation using the CMS FLT we estimate that outlier payments are 5.30%.

| Data Source | Operating IPPS Payments Net of IME, DSH and Outlier Amounts ($) (Does not include Capital | Outlier Payments ($) | Outlier Payment Level (%) | Total Medicare Payment ($) |
|---|---|---|---|---|
| MedPAR 2017 Actual Outlier Payments, FY 2017 Final Rule Impact File Adjustment Factors. | $ 83,278,767,052 | $ 4,414,651,611 | 5.30% | $ 110,546,869,819 |

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

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

| Federal Fiscal Year (Month of HCRIS release) | Number of cost reports | IPPS Payments Net of IME, DSH and Outlier amounts | Outlier Payments | Outlier Payment Level (%) | Target Outlier Payments (5.1%) | Shortfall in Outlier Payments |
|---|---|---|---|---|---|---|
| FY 2013 (December) | 2,875 | $75,513,803,937 | $3,820,292,807 | 4.82% | $4,058,170,707 | ($237,877,900) |
| FY 2013 (March) | 3,047 | $80,760,714,604 | $4,270,125,578 | 5.02% | $4,340,143,777 | ($70,018,199) |
| FY 2014 (December) | 2,388 | $63,505,784,324 | $3,085,415,408 | 4.63% | $3,412,850,369 | ($327,434,961) |
| FY 2014 (March) | 3,054 | $82,479,662,313 | $4,343,131,876 | 5.00% | $4,432,521,368 | ($89,389,492) |
| FY 2015 (December) | 2,850 | $78,849,610,927 | $3,847,264,205 | 4.65% | $4,238,185,938 | ($390,921,733) |
| FY 2015 (March) | 3,036 | $84,552,076,553 | $4,283,484,754 | 4.82% | $4,543,853,974 | ($260,369,220) |
| FY 2016 (December) | 2,852 | $81,185,256,122 | $4,223,366,030 | 4.94% | $4,362,921,000 | ($139,554,970) |
| FY 2016 (March) | 3,048 | $87,553,087,944 | $4,689,098,313 | 5.08% | $4,705,190,000 | ($16,091,687) |
| FY 2017 (March) | 547 | $15,088,646,066 | $720,451,966 | 4.56% | $810,875,000 | ($90,423,034) |

Note: 2017 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.

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

**Analysis 6: Explorations on high charge cases**

As evidenced in Analysis 5, the Fixed Loss Threshold has been adjusting over time, and the FY 2019 Proposed Rule Fixed Loss Threshold is nearly $1,000 higher than the FY 2018 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 total charges greater than particular thresholds. This removed the case if the *total charges* were greater than a threshold. (Note: For the actual calculation of cost for the Fixed Loss Threshold, covered charges are used.)

The following table shows the results at different trim points.

| Trim threshold | Number of cases removed | Calculated FLT | Percentage of cases trim removes |
|---|---|---|---|
| None | - | $27,549 | 0.000% |
| $2,000,000 | 1,024 | $26,029 | 0.011% |
| $1,750,000 | 1,476 | $25,676 | 0.016% |
| $1,500,000 | 2,334 | $25,161 | 0.025% |
| $1,250,000 | 3,874 | $24,437 | 0.041% |
| $1,000,000 | 7,237 | $23,312 | 0.077% |
| $750,000 | 15,832 | $21,525 | 0.168% |
| $500,000 | 45,897 | $18,285 | 0.487% |

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 FY2017 data, this trend continued. There is an increase at a much faster rater than previous years for this 2017 data.

| Year | Number of cases over $1.5 million | Percentage of total cases | Number of unique providers |
|---|---|---|---|
| 2011 | 926 | 0.0088% | 272 |
| 2012 | 994 | 0.0098% | 272 |
| 2013 | 1,092 | 0.0111% | 283 |
| 2014 | 1,329 | 0.0141% | 306 |
| 2015 | 1,539 | 0.0161% | 320 |
| 2016 | 1,733 | 0.0185% | 334 |
| 2017 | 2,291 | 0.0250% | 403 |

**Analysis 7: Modeling of FY2018 outlier percentage**

WPA was asked to examine if it would be possible to provide any estimates of the proportion of outlier payments for FY2018. WPA has made some estimates, but they are subject to

significant assumptions. The difficulty is that the FY2018 MedPAR data released and the year is still ongoing.

WPA estimated it in two ways, and generated an operating outlier proportion.

1) Using the FY2017 Final data, but the FY2018 Final Rule impact file and payment factors. The charge inflation factor was reduced to one year as opposed to two. Using this approach, generated an operating outlier proportion of 5.0457% versus the target of 5.1%.
2) Using the FY2017 Final data, with the FY2018 Final Rule impact file and payment factors. The charge inflation factor was reduced to one year as opposed to two. However, for the provider CCRs, used the CCRs from the FY2019 Proposed rule, and removed the CCR reduction factors from the calculations. Using this approach, generated an operating outlier proportion of 5.1420% versus the target of 5.1%.

However, these results should be used with significant caution since both estimates make the assumption that the FY2018 cases will match the FY2019 cases. Different distributions of cases will lead to different results.