Federation of American Hospitals®

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June 17, 2016

Andy Slavitt
Acting 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

SUBJECT: CMS-1655-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 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; and Technical Changes Relating to Costs to Organizations and Medicare Cost Reports; April 27, 2016

Dear Administrator Slavitt:

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 parts of 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 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; and Technical Changes Relating to Costs to Organizations and Medicare Cost Reports; April 27, 2016 ("Proposed Rule").

EXECUTIVE SUMMARY

Medicare Disproportionate Share Hospital Payments

FAH appreciates CMS's past engagement of the hospital industry, particularly in 2013, with regard to the calculation methodology that Congress has required to determine uncompensated care payments to disproportionate share hospitals under Section 3133 of the Affordable Care Act of 2010 ("ACA"), codified at 42 U.S.C. § 1395ww(r) ("UC-DSH"). We are very concerned, however, that CMS is moving too quickly to use a form, Worksheet S-10, to distribute UC-DSH funds that is not clear in its construction and instructions, not consistently prepared by hospitals, and not yet subject to audit for accuracy. CMS simply has not done enough, many say very little, to fix the problems inherent in this form. We have pointed out that it has not been redesigned to align with purposes of the UC-DSH program to cover those areas where ACA might not reach, that is, "the amount of uncompensated care…costs of subsection (d) hospitals for treating the uninsured…."

The significant dislocation and misallocation in funding that occurs if the as-filed FY 2014 Worksheet S-10 is used simply cannot be allowed to occur given the problems we have identified with that form. In particular, the form does not measure the amount of uncompensated care that Section 3133 is designed to compensate; the problems inherent in reporting data in the existing form has not abated; and any audit process put in place once the final rule here is issued will not be sufficiently timely to address the inconsistencies in the ways that hospitals prepared the form, and such audits would not correct at all the deficiencies in the form. In particular, CMS needs to amend its Worksheet S-10 instructions to allow for reporting discounts provided to the uninsured as part of the total uncompensated care cost Worksheet S-10 purports to measure.

Until these issues are sufficiently corrected and hospitals are confident that the form yields fair, accurate, uniform, and audited data, it should not be deployed. If CMS chooses to move sooner, the proposed transition to the form should be delayed, extended, and initially nominalized to give CMS the time it needs to address its many problems before data from the form is allowed to have a significant impact on the allocation of UC-DSH funds.

Two- Midnight Policy

FAH supports and very much appreciates CMS's proposal to permanently remove, beginning in FY 2017, the 0.2 percent reduction to the IPPS rates that was applied in FYs 2014, 2015, and 2016. The FAH also supports CMS's proposal to temporarily increase the FY 2017 rates to reverse the effect of the 0.2 percent reduction to the IPPS rates that was applied in FYs 2014, 2015, and 2016. FAH also agrees that CMS's authority to apply an adjustment to rates in a given year to reverse the effect of an error in rates in prior years is limited to the circumstances of the Two Midnight 0.2 percent reduction, and does not extend to circumstances beyond this particular instance.

ATRA Recoupment

FAH strongly opposes CMS's proposal to deviate from its earlier plan to impose a ladder type adjustment of -0.8 percent per year from FFYs 2014 through 2017, to implement the American Taxpayer Relief Act of 2012 ("ATRA") section 631 recoupment. CMS proposes to

increase the added adjustment to -1.5 percent (from -0.8 percent) during FY 2017. This added adjustment creates two problems. First, we believe that it is not consistent with ATRA section 631 and that the assumptions underlying its calculation are flawed. Nor does it account for changes in policy such as the Two Midnight rule which shifted cases from inpatient to outpatient and the readmission reduction program, as well as the ongoing beneficiary migration, encouraged by policymakers, to Medicare Advantage. Second, should CMS retain a cut greater than 0.8 percent, it must fill the gap left between its increased adjustment for FFY 2017 and the restoration schedule Congress set forth in Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"). CMS clearly has the authority to fill that gap and thereby satisfy MACRA's mandate without perpetuating the ATRA adjustment beyond the savings Congress sought to achieve with MACRA.

Hospital Quality Programs

The FAH has a history of supporting public reporting in payment programs, and recommending that the information reported to the public be accurate and comparable across providers. In addition, the FAH believes 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. Our experience is that this has not always been the case. Across all programs, too many measures have been introduced prematurely leading to significant implementation issues. The cost of fixing these issues is substantial and falls on the hospitals/facilities, contractors and CMS. These costs could and should be avoided so that time and resources could more appropriately be devoted to patient care and quality improvement rather than fixing technical issues.

The FAH recommends that CMS give much greater attention to the burden associated with implementing measures and ensure that the measures are appropriately and precisely specified for that setting, NQF endorsed, and field tested before being deployed in any payment program. The field testing should be robust and include significant opportunity for feedback from the providers attempting to collect the data. Further, FAH recommends that CMS adopt "minimum standards" for all measure specifications for all future measures. Finally, FAH is concerned about the inclusion of measures that cannot be replicated, and offer access to certain data only once each year. Absent an opportunity for on-going self-assessment, hospitals have limited ability to use these measures to inform quality improvement strategies, which should be the primary goal of a program.

The FAH supports the proposal to align the requirements for reporting of electronic measures in the IQR Program with the EHR Incentive Program. However, based on our member hospitals' experience to date with reporting eCQMs, we believe that the proposal to require reporting of 15 eCQMs for purposes of both the IQR Program and the EHR Incentive Program in 2017 is overly ambitious. For 2016, hospitals must report four eCQMs and given the ongoing technical issues with vendor and CMS systems, we do not believe that it is feasible to require all participating hospitals to report 15 measures at this point. Problems with CMS' technical ability to receive the measure data have led CMS to significantly delay reporting deadlines. We recommend that for 2017 hospitals be required to report at least six electronic measures, with the option of reporting all 15 measures. This will allow CMS and vendors more time to work out technical issues.

Long-Term Care Hospital Prospective Payment System

As CMS moves forward with implementation of the Pathway for Sustainable Growth Rate Reform Act of 2013 (Pub. L. 113-67) ("PSRA"), the FAH is concerned about policy proposals that could frustrate Congressional intent, especially regarding payment for site neutral cases. The FAH strongly disagrees with CMS's proposal to apply a .949 budget neutrality factor to LTCH site neutral cases that qualify for high cost outlier payments. These cases are paid based on the short stay hospital inpatient prospective payment system (IPPS), and a budget neutrality adjustment to account for outlier cases has already been applied to reduce those IPPS payments. CMS's proposal, therefore, results in a duplicative reduction for site neutral cases, and should be withdrawn, a view that is shared by MedPAC.

In addition, while FAH believes there are compelling reasons for CMS to completely retire the 25% Rule, effective October 1, 2016, at a minimum CMS should not apply the Rule to LTCH cases paid at the site neutral rate. The application of the 25% Rule to these cases is duplicative, unnecessary and punitive. Further, because the site neutral payment rate will be a fraction of the traditional LTCH PPS standard Federal payment rate, there is no reason to believe that LTCHs are inappropriately accepting the transfer of site neutral cases from discharging hospitals. As such, applying the 25% Rule to those cases paid at the site neutral rate will essentially penalize the LTCH twice for the same case, an outcome at odds with Congressional intent.

ATRA Recoupment

II.D.6. Recoupment or Repayment Adjustment Authorized by Section 631 of the America

CMS proposes to deviate from its earlier plan to impose a ladder type adjustment of -0.8 percent per year from FFYs 2014 through 2017, to implement the American Taxpayer Relief Act of 2012 ("ATRA") section 631 recoupment. CMS proposes to increase the added adjustment to -1.5 percent (from -0.8 percent) during FY 2017. This added adjustment creates two problems. First, we believe that it is not consistent with ATRA section 631 and that the assumptions underlying its calculation are flawed. Second, should CMS retain a cut greater than 0.8 percent, it must fill the gap left between its increased adjustment for FFY 2017 and the restoration schedule Congress set forth in Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"). CMS clearly has the authority to fill that gap and thereby satisfy MACRA's mandate without perpetuating the ATRA adjustment beyond the savings Congress sought to achieve with MACRA.

A. CMS's Proposed Method to Address the Final Year of the ATRA Recoupment is not Consistent with Congressional Intent and is Overly Aggressive.

1. Section 631 of the ("ATRA") And Regulatory Implementation

Section 631(b)(2) of ATRA (emphasis added) provides in relevant part:

(ii) make *an additional adjustment to the standardized amounts* under such section 1886(d) *based upon the Secretary's estimates for discharges occurring only during fiscal years 2014, 2015, 2016, and 2017 to fully offset $11,000,000,000* (which

> represents the amount of the increase in aggregate payments from fiscal years 2008 through 2013 for which an adjustment was not previously applied).

It is plain from the wording of the statute that Congress was not requiring more than an estimated offset of the presumed $11 billion overpayment. In fact, the section provides a calculation that starts with an estimate, the number of discharges in each of the relevant years, and the derivation of a negative adjustment to the standardized amount such that aggregating the estimates over the four-year period equals $11 billion.

This language is similar to the methodology for calculating the Medicare cost outlier threshold under 42 U.S.C. § 1395ww(d)(5)(A), which also sums to an aggregate figure based on a percentage of total DRG payments for a year:

> (iv) The total amount of the additional payments made under this subparagraph for discharges in a fiscal year may not be less than 5 percent nor more than 6 percent of the total payments projected or estimated to be made based on DRG prospective payment rates for discharges in that year.

In the context of this language, the Secretary has successfully asserted in two U.S. Court of Appeals cases that the aggregate payment amount for outlier payments must be a projection because it is premised on a projection or estimate, not an actual aggregate payment requirement for each year and CMS has no obligation to reconcile the payments to actual at year end.

It is equally clear from the ATRA statute that Congress considered the amount of each annual contribution to the aggregate estimate of $11 billion to be independent. That independence is evident from the statute because Congress called for an adjustment "to the standardized amounts," that is to be applied to "estimates for discharges occurring only during fiscal years 2014, 2015, 2016, and 2017…." There is no indication that Congress intended a look back to each year to determine the amount that was actually withheld from each year's IPPS claims for purposes of adjusting the estimate to actual for the year that had passed. In fact, just the opposite. CMS was to estimate for each year. So while it appears the Secretary was authorized to put a system in place in the first year of the recoupment estimating each year's discharges and the related recoupment, there is no indication that such estimates were to be disturbed in the succeeding years. But for the first three years of the recoupment, CMS did just that in the FY 2017 proposed rule. So under the statute, it appears CMS could have put a plan in place in FY 2014 that was based on its estimates for the four years at that time, or it could estimate each year independently. It actually did suggest such a four-year plan as part of the FY 2014 IPPS rulemaking:

> If adjustments of approximately -0.8 percent are implemented in FYs 2014, 2015, 2016, and 2017, using standard inflation factors, we estimate that the entire $11 billion would be accounted for by the end of the statutory 4-year timeline.

But implementing the four-year recoupment in the way that CMS proposes for FY 2017 does not to us appear consistent with the statute because it is revisiting its estimates in each of the preceding years, and adjusting them to an actual number for purposes of calculating the FY 2017 adjustment. In our view, based on the above, CMS should either leave the ladder based -0.8 percent adjustment in effect for all four years, because that is consistent with the statute. Or CMS should credit the $11 billion recoupment for its estimated recoveries in each of the final IPPS

Rules for FFYs 2014 through 2016, and calculate the remaining adjustment for FFY 2017 based on the residual. But CMS cannot do what it has set forth in the FY 2017 proposed rule, because revisiting each fiscal year's actual recoupment retrospectively is not an option under the statute. Nor is it consistent with Congress view of the extent of the recoupment in subsequent legislation. See below at page 8.

2. CMS is not Considering Significant Relevant Factors in its Calculation of the FY 2017 ATRA Adjustment

If CMS imposes an adjustment of -3.2% in FY 2017 it will in actuality likely recover more than the ATRA aggregate $11 billion projection. The reason that occurs also explains why discharges have been decreasing under Medicare Part A during the period of the ATRA adjustments. During this period, from about 2013 through 2017, CMS has successfully encouraged a large shift of Medicare patients from Medicare Parts A and B to Medicare Part C. Indeed, as demonstrated by the following table developed from Medicare Advantage Penetration by county that CMS has provided on a monthly basis from the following web site: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/MA-State-County-Penetration.html, between 2012 and 2016 Medicare Part C enrollment has increased dramatically:

Year	MA Penetration
2012	27.0%
2013	28.5%
2014	30.2%
2015	31.9%
2016	32.2%

In 2013, when CMS was proposing the ladder adjustment system for ATRA based on a -.8% annual increase through FY 2017, MA penetration was at the 28.5% level and has grown since. Those beneficiaries' inpatient stays would have shifted out of Part A and into Part C. That does not mean CMS would not recover the ATRA recoupment from those shifted patients.

In the context of the Medicare Part C shift, because the ATRA adjustment is imposed through the CMS PC-Pricer software (universally used to price Medicare Part C payments to providers), it is also captured by the method CMS uses to calculate payments to MA plans. The most recent CBO estimates indicate that Medicare Part C penetration will reach 48.8% of total Medicare fee for service during FY 2017. Just the change in that enrollment from the baseline at the implementation of ATRA in FY 2014 to FY 2017 impacts the ATRA calculation by approximately $200 million in shifted discharges in FY 2017 alone. And if the impact of the ATRA adjustment is considered in payments for all Medicare Part C discharges for just FY 2017, we believe ATRA will save the program $1.4 billion in FY 2017 alone. See the below table:

Calculation on MA Payments of ATLA Adjustment:	
Claims in 2014 MEDPAR File	
MA Discharges	3,175,315
FFS Discharges	9,158,565
MA Volume as a % of FFS	34.67%
Projected Savings in 2017 with .8% Adjustment	4,000,000,000
Total Estimated Savings on MA Discharges	**1,386,817,695**

Notes:
MA Savings may be understated due to growth in MA Enrollment compared to FFS over the past several years. Claims data utilized in this calculation is 3 years before the 2017 projection year. MA savings may be overstated if the full 3.2% ATRA cut has not been included in the baseline, but our members' experience suggests that the vast majority of MA plans use the Pricer for payment purposes.

In comments the FAH, AHA and AAMC have filed for OPPS purposes this year, the Two Midnight policy has shifted a significant number of inpatient cases to outpatient cases. If CMS normalizes its data to account for this shift it likely would find that a -3.2% adjustment is more than enough to address the ATRA aggregate projection. It would be more than a little disingenuous to further penalize hospitals for the far larger savings that compliance with CMS policies and goals of reducing admissions achieves. The projections above do not include a calculation to normalize discharges for the decrease in inpatient stays prompted by the two midnight policy. But CMS has that data now and it was also included in the OPPS and Shands Notice comments of the FAH, AHA and AAMC.

For all of the foregoing reasons we think CMS is on good statutory footing to limit its ATRA adjustment for FY 2017 to the planned -3.2% amount. Indeed, such an approach is further evidence that the correct reading of that ATRA statute is that the adjustment makes the most sense when put in place in its entirety as a plan in 2014, because it would be based on policies then in effect, rather than evolving policies that cause variance in inpatient stays.

3. There is Too Much Variance in the Estimation of the Number of Inpatient Stays in FY 2017 for CMS to Take an Aggressive Approach to the ATRA Adjustment Estimation.

Two concerns are apparent from the OACT memorandum in support of the proposed ATRA adjustment for FY 2017. Estimate of Medicare Documentation and Coding Adjustments, CMS, Office of the Actuary, April 15, 2016. The first concern is that clearly, OACT did not consider any recovery under ATRA from the Medicare Advantage program in determining whether the ATRA recoupment was satisfied. As we noted above, if such a recovery is considered, there is little need for an increase in the adjustment. Second, to conclude his report, the Actuary states: "Since we do not know how many Medicare beneficiaries will choose to enroll in a Medicare Advantage plan, for example, or the degree to which the remaining fee-for-service

enrollees will use hospital services, there is much uncertainty in these estimates." We have witnessed such language before from the Actuary in support of the reductions associated with the Two Midnight policy and ultimately that lack of concrete support resulted in CMS withdrawing the reduction this year.

The lack of confidence expressed by OACT is alarming given the size and suddenness of this increase to the payment cut -- the ATRA adjustment CMS proposes for FY 2017 is slightly less than double the size of the adjustment it has implemented for the last three years. There should be much greater certainty about this estimate before such an adjustment is imposed. The various figures that OACT sets forth in the memorandum for its projections in 2013 and 2016 bare so little resemblance to each other that both strain credibility. Additionally, the outside consultants that we tasked with replicating the Actuary's figure in its most recent estimate could not replicate it at all, principally because OACT did not provide any source data files for these estimates.

We respectfully suggest that CMS work to achieve a result consistent with its initial approach to implement the ATRA adjustment for FY 2017, consistent with concerns referenced above.

B. Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA").

In implementing Section 631(b) of ATRA the Secretary laid out a plan to impose an escalating adjustment for each of the four years based on actuarially projected discharges in each year such that the adjustment in the first year, FFY 2014, would equal a -0.8% reduction to the standardized amount, escalating by -0.8% in each year until the adjustment equaled -3.2% in 2017. While CMS did not commit to this plan in the FY 2014 rulemaking, CMS also stated:

> [T]he adjustment required under section 631 of the ATRA is a one-time recoupment of a prior overpayment, not a permanent reduction to payment rates. Therefore, any adjustment made to reduce rates in one year would eventually be offset by a positive adjustment, once the necessary amount of overpayment is recovered.

Clearly at the time ATRA was passed both Congress and the Secretary recognized that the ATRA recoupment would end with FY 2017.

In an effort to generate savings to pay for a permanent fix to the sustainable growth rate for physician payments under Medicare, Congress determined to delay the restoration of the one-time adjustments created by ATRA § 631(b) in FY 2018, by spreading the restorative adjustments over 6 years. Section 414 of MACRA amends ATRA § 631(b) by the addition of a clause to reverse the impact of the negative adjustments and requires the Secretary to:

> (iii) make an additional adjustment to the standardized amounts under such section 1886(d) of an increase of 0.5 percentage points for discharges occurring during each of fiscal years 2018 through 2023 and not make the adjustment *(estimated to be an increase of 3.2 percent)* that would otherwise apply for discharges occurring during fiscal year 2018 by reason of the completion of the adjustments required under clause (ii).

Clearly Congress anticipated in this 2015 legislation that the final adjustment in FY 2017 to implement ATRA § 631 would approximate 3.2%. Indeed, that percentage is reflected in the

statutory language. The subsequent restorative adjustments are closely tied to that amount. In the FY 2016 IPPS Final Rule, CMS indicated that in addition to finalizing the implementation of ATRA § 631 in FY 2017 it will would respond to MACRA §414. Unfortunately, the proposed rule for FY 2017 reserves that response for a later date.

Whatever Congress may have intended with the amendment of ATRA § 631(b) by MACRA § 414, it is clear that Congress did not intend to create a large permanent negative adjustment to the IPPS standardized amount. The MACRA provision specifically identifies the final ATRA adjustment in FY 2017 of -3.2% and not at some higher level because actual discharges have not achieved the actual levels that CMS projected when it placed the ATRA adjustment on a -0.8% escalating path. This is clear both from ATRA and MACRA. MACRA § 414's specific reference to the -3.2% adjustment is further evidence that Congress expected no more than that adjustment for FY 2017. Indeed, this provision is a specific amendment to the statutory language of ATRA. We acknowledge that there is a .2% difference between Congress' expectation for the ATRA adjustment and the extended restoration, but that is the extent of the limit Congress placed on CMS with regard to it authority under the MACRA provision.

MS-DRG Classifications

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

CMS has continued to receive requests related to replication issues between ICD-10 MS-DRGs and ICD-9 MS-DRGs. For FY 2017, many of the proposed MS-DRG classification changes are due to replication issues. It is important to note that there are over 2,000 codes within the proposed rule that were identified as being involved in replication errors.

Based on review of the proposed rule, FAH agrees overall with the proposed changes being recommended for MS-DRG and/or ICD-10 code classification changes for FY 2017 other than the items noted below.

II.F.5.b. MDC 5 (Diseases and Disorders of the Circulatory System) - endovascular thrombectomy of the lower limbs

We agree with the reconfiguration of ICD-10-PCS code translations and the MS-DRG Classification change to reflect endovascular thrombectomy of the lower limbs. However, of the 51 ICD-10-PCS codes proposed in the table in this section, there appear to be some ICD-10-PCS codes that represent veins of the upper limbs as well as lower limbs. A few examples of the upper limb codes included in this table are:

- 05CG3ZZ Extirpation of matter from right hand vein, percutaneous approach
- 03C93ZZ Extirpation of matter from right ulnar artery, percutaneous approach
- 05CT3ZZ Extirpation of matter from right face vein, percutaneous approach

It is recommended that CMS review and remove if applicable, codes that represent upper limb endovascular thrombectomy procedures from the table of ICD-10-PCS codes in this section to align with the intent of this MS-DRG Classification change.

II.F.5.c. MDC 5 (Diseases and Disorders of the Circulatory System) - pacemaker procedures code combinations and MS-DRG classification changes

FAH agrees with the CMS proposal to simplify the approach to the classification of MS-DRGs 242, 243, 244, 258, 259, 260, 261 and 262. We also agree with the ICD-10-PCS codes listed for the initial implant MS-DRGs 242, 243 and 244 as well as the ICD- 10-PCS codes list for replacement device MS-DRGs 258 and 259.

For MS-DRGs 260, 261 and 262, Cardiac Pacemaker Revision Except Device with MCC, CC and without CC/MCC, we agree with the ICD-10-PCS codes listed in the table. However, we noted issues with narrative descriptions on some of these codes listed in the table versus the narrative description in the actual ICD-10-PCS code below. Included below is an example.

The "J" character in the device character field of the narrative code via the ICD-10-PCS code book describes cardiac lead, pacemaker (02HK0JZ, 02HK3JZ, and 02HK4JZ) rather than a monitoring device

- ***Proposed Rule narrative- 02HK3JZ Insertion of* monitoring *device into right ventricle, percutaneous approach***
- *Code book narrative - 02HK3JZ Insertion of Cardiac Lead, Pacemaker, percutaneous approach*

It is recommended that CMS update the narrative of the ICD-10 PCS codes in the final rule where applicable to align with the description of the procedure codes in the code book.

II.F.11. MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services): Logic of MS-DRGs 945 and 946 (Rehabilitation with and without CC/MCC, Respectively)

CMS received several requests to examine the MS-DRG logic for MS-DRGs 945 and 946 due to the concerns that the ICD-9-CM codes that clearly identified an encounter for rehabilitation services such as codes V57.89 (Care involving other specified rehabilitation procedure) ad V57.9 (Care involving unspecified rehabilitation procedure) were not included in ICD-10-CM Version 33. Additionally, there have been significant changes to the ICD-10 guidelines for coding of admissions/encounters for rehabilitation.

Under Grouper Logic, cases are assigned to MS-DRGs 945 and 946 in one of two ways:

- The encounter has a principal diagnosis code Z44.8 (Encounter for fitting and adjustment of other external prosthetic devices) or Z44.9 (Encounter for fitting and adjustment of unspecified external prosthetic device). Both of these codes are included in the list of principal diagnosis codes assigned to MDC 23.
- The encounter has an MDC 23 principal diagnosis code and one of the rehabilitation procedure codes listed under MS-DRGs 945 and 946.

If the case does not have a principal diagnosis code from the MDC 23 list, but does have a procedure code from the list included under the Rehab Procedures for MS-DRGs 945 and 946, the case will NOT be assigned to MS-DRGs 945 or 946. Instead, the case will be assigned to a MS-DRG within the MDC where the principal diagnosis code is found. For example, a common

reason a patient is admitted to rehab includes a principal diagnosis code of I69.351, Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side with procedure code F01ZDYZ, Gait and/or Balance Assessment using Other Equipment which groups to MS-DRG 57, Degenerative Nervous System Disorders w/o MCC instead of MS-DRGs 945 or 946.

FAH agrees that the logic for MS-DRGs 945 and 946 should be more closely examined. We do not believe either of the three options presented in the proposed rule would accomplish the goal of better alignment without creating unintended consequences. The FAH recommends that CMS assemble a technical advisory panel (TEP) made up of industry stakeholders, such as rehab providers and other industry representation, to conduct a thorough evaluation and proposed a recommended DRG logic change for FY18.

The FAH also submits an alternative approach to address this issue which includes creation of a new ICD-10-CM diagnosis code and changes to the MS-DRG GROUPER logic. This alternative approach would be to:

1) Work with the ICD-10 Coordination and Maintenance Committee, the federal committee co-chaired by CMS and the Centers for Disease Control and Prevention (CDC), to create a single new ICD-10-CM diagnosis code ("Z-code") to replicate the ICD-9-CM code category V57, Care involving use of rehabilitation procedures.

2) Maintain the existing ICD-10-CM Official Guidelines for Coding and Reporting to allow the sequencing of the diagnosis code for the condition for which the service is being performed as the principal diagnosis when the purpose for the admission/encounter is rehabilitation. In addition, recommend revision of the ICD-10-CM Official Guidelines for Coding and Reporting so that the "Z-code" is reported as a secondary diagnosis when the purpose for the admission/encounter is rehabilitation. Our understanding is that in the past providers, researchers and others had expressed an interest in identifying the actual medical condition as the principal diagnosis rather than the generic codes from ICD-9-CM category V57.

3) Recommend CMS add the "Z-code" to MDC 23 and grouping cases to MS-DRGs 945 and 946 on the basis of the secondary diagnosis code using the "Z-code." There is precedence for the GROUPER logic to use the secondary diagnosis to drive the MS-DRG as in MS-DRGs 280 to 285 (acute myocardial infarction) and MS-DRGs 969, 970, and 970-977 (human immunodeficiency virus) which are grouped on the basis of the codes for acute myocardial infarction or human immunodeficiency virus in either the principal diagnosis or secondary diagnoses position.

Wage Index

The FAH supports many of the proposals CMS has advanced with respect to the Medicare wage index. Our comments primarily request clarifications where implementation questions were raised and reflect our appreciation of the opportunity to comment. Those comments follow.

III. H. Proposed Application of the Proposed Rural, Imputed, and Frontier Floors

In the FY 2017 IPPS proposed rule, CMS states that it intends, for the 7th consecutive time, to extend the imputed rural floor policy for 1 year until September 30, 2017. 81 Fed. Reg. at 25067-25068 (April 27, 2016). 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 opposes the proposal by CMS to extend the use of the imputed floor. We agreed with CMS's assessment in the FY 2008 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. We appreciate that CMS is being thoughtful in their assessment of wage index reforms, but year-over-year continuation of this bad policy needs to be addressed as soon as practicable.

III. J.2.b. Requirements for FY 2018 Applications and Proposed Revisions Regarding Paper Application Requirements

CMS is proposing to revise the regulation at §412.256(a)(1) to specify that an application for reclassification or redesignation must be submitted to the MGCRB according to the method prescribed by the MGCRB in the application instructions, with an electronic copy (e-mail) of the application sent to CMS. 81 Fed. Reg. 25069. The FAH supports CMS's proposed change in the submission of MGCRB applications to CMS by electronic means beginning in 2018. We agree that this will make the application process easier. We request, however, that CMS (and the MGCRB if they choose a similar method) should provide an e-mail response to the applicant to verify that the application has been received.

In addition, CMS should provide instructions on how providers can complete an e-mail reclassification or redesignation request if the full application is too large to be sent in a single e-mail. The logical answer would be to send more than one e-mail. Our concern is making sure that CMS can tie the multiple e-mails to the same application and that as long as all of the e-mails are received by the prescribed deadline, nothing needed for the application is deemed untimely because it was in a separate e-mail that may or may not have arrived in conjunction with another e-mail.

On a related topic, when the MGCRB is promulgating their next set of instructions for individual and group reclassification and redesignation requests, the FAH requests that CMS ask the MGCRB to be more specific in the documentation requirements for the mileage threshold criteria. In the past, law enforcement officer affidavits of driving distance were considered sufficient documentation, even perhaps the best form of documentation, of mileage between a hospital and a particular county line. More recently, the MGCRB has thought to include computerized mapping software such as Bing® and Google Maps® as acceptable to document distance. We appreciate that an electronic alternative for mapping distance has been provided, but we are concerned over indications that the computerized software results are being relied on more heavily than the results of a law enforcement officer's sworn affidavit. Computerized mapping programs are not infallible and where evidence is presented that an actual live human being drove the route and measured it at a certain amount, that evidence should be given the greatest weight in the determination of whether or not the hospital meets the mileage criteria.

The instructions are also unclear on the point of when and how the special access rules for sole-community hospitals (SCHs) and rural referral centers (RRCs) apply to rural, formerly

urban, providers. It would be helpful if the instructions clearly indicated that the proximity requirement is 35 miles and that these rural, formerly urban hospitals can reclassify (assuming all other criteria are met) to any MSA within 35 miles or to the closest MSA if there is not a target MSA within 35 miles at the option of the hospital.

III. J.3. Redesignation of Hospitals Under Section 1886(d)(8)(B) of the Act

The FAH supports and appreciates CMS's clarifications that the wage index of a Lugar hospital that also has a rural reclassification under §412.103 will be based on the Lugar status for wage index purposes. This clarification will eliminate the need for some of these hospitals to submit MGCRB applications to receive a higher Lugar wage index.

III. L. Notification Regarding Proposed CMS "Lock-In" Date for Urban to Rural Reclassifications Under §412.103

CMS is proposing to revise § 412.103(b) by adding a new paragraph (6) to incorporate this proposed policy. Proposed § 412.103(b)(6) would specify that in order for a hospital to be treated as rural in the wage index and budget neutrality calculations under §§ 412.64(e)(1)(ii), (e)(2), (e)(4), and (h) for payment rates for the next Federal fiscal year, the hospital's filing date must be no later than 70 days prior to the second Monday in June of the current Federal fiscal year and the application must be approved by the CMS Regional Office in accordance with the requirements of § 412.103."

The FAH understands this only impacts the annual wage index and budget neutrality calculations and would not impact the specific payment calculation for a hospital that receives a rural reclassification. The FAH seeks clarification and affirmation of our understanding. If our understanding is correct we support the need to have a cutoff date for data needed in the annual rate development process and feel what CMS is proposing is reasonable.

III. O. Solicitation of Comments on Treatment of Overhead and Home Office Costs in the Wage Index Calculation

The FAH wants to commend CMS in the open and transparent manner they are reviewing the "Treatment of Overhead and Home Office Costs in the Wage Index Calculation". This is a complicated area that will need significant feedback and input from the hospital community before implementing changes to the form and/or calculation. The FAH strongly encourages CMS to seek more direct hospital input for any specific changes to the cost report and cost report instructions in this area. Specific recommendations are noted below:

A. FAH recommends that CMS continue to estimate and remove overhead wage-related costs associated with excluded areas from the unadjusted wage index.

The FAH strongly agrees with CMS that there is a need for CMS to continue to estimate and remove the overhead wage-related cost associated with excluded areas from the unadjusted wage index calculations. The current cost report instructions for Worksheet S-3, Part II instruct providers that wage-related costs associated with excluded areas be removed from line 17, but providers are not instructed to remove overhead wage-related costs associated with excluded areas from Line 17 and it is clear that in most, if not all cases, providers are not self-identifying and removing this amount. Therefore, the FAH recommends that CMS continue to estimate and

remove overhead wage-related costs associated with excluded areas from the unadjusted wage index.

B. FAH would support adding an additional footnote to the cost report instructions for Worksheet S-3, Part II, Line 17 so that providers are clear on the expectation.

We believe adjusting Worksheet S-3 Part II to capture what CMS's Step 4 process already produces would be redundant, increase administrative burden and not generate any additional benefit. Also, any plan to allow or require hospitals to perform their own calculation to estimate and remove excluded overhead could create inconsistent results unless very specific instructions were given and adhered to. CMS's Step 4 process is fair and equitable for all providers and should continue. If CMS, in an abundance of caution, wanted to insure that all providers were including all of their overhead wage-related costs in Line 17 (on the off chance that there is a hospital removing the excluded overhead of their own accord) so that all providers were being equally subjected to CMS's estimate and removal calculation in Step 4, the FAH would support adding an additional footnote to the cost report instructions for Worksheet S-3, Part II, Line 17 so that providers are clear on the expectation.

C. FAH recommends that they add a schedule to the cost report that performs the wage index calculation that CMS uses to calculate the unadjusted wage index.

If CMS chooses to pursue building the overhead allocation into the cost report we would recommend that they add a schedule to the cost report that performs the wage index calculation that CMS uses to calculate the unadjusted wage index. In this scenario, this worksheet should require no additional input or administrative burden since all the data elements come from various parts of Worksheet S-3. The disadvantage is that this workbook would need to be updated if the wage index calculation is revised.

D. The FAH recommends that the alternate overhead allocation basis be collected and any other allocation basis be approved by the MAC

In terms of CMS's request related to cost report completion of lines 17 through 25, the FAH believes that most hospitals allocate the wage-related cost on lines 17 through 25, based on salaries and feel that should be the preferred method. If CMS makes an adjustment to Worksheet S-3 Part II we would recommend that the allocation basis be collected and any other allocation basis be approved by the MAC at some point in the future for the hospitals to continue to utilize this method. The hospital would need to document with the MAC that an alternative method would be more accurate than salaries.

E. The FAH would recommend that CMS subscript line 14 into overhead and non-overhead cost and hours

The FAH believes that most hospitals report home office salaries on Worksheet A-8-1 with an appropriate adjustment in Column 6 of Worksheet A. Home office costs would be in scope on most cost report audits where a home office exists and those audits would reveal problems if hospitals were routinely not making appropriate adjustments for home office salaries. In addition, based on member experience and our plain reading of the cost report instructions, the FAH feels that most hospitals report their entire home office salary and hour allocation on line 14 Worksheet S-3 Part II without removing an allocation for excluded areas.

If CMS decides that an allocation is needed for overhead cost contained in the home office allocation to excluded areas, we would recommend that CMS subscript line 14 into overhead and non-overhead cost and hours. The overhead portion could then be allocated in the same manner that the hospital overhead cost is currently allocated.

F. FAH suggests that any change in the wage index calculation be evaluated after the additional information is gathered

The FAH also suggests that any change in the wage index calculation be evaluated after the additional information is gathered so that it can be evaluated similar to CMS efforts in relation to the overhead allocation. CMS should disclose their findings and any proposed changes to the wage index calculation in a notice and comment rule making.

Disproportionate Share Hospital Payment

IV.F. Proposed FY 2016 Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs)

FAH appreciates CMS's past engagement of the hospital industry, particularly in 2013, with regard to the calculation methodology that Congress has required to determine uncompensated care payments to disproportionate share hospitals under Section 3133 of the Affordable Care Act of 2010 ("ACA"), codified at 42 U.S.C. § 1395ww(r) ("UC-DSH"). In particular, we very much appreciate the actions CMS took in the FY 2015 rule-making to correct an inequity that occurred in the FY 2014 rule-making commentary that penalized hospitals that had merged in periods where CMS used data to calculate hospitals payments in Factor 3, as set forth in ACA Section 3133. Restoring the correct level of uncompensated care payments to hospitals that have merged, where the surviving hospital has accepted assignment of the provider agreement of the retired provider, affected a small number of hospitals, but many of those are safety net hospitals dependent on such payments.

We provide below our analysis of continuing problems we have found in the way that CMS calculates Factor 1 of Section 3133 payments to hospitals. We believe there is a general lack of transparency in this calculation and that, for FY 2017, it contains significant errors.

We are particularly concerned with both the payment accuracy and equity of CMS too quickly pushing the Factor 3 calculation to the use of an immature form, Worksheet S-10, not clear in its construction and instructions, not consistently prepared by hospitals, and not yet subject to audit for accuracy. The FAH has supported eventually using the S-10. But as we noted in our comments to the FY 2016 proposed rule that: "CMS correctly concluded in last year's final rule that available Worksheet S-10 (hereinafter "S-10") data is too unreliable to use as a basis to allocate many billions of dollars in hospital payments and has reiterated those concerns in the FY 2015 proposed rule. 79 Fed. Reg. at 28100." CMS simply has not done enough, many say very little, to fix the problems inherent in a form that we have pointed out since our comments in 2013 has not been redesigned to align with purposes of the UC-DSH program.

The significant dislocation and misallocation in funding that occurs if the as-filed FY 2014 Worksheet S-10 is used simply cannot be allowed to occur given the problems we identify with that form in the following sections of this letter. In particular, the form does not measure the amount of uncompensated care that Section 3133 is designed to compensate, the problems inherent in reporting data in the existing form that we have addressed in our prior comments has not abated, and any audit process put in place once the final rule here is issued will not be sufficiently timely to address the inconsistencies in the ways that hospitals prepared the form and such audits would not correct at all the deficiencies in the form.

Thus, as explained in more detail below, we do not believe the form can rationally be used by FY 2018 and should not be used until the issues we address are sufficiently corrected and hospitals are confident that the form yields fair, accurate, uniform, and audited data. If CMS chooses to move sooner, the proposed transition to the form should be extended and initially nominalized to give CMS the time to address the problems noted here before data from the form is allowed to have a significant impact on the allocation of the Factor 2 fund to DSH eligible hospitals.

I. UC-DSH FACTOR 1

We have reviewed the FY 2017 IPPS Proposed Rule: Medicare DSH Supplemental Data File, particularly the spreadsheet titled "FY 2017 NPRM Medicare DSH Estimates" that CMS has made available on its website in support of the proposed rule. We continue to be concerned with the opacity of the calculations that underlie the Factor 1 calculation that is summarized in the Table FACTORS APPLIED FOR FY 2014 THROUGH FY 2017 TO ESTIMATE MEDICARE DSH EXPENDITURES USING 2013 BASELINE, appearing in 81 Fed. Reg. at 25085. The data files CMS provided simply do not explain or provide data for the important calculation in the table.

We are concerned that CMS chose to use an "Other" factor of 0.9993 for FY 2016 in its build-up calculation of Factor 1 for FY 2017. 81 Fed. Reg. at 25,085. While the details of the "Other" factor in the calculation are not provided by CMS in the proposed rule (a separate problem that causes inadequate notice for comment purposes under the APA), CMS has indicated that one component of "Other" concerns the expansion (or contraction) of the Medicaid population, which has an impact on the calculation of DSH payments. In our FY 2016 comments we noted that CMS used the exact same .9993 factor from the "Other" column for FY 2014, the first year of the Medicaid expansion, and we were extremely critical that such a figure would be used there given the pent up demand for Medicaid services by that population. Without explanation, in the proposed 2017 version of the table, that figure for FY 2014 has been updated to 1.04795, proving that CMS understated the calculation of Factor 1 for FY 2016. Now we see the same .9993 figure appearing in the "Other" column for FY 2016, when CMS had projected a figure of 1.045 in the FY 2016 final rule.

CMS does not explain its change in thinking in either instance, although clearly, CMS was wrong when it calculated the Factor 1 in FY 2016 with the understated "Other" figure for FY 2014. In this case the difference between the FY 2016 final rule figure for "Other" for FY 2016, and the reduction of that figure to .9993 in this proposed rule, equates to an understatement of about $650 million in the Factor 1 pool. Without some explanation by CMS as to what

prompts these changes in figures for the same periods, it is impossible for us to meaningfully comment on them, except to note the extreme discrepancies.

II. UC-DSH FACTOR 3

A. Discounted Care for the Uninsured

When Congress enacted ACA in 2010 it changed the calculus of patient access to health coverage in many respects. ACA as passed expanded Medicaid to include virtually everyone in the United States with incomes at or below 138% of the FPL, and it provided low income subsidies for premiums and cost sharing for individuals with incomes above that level. While the Supreme Court may have frustrated aspects of the actual implementation of this expansion of coverage by allowing state Medicaid programs to opt out of the expansion, Congress' intention with regard to such coverage expansion permeates virtually every other provision of the law, including Section 3133 creating the UC-DSH program.

The traditional Medicare DSH program focused on providing additional revenue to hospitals that cared for a disproportionate share of low income patients under the assumption that such patients were sicker and more costly to treat than others because they did not otherwise have ready access to care and some of the costs of their care was otherwise unreimbursed. But clearly, in the collective mind of Congress, that program was viewed as not well targeted to an environment where low income patients almost universally would be covered by insurance and have access to primary care. So it was no surprise that in taking 75 percent from the traditional DSH program to fund the UC-DSH program, Congress chose to target the distribution of those funds based on the new paradigm of ACA, to cover those areas where ACA might not reach, that is, "the amount of uncompensated care…costs of subsection (d) hospitals for treating the uninsured…." 42 U.S.C. § 1395ww(r)(2)(C)(i). The statute does not mention charity care, or even gross non-Medicare bad debt, it simply focuses on the uncompensated care costs of the **uninsured**. Indeed, under the Factor Two calculation of section 3133, the size of the available funding pool decreases as the uninsured population decreases.

It is therefore surprising that in proposing a transition from the current proxy measure used to distribute UC-DSH payments, CMS desires to use data from a form, Worksheet S-10, that was not designed with Section 3133's objectives in mind (i.e., the uncompensated cost of care provided to the uninsured). We explain below in more detail why we believe CMS needs to amend its Worksheet S-10 instructions to allow for reporting discounts provided to the uninsured as part of the total uncompensated care cost Worksheet S-10 purports to measure.

1. The Current Worksheet S-10 Frustrates Rather than Furthers the Purpose of ACA Section 3133

The instructions to Worksheet S-10 are set forth in PRM-II section 4012, which define uncompensated care as:

> [C]harity care and bad debt which includes non-Medicare bad debt and nonreimbursable Medicare bad debt. *Uncompensated care does not include courtesy allowances or discounts given to patients*. [Emphasis added.]

This definition has created some confusion in the hospital industry as to how related data should be reported because it is unclear if "courtesy" applies to both "allowance" and "discounts" or whether the term "discounts" is unmodified by "courtesy." Uninsured discounts are certainly not the same as courtesy discounts. Uninsured discounts are prompted by the financial needs of the uninsured. For a number of years in the mid-2000s hospitals developed sliding scale charge structures to address the financial limitations of their patients that were based on some limited financial reporting of income by patients. But procuring such information from patients was and still is difficult and the industry was concerned with essentially penalizing uninsured patients that simply could not comply with the provision of such information. Instead, they recognized that the vast majority of the uninsured patients simply do not have the financial means to procure coverage. So hospitals developed uninsured discount programs to address the needs of these patients. Some states, like Tennessee, require uninsured discounts and do not allow hospitals to request financial information from the uninsured.

The inclusion of only "charity care and bad debt" in the definition of uncompensated care also suggests that discounts provided because a patient is uninsured are not counted in uncompensated care. Clearly such discounts are not bad debt, but the definition of "charity care" seems to indicate that uninsured discounts do not fit the definition of "uncompensated care" either:

> Health services *for which a hospital demonstrates that the patient is unable to pay*. Charity care results from a hospital's policy to provide all or a portion of services free of charge to patients who meet certain financial criteria. [Emphasis added.]

Apparently, even though Congress specifically structured Section 3133 to cover the uncompensated care costs of the uninsured, the instructions above for Worksheet S-10 do not consider uninsured status a financial criterion. Indeed, the instructions appear to explicitly exclude it:

> **Do not include charges for …uninsured patients given discounts without meeting the hospital's charity care criteria…**

Perhaps it is not surprising that Worksheet S-10 does not capture the information relevant to the purposes of Section 3133. It was designed for an entirely different purpose. The current version of the worksheet was introduced in 2010 for purposes completely unrelated to Section 3133. It was modified and reissued to capture data necessary to make Electronic Health Record (EHR) incentive payments under section 4102 of the American Recovery and Reinvestment Act of 2009, codified at 42 U.S.C. § 1395ww(n). In particular, subsection (n)(2)(D)(ii) (emphasis added) defines part of the payment formula for EHR incentive payments associated with the Medicare share of the payment amount as follows:

> (ii) the denominator of which is the product of--
> ``(I) the estimated total number of inpatient-bed-days with respect to the eligible hospital during such period; and
> ``(II) the estimated total amount of the eligible hospital's charges during such period, *not including any charges that are attributable to charity care*

> *(as such term is used for purposes of hospital cost reporting under this title),* divided by the estimated total amount of the hospital's charges during such period.

Even CMS acknowledges that Worksheet S-10 was redesigned in part to capture the data necessary to implement the EHR incentive payment system noted above. *See* 75 Fed Reg. at 44453, col 3 (July 28, 2010) ("Since the publication of the proposed rule, we have adopted various changes to the Medicare cost report, including changes designed to accommodate the appropriate computation and final settlement of EHR incentive payments for qualifying hospitals.") In particular, the instructions to prepare the worksheet as originally adopted through Transmittal 1, December 2010, for PRM-II, Chapter 40 for Form CMS 2552-10 at new section 4012 state:

> *Charity care charge data, as referenced in section 4102 of American Recovery and Reinvestment Act of 2009, may be used to calculate the EHR technology incentive payments* made to §1886(d) hospitals and critical access hospitals (CAHs). CAHs, as well as §1886(d) hospitals, will be required to complete this worksheet. *Note that this worksheet does not produce the estimate of the cost of treating uninsured patients required for disproportionate share payments under the Medicaid program.*

While some refinements have been made to section 4012, the language noted above still appears at the beginning of the instructions, unmodified. Those refinements have no impact on the reporting of the cost of treating the uninsured. Consequently, CMS has not altered the form to accommodate the differing purposes of ARRA section 4102 and ACA Section 3133. Indeed, the instruction above specifically notes that the form *does not produce an estimate of the cost of treating the uninsured consistent* with Medicaid DSH requirements. The form not only completely ignores costs consistent with the purpose of Section 3133, it directs hospitals, at least implicitly, not to report them.

2. CMS Has Defined the Cost of the Uninsured, Consistent with the Intent of Section 3133, in its Medicaid Regulations.

Worksheet S-10 does not define uncompensated care consistent with a policy designed to capture the actual cost of uninsured patients as Congress intended. Yet CMS clearly knows how to define uncompensated care for the uninsured to achieve that purpose. It is revealing that CMS would develop such a definition for Medicaid purposes, and require hospitals to report data in that fashion, and not adopt a consistent approach to implement ACA Section 3133. Certainly, the Medicaid definitions lend themselves to the same purpose that ACA Section 3133 seeks to achieve. Through 42 C.F.R. §§ 447.295-447.299, CMS defines an uninsured patient and the uncompensated care costs of those uninsured patients. In the evolution of these Medicaid regulations, CMS explained in the regulatory commentary how uninsured discounts are to be treated to allow for consistent treatment of such costs across states:

> The commenter recommends a revision to clarify that discounts for the uninsured are not applied to reduce the hospital's uncompensated care costs. The full cost should be recognized as uncompensated notwithstanding the discount or allowance process. Response: *We agree that the amount of calculations of uncompensated care* ***should not*** *be reduced by amounts that are not paid because*

> *of a provider discounted charge.* The statute provides for costs of furnishing services to uninsured patients to be reduced only by the amount of payments received from or for those patients, except for payments for care to indigent patients from a State or unit of local government within a State. We have clarified the data elements in this final rule, and we believe they more clearly track those statutory elements.

73 Fed Reg. at 77921, col. 3(Dec. 19, 2008) (2008 Medicaid DSH Final Rule) (emphasis added). Where possible, to implement common statutory purposes, CMS should promote uniform data gathering by hospitals. Here, that objective could be achieved by adopting the Medicaid requirements for reporting uninsured patient uncompensated care costs on Worksheet S-10. In that eventuality, CMS could drop the statement from its Worksheet S-10 instructions "that this worksheet does not produce the estimate of the cost of treating uninsured patients required for disproportionate share payments under the Medicaid program" and the form could actually serve the purpose that Section 3133 requires, by measuring the amount of uncompensated care provided to the uninsured.

As noted above in the comments and responses to the Medicaid DSH rule, gross charges must be used to determine the cost of care, or the cost of uncompensated care. The cost to charge ratios are calculated based on gross charges as required by CMS cost finding principles, and such cost to charge ratios must be applied to gross charges to accurately calculate cost. That is why CMS required in the Medicaid DSH rule that "*the amount of calculations of uncompensated care **should not** be reduced by amounts that are not paid because of a provider discounted charge.*" Id.

3. Including in Uncompensated Care the Undiscounted Cost of Caring for the Uninsured Promotes Good Public Policy and Avoids Adverse Incentives in the Hospital Industry

Through a series of examples below we show the impact that CMS's apparent policy to exclude the discounted portion of uncompensated care to the uninsured has on the amount appearing on Worksheet S-10. The examples assume that except for the uninsured discount policy, the hospitals are identical in all other respects. Example 1 below addresses a patient that pays nothing. Example 2 illustrates a care where an uninsured patient pays $2,000 of the patient bill.

EXAMPLE 1

Discounting Example

From CMS 2552-10 Worksheet C						
Total Costs[1]	Line (200, Col 3)	$ 243,437,929				
Total Hospital Charges (Gross Charges)[2]	Line (200, Col 8)	$ 1,137,011,076				
Cost to Charge Ratio (Worksheet S-10, Line 1)		0.2141				
I. Patient Pays $0						
		No Discounting		Discounting		
		Self-Pay	Charity	Self-Pay	Charity	Charity
	S-10 Ref	Example A.1 - Hospital Does Not DiscountUninsured Self-Pay	Example A.2 - Hospital Provides 100% Charity	Example B.1 - Hospital Discounts Uninsured Self-Pay 75%	Example B-2 - Hospital Charity 75% & Reports Net Charity on S-10	Example B-3 - Hospital Charity 75% & Reports Gross Charity on S-10
Charity						
Gross Charges for Services Rendered			$ 50,000		$ 50,000	$ 50,000
Charity Discount			(50,000)		(37,500)	(37,500)
Self-Pay Amount			-		12,500	12,500
Charity Charges Reported on S-10	Line 20		50,000		37,500	50,000
Cost to Charge Ratio	Line 1		0.2141		0.2141	0.2141
Cost of Charity Care	Line 21		$ 10,705		$ 8,029	$ 10,705
Paid By Patient (S-10 Line 22)	Line 22		-		-	-
S-10 Net Cost of Charity Care	**Line 23**		**$ 10,705**		**$ 8,029**	**$ 10,705**
Bad Debt						
Gross Charges for Services Rendered		$ 50,000	-	$ 50,000	50,000	50,000
Charity Discount					(37,500)	(37,500)
Uninsured Discount		-	-	(37,500)	-	-
Charges net of Discount		50,000	-	12,500	12,500	12,500
Paid By Patient		-	-	-	-	-
Non-Medicare Bad Debt - Reported on S-10	Line 28	50,000	-	12,500	12,500	12,500
Cost to Charge Ratio	Line 1	0.2141	0.2141	0.2141	0.2141	0.2141
Cost of non-Medicare Uncompensated Care	**Line 29**	**$ 10,705**	**$ -**	**$ 2,676**	**$ 2,676**	**$ 2,676**
Total Uncompensated Cost S-10 (Ln. 23 + Ln 29)	**Line 30**	**$ 10,705**	**$ 10,705**	**$ 2,676**	**$ 10,705**	**$ 13,381**

In Example 1 above, an uninsured patient pays no portion of the hospital bill with gross charges of $50,000. In the columns labeled "No Discounting" under Example A-1 the hospital provides no discount and records bad debt on line 28 of $50,000. After applying the applicable cost to charge ratio (*i.e*, total allowable cost divided by total *gross* charges), the amount reported as the cost of uncompensated care on line 30 is $10,705. In Example A-2, the hospital qualifies the patient for a 100% charity allowance and reports charity charges of $50,000 on line 20. After the hospital cost to charge ratio is applied, $10,705 is reported on line 30. The $10,705 represents the total cost of care incurred by the hospital for treating the uninsured patient, determined in accordance with established Medicare cost finding principles. Consequently, for purposes of the worksheet, it does not matter whether the hospital is charitable to its patients or not, the same amount is allowed as uncompensated care.

Hospital practices with regard to providing charity care and discounts vary dramatically; too dramatically to be captured by the few examples we provide here. But such variance in these practices strikes us as unimportant under the standard in ACA Section 3133, which requires CMS to capture on a relative basis "the amount of uncompensated care…costs of subsection (d) hospitals for treating the uninsured…." For this calculation to actually work, and because the comparison is relative, each hospital's costs must be calculated on a uniform basis. In Example B-2 above, the hospital provides the same patient with an uninsured discount of 75% and only seeks to collect from the patient 25% of its $50,000 charge. Under these examples, Worksheet S-10's methodology dramatically penalizes the hospital providing an uninsured discount of 75% (see Example B-1) when compared to hospitals that provided no discount at all to an uninsured patient but claimed all charges as bad debt (see Example A-1), a 100% charity care discount (see Example A-2) or the hospital that reported a 75% charity care discount and claimed the remainder as bad debt (see Example B-2). In this eventuality, the hospital in Example B-1 is allowed to record only $2,676 as the total uncompensated care cost on line 30 of the form as

compared to the other three hospitals all of which claimed a cost of uncompensated care of $10,705.

The point here is that the uncompensated cost of care for this uninsured patient is the same at each hospital in the examples; however, because CMS instructions disregard the uninsured discount in Example B-1, the cost of uncompensated care at that hospital is under counted. This disparity makes little sense and arguably creates a disincentive for hospitals that are DSH eligible to maintain generous uninsured discount programs, an outcome at odds with Congressional intent.

In Example B-2 above, the hospital is allowed to record the uninsured discount of 75% as a charity discount (or CMS could provide a new line for uninsured discounts), and that discount plus the amount not collected from the patient as bad debt yields the same amount on line 30 as Examples A-1 and A-2. We believe this equitably treats hospitals that are willing to provide uninsured discounts and places them on equal footing with hospitals that attempt to collect on a non-discounted basis from uninsured patients the full amount of their charges.

EXAMPLE 2

II. Patient Pays $2,000

		No Discounting		Discounting		
		Self-Pay	Charity	Self-Pay	Charity	Charity
	S-10 Ref	Example A.1 - Hospital Does Not DiscountUninsured Self-Pay	Example A.2 - Hospital Provides 100% Charity	Example B.1 - Hospital Discounts Uninsured Self-Pay 75%	Example B-2 - Hospital Charity 75% & Reports Net Charity on S-10	Example B-3 - Hospital Charity 75% & Reports Gross Charity on S-10
Charity						
Gross Charges for Services Rendered			$ 50,000		$ 50,000	$ 50,000
Charity Discount			(50,000)		(37,500)	(37,500)
Self-Pay Amount			-		12,500	12,500
Charity Charges Reported on S-10	Line 20		50,000		37,500	50,000
Cost to Charge Ratio	Line 1		0.2141		0.2141	0.2141
Cost of Charity Care	Line 21		$ 10,705		$ 8,029	$ 10,705
Paid By Patient (S-10 Line 22)	Line 22		-		2,000	2,000
S-10 Net Cost of Charity Care	**Line 23**		**$ 10,705**		**$ 6,029**	**$ 8,705**
Bad Debt						
Gross Charges for Services Rendered		$ 50,000	-	$ 50,000	50,000	50,000
Charity Discount					(37,500)	(37,500)
Uninsured Discount		-	-	(37,500)	-	-
Charge net of Discount		50,000	-	12,500	12,500	12,500
Paid By Patient		2,000	-	2,000	2,000	2,000
Non-Medicare Bad Debt - Reported on S-10	Line 28	48,000	-	10,500	10,500	10,500
Cost to Charge Ratio	Line 1	0.2141	0.2141	0.2141	0.2141	0.2141
Cost of non-Medicare Uncompensated Care	**Line 29**	**$ 10,277**	**$ -**	**$ 2,248**	**$ 2,248**	**$ 2,248**
Total Uncompensated Cost S-10 (Ln. 23 + Ln 29)	**Line 30**	**$ 10,277**	**$ 10,705**	**$ 2,248**	**$ 8,277**	**$ 10,953**

[1] Total costs - Allowable costs for *all* patients as determined under the Medicare principles of reimbursement.

[2] Total charges - this is the sum of colums 6 and 7.

Columns 6 and 7--Enter on each cost center line the *total inpatient and outpatient gross patient charges including charges for charity care patients* and, where applicable, standard customary charges for items reimbursed on a fee schedule (e.g., DME, oxygen, prosthetics, and orthotics). Also include the total inpatient and outpatient gross charges for cost centers which have a credit balance on Worksheet B, Part I, column 26 and, therefore, do not contain "cost" in column 1 of Worksheet C, Part I. [emphasis added.]

Source: CMS Pub. 15-2 §4023

In Example 2 above, all of the scenarios for payment involve a patient with $50,000 in charges that pays $2,000 of his bill except in the case of a 100 percent charity determination in Example A-2. The same disincentives apply if the uninsured discount is not recognized and still even partially continue as between no discount and a claim of bad debt for the remaining $48,000 of charge in Example A-1, as compared to a 75 percent uninsured discount in Example B-2, but the disparity is at least minimized.

These examples establish that the current policy of excluding the cost of uninsured discounts establishes irrational policy because it favors hospitals unwilling to discount care over those that do, and in so doing could lead hospitals to question their current practice of discounting care to the uninsured.

Finally, in each of Examples 1 and 2 above, there is a further Example B-3 in the last column. We have included this sub-example to show CMS how some hospitals may have interpreted the ambiguity in the instructions for line 20 to Worksheet S-10 and double counted some costs as partial charity and bad debt. The results of such a reading of the instructions causes those hospitals to report more in uncompensated care costs than if they provided a 100 percent charity discount, which should not occur. We have provided this example for informational purposes only, and to further illustrate the need for CMS to thoroughly review, and amend as needed, the S-10 and its instructions.

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As we have established above, Worksheet S-10 was revised to implement ARRA section 4102, which has a purpose different than the goals of ACA Section 3133, and it has not been adequately revised to implement the purposes of the UC-DSH program. As currently implemented, the form creates undesirable policy choices for hospitals. But fixing the form requires little effort by CMS, because it already has a regulatory protocol in place to recognize the cost of uncompensated care to the uninsured under Medicaid, and CMS simply needs to implement that protocol for Medicare, which hospitals already are obliged to follow now in reporting such data to state Medicaid programs.

B. Using Worksheet S-10 Data as the Basis for Apportioning Payment to DSH Eligible Hospitals Under Factor 3 Would Yield Arbitrary Results

CMS correctly concluded in the FY 2015 IPPS Final Rule that available Worksheet S-10 (hereinafter "S-10") data is too unreliable to use as a basis to allocate many billions of dollars in hospital payments and has reiterated those concerns since the inception of the UC DSH payment methodology. CMS acknowledged in the FY 2016 IPPS Final Rule that "Although we have not decided upon revisions to the Worksheet S–10 instructions at this time, we remain committed to making improvements to Worksheet S–10 if we find they are warranted." 80 Fed. Reg. at 49525, col. 2. In this year's proposed rule CMS seemingly abandons its concerns with regard to Worksheet S-10 and only proposes two actions with regard to S-10 data (1) to change the triggering event for the period when charity care charges are recorded on S-10, (2) and an edit for high cost to charge ratio hospitals that replaces the high hospital specific cost-to-charge ratio with a state wide average. At the same time CMS indicates that:

> As discussed in section IV.F.3.d. of the preamble of this proposed rule, since the introduction of the uncompensated care payment in FY 2014, we believe that hospitals have been submitting more accurate and consistent data through Worksheet S–10 and that it is appropriate to begin incorporating Worksheet S–10 data for purposes of calculating Factor 3 starting in FY 2018.

But the most recently available HCRIS data indicates that hospitals are not doing meaningfully better at accurately, from hospital to hospital, reporting S-10 data. CMS has done little if anything to audit that data for accuracy, and such audits would inform hospitals about

inaccuracies in reporting the data, or put in place an audit protocol like the wage index audits, to accomplish that result. Finally, other than changing the trigger date for submitting charity care data, CMS has not adjusted the form, structure or instructions to complete the S-10 in any way to conform to the requirements of Section 3133.

1. The Worksheet S-10 Data in the March 31, 2013, 2014, and 2015 HCRIS Data Files Contains Significant Anomalous Data

When we commented on last year's proposed rule we noted the following problems from S-10 reported in the March 31, 2013 HCRIS database.

- 242 or 9% of the 2,666 DSH hospitals did not have any bad debt expense indicated on S-10 on line 26. 226 of these 242 hospitals (93%) had Medicare Bad Debts indicated on line 27. It is difficult to imagine that some hospitals did not have any bad debt expense or that they only had Medicare bad debt.
- 6 of the 2,666 hospitals had more charges indicated on S-10 than the gross charges indicated on Worksheet C. In total these 6 hospitals had $9,913,024,894 in charges on S-10 compared with $6,868,691,477 on worksheet C of the cost reports. The charges on S-10 were developed by adding lines 6, 10, 14, 20 and 26 together. Column 3 was utilized for line 20. One hospital had $1,801,748,773 in charges on S-10 versus $103,918,204 on Worksheet C.
- 5 hospitals had a ratio of cost to charges (CCR) indicated on S-10 equal to 100%. In reviewing these hospitals' Worksheet G, their CCR should be under 1.00. These hospitals are all inclusive rate facilities in New York. Such CCRs would appear to inflate these hospitals uncompensated care cost. CMS should review these hospitals and correct the CCRs.
- 97 hospitals have a CCR of greater than 60% including 2 of the 6 hospitals where the S-10 charges exceed Worksheet C. The national average CCR is .343. CMS should review all hospitals with a high CCR to insure it is correct.
- None of the 2,633 hospitals that received Medicare DSH payments based on their latest 2552-10 cost report have an audited S-10 in HCRIS.

Those problems continued to persist in the March 31, 2014 HCRIS data base for all Form 2552-10 cost reports, which includes the current S-10:

- Within the database, only 69 cost reports from 6,935 cost reports with DSH payments have been settled with audit and there is no evidence in the cost reports that have undergone an audit of adjustments to S-10 data, perhaps not surprising given FAH member experience that the electronic health records audits (which would include an audit at least of the charity lines of the worksheet) of payment data began in late calendar year 2013
- Within that same data base, 569 cost reports are showing no bad debt on S-10;

- For 23 cost reports, charges on S-10 exceed total hospital charges on Worksheet C for the entire patient population, in 19 instances by more than a factor of 10, and in the aggregate for these hospitals S-10 charges exceeded Worksheet C charges by $25,047,313,021;

- 50 S-10s show a cost to charge ratio greater than or equal to 100% and 10 of those show a cost to charge ratio of exactly 100%;

- 308 S-10s show a cost to charge ratio greater than 60%, where the average cost to charge ratio is 33.85 percent;

Those problems also continued to persist in the March 31, 2015 HCRIS data base for all Form 2552-10 cost reports, which includes the current S-10:

- Within the data base, only 355 cost reports from 9,892 cost reports with DSH payments have been settled with audit;

- Within that same data base, 717 cost reports are showing no bad debt on S-10;

- For 30 cost reports, charges on S-10 exceed total hospital charges on Worksheet C for the entire patient population, in 10 instances by more than a factor of 10, and in the aggregate for these hospitals S-10 charges exceeded Worksheet C charges by $29,587,792,079;

- 64 S-10s show a cost to charge ratio greater than or equal to 100% and 24 of those show a cost to charge ratio of exactly 100%;

- 427 S-10s show a cost to charge ratio greater than 60%, where the average cost to charge ratio is 33.78 percent.

- The data suggests little improvement in the accuracy of hospitals' reporting of data in S-10, with more hospitals continuing to report aberrant data or missing essential data for a fair implementation of S-10 as the basis for payment from the UC DSH pool.

Even the most current version of HCRIS, the March 31, 2016 HCRIS database for all Form 2552-10 cost reports, which includes the current S-10, supports the notion that S-10 cannot be used to determine uncompensated care costs and allocate the Factor 2 pool of uncompensated care funds:

- Within the data base, only 694 cost reports from 12,793 cost reports with DSH payments have been settled with audit;

- Within that same data base, 832 cost reports are showing no total bad debts on S-10;

- For 36 cost reports, charges on S-10 exceed total hospital charges on Worksheet C for the entire patient population, in 15 instances by more than a factor of 10, and in the aggregate for these hospitals S-10 charges exceeded Worksheet C charges by $32,635,591,167;

- 82 S-10s show a cost to charge ratio greater than or equal to 100% and 29 of those show a cost to charge ratio of exactly 100%;

- 540 S-10s show a cost to charge ratio greater than 60%, where the average cost to charge ratio is 37.23 percent.

- Again, the data suggests little improvement in the accuracy of hospitals' reporting of data in S-10. In order to move the S-10 data into an acceptable range of accuracy, fundamental changes are required as detailed further in these comments.

With regard to specific errors in cost reports beginning in FY 2014 that CMS proposes to utilize beginning in FY 2018 the following is apparent from the 3-31-16 HCRIS data base:

- A limited number of the hospitals have a very high percentage of charges on the S-10 compared to Worksheet C. Several of these hospitals are receiving the largest benefit of the proposed distribution change. The overall ratio is .261 for the 2,870 IPPS hospitals that have DSH payments. The following breakdown comes from the 3-31-16 HCRIS files for cost reports beginning in FFY 2014 and that have DSH payments indicated on Worksheet E Part A:

    - Four have charges indicated on S-10 that exceed 10 times the charges on Worksheet C,
    - Eight have charges indicated on S-10 that exceed 1 times the charges on Worksheet C,
    - Thirty-seven have charges indicated on S-10 that exceed 70% the charges on Worksheet C,
    - Seventy-six have charges indicated on S-10 that exceed 60% the charges on Worksheet C, and
    - One hundred and twenty-three have charges indicated on S-10 that exceed 50% the charges on Worksheet C.

- Seventy of the 2,870 DSH IPPS hospitals do not have S-10 data included in the data at all. Some of these are IHS hospitals.

- None of these cost reports have been settled with audit and only 79 of the 2,841 IPPS DSH Hospital cost reports beginning in FY 2013 have an indication that they have been settled with an audit. If the trend continues for FY 2018 only 2.8% of the 2014 cost reports that CMS plans to utilize would have been settled with audit.

While the above anomalies are reported in the aggregate from the HCRIS data base, a review of each of these problem areas in the data indicate that the problems arise at consistent levels from FY 2012 through FY 2014 Worksheet S-10s with little to no improvement. For example, from FYs 2012 through 2014, 125, 152 and 129 respectively reported no bad debt. We have included the breakdown by year for these problems with reported S-10 data in the table below:

Summary of S-10 Data Reporting Problems by Fiscal Year from the 3-31-16 HCRIS File

CR Status	Hospitals	Empirical DSH Pmts	No Bad Debts on S-10	Negative Bad Debts - on S-10	S-10 Charges > W/S C	CCR = 1.0 on S-10	CCR 1 or Great on S-10	Sum of CCR >.6	Average of CCR
2010	**996**	**4,563,357,722**	**181**	**167**	**4**	**8**	**16**	**65**	**0.3774**
AMENDED	53	635,986,321	6	6	1	0	0	2	0.2955
AS SUBMITTED	101	623,638,939	37	37	1	3	5	8	0.3630
REOPENED	127	573,011,376	26	26	0	0	0	4	0.2936
SETTLED W/O AUDIT	593	1,857,219,311	95	83	1	5	10	48	0.4046
SETTLED WITH AUDIT	122	873,501,775	17	15	1	0	1	3	0.3802
2011	**2,759**	**11,438,379,081**	**227**	**214**	**6**	**5**	**15**	**119**	**0.3197**
AMENDED	158	1,767,926,405	3	4	3	0	3	5	0.3798
AS SUBMITTED	264	1,379,661,681	55	57	0	2	2	10	0.3099
REOPENED	321	1,178,644,607	13	10	0	0	1	12	0.3155
SETTLED W/O AUDIT	1,737	5,091,513,894	140	127	1	1	7	85	0.3221
SETTLED WITH AUDIT	279	2,020,632,494	16	16	2	2	2	7	0.2855
2012	**2,794**	**11,691,165,952**	**125**	**91**	**10**	**6**	**17**	**116**	**0.3458**
AMENDED	254	2,459,821,952	6	8	5	0	2	5	0.3375
AS SUBMITTED	305	2,188,068,756	11	11	1	2	3	10	0.3681
REOPENED	158	583,666,917	3	2	0	0	0	5	0.2987
SETTLED W/O AUDIT	1,863	5,042,833,007	97	64	3	3	11	93	0.3542
SETTLED WITH AUDIT	214	1,416,775,320	8	6	1	1	1	3	0.2862
2013	**2,841**	**8,324,676,900**	**152**	**83**	**8**	**5**	**18**	**122**	**0.3398**
AMENDED	705	3,298,001,883	31	12	1	1	5	17	0.3279
AS SUBMITTED	1,192	3,096,824,406	52	41	6	4	8	57	0.3153
REOPENED	24	43,650,895	0	0	1	0	0	2	0.3068
SETTLED W/O AUDIT	841	1,455,314,862	63	27	0	0	5	45	0.3919
SETTLED WITH AUDIT	79	430,884,854	6	3	0	0	0	1	0.2831
2014	**2,870**	**3,178,551,764**	**129**	**80**	**8**	**5**	**14**	**104**	**0.3689**
AMENDED	476	731,211,285	14	13	2	0	1	8	0.6366
AS SUBMITTED	2,390	2,445,899,539	115	67	6	5	13	96	0.3151
SETTLED W/O AUDIT	4	1,440,940	0	0	0	0	0	0	0.2740
2015	**533**	**553,473,671**	**18**	**16**	**0**	**0**	**2**	**14**	**0.9622**
AMENDED	6	2,642,635	0	0	0	0	0	0	0.3197
AS SUBMITTED	527	550,831,036	18	16	0	0	2	14	0.9696
Grand Total	**12,793**	**39,749,605,090**	**832**	**651**	**36**	**29**	**82**	**540**	**0.3723**

2. We Agree with CMS that Considerable Work Needs to be Done to Clarify S-10 Instructions and Audit that Data Before it is Used to Apportion DSH Payments Under Factor Three

In the FY 2016 IPPS proposed rule CMS acknowledges that:

> We believe this methodology would give hospitals more time to learn how to submit accurate and consistent data through Worksheet S–10, as well as give CMS more time to continue to work with the hospital community and others to develop the appropriate clarifications and revisions to Worksheet S–10 to ensure standardized and consistent reporting of all data elements. [80 Fed. Reg. at 24,487 col. 1].

Before the S-10 data can achieve the level of reliability the CMS notes above, the instructions associated with its preparation need to be clarified to allow the consistent reporting of the relevant data across all affected hospitals. The only change CMS has proposed to the instructions concerns the time for claiming the cost of charity care. None of the other proposals we have suggested since our comments to the FY 2014 IPPS proposed rule have been heeded and we reiterate those below. CMS should endeavor to revise S-10 to capture relevant data, such as our suggestion in Section A above with respect to the uncompensated care of the uninsured, as well as those suggestions below, and revise instructions so that such data can be reported consistently by all hospitals and audited. We offer the below comments to assist in the revision of S-10 and its instructions.

a. Definitional Issues with S-10

The definition of "uncompensated care" and its constituent components "charity care" and "bad debt" are not sufficiently defined to support consistent reporting by hospitals. The following are examples of areas within the S-10 instructions that require clarification.

Extent of Reportable Charity Care Charges - The initial instructions for Worksheet S-10 refer to the statutory requirement for hospitals to report costs "incurred by the hospital for providing inpatient and outpatient hospital services." However, the instructions for line 20 direct the hospital to report gross charges for charity care for the "entire facility," which is generally understood to include portions of the facility on the cost report that are not paid under inpatient PPS/outpatient PPS such as inpatient rehabilitation/psychiatric facilities and skilled nursing facilities. This is problematic as charity care is reduced to cost on line 21 using the hospital cost to charge ratio (CCR) on line 1. Given that the CCR for the hospital and the subparts are in many instances very different, this will lead to an inappropriate reporting of charity care costs. A similar problem occurs on line 26 for bad debt reporting. CMS needs to clarify its instructions in two respects: (1) whether providers should report only charity care charges and bad debt expense related to IPPS areas and outpatient services on line 20 and 26 and, (2) if CMS truly means the entire facility for such charges, that is, all units of the hospital whether inpatient, outpatient, IPPS or not, what cost to charge ratio should be used to reduce those charges to costs. We believe this instruction has caused a great deal of inconsistency in the reporting of bad debt and charity charges with some hospitals limiting charges to IPPS areas and outpatient and some hospital reporting that information for all units of the hospital.

Indigent Care Program Versus Charity - CMS indicates "[c}harity care results from a hospital's policy to provide all or a portion of services free of charge to patients who meet certain financial criteria." Id. The instruction for line 20 further provides: "Charges for non-covered services provided to patients eligible for Medicaid or other indigent care program … can be included, if such inclusion is specified in the hospital's charity care policy and the patient meets the hospital's charity care criteria." We believe government providers are misreporting data related to charity care under the above definition by including all charges for their indigent care/general relief patient populations in the definition. These programs are not uncompensated, but are funded through local and state tax assessments. CMS needs to clarify that patient charges cannot be included in the cost of charity care unless, as provided above, the related services are not covered by an indigent care program.

Medicaid Non-Covered Charges – S-10 line 20 instructions specify that "Charges for non-covered services provided to patients eligible for Medicaid or other indigent care program (including charges for days exceeding a length of stay limit) can be included, if such inclusion is specified in the hospital's charity care policy and the patient meets the hospital's charity care criteria." Many hospitals non-covered charges for Medicaid beneficiaries simply fall into a deduction from revenue category that summarizes into the Medicaid financial class, not in the charity GL financial accounts. Most hospitals' charity care policies do not specifically deem non-covered Medicaid charges as charity care for financial statement purposes, even though such patients financially qualify as such. The form instructions do have a separate line for Medicaid charges in excess of day limits for Medicaid coverage, but not simply non-covered charges separate and apart from the day limitation. That line item should aggregate both items, and there should be no separate requirement that Medicaid beneficiaries be mentioned in the charity policy.

Timing of Bad Debt Determination - Bad debts reflected on the S-10 do allow the reporting of total hospital bad debts on a full accrual basis since the form instructions for line 26 clearly state: "bad debts (bad debt expense) written off or expected to be written off on balances owed by patients delivered during the cost reporting period." CMS needs to clearly state they mean fully allowed for bad debt expense as reflected on a hospital's financial statement. Also, the reference in the Non-Medicare bad debt definition to the line 25 instruction is incorrect and should refer to the line 26 instruction.

Using Generally Accepted Accounting Principles to Report Bad Debt and Charity Care on S-10 Consistent with Hospital Financial Statement Reporting - We are concerned that timing differences between when services are provided and charity and bad debt determinations are made will vary so significantly among providers under current S-10 instructions used to report such data that hospital to hospital comparisons are almost meaningless. To cure these timing differences, we strongly recommend that S-10 instructions be amended to require that hospitals report on that form the same bad debt and charity care amounts that they report for purposes of GAAP on their financial statements.

b. Consistency in Calculating Uncompensated Care Costs

The payment system that Section 3133 imposes for UC-DSH requires absolute consistency in calculation among hospitals to ensure that funds are equitably distributed. We are concerned that the S-10 instructions are insufficiently specific to ensure that hospitals consistently reduce charges to costs, particularly with regard to calculating bad debt costs. Set forth are several examples to show how results will differ in calculating costs depending on the view of what the charge actually is in a given instance.

In this first example, a hospital has a PPO arrangement with an insurer where it has agreed to accept a per diem for patient services and the beneficiary pays a flat copayment amount of $200 for inpatient care. In this example gross charges are $50,000, the hospital accepts as payment $50,000, the hospital accepts as payment from the insurance plan $25,000 for a ten-day stay, and the hospital is unable to collect the $200 copayment from the beneficiary and it has a cost to charge ratio of 0.2. What is the cost of the unpaid copayment? If gross charges are allocated between the insurer's payment and the beneficiary's liability, the charge applicable to the copayment is $400 and after application of the cost to charge ratio the cost is $80. But the hospital never expected to collect more than the $200 from the beneficiary so should a hospital be allowed to gross-up that amount to $400 before application of the cost to charge ratio? If the $200 is not grossed-up, the cost of that portion of the service is $40, not $80, or half of the reported amount. We believe the simplest and most consistent approach to this is to make clear in the instructions that the hospital cost to charge ratio be applied to the uncollected patient liability, the amount the hospital agreed to accept as payment in full.

In the second example, the insurer pays 80% of charges, and the beneficiary is responsible for 20% of charges. Gross charges are $50,000 and the cost to charge ratio is 0.2. The beneficiary is liable for the $10,000 copayment, but does not pay the patient liability. The cost of the bad debt in this instance is $2,000 because the beneficiary liability is full charges. However, if the insurer's discount extended to the beneficiary copayment, the cost of the bad debt should be lower by a corresponding amount.

We believe that hospitals address each of these examples inconsistently when reporting information on S-10, and that it is critical to fair apportionment of payments that such data be reported consistently.

3. Nothing Has Been Done to Audit the S-10 Data to Correct Reporting Problems

Very little audit activity has occurred with respect to reported S-10 data from FYs 2012 through 2014. As the table below indicates, since FY 2012 only 293 cost reports have been audited at all, and none have been settled with audit for FY 2014, the period from which CMS proposes to use the Worksheet S-10 for the calculation of Factor 3 for FY 2018. There is no indication that any of the audits of FYs 2012 and 2013 cost reports even touched on the Worksheet S-10. Even for the hospitals with the problem situations noted above, that table indicates very little audit activity occurred. Finally, we were able to procure the audit protocol used for the very few EHR audits that have occurred to date by at least one of the responsible MACs, see attachment A. That audit protocol indicates that the focus of such audits is the charity care data, and not surprisingly, there is no focus in the audits of the reported non-Medicare bad debt amounts. This is not surprising because non-Medicare bad debt is not a payment factor for EHR incentive payments. But such bad debt costs also are not reimbursed by Medicare, so it is extremely unlikely that bad debt data on Worksheet S-10 has ever been audited. Nonetheless our membership has experienced very few audits of even charity care data in Worksheet S-10, even for purposes of the EHR payment audits.

Status of Cost Reports From 3-31-16 HCRIS File

DSH Hospital	1						
Number of Hosp	**Column Labels**						
CR Status		**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**Grand Total**
AMENDED		53	158	254	705	476	6	1,652
AS SUBMITTED		101	264	305	1,192	2,390	527	4,779
REOPENED		127	321	158	24			630
SETTLED W/O AUDIT		593	1,737	1,863	841	4		5,038
SETTLED WITH AUDIT		122	279	214	79			694
Grand Total		**996**	**2,759**	**2,794**	**2,841**	**2,870**	**533**	**12,793**

There is simply no basis in fact for the proposition that hospitals reported S-10 data more accurately or consistently from hospital to hospital in FY 2014 than they did for FY 2012. CMS's assertion that hospitals are reporting the data more consistently in their FY 2014 cost reports is simply not supported by the data. The additional assertion by CMS, that its outside contractor has identified a strong correlation between charity care reporting on S-10 and IRS Form 990, might simply mean that such data by any given hospital is being reported consistently on the two forms, but still incorrectly. *See* 80 Fed. Reg. at 25090, col.2. While CMS acknowledges that the comparison is only available for non-profits, CMS ignores the fact that from an anomalous charge data perspective, many of the hospitals with problematic data are government owned facilities that are not subject to IRS Form 990. Additionally, assuming arguendo, while nonprofits may have more experience reporting charity care data because of the IRS experience, that would leave a substantial segment of the hospital population without such experience and reporting inconsistently. Because Factor 3 is a hospital relative factor, the absence of hospital to hospital variation is key to an accurate distribution of these payments.

CMS misses the mark by demonstrating that hospitals reporting on Worksheet S-10 are also reporting with a high correlation on IRS Form 990:

> Key findings indicate that the amounts for Factor 3 derived using the IRS Form 990 and Worksheet S–10 data are highly correlated. In addition, the correlation coefficient between the amounts for Factor 3 calculated from the IRS Form 990 and Worksheet S–10 has increased over time, from 0.71 in 2010 to 0.80 in 2012, suggesting some convergence in the data sources over time. [*See* 80 Fed. Reg. at 25090, col.2]

Whether these hospitals are reporting consistently between the two federal programs is irrelevant to accurate payments under Factor 3. What is important is consistent reporting of relevant data between all participating hospitals. And the agency has a long way to ensure that has occurred or is occurring.

4. CMS Still Has Policy Issues to Resolve with Regard to the Worksheet S-10

a. Combined data from multiple periods

Thirty-nine hospitals reported S-10 data from multiple cost report periods included in their FY 2014 S-10 data. Some of these cost reporting periods represent more than 12 months data. CMS indicates at 80 Fed. Reg. at 25089, col. 2 that they are "proposing to combine data from multiple cost reports so that a hospital may have a Factor 3 calculated using more than one cost report period" for FFY 2017. CMS invited public comment on this proposal.

In our view, individual hospital data in Worksheet S-10 needs to represent a twelve-month period, so that the data is evenly weighted among all DSH hospitals. Inconsistences in the length of cost report periods will result in erroneous UC DSH payment allocations. At page 25088 of the proposed rule CMS states:

> As in prior years, if the more recent of the two cost reporting periods did not reflect data for a 12-month period, we used data from the earlier two periods so long as that earlier period reflected data for a period of 12 months. If neither of the two periods reflected 12 months, we used the period that reflected the longer period of time.

We oppose the use of multiple cost reports if it would result in a hospital having more than 12-months of data in the Factor 3 calculations. To resolve this CMS could prorate the data down to an equivalent 12-month period.

b. We support the exclusion of Medicaid shortfalls from the Factor 3 calculation

We agree with CMS that Section 3133 does not allow for the inclusion of Medicaid shortfalls in the Factor 3 calculation. As we noted in Section A above, the Section contemplates that Factor 3 will address the relative amount of uncompensated care for the uninsured. Also within Section 3133, Congress requires that the Factor 2 calculation include a reduction of the payment pool equal to the growth in the insured population from a base year, and it does so by reference to a specific CBO process for determining the insured patient rate. Congress was well aware that CBO includes within the insured rate the growth in the Medicaid population. So clearly, Congress did not intend that Medicaid patients would be considered uninsured under the Factor 3 calculation.

c. We support the use of an SSI proxy for Puerto Rico Hospitals

We support CMS's efforts to finally provide some equity to Puerto Rico hospitals under the DSH system. The use of a proxy to cover Puerto Rico's equivalent of Supplemental Security Income is long overdue. We have two concerns however with CMS's implementation of this provision. First, we think it doubtful under Puerto Rico's current economic crisis that using a 50 state average for SSI factor is enough to constitute a proxy. But we are sure that the Puerto Rico Hospital Association will address that in more detail in its comments.

Our larger concern is that CMS is taking a shrinking pie, and cutting it into even finer slices. While we agree that a proxy is appropriate here, we think it should be accompanied by a corresponding increase in Factor 1, and the law suggests this is long overdue. Traditional DSH payments are based, in part, on the Medicare/SSI Fraction, established under 42 U.S.C. §1395ww(d)(5)(D)(vi)(I), which is the percentage of a hospital's inpatients who were entitled to Medicare Part A benefits and were also entitled to supplemental security income ("SSI") benefits under Title XVI of the Social Security Act when they were receiving inpatient services at the hospital. The problem for Puerto Rico is that it does not have an SSI program.

In 1974, Congress enacted the Title XVI SSI program to replace the cash assistance provisions of Titles I, X, XIV, and XVI of the Social Security Act but SSI did not extend that program to Puerto Rico, which retained the cash assistance provisions of Titles I, X, XIV, and XVI. However, *anyone eligible for cash assistance under Titles I, X, XIV, and XVI also would qualify for benefits under the Title XVI SSI eligibility criteria.* In fact, certain individuals who do not meet the criteria under Titles I, X, XIV, and XVI nevertheless meet the Title XVI SSI eligibility criteria.

When Congress expanded IPPS to include Puerto Rico Hospital in OBRA 1986, Congress addressed the lack of an SSI program issue in 42 U.S.C. §1395ww(d)(9)(D):

> The following provisions of paragraph (5) shall apply to subsection (d) Puerto Rico hospitals receiving payment under this paragraph ***in the same manner and to the extent as they apply to subsection (d) hospitals receiving payment under this subsection:***
>
> (iii) Subparagraph (F) (relating to disproportionate share payments) . . . . [Emphasis added.]

In order to ensure that Puerto Rico Hospitals are paid DSH "in the same manner and to the extent" as hospitals in the States, Congress made clear that days should be included for Puerto Rico Medicare beneficiary residents who would qualify for SSI benefits if they were residents of a State.

Despite this clear direction from Congress, CMS has historically calculated DSH payments for Puerto Rico hospitals by including in the Medicare/SSI Fraction inpatient hospital days only for those entitled to SSI. Under CMS's implementation of the DSH statute, the only inpatient hospital days for those entitled to Medicare Part A counted in the Medicare/SSI Fraction for DSH purposes for Puerto Rico hospitals were those relating to residents of the States who were entitled to SSI benefits and who happen to receive inpatient services at a Puerto Rico

hospital. No days related to Puerto Rico resident Medicare beneficiary patients were counted, even if they met the SSI eligibility criteria. CMS's refusal to include in the DSH calculation inpatient hospital days attributable to Puerto Rico resident Medicare beneficiaries who met the SSI criteria, significantly reduced, and in some cases totally eliminated, DSH payments to which Puerto Rico hospitals otherwise would have been entitled.

The absence of a Title XVI SSI program in Puerto Rico does not mean that Puerto Rico does not have low-income Medicare beneficiaries. However, CMS's application of the DSH statute presumes just that. This is unreasonable because the population of Puerto Rico ranks significantly lower than any State with regard to average resident income. Moreover, CMS's interpretation has never been explained in any regulation, manual, or other agency issuance.

CMS's interpretation that only Title XVI SSI program days "count" when calculating the DSH payment for hospitals in Puerto Rico - when Puerto Rico has no such program - turns the clear intent of the statute on its head. CMS interprets a provision that was intended to ***provide*** for a DSH payment to the Hospitals into one that ***prohibits*** such a payment. It is simply improper to think that Congress would provide an explicit DSH payment to Puerto Rico hospitals while, at the same time, requiring the payment to be calculated in a way that essentially takes the payment away. CMS interpretation does just that.

We believe that now that CMS has acknowledged this disparity it should treat Puerto Rico hospitals consistently for traditional DSH purposes and increase Factor 1 accordingly.

d. Supplemental data collection

FAH supports CMS's proposed change to the timing for reporting charity care to the period the account is written off. This would make such reporting consistent with the timing for bad debt. We encourage CMS to institute a supplemental data collection if necessary, because it chooses to use as the S-10 period for the Factor 3 calculation a period that already has passed.

Concurrent with this supplemental data collection to correct the timing of charity care, CMS should also correct, as we requested in Section A above, the instruction not to report uninsured discount. There is no reason that such a correction also cannot be addressed through a supplemental data collection through reporting additional data that represents the unreported uncompensated cost of care for the uninsured, or by correcting the definition of charity care to include the uninsured as a financial criterion therein, to allow such costs to be reported with charity care.

e. Trims to Apply to Cost to Charge Ratios Reported on Line 1 of Worksheet S-10 and related matters

We appreciate CMS acknowledging the problem of hospitals overstating their cost of uncompensated care in Worksheet S-10 because they have overstated their cost to charge ratio ("CCR"). While we believe at least in the initial years of its use all data in Worksheet S-10 should be audited before it is used, we agree that areas that have a particularly serious impact on the Factor 3 allocation should receive audit priority. While we agree that identifying CCRs that are aberrant through an edit is an efficient course to target an adjustment, we do not agree that such hospitals universally should be subject to a statewide average CCR. We have identified 104 hospitals in FY 2014 with CCRs in excess of 0.6 and believe that such CCRs are aberrant.

We believe an edit of 3 standard deviations above the mean captures too few problems in this area. But a single data element for 104 hospitals should not be an insurmountable audit priority. Replacing such a CCR with the statewide average CCR is "too rough justice." A large portion of these hospitals may be no charge structure or all-inclusive rate public providers whose equivalent CCR is a good bit higher than the statewide average because their equivalent to a charge is much closer to their costs. So a cookie cutter approach would not be fair under these circumstances. We would recommend that hospitals with extremely high CCRs be audited and an appropriate CCR determined versus arbitrarily trimming these high CCRs to a statewide average.

Cost to charge ratios are not the only obvious area of misstatement in the Worksheet S-10 data and these other items are equally well covered with targeted audits based on a variance analysis approach. In our comments above at page 25, we note that a number of hospitals have reported S-10 charges for charity and bad debt that exceed total charges for the hospital under Worksheet C (which is an audited worksheet for Medicare cost reporting purposes). But it is not simply S-10 charges that exceed Worksheet C charges with which CMS should be concerned. Any hospital that reports S-10 charges at a rate that dramatically exceeds a normal percentage of Worksheet C charges should have its S-10 charge data subject to audit.

5. CMS Needs to Establish an Audit Protocol for Worksheet S-10 Data, and Perform Such Audits Before Committing to Use the Data for Payment Purposes.

It is critical that CMS subject the S-10 data that would be utilized to distribute the UC-DSH payments to an audit review. 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 year since charity charges have only rarely been audited for any hospitals (and only for EHR payment purposes) and the auditors have no experience with either (a) non-Medicare bad debts or (b) as we discuss in Section A above, the uncompensated care costs for uninsured patients (a concept defined but Medicaid, as we indicated, but not yet for Medicare). 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. So hospitals have an even greater interest in the correctness of such audit than for the wage index so the process for hospital feedback in such audits must at least equal the process for the wage index.

We are extremely concerned that there is not enough time to utilize such audited data for FY 2018, as proposed by CMS. The FY 2018 wage index review process began in May 2016 and will be completed only in time for implementation. Any S-10 review will likely take more time and resources to cause the data to be accurate and has not and could not commence until CMS puts such a process in place at the earliest in August with the publication of the final rule. There is simply insufficient time to implement the use of audited data for FY 2018.

In addition to the above, we recommend that CMS perform an in depth review on a limited number of hospitals on the 2014 data to identify key issues for a full review of FY 2015 and later information. This could also be used to educate all providers, refine cost report instructions and provide FAQs on S-10. Such a review should be performed by a single MAC for consistency. The review should include the following hospitals:

- Hospitals with unusual data on S-10 charges compared to Worksheet C, and CCRs,
- Most significant data "winners",

- A random mix of hospitals by type, location and impact, and

The focus of the review should be on the elements of the S-10 that CMS plans to utilize in the Factor 3 calculation in the future.

We believe the above steps are necessary for CMS to implement, at a minimum, to protect the integrity of the allocation of the $6 billion pool of funds under the UC DSH program Factor 3. We were extremely surprised that CMS did not suggest such steps as part of this year's proposed rulemaking to implement the use of S-10 data for FY 2018.

C. Recommended Course of Action to Implement Worksheet S-10

The FAH and its members strongly believe that it would be a grave mistake to implement the use of Worksheet S-10 to calculate Factor 3 for the distribution of the UC-DSH pool until CMS addresses the problems noted above, including addressing missing elements from the calculation of uncompensated care costs for the uninsured, definitional issues that have led to inconsistent reporting between hospitals of the relevant data from Worksheet S-10 and a thorough audit of such data once the preceding problems are addressed in a revised form S-10 and instructions. We have noted these issues for years and CMS simply did not take the steps necessary to implement them in a fashion that would have allowed it to proceed with an accurate use of the S-10 data in FY 2018, even though it acknowledged the necessity to do so. 80 Fed. Reg. at 24,487 col. 1.

There is simply too much at stake to allow incomplete relevant data, and inaccurate and inconsistent data, to be used for purposes of this process.

In addition, the environment that Congress intended for purposes of the UC-DSH pool calculation does not currently exist, but we are certainly progressing to a point in time when that environment may be present. When Congress enacted ACA, it intended that all state Medicaid programs would expand uniformly such that the insured population would be spread proportionately among the states. The Supreme Court's decision in *King v. Burwell* allowing the states flexibility in their decision whether to expand their Medicaid programs under the ACA standard, changed Congress's equation and has created a significant disparity among the states with respect to the extent of Medicaid expansion. This has resulted in an uneven spread of uninsured patients that Congress never intended would need to be covered as "uninsured" for purposes of the Factor 3 calculation, the newly Medicaid eligible. Over time, many new states have chosen to expand Medicaid and to continue to take steps in that direction. Continued use of the proxy data will allow more time for the coverage environment that Congress intended to take hold, and for the S-10, with the improvements recommended, to serve as a trusted instrument for the Factor 3 distribution.

Because there is insufficient time to take the steps necessary to cause the use of Worksheet S-10 data to accurately allocate payments under Factor 3 by FY 2018, we strongly encourage CMS to take the steps now to revise the form and its instructions to collect the relevant information in a consistent fashion. **We believe that through the use of supplemental filings more robust S-10 data could begin to be available by FY 2019. But we also suggest that CMS extend the proposed transition to Worksheet S-10 to ensure that such data is accurate and well audited. Consequently, we suggest a 6-year transition with S-10 data accounting for 5 percent of the Factor 3 for each hospital in FY 2019, and then doubling**

each year, so 5, 10, 20, 40, and 80 percent, and finally full adoption of S-10 in 2024. That transition would allow time for revisions to the forms and instructions and further revisions with reporting and audit experience before the S-10 data becomes the sole source for the Factor 3 calculation. It would also provide states with more time to expand Medicaid so that Factor 3 is operating as intended, not as a substitute payment for state Medicaid coverage.

Hospital Readmissions Reduction Program

IV. G. Readmissions Reduction Program

The FAH believes that CMS should establish and then meet a regular, deadline for the release of the annual data on hospital excess readmission ratios, and also make clear when the data will be made available to the public on the Hospital Compare website. Currently, the public release of the data shifts from year-to-year. Given that by statute hospitals must be provided an opportunity to review their own readmission data prior to the start of the fiscal year in which a penalty may be assessed, it is not unreasonable for CMS to establish a date to publish the data and ensure that the data is published on that date. Members of the public and stakeholders with an interest in this information should have assurance of predictability regarding the data releases and public access to the data.

In addition, the FAH believes that CMS should calculate and more frequently report to hospitals their performance on the readmission measures. The current annual calculation and release of data does not enable hospitals to use the data for purposes of continuous quality improvement, a critical tool if the readmission reduction program is to be a quality program and not simply a tool for administering payment penalties. In addition, hospitals do not have access to all of the CMS claims data used in the formula, which hampers their ability to replicate data independently and take appropriate quality improvement actions. Routine quarterly or even semi-annual reports, even if they are a rolling multiyear measure, would be a significant improvement over the annual-only release of this information. Finally, hospitals spend significant time and resources in reviewing CMS reports and are very concerned about the regularly occurring errors in the *Hospital Compare* database and preview reports prepared by CMS contractors. The continuing series of errors cause hospitals to lose confidence in the results reported in the hospital quality Readmission Reduction Program.

- **Adjusting Quality Program Measures for Sociodemographic Factors**

The FAH members have a long-standing belief that additional risk adjustment should be used to address sociodemographic (SDS) factors, in particular for readmissions and other outcome measures used in payment programs like the Hospital Readmission Reduction Program (HRRP) and the Hospital Value-Based Purchasing (HVBP) Program. We continue to urge CMS to review its claims-based readmission and outcome measures and submit them to the trial period assessment process approved by the National Quality Forum ("NQF") Board in July 2014. Under the two-step NQF process, SDS factors are added to the risk adjustment models used for accountability purposes, while stratifying on SDS factors for the purposes of identifying and reducing quality disparities.

In addition, we look forward to release of the Office of the Assistant Secretary for Planning and Evaluation (ASPE) report on the SDS effects on quality, cost and other measures.

Prior to its release, we ask that additional details around the scope and analyses that are underway be provided. Currently, researchers, hospital associations, and others are examining the degree to which patient-, hospital- and community-level SDS effect impact a patient's risk of readmission and these findings should be used to inform measure developers and CMS on this issue. For example, the Missouri Hospital Association (MHA) performed an analysis around several SDS factors and patients' risk of readmission.[1] This study, which is now reported for participating hospitals in MHA's Focus on Hospitals web site, demonstrated that the inclusion of these factors can more precisely predict which patients are more likely to be readmitted.

We are concerned with the general conclusion that has been made in the proposed rule that inclusion of these factors would obscure potential disparities or dis-incentivize improvement for disadvantaged populations. These determinations should be made on each measure and results found through comprehensive testing of the SDS factors in the risk adjustment models. We believe that SDS adjustment and stratification are important tools for accurately assessing health care provider performance for public reporting and accountability programs, particularly with respect to outcomes measurement and resource use/cost measurement. Most importantly, the FAH believes that risk adjustment for SDS factors will avoid the unintended consequences that can result without such adjustment when providers serving vulnerable populations are subject to payment penalties.

Hospital Value Based Purchasing Program

IV.H. Value-Based Purchasing

In the initial development of the HVBP Program, CMS emphasized the need for program performance results to be transparent to and useable by consumers. In the years since its initial implementation, the program has taken on added levels of complexity that make it challenging for hospitals. In the initial final VBP rule CMS stated: "To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across Medicare's and Medicaid's public reporting and payment systems. CMS also seeks to develop a focused core-set of measures appropriate to each specific provider category that reflects the level of care and the most important areas of service furnished by that provider. The collection of information should minimize the burden on providers to the extent possible. As part of that effort, CMS will continuously seek to align its measures with the adoption of meaningful use standards for health information technology (HIT)." The FAH believes these goals continue to be appropriate and are concerned that some of the proposed changed to the HVBP lose sight of these goals.

Hospitals' trust in the equity of the HVBP Program payment adjustment is tied to having a strong understanding of their own performance on all measures. Unfortunately, that trust is limited by the inclusion of measures that cannot be replicated and by providing access to certain data only once each year. The FAH continues to be concerned that hospitals do not receive sufficient feedback on HVBP Program claims-based measures to make them useful for informing quality improvement activities. Data are shared with hospitals with respect to their performance on the mortality, Medicare Spending Per Beneficiary ("MSPB"), and hip/knee complication measures only once a year. Hospitals are unable to replicate their scores on claims-based

[1] Reidhead, M. (2016, February). Including Sociodemographic Factors in Risk-Adjusted Readmission Measures. HIDI HealthStats. Missouri Hospital Association. Hospital Industry Data Institute. Available at http://web.mhanet.com/hidi.

measures using their own internal data. Because feedback is only provided once a year without any opportunity for on-going self-assessment, hospitals have limited ability to use these measures to inform quality improvement strategies, which should be the primary goal of the HVBP Program. Hospitals' understanding of their measure results also are hampered by the regularly occurring errors in the *Hospital Compare* database and preview reports prepared by CMS contractors.

Proposed New Measures. The FAH opposes the proposed addition to the HVBP of 30-day risk adjusted episode payment measures for heart attack (NQF #2436) and acute myocardial infarction (AMI) (NQF #2431) beginning with the 2021 payment determination for a number of reasons. First, the FAH continues to believe that this type of Medicare spending measure is not suited for inclusion in the HVBP program. Hospitals have little ability to affect spending during the defined episode (generally three days prior to admission and 30 days post-discharge) with the exception of addressing preventable readmissions, and readmissions are measured independently for the quality reporting program and the Readmissions Reduction Program. Performance on the type of Medicare spending measures proposed is largely determined by factors beyond a hospital's control, such as the quality of care provided by a post-acute care provider (skilled nursing facility or home health agency), physician/practitioner follow-up, patient compliance, and community services. In addition, hospitals are required through the Conditions of Participation to make available to patients a comprehensive list of resources for post-acute care, and the patient makes the choice of his/her follow-up care. For these reasons, the FAH believes that measures of Medicare spending per beneficiary are more appropriate for use in assessing performance of alternative payment models or similar integrated provider systems.

We also specifically oppose the addition of these specific proposed measures (NQF #2436 and #2431) because the Measure Applications Partnership (MAP) did not support their addition, and, at this time, the measures are undergoing appeal of their NQF endorsement. The FAH and other stakeholders have appealed the endorsement of these measures and the related pneumonia episode payment measure (NQF #2579) because we believe the measure developer and the NQF measure review committee did not consider appropriate risk adjustment for sociodemographic status (SDS). The specific concerns raised in the appeal involve inaccurate representation of the recommendations of NQF's Expert Panel on Risk Adjustment and SDS in the measure evaluation criteria, a flawed empirical analysis used to test whether cost and resource use measures should be SDS adjusted, insufficient criteria and materials provided by NQF staff to the Standing Committee and measure developers on what should be provided for SDS variable selection and testing to guide the evaluation; and insufficient resolution of all of the conditions set by the NQF Board for endorsement in 2015. Until these issues can be resolved and stakeholders can evaluate the final measures, CMS should refrain from including the measures in the HVBP program.

If CMS chooses to include these measures in the FY 2021 payment determination despite these concerns, the current measure of total Medicare spending per beneficiary (MSPB) should be modified to remove heart failure and AMI cases in order to ensure there is no double counting of these cases within the efficiency domain measures.

CMS proposes to adopt measures for the HVBP program using a shortened performance period. In general, FAH recommends that CMS refrain from pushing to adopt measures for the HVBP Program when doing so would require using shortened performance periods. For example, the adoption of the expanded pneumonia cohort is proposed to begin with FY 2021

payment, which requires using a shortened 23-month reporting period in the initial year. The FAH believes that CMS should wait until FY 2022 to adopt this change when a full 36-month performance period would apply. The proposed rule did not supply adequate assurance that measures with differing performance periods were reliable or adequately tested using shortened performance periods.,

Scoring Episode Payment Measures. With respect to the proposal for scoring the episode measures in the same manner as the current total Medicare Spending per Beneficiary (MSPB) measure, the FAH believes that CMS should instead treat these episode measures in the same way as the other HVBP Program measures. This means setting the achievement threshold performance target in advance of the performance year rather than using data from the performance year itself to establish the achievement threshold. Under the current approach, by definition half the hospitals cannot receive any achievement points on these measures. While we understand the concern that changes in program policy could affect performance relative to a threshold set during the baseline period, it should be possible for CMS to develop a methodology for adjusting the baseline median achievement threshold in order to reflect aggregate changes in Medicare spending per beneficiary that result from payment policy differences between the baseline and performance periods.

Weighting of the Efficiency Domain**.** CMS proposes to retain for FY 2018 the same domain weights previously adopted for FY 2018, including a 25 percent weight for the efficiency and cost reduction domain. The FAH continues to believe that this domain weight is too high. To some degree, performance on Medicare spending measures is correlated with readmissions and therefore overlaps with the readmissions reduction program. In addition, as noted earlier, Medicare spending measures largely reflect factors beyond a hospital's ultimate control, such as the quality of care provided by a post-acute care provider (skilled nursing facility or home health agency), physician/practitioner follow-up, patient compliance and availability of community services. We remain concerned that the MSPB measure may encourage hospitals to avoid taking high-risk patients or to sacrifice quality of care following discharge by placing patients in a lower-cost post-acute care setting. In other words, the MSPB measure and Readmissions Reduction program incentives are at odds with one another. The readmission program may incentivize some hospitals to encourage patients to seek care at a higher quality provider, however, that provider may have higher costs thus reducing the hospital's readmission rate, but increasing the hospitals MSPB. Thus hospitals may be forced to choose the measure on which it will seek better performance to avoid the negative impact of the MSPB. For these reasons we recommend that the MSPB domain weight be reduced.

Changes to Implementation of the Immediate Jeopardy ("IJ") Exclusion. The FAH supports the CMS proposal to increase from two to three the number of surveys for which a hospital must be cited for "immediate jeopardy" before it is excluded from the HVBP Program. Because HVBP Program measure performance periods can span several years it is possible under current policy for a hospital to be excluded from the program for a number of years based on two citations. The immediate jeopardy process is an important tool for monitoring and preventing serious adverse events. The FAH believes that the proposed change would strike a better balance with respect to which hospitals should be excluded from the HVBP Program. On a related issue, our members have found that implementation of immediate jeopardy standards can vary across CMS regional offices, and therefore we encourage CMS to undertake take steps to ensure more consistent enforcement of standards across the country.

Hospital-Acquired Conditions

IV. I. Hospital-Acquired Condition Reduction Program

CMS proposes changes to the HAC Reduction Program scoring system that would seem to avoid the frequent tied scores that have resulted from the current decile-based system. At the same time, however, implementation of a "Winsorized Z-score" methodology is a setback from the standpoint of building hospital confidence in the payment system by keeping it easily understood. CMS should work to improve the transparency of scoring individual measures.

We recognize that the legislation underlying the HAC program limits the ability of CMS to make program improvements. While hospitals should always strive for harm-free patient care, it is not reasonable to expect perfection on these measures and even if near-perfection were to occur, the law requires that one quarter of all hospitals receive a substantial payment penalty. Further, each of the HAC Reduction Program measures is duplicated in the HVBP Program.

With regard to newly opened hospitals, CMS clarifies that participation in the HAC Reduction program is not voluntary, and proposes that the deadline for reporting depends on whether or not the hospital elects to participate in the IQR Program. A hospital filing a notice of participation (NOP) with the Hospital IQR Program within 6 months of opening would be required to begin submitting data for the CDC National Healthcare Safety Network (NHSN) Healthcare-acquired Infection (HAI) measures no later than the first day of the quarter following the NOP. If however, a hospital does not file a NOP with the Hospital IQR Program within six months of opening, the hospital would be required to begin submitting data for the CDC NHSN HAI measures on the first day of the quarter following the end of the 6-month period to file the NOP. While we appreciate the clarification in the proposed rule, our members find that this policy confuses Medicare contractors and hospitals receive conflicting advice. Consequently, the FAH recommends the CMS establish a single date under which HAC Reduction Program reporting must begin regardless of a hospital's decision about participation in the IQR Program.

Observation Services Notice to Beneficiaries

IV. L. Proposed Hospital and CAH Notification Procedures for Outpatients Receiving Observations Services

In the FY17 IPPS Proposed Rule, CMS proposes to implement the *Notice of Observation Treatment and Implications for Care Eligibility Act of 2015* ("NOTICE Act") by requiring hospitals to provide the Medicare Outpatient Observation Notice ("MOON") to Medicare and Medicare Advantage beneficiaries receiving hospital outpatient observation services. The FAH supports CMS efforts to increase transparency of cost-sharing obligations for Medicare beneficiaries, as cost-sharing transparency is integral to transforming the health care delivery system.

The FAH, however, has concerns that certain proposed provisions regarding the MOON undermine the ability of hospitals to effectively provide patients with information that is clear, accessible, and actionable so that beneficiaries can more readily determine their potential financial liability under Medicare for patient co-payments and non-covered services. Further, the MOON also could undermine quality patient care. To that end, the FAH offers

recommendations for improving implementation of the MOON such that this notice can be provided to patients in a manner that is both appropriately timed and delivered.

A. CMS Should Clarify That Hospitals Can Provide the MOON Prior to the 24-Hour Triggering Event

The Proposed Rule contains a requirement triggering the hospital's obligation to provide the MOON to a Medicare patient "when such individual receives observation services as an outpatient for more than 24 hours. Notice must be provided to the individual not later than 36 hours after observations services are initiated or sooner if the individual is transferred, discharged or admitted." It is unclear from the regulatory language whether hospitals may provide the MOON before 24 hours has passed. We believe that it should.

CMS should be clear that hospitals have the flexibility to provide the MOON at any point prior to 36 hours or, if earlier, prior to transfer, inpatient admission, or discharge. The FAH believes this clarification is in conformance with the NOTICE Act, which requires hospitals to provide the MOON "to each individual who receives observations services as an outpatient at such hospital . . . for more than 24 hours [and] to provide [the MOON to] such individual not later than 36 hours after the time such individual begins receiving such services."[2] Allowing hospitals flexibility in providing the MOON ahead of the 24-hour trigger would be within the 36-hour deadline and consistent with the statutory language in the NOTICE Act.

If CMS were to take the position the MOON can only be given after 24 hours of observation has elapsed, hospitals might face practical problems in fulfilling their obligations. For example, a patient undergoing needed diagnostic testing could be unavailable for a substantial portion, or potentially the entire, window of time from the 24th hour to the 36th hour (effectively, a 12-hour period) described in the Proposed Regulation. The patient also might be sleeping or otherwise unresponsive during this period. Additionally, a patient may not have the ability to comprehend the MOON during this 12-hour window due to his or her treatment, medications, and a variety of other factors. And, although the Proposed Rule allows communication with a patient representative, the availability of a representative to receive the MOON on behalf of the patient is by no means certain during this short, 12-hour period.

The requested flexibility also would serve other beneficial purposes. Allowing hospitals to provide the MOON prior to the 24th hour would enable hospitals to incorporate the requirements for the MOON into existing processes. Hospitals could furnish the MOON to the patient as part of patient registration, or when the patient was first placed in observation, allowing hospitals a more opportune time to discuss with Medicare beneficiaries their cost-sharing obligations instead of intervening later, during patient care, to meet stringent regulatory timeframes. Patients also would have more time to gather the appropriate information and determine their most appropriate options. This timing also aligns with the existing framework and flexibility provided by CMS with respect to other important patient messaging (i.e., advanced beneficiary notice). Hospitals also could better assign responsibility for providing the MOON to the appropriate administrative personnel, who also can answer patient questions about

[2] NOTICE OF OBSERVATION TREATMENT AND IMPLICATION FOR CARE ELIGIBILITY ACT, PL 114–42, August 6, 2015, 129 Stat 468 (emphasis added) (codified at 42 U.S.C.A. § 1395cc(a)(1)(Y) (West)).

the MOON, instead of potentially detracting from patient care by having health care practitioners provide the notice.

In sum, the FAH urges CMS to clarify the timing requirement and provide more flexibility for hospitals to operationalize the MOON. Specifically, the FAH requests CMS to clarify that hospitals may provide the MOON to the patient at any time prior to the 36-hour deadline or sooner if the patient is admitted as an inpatient, discharged, or transferred. This will encourage the meaningful interaction between hospital personnel and Medicare beneficiaries regarding cost-sharing obligations—as intended by the MOON—and provide hospitals with flexibility to furnish the MOON, at the appropriate time, even if this is before the 24 hours has elapsed.

B. Hospitals Should be Permitted to Provide the MOON in an Appropriate Electronic Format to Medicare Beneficiaries.

The Proposed Rule appears to limit the ability of hospitals to incorporate the MOON as part of the hospitals' electronically generated and stored information. This is inconsistent with the general trend towards electronic health records and away from paper records. **The FAH requests that CMS expressly allow hospitals the option to provide the MOON electronically, which would still advance the goal of cost-sharing transparency by notifying Medical beneficiaries in a timely manner, while also reducing the hospital's usage of paper and burden of maintaining paperwork.** The hospital could provide a paper copy of the MOON to the beneficiary, but retain the actual signed document in electronic form, thereby achieving the appropriate objectives of patient notification and paper reduction.

C. CMS Should Provide an Opportunity for Comment to the Oral Notification Requirements of the MOON

The Proposed Rule states that CMS "will provide guidance for oral notification in [CMS's] forthcoming Medicare manual provisions." The FAH believes that oral notification requirements of the MOON should follow the normal notice and comment rulemaking process. **Therefore, the FAH requests CMS to allow an opportunity to comment on the proposed oral notification requirements in formal rulemaking, as similarly done for the written notification requirement.**

D. The MOON Should not be Required When Medicare or Medicare Advantage is the Secondary Payor

The Proposed Rule is silent regarding whether hospitals must provide the MOON when Medicare is the secondary payor. **We urge CMS to clarify that the MOON applies only when Medicare/Medicare Advantage is a beneficiary's primary payor.** If the MOON were required in circumstances where Medicare is the secondary payor, it could create confusion for a beneficiary. Certain primary payors, such as commercial plans, often have their own cost-sharing and coverage limitations, which could conflict with those described in the MOON. As a result, providing the MOON when Medicare is not primary would not communicate clear and actionable information to beneficiaries. For these reasons, the FAH requests CMS to provide clarification that the MOON is not required when Medicare is the secondary payor.

E. Overlap with State Law Should be Expressly Preempted by CMS

The MOON provisions of the Proposed Rule overlap with a number of state laws that impose similar mandated notifications. **The FAH requests that CMS clarify which requirements take precedence and expressly preempt state laws with similar requirements as the MOON.**

F. CMS Should Postpone the Effective Date of the MOON Provisions

It is critical that hospitals have the time necessary to operationalize the requirements pertaining to the MOON. The current effective date of the MOON provisions is August 6, 2016. However, the final rule for FY 2017 IPPS final rule, containing the final guidance on the MOON requirements, is slated for publication in early August of 2016. As a result, hospitals will have, at most, only five days to review the final regulations, implement process changes, update internal policies, develop the MOON notice, and educate hundreds or even thousands of necessary employees on the MOON provisions prior to the effective date of August 6, 2016. This clearly is not an adequate timeframe.

Therefore, we urge CMS to postpone the effective date for a period equal to 60 days from publication of the final rule to allow the necessary amount of time to incorporate and operationalize the MOON. Alternatively, at a minimum, CMS should delay enforcement of the MOON provisions for an equivalent 60-day period from publication of the final rule.

2-Midnight Policy

IV. O. Adjustment to IPPS Rates Resulting from 2-Midnight Policy

FAH supports and very much appreciates CMS' proposal to permanently remove, beginning in FY 2017, the 0.2 percent reduction to the IPPS rates that was applied in FYs 2014, 2015, and 2016. The FAH also supports CMS' proposal to temporarily increase the FY 2017 rates to reverse the effect of the 0.2 percent reduction to the IPPS rates that was applied in FYs 2014, 2015, and 2016. We do note below that a very small number of hospitals will not receive the benefits of this one-time adjustment and if that was not CMS' intent suggest CMS develop an exceptions process to provide some relief to those hospitals.

A. The Temporary 0.6 Percent Increase Does Not Address Closed or Converted Hospitals

FAH is concerned that the application of a one-time 0.6 percent adjustment to FY 2017 rates does not address hospitals that were in operation and paid under IPPS during FY 2014, 2015, and/or 2016, but that closed or converted to a non-IPPS payment system before the completion of FY 2017. By virtue of not being paid under IPPS for the entirety of FY 2017, any such hospital would not receive the full benefit (or, in the case of hospitals that close prior to FY 2017, any benefit) of the temporary adjustment intended to reverse the 0.2 percent reduction applied to the three prior years. Because hospitals that were open and subject to IPPS during FYs 2014, 2015 and/or 2016 were subject to the 0.2 percent reduction, an exception mechanism intended to reverse those reductions should ensure payment to those hospitals, even if they were not open and subject to IPPS during FY 2017.

This issue is a concern for the very small percentage of hospitals that was subject to the 0.2 percent reduction in FYs 2014, 2015 and/or 2016, and that closed or converted to a non-IPPS payment system prior to the conclusion of FY 2017. Under the proposed remedy, CMS offers a one-time 0.6 percent adjustment that will be applied to a single full fiscal year (FY 2017), intended to reverse the effect of three separate 0.2 percent adjustments applied in each of the prior three full fiscal years (FY 2014, 2015 and 2016). To the extent a hospital was not open or paid under IPPS during FY 2017, or for only part of that year, but was open and paid under IPPS during some or all of FY 2014, 2015 and/or 2016, the remedy will fall short. In these cases, the adjusted FY 2017 rates will either not apply at all or apply to a much smaller volume of discharges (corresponding to the dates the hospital was in operation and paid under IPPS during FY 2017), and will therefore produce a smaller payment to the hospital than CMS presumably intends. Whether or not the hospital is in operation for the entirety of FY 2017, however, has no bearing on whether it was subject to the 0.2 percent reduction in years prior.

For example, a hospital that has operated and been paid under IPPS since 1985, but that closes or converts to a non-IPPS payment system on June 30, 2017, was subject to the 0.2% reduction as applied to a full year of discharges for each of the fiscal years 2014, 2015, and 2016. Under CMS' proposed mechanism to reverse these reductions, that hospital would receive the positive 0.6 percent adjustment to its FY 2017 rates. Those increased 2017 rates, however, would only be applied to the hospital's discharges during the hospital's limited dates of operation in FY 2017, that is, October 1, 2016 – June 30, 2017.

The purpose of CMS's proposed 0.6 percent positive adjustment to FY 2017 rates is to reverse the effects of the 0.2 percent reduction to rates that were applied in each of the prior three years. For the vast majority of hospitals that remedy is equitable. But for a very few, likely under 30 nationally, it might not be fair. In short, we encourage CMS's to develop an exceptions mechanism to compensate hospitals in the above situations. We think that exceptions mechanism can be informal, through written notice to a designated person at CMS of the relevant facts. We also note that the reverse of the above situation can occur for new hospitals in FY 2017 that experienced no payment shortfall in prior years. We leave it to CMS's discretion as to how it should address that situation.

B. CMS's Authority to Implement the 0.6% Increase is Limited to this Case

CMS distinctly states in the Proposed Rule that "taking all the foregoing factors into account, and given the unique nature of this situation in which the court has ordered us to further explain the assumptions underlying an adjustment applicable to past years, we believe it would be appropriate to use our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act to temporarily increase the rates, only for 2017, to address the effect of the 0.2 percent reduction to the rates in effect for FY 2014…FY 2015…and…FY 2016." CMS goes on to acknowledge that "[w]hile we generally do not believe it is appropriate in a prospective system to retrospectively adjust rates even where we believe a prospective change in policy is warranted, we take this action in the specific context of this unique situation, in which we have been ordered by a Federal court to further explain the basis of an adjustment we have imposed for past years."

The FAH agrees that CMS's authority to apply an adjustment to rates in a given year to reverse the effect of an error in rates in prior years is limited to the circumstances of the Two Midnight 0.2 percent reduction, and does not extend to circumstances beyond this particular

instance. In other words, sections 1886(d)(5)(I)(i) and 1886(g) of the Act do not provide CMS with the broad authority to apply an adjustment to rates in a given year to reverse the effect of an error in rates in prior years.

C. CMS Failed to Address Specific Comments Regarding the Reduction

The FAH has concerns regarding the adequacy of CMS's response to the comments relating to the 0.2 percent reduction. In particular, FAH is concerned with CMS' failure to address data presented by stakeholders via comment. In the FY 2014 Final Rule, CMS estimated that implementation of the Two Midnight policy would increase expenditures by approximately $220 million in FY 2014 due to an expected net increase in patient encounters, thereby supporting a 0.2 percent reduction to IPPS rates. During the comment period following the publication of CMS' December 1 court-ordered Notice of Explanation, stakeholders not only refuted CMS's assumption that inpatient admissions increased due to implementation of the 2 Two Midnight policy, but they also provided data that showed the implementation of the two midnight policy had resulted in a decrease in all relevant lengths of stay, thereby decreasing the Medicare program's IPPS costs. CMS failed to address these comments in the FY 2017 IPPS Proposed Rule at all. The FAH appreciates CMS's admission that its original estimate for the 0.2 percent reduction "had a much greater degree of uncertainty than usual," and that CMS proposes the mechanism by which it will reverse the effects of the 0.2 percent reduction applied in FYs 2014 – FY 2016. However, FAH is troubled by CMS's failure to address, or even acknowledge, the data provided by commenters that demonstrated that IPPS costs have decreased as a result of the Two Midnight policy.

D. We are Concerned About the Delay by QIOs in Completing Their Short Stay Reviews and the Impact Such Delays Have on Timely Rebilling

We wish to draw to CMS' attention the current backlog of delays of the short stay reviews by the Quality Improvement Organizations and the impact on hospitals in availing themselves of the CMS rebilling policy. FAH supports CMS decision to move review of medical review of cases shorter than two midnights to the purview of the QIOs. QIOs are most qualified to review such cases given their focus on clinical quality improvement and access to a panel of physician reviewers to lead the process.

FAH appreciates the fact that QIOs had little time to prepare for the implementation of this program. Some QIOs have indicated they are implementing organizational changes to manage the new workload. But in response to this need to make such necessary changes there have been significant delays by QIOs in providing initial review results letters, subsequent provider education and final determination letters for the first round of review. This delay and the recent announcement to pause the reviews only exacerbates an existing problem that CMS must address.

For example, many California hospitals have not received final determination letters. Such letters are necessary to rebill or appeal a claim should it be denied by the QIO. Additionally, there is current re-review of all claims by the QIO at CMS request in order to ensure accurate and consistent application of CMS policy by the contractors.

While the pause and a concern about consistent application of the two-midnight policy are entirely appropriate, CMS must make sure that providers subject to these reviews have the

ability to rebill denied claims even if the delay exceeds the 12-month rebilling period. We recommend that CMS waive the 12-month rebilling window for all claims currently under review.

Long-Term Care Hospital PPS

VII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2017

F. Proposed Modifications to the "25-Percent Threshold Policy" Payment Adjustments

CMS is proposing to continue to apply the 25% Rule payment adjustment policies through a new proposed regulation at 42 C.F.R. § 412.538. The new regulation would be effective for LTCH discharges on or after October 1, 2016. The existing 25% Rule regulations at 42 C.F.R. §§ 412.534 and 412.536 would continue to apply to LTCH cost reporting periods identified in those regulations, although the headings would be amended to limit their application to discharges before October 1, 2016.

It is imperative that **CMS not apply the Rule to LTCH cases paid at the site neutral rate. The application of the 25% Rule to these cases is duplicative, unnecessary and punitive.** By its terms, the 25% Rule adjusts payments for discharges that exceed the threshold amount to an IPPS equivalent amount. We understand the IPPS comparable per diem amount for calculating payments for site neutral discharges will often be lower (and never higher) than the IPPS equivalent amount paid under the 25% Rule. As a result, LTCH cases paid at the site neutral rate have already been adjusted to an IPPS comparable rate. Further, because the site neutral payment rate will be a fraction of the traditional LTCH PPS standard Federal payment rate, there is no reason to believe that LTCHs are inappropriately accepting the transfer of site neutral cases from discharging hospitals. As such, applying the 25% Rule to those cases paid at the site neutral rate will essentially penalize the LTCH twice for the same case. This can only be viewed as punitive. **The FAH urges CMS to abandon its proposal to apply the 25% Rule and its associated payment adjustments to cases paid at the site neutral payment. If CMS asserts that the 25% Rule must be maintained, cases paid at the site neutral rate should not be considered in the calculation.**

The FAH continues to believe that CMS should completely retire the 25% Rule, effective October 1, 2016. The new LTCH patient criteria and two-tiered payment system address the same policy concern that the 25% Rule was initially developed to address – patients who may have been transferred to the LTCH setting to maximize reimbursement and not because the LTCH was the most appropriate care setting for the patient. Now that LTCHs are only eligible for payment at the LTCH PPS standard Federal payment rate for a subset of historic LTCH patients with LTCH approved, very specific conditions, the FAH does not think the 25% Rule is necessary. Further, the FAH believes it is arbitrary for CMS to continue to stand behind a policy that pays for care rendered to some LTCH appropriate patients at the LTCH rate while paying for care rendered to other LTCH appropriate patients at the IPPS equivalent rate when the sole difference is the number of patients who have been discharged to the LTCH from the discharging hospital. If the patient is appropriately treated and classified as an LTCH patient such that the LTCH is eligible for reimbursement at the LTCH PPS standard Federal payment rate, the patient's care should be paid as such, regardless of the percentage of discharges to the LTCH from the discharging or transferring hospital.

In addition, the FAH believes the 25% Rule policies are inconsistent with the statutory mandate regarding the development of the new patient criteria. In the Pathway for Sustainable Growth Rate Reform Act of 2013 (Pub. L. 113-67) ("PSRA"), Congress specified that patient discharges meeting the new patient criteria would be paid at the standard LTCH PPS payment amount, not an amount that approximates the IPPS payment amount. Congress was clear that Medicare should *not* treat these patients who meet the new patient criteria and are otherwise reimbursable under the LTCH PPS standard Federal payment like IPPS patients for payment purposes. By maintaining the 25% Rule, this is exactly what CMS is doing.

While CMS did previously indicate that it intended to retire the 25% Rules, if CMS now believes that it needs more time to evaluate the 25% Rule policies until the transition period to site neutral payment is complete, CMS should, in addition to not applying the rule to site neutral cases: (i) extend the statutory moratorium for an additional two years; and (ii) not establish the new 25% Rule regulation at 42 C.F.R. § 412.538.

Regarding the new proposed 25% Rule regulation, FAH believes the effective date - discharges on or after October 1, 2016 -is problematic. Because it conflicts with the statutory moratorium period and because it is inconsistent with the longstanding effective dates of sections 412.534 and 412.536. If retained, this effective date will subject LTCHs to two different standards during the cost reporting period that includes October 1, 2016 (except for the relatively few LTCHs with cost reporting periods that begin on October 1). This will cause confusion and inconsistent (perhaps arbitrary) application of the 25% Rule regulations to LTCHs. To avoid these problems, CMS should change the effective date to "cost reporting periods beginning on or after October 1, 2016." CMS should also *not* amend the headings of existing sections 412.534 and 412.536 to change the effective dates of the existing regulations.

In an effort to simplify the 25% Rule policies, CMS made changes to these policies at proposed section 412.538 that are different and more onerous than existing sections 412.534 and 412.536. CMS omitted "urban single" referring hospitals from the proposed regulation 412.538. The higher percentage threshold for LTCH discharges that are referred from an urban single hospital should be included in this new regulation, if finalized. Both of the existing 25% Rule regulations provide higher percentage thresholds for rural LTCHs, LTCH patients admitted from MSA-dominant hospitals, *and LTCH patients admitted from urban single hospitals*. *See* 42 C.F.R. §§ 412.534(d),(e) and 412.536(c),(d). However, only the first two special categories were included at proposed section 412.538(e). CMS did not explain why the special category for urban single hospitals was omitted. Because the existing regulations provide a higher percentage threshold for patients admitted from urban single hospitals, the proposed regulation should as well.

CMS should not require that all locations of the LTCH or referring hospital satisfy one of the special categories in order to be eligible for the higher percentage thresholds they confer. The current 25% Rule regulations and guidance do not include this requirement. This proposed change will make it harder for LTCHs to qualify for the special categories and unfairly subject more of their discharges to the 25% Rule payment adjustments. Payment adjustments under the 25% Rule can still be calculated on a provider number basis using the CCN on claims, with MACs looking at the location identifier on the claim to identify each hospital location. If one hospital location qualifies for a special category (rural, MSA-dominant or urban single), that higher percentage threshold should apply to the calculation.

The FAH agrees with CMS's proposal to exclude Medicare Advantage (Part C) cases from the 25% Rule policies, consistent with current CMS policy.

Addendum—Proposed Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective with Cost Reporting Periods Beginning on or after October 1, 2016 and Payment Rates for LTCHs Effective for Discharges occurring on or after October 1, 2016

V. Proposed Changes to the Payment Rates for LTCH PPS for FY 2017

D. Proposed Adjustment for LTCH PPS High-Cost Outlier ("HCO") Cases

CMS has made a number of proposals relative to high-cost outlier ("HCO") cases. First, as in FY 2016, CMS is proposing to maintain separate FY 2017 fixed-loss amounts for the two categories of LTCH cases. For LTCH PPS standard Federal payment rate cases CMS is proposing a fixed-loss amount of $22,728, while it is proposing a fixed-loss amount of $23,681 for cases paid at the site neutral payment rate. In addition, as in FY 2016, CMS is proposing to maintain two separate HCO targets, one for long term acute care hospitals ("LTCHs") paid at the LTCH PPS standard Federal payment and one for cases paid at the site neutral rate. In FY 2017, CMS is proposing to continue to use an 8 % target for HCO payments for LTCH standard Federal payment rate cases and to use the IPPS HCO payment target of 5.1% for HCO payments for site neutral cases. Finally, CMS is proposing to continue to apply a budget neutrality adjustment ("BNA") factor of .949 to all cases paid at the site neutral rate.

Although the FAH generally supports using a target amount of 8% for HCOs paid at the LTCH PPS standard Federal payment rate, it is concerned about the proposed, significant increase in the fixed-loss amount for these cases for FY 2017. CMS recognizes that the proposed fixed-loss amount of $22,728 for FY 2017 for LTCH PPS standard Federal payment rate cases is "notably higher" than the fixed-loss amount in FY 2016 - nearly a 40% increase from FY 2016. The FAH is concerned that such a substantial increase is inconsistent with CMS' stated policy goal of mitigating instability in the HCO fixed-loss amounts for LTCH PPS standard Federal payment rate cases. CMS has indicated that it expects the annual changes in the fixed-loss amount to stabilize over time as it gains more experience with the effects and implementation of the new dual-rate LTCH PPS payment system. Notwithstanding, the FAH believes it is important for CMS to be more transparent about the year-to-year fluctuations in the fixed-loss amounts.

The FAH supports CMS' proposals to use the FY 2017 IPPS fixed-loss amount of $23,681 for site neutral payment rate cases, and the same 5.1% target as the IPPS for HCO payments to these cases. The FAH does not believe, however, that CMS should automatically use the IPPS fixed-loss amount and target for site neutral HCO cases every year. Instead, the FAH suggests that once data becomes available following the transition to the new two-tiered LTCH payment system, CMS should calculate the fixed-loss amount and target amount for site neutral HCO cases independently. Until then, the FAH finds the use of the IPPS fixed-loss amount and target amount to be a reasonable proxy.

The FAH strongly disagrees, however, with CMS' proposal to apply a .949 budget neutrality factor to LTCH site neutral cases that qualify for HCO payments. First, there is

no precedent in the LTCH PPS for an annual budget neutrality adjustment to the LTCH site neutral payments. Furthermore, perhaps more importantly, CMS has already accounted for site neutral HCO budget neutrality by using the IPPS and Capital PPS payment rates for the IPPS comparable per diem amounts. **Because only site neutral cases paid based on the IPPS comparable per diem amount will be eligible for HCO payments, the budget neutrality factor is duplicative because these cases are paid based on an IPPS comparable per diem amount that is comprised of IPPS and capital PPS rates that have already been reduced for budget neutrality.** Importantly, MedPAC agrees. Specifically, in its May 31, 2016 comment letter to CMS, MedPAC stated that CMS should not apply a separate budget neutrality adjustment to site neutral high-cost outliers because "the IPPS standard payment amount is already adjusted to account for HCO payments." *See* MedPAC Comment Letter to CMS re: File Code CMS-1655-P at 16 (May 16, 2016). MedPAC further suggested that applying this budget neutrality factor to site neutral cases was "duplicative and exaggerates the disparity in payment rates across provider settings. Given this duplication, CMS should not adjust the site-neutral rate further." *Id.* at 16-17.

As such, the FAH believes that **CMS should withdraw the proposed .949 budget neutrality adjustment for site neutral cases that qualify as HCOs**. This adjustment is not supported in LTCH PPS and CMS has already reduced the FY 2017 site neutral payment amount for estimated outlier payments through the IPPS HCO outlier factor and the capital PPS outlier factor. Applying the budget neutrality adjustment for the site neutral cases is an improper duplicative hit for the site neutral cases that qualify for HCO. In addition, since this budget neutrality adjustment has already been applied to site neutral HCO cases in FY 2016, the FAH also urges CMS to reverse this adjustment to all FY 2016 payments.

Other Comments/Considerations

A. Technical Correction of Definition of "Subsection (d) Hospital" for Site Neutral Payment Rate

Under the new two-tiered LTCH payment system, in order for a stay to qualify for payment under the LTCH PPS standard Federal payment rate under either the ICU criterion or the ventilator criterion, the LTCH admission must be immediately preceded by a discharge from a subsection (d) hospital. In the FY 2016 IPPS/LTCH PPS final rule, CMS adopted a definition of "subsection (d) hospital" in the regulation at 42 C.F.R. § 412.503: "*Subsection (d) hospital* means, for purposes of § 412.526, a hospital defined in section 1886(d)(1)(B) of the Social Security Act and includes any hospital that is located in Puerto Rico and that would be a subsection (d) hospital as defined in section 1886(d)(1)(B) of the Social Security Act if it were located in one of the 50 States." CMS now proposes to amend this definition so that it applies to the site-neutral payment rate regulation at section 412.522 instead of the payment provisions for "subclause II" LTCHs at section 412.526. CMS states that this is being done to correct an "inadvertent cross-reference error."

The FAH agrees that CMS should correct the definition of "subsection (d) hospital" at section 412.503 to refer to the site-neutral payment rate regulation. In addition, the FAH believes CMS should make two additional changes to clarify that (i) a subsection (d) hospital is not required to submit a Medicare claim, and (ii) a subsection (d) hospital is not required to be enrolled in Medicare as an IPPS hospital. These changes are necessary so that Medicare payment contractors will pay LTCH claims correctly for cases that meet LTCH patient criteria.

Through the FY 2016 IPPS/LTCH PPS final rule and in subsequent guidance CMS issued to its payment contractors in Transmittal 1544, CMS has stated that in order to assess whether an LTCH admission was "immediately preceded" by a discharge from a subsection (d) hospital, it will look to Medicare claims data from the subsection (d) hospitals. In its guidance, CMS specifically provided that the Medicare contractor "shall reject the LTCH claim if a qualifying IPPS history claim . . . is not found." *See* Implementation of Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) Based on Specific Clinical Criteria, CMS Transmittal 1544, Change Request 9015 (Sept. 22, 2015).

This guidance is problematic in that it inappropriately excludes patients who have had qualifying stays immediately preceding the LTCH admission in a subsection (d) hospital when that stay did not result in the submission of a Medicare claim. This could be, for example, when an IPPS claim is not submitted from the subsection (d) hospital because the patient did not use his or her Medicare benefits during that stay and the subsection (d) hospital billed another payor. Alternatively, the subsection (d) hospital may not submit any claim for payment, or a claim may be submitted as a "no-pay" claim. Although in these examples the patients had the requisite stay at a subsection (d) hospital immediately before the LTCH admission, CMS guidance would seem to prevent the LTCH from being paid the proper LTCH PPS standard Federal payment rate for these cases. As such, the FAH believes CMS should amend the definition of a subsection (d) hospital at section 412.503 to clarify that a subsection (d) hospital patient stay does not need to result in the submission of a Medicare claim under the IPPS, and should make conforming changes and re-issue Transmittal 1544 accordingly.

In addition, the instruction in Transmittal 1544 is too narrow in that it inappropriately limits subsection (d) hospitals to *only* hospitals that are paid by Medicare under the IPPS or under a Medicare waiver for Maryland hospitals. Military and VA hospitals, for example, in our experience often do not have a Medicare provider number as an IPPS hospital. A patient stay immediately prior to an admission to an LTCH in such a hospital that meets the definition of a subsection (d) hospital at section 1886(d)(1)(B) of the Social Security Act should be sufficient for the LTCH to qualify for payment at the LTCH PPS standard Federal payment rate. This is critical to ensure that these military personnel, their families, and veterans receive the hospital care they need in the appropriate care setting. CMS should amend the definition of a subsection (d) hospital at section 412.503 to clarify that a subsection (d) hospital does not need to participate in Medicare as an IPPS hospital. This revision should be carried through a revised, updated Transmittal 1544.

B. LTCH Discharge Payment Percentage Proposals

Pursuant to section 1886(m)(6)(C)(iv) of the Social Security Act, as amended by the PSRA, CMS promulgated 42 C.F.R. § 412.522(d)(1) to define an LTCH's discharge payment percentage as the ratio (expressed as a percentage) of Medicare discharges excluded from the site neutral payment rate (*i.e.*, LTCH PPS standard Federal payment rate cases) to total Medicare discharges paid under the LTCH PPS in accordance with 42 C.F.R. Part 412, Subpart O (*i.e.*, standard Federal payment rate cases plus site neutral cases) during the cost reporting period. Section 1886(m)(6)(C)(ii) of the Social Security Act requires, for cost reporting periods beginning on or after October 1, 2020, that any LTCH whose discharge payment percentage for the period is not at least 50% will be notified by CMS and all of the LTCH's discharges in subsequent cost reporting periods will be paid the subsection (d) hospital payment amount. Congress left open for CMS the ability to establish a process for reinstatement of payments to the

hospital at the LTCH PPS rates. To date, CMS has not made any proposals related to this 50% discharge payment percentage requirement or the process for reinstatement. In the FY 2016 IPPS/LTCH PPS final rule, CMS had indicated that it intended to develop these processes through "operational guidance" instead of by rulemaking.

The FAH believes that CMS should use the rulemaking process to develop: (i) the process to notify LTCHs when their discharge payment percentage under section 412.522(d) is below 50%; (ii) a cure period to continue to receive payments at LTCH PPS rates; and (iii) the process for reinstatement of a LTCH's payment at LTCH PPS rates. This guidance should not be issued through the sub-regulatory process as it will create substantive new requirements and processes that LTCHs should be given the opportunity to review and comment upon through notice-and-comment rulemaking.

Regarding the "cure period" for LTCHs that do not maintain a discharge payment percentage of at least 50% in a cost reporting period beginning on or after October 1, 2020, FAH believes it should resemble the cure period currently used to confirm LTCH compliance with the ALOS requirements. If an LTCH is notified that it did not have a discharge payment percentage of at least 50%, the payment contractor should be required to evaluate the LTCH's discharge payment percentage for at least 5 of the 6 months immediately preceding the date it conducts the cure period evaluation. If the LTCH has a discharge payment percentage of at least 50% for this cure period, then the LTCH is deemed in compliance and the LTCH PPS rates continue to apply. If, after this secondary review, the LTCH falls short of 50%, the LTCH would no longer be paid under the LTCH PPS effective at the start of the LTCH's next cost reporting period (per 42 C.F.R. § 412.23(i)). In addition, the FAH believes that LTCHs should be permitted to apply for reinstatement of their right to payment under LTCH PPS after demonstrating that it has satisfied the discharge payment percentage requirements for the period of at least 5 of the preceding 6 months.

C. Access to LTCH Services for Wound Care Patients

The dual-rate LTCH PPS payment system only reimburses LTCHs at the full LTCH PPS standard Federal payment rate for patients that meet the ICU criterion or the ventilator criterion. Many patients who have serious, complex or multiple wounds who are treated in LTCHs will likely not fit within either the ICU or ventilator category. Patients with serious, complex and/or multiple wounds require extensive resources over a relatively long stay which is often complicated by multiple comorbidities – care that has traditionally been provided in LTCHs because of their specialized, effective wound care programs. However, the intensive care required for these patients will not be adequately be covered at the current site neutral rate.

In the Proposed Rule, CMS indicated that it would address Section 231 of Consolidated Appropriates Act, 2016 (Pub. L. 114-113), enacted December 18, 2015, in separate rulemaking. In this rulemaking, the FAH urges CMS to revise its LTCH PPS payment policies to address this access to care concern and establish new payment adjustments that would provide for additional payment to LTCHs that treat patients with serious, complex or multiple wounds. CMS has established other similar payment policies by regulation, including, for example, policies addressing high-cost outliers, short-stay outliers, and interrupted stays. As such, the FAH believes a new payment adjustment policy to increase or provide additional LTCH payments for wound care cases would be an appropriate agency response to maintain access to quality wound care at LTCHs nationwide.

Quality Data Reporting

VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

The FAH has a history of supporting public reporting in all of the payment programs in this section of the regulation. The FAH believes it is vitally important that the information reported to the public be accurate and comparable across providers. Further, the FAH believes 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. In other words, CMS should recognize the burden of data collection, and understand the resources available to facilities should be focused on the collection of data that is the most clinically relevant and actionable to the hospital/facility and its patients.

The process CMS follows to assess the feasibility of new measures should take into account the burden of operational and technical data extraction, feasibility and data review along with the ability of the provider and patient to use the data generated by the measure. The FAH also recommends that CMS give considerably more attention to the measures' potential for being able to measurably improve the process, outcome and quality of patient care.

The FAH appreciates that CMS often establishes Technical Expert Panels (TEPs) to provide insight from the field on the feasibility of new measures under consideration. The FAH appreciates the opportunity to nominate candidates for these panels and also to respond to the TEP reports. The input from multiple stakeholders makes the overall process stronger.

The FAH would recommend, however, that CMS give greater attention to the burden associated with implementing new measures and ensure that the new measures are appropriately and precisely specified for that setting, and field tested before being deployed in any payment program. The field testing should be robust and include significant opportunity for feedback from the providers attempting to collect the data.

Finally, FAH recommends that CMS adopt "minimum standards" for all measure specifications for all future measures. CMS adopted in FY 2015 OP-29 and OP-30 and in FY 2016 OP-33, and three new behavioral health measures as web-based measures requiring hospitals to submit data by entering numerator and denominator values into the Quality Net website. Each of these measures lacked detailed measure specifications resulting in hospitals and or vendors interpreting and establishing numerator and denominator definitions on their own. This resulted in CMS receiving data that was not consistent across hospitals resulting in the potential for consumers to make healthcare decisions on data that was not valid or reliable or comparable across hospitals. The FAH recommends that "minimum standards" must contain the following:

- Complete numerator definition
- Complete denominator definition including ICD-10 diagnosis and procedure codes.
- An algorithm/flow chart that clearly articulates how cases are determined to be in the denominator, numerator, or are excluded from the measure.
- Sampling criteria
- Rationale
- Improvement notes as indicator

- Included and excluded populations
- Data elements included in the measures
- References that support the adoption of the measure and the specifications

CMS recently had to extend the beginning collection date for three new behavioral health measures for a second time due to concerns about the limited measure specifications issued by CMS. Having minimum standards for all measure specifications would have avoided these delays.

FAH also recommends that CMS be able to accept both aggregate and patient level data on all measures and that this data be electronically submitted. Failure to accept patient level data prevents CMS from being able to validate the data that is publicly reported on *Hospital Compare*. Electronically submitted data prevents simple data entry errors and reduces the burden on hospitals. Currently CMS requires web-based data entry for PC-01, OP-29, OP-30, OP-33 and all of the HBIPS measures.

VIII. A. Inpatient Quality Reporting Program

Removal of eCQMs. The FAH supports the proposed removal of thirteen eCQMs, but we note that seven of the measures are proposed for removal because it is no longer feasible to implement the measure specifications. For example, CMS discusses feedback from hospitals regarding difficulties with interpreting critical timing requirements with respect to the measures PN-6: Initial Antibiotic Selection for Community-Acquired Pneumonia in Immuno-compromised Patients and SCIP-Inf-9, which involves post-operative urinary catheter removal. As FAH has noted in earlier comment letters, it is imperative that all measures be sufficiently tested before they are proposed and adopted for the IQR program. Through pilot testing, any gaps in measure specifications, data element availability in electronic health record systems, and other issues relating to the feasibility of implementation can be identified. Once a measure is finalized for adoption, hospitals and vendors invest resources to ensure accurate and timely reporting, and these funds are completely wasted when measures are subsequently withdrawn because they have been shown to be infeasible. Pilot testing is an integral part of ensuring that quality improvement activities are focused on the measures that will result in the greatest benefit for patients, providers and the Medicare program.

The FAH recommends that EHR pilot testing exceeds two hospitals and two EHR systems. That simply is insufficient to fully understand how the eCQMs will work. Often times pilot testing is done in “optimal” not “real-life” conditions. Therefore, the FAH recommends that CMS collect a minimum of one year’s worth of data from all hospitals and vendors chosen to participate in the EHR pilot testing. This data should be considered “test” data and not released publicly but instead be released to hospitals for feedback to CMS. CMS also should consider establishing a multi-stakeholder group consisting of vendor, hospital, and CMS representatives to review the data, findings from the data and issues related to the specifications. This is new and extremely complex work for hospitals and vendors. Until it is in place in the real world, numerous issues will go unidentified. In addition, the pilot testing must be conducted on a representative sample of hospitals. The FAH believes that 30 or more hospitals would be necessary in order to ensure a wide variety of patient scenarios are encountered, able to be captured, and accurately reported.

Alignment of IQR and EHR Incentive Program Requirements. The FAH supports the proposal to align the requirements for reporting of electronic measures in the IQR Program with the EHR Incentive Program. However, based on our members' experience to date with reporting eCQMs, we believe that the proposal to require reporting of 15 eCQMs for purposes of both the IQR Program and the EHR Incentive Program in 2017 is overly ambitious. For 2016, hospitals must report four eCQMs, but given the ongoing technical issues with vendor and CMS systems, we do not believe that it is feasible to require all participating hospitals to report 15 measures at this point. Thus far CMS has received data from fewer than 100 hospitals, and it has been for a small number of measures. Combine that with the constantly changing QRDA file layout from CMS, and the fact that CMS has not yet received data from all hospitals on the four measures required for FY 2016, the FAH is concerned that CMS has not fully tested its capabilities for managing the technical issues that will arise. Problems with CMS's technical ability to receive the measure data have led CMS to significantly delay reporting deadlines. We suggest that for 2017 hospitals be required to report at least six electronic measures, with the option of reporting all 15 measures. This will allow CMS and vendors more time to work out technical issues.

In addition, we recommend that CMS consider requiring quarterly rather than annual reporting of electronic measures for several reasons. First, it would reduce the volume of data that vendors and CMS must process at one time, reducing stress on CMS technical systems. Second, it would give providers more frequent benchmarking of their performance on these measures, which is beneficial to quality improvement strategies. Finally, quarterly reporting would make the timing of electronic reporting consistent with reporting of chart-abstracted measures.

The FAH also recommends that CMS encourage vendors to submit on behalf of their hospitals. The FAH believes that the vendors are in a better position to submit the data. Plus permitting vendors to do the submissions will improve the data accuracy and more readily identify submission issues and reduce the burden on hospitals.

The FAH is concerned about a change made outside of rulemaking regarding the specifications for Quality Reporting Document Architecture (QRDA) files for 2016. Specifically, the requirement for one file per episode has now been changed to be one file per patient. No explanation was offered for this change, and we are concerned about how data will be combined to form a patient-level record. Tying back to our previous comment, there has not been an adequate pilot period to test this new QRDA layout, so the FAH members do not feel confident that all facilities and vendors will implement the file layout change correctly. As far as our members can tell, there are no safeguards in place on the CMS side that would disallow submission of multiple QRDA files for a single patient.

Finally, the FAH recommends that CMS require data reported on eCQMs to be captured directly from the EHR. In this proposed rule CMS proposes that hospitals may continue to either use abstraction or to pull data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I files. Slide 20 of the CMS-led May 9, 2016 webinar on the IPPS Proposed Rule even specifically called this out as an option. The exact wording on Slide 20 reads: "Hospital May continue to either use abstraction or pull the data from non-certified sources in order to then input these data in CEHRT for capture and reporting QRDA1 files."

Measures reported using this type of data collection defeat the purpose of CEHRT, and are more like chart-abstracted measures. Public reporting of eCQM results should not include such data, and any analysis CMS undertakes to compare performance on related chart-abstracted and electronic measures should make sure that only results from discrete encoded fields be referenced when capturing the data for the eCQMs.

Modified PSI-90 and Proposed Reporting Period. Because it is included in the HVBP Program and heavily weighted in the HAC Reduction Program, PSI 90 is a critical metric for hospital performance-based payment adjustments. The FAH is concerned that the proposed combination of a re-specified measure and shortened performance period makes this measure and its resulting impact on hospital payment less transparent and predictable.

On its face, the modified version of PSI 90 that CMS proposes to adopt beginning with FY 2018 seems to be an improvement. The changes have been endorsed by NQF and address some of the concerns raised about this measure. In particular, we support the removal of the measure PSI-7 of central venous catheter-related blood stream infection rates, which duplicates the National Healthcare Safety Network CLABSI measure. Other improvements include re-specifying and reweighting the accidental puncture and laceration component.

However, stakeholders will be unable to fully assess the modified measure until AHRQ provides a version of the PSI 90 software that reflects the adoption of ICD-10 and the modified measure specifications. Although the implementation of ICD-10 was years in the planning, this software has yet to be made available. Since the ICD-10 was introduced in October 2015 hospitals have been unable to internally track performance on this measure for quality improvement purposes because of the lack of an ICD-10 updated version of the AHRQ software. In the proposed rule CMS states that a risk-adjusted ICD-10 version of this software will not be available until late calendar year 2017.

The FAH finds this situation untenable and urges that CMS work with AHRQ, and provide financing if that is what is required, to ensure that software is updated promptly so that hospitals can assess their performance on the modified measure in real time for purposes of quality improvement and predictability of Medicare payments.

In order to avoid mixing performance using ICD-9 and ICD-10 claims, CMS proposes to shorten the reporting period for PSI-90 to 15 months for FY 2018 (July 1, 2014 through September 30, 2015). As the measure steward, AHRQ has specified this measure for a 24 month reporting period, and this is the version that was endorsed by NQF in 2015. In addition, the proposed shortened performance occurs largely before the change would be finalized through this year's rulemaking process.

While we understand the complication that the shift to ICD-10 creates, and support CMS's view that ICD-9 and ICD-10 claims data should not be mixed, CMS has not provided any assurances that a shortened reporting period will result in accurate comparison of hospital performance. The proposed rule cites a 2011 study by Mathematica and says "...that the majority of hospitals attain a moderate or high level of reliability for the PSI 90 measure after a 12-month period." However, the analysis referenced applies to the previous version of PSI 90, not the modified version. One of the key changes in the modified measure, in addition to the replacement of some of the individual indicators, is the change in weighting. Due to the modifications in the events addressed in the PSIs and the new weighting scheme, the previous

reliability results do not provide sufficient information on the reliability of the modified measure, in general and more specifically, when a shortened 15-month period is used. In addition, the FAH suggests that CMS release the results of the Mathematica study so hospitals have the opportunity to review the effect of the change on the types and sizes of hospitals.

In light of the shift to ICD-10, the lack of an updated AHRQ tool, the application of the Mathematica study to a scenario different from the one upon which the study's results were based, and the general lack of transparency around the modified PSI-90 measure, FAH believes that CMS should temporarily suspend this measure from the IQR program, the HACRP program and the VBP program. The suspension should last until it is possible to establish a 24-month performance period using the ICD 10 version of the modified measure, and hospitals have access to the software necessary to engage in quality improvement activities around this measure.

Proposed New Measures. The FAH does not support the addition of the four proposed new measures for the IQR Program beginning with FY 2019 payment. None of the measures are endorsed by NQF nor were they recommended for inclusion in the program by the MAP. The proposed measures include three episode payment measures (for cholecystectomy/common bile duct exploration, aortic aneurysm, and spinal fusion) and a measure of excess days in acute care after hospitalization for pneumonia. As noted earlier, the hospital community is appealing the NQF endorsement of two similar episode payment measures for heart failure and AMI, and we urge CMS to develop SDS adjustments for these variables before proceeding with NQF endorsement and subsequent addition to the IQR Program.

With respect to the excess days in acute care measure, we have several concerns with the implementation of the measure in this program. First, we disagree with CMS's assertion that the two-midnight policy would not affect this measure. Second, this measure includes unplanned readmissions, which leads to concerns of double counting since a measure of unplanned readmissions for patients with pneumonia is already in the program. In addition, CMS recently completed testing on the impact that SDS factors have in the risk models for several of the readmission and excess days in acute care measures. We remain concerned with the general conclusion that has been made in the proposed rule that inclusion of these factors would obscure potential disparities or dis-incentivize improvement for disadvantaged populations. As demonstrated in the materials on several measures submitted to NQF for review, the results on whether a hospital's score shifts significantly based upon the inclusion of SDS factors should be made on each measure rather than a general determination.

Future Measures and Public Reporting. The FAH does not support the idea that CMS has under consideration for public reporting of hospital performance on quality measures on Hospital Compare by race, ethnicity, sex and disability. The reasons for variation in performance by patient characteristics may or may not be related to hospital performance, and this type of reporting therefore raises more questions than it answers and could lead to misinterpretation and unintended consequences. The FAH continues to urge CMS to work to refine risk adjustment to provide the most meaningful comparison of hospital performance, and as noted earlier, we believe this includes adjustment for SDS.

Regarding possible adoption of the NSHN measure on antimicrobial use (NQF # 2720), the FAH agrees that this is an important area of concern for patient safety, but we are concerned about the possible unintended consequences of adding this measure to the IQR Program at this time. In particular, because the measure focuses on the amount of antibiotic use it may create a

disincentive for appropriate use. CMS should not propose this measure for inclusion in the IQR Program until there is sufficient experience and testing to determine its suitability for public reporting.

FAH supports CMS' pursuit of a modification to the stroke mortality measure to include the National Institutes of Health Stroke Scale as a measure of stroke severity. We agree that the Stroke Scale is predictive of stroke mortality, and this change would improve the risk adjustment for the mortality measure. We understand that the revised measure was submitted for review and endorsement by the NQF, and CMS should wait until endorsement is received before proposing this measure for addition to the IQR Program.

Validation of eCQMs. The FAH has consistently supported the need for data validation as a critical element of the public reporting of hospital performance on quality measures. For this reason, we support CMS's plan to introduce data validation with respect to eCQMs. However, the experience of our members who voluntarily participated in the eCQM data validation pilot program suggests that more time is needed before data validation can be successfully implemented in the broader program. In addition, the FAH strongly recommends that no measure be included in the VBP program or the Star Rating program until it has successfully gone through CMS validation.

The FAH appreciates that CMS released the eCQM Validation Pilot Summary on June 10, 2016, however, the summary does not contain quantifiable results of the pilot. The Validation Pilot did identify significant issues with data mapping and clinical workflow. Both of these are critical to having accurate data. Therefore, the FAH recommends that CMS conduct validation pilots and not publicly report or include any eCQM measures in pay for performance programs until such pilots are completed and the results made publicly available. Moreover, these validation pilots should follow the same methodology proposed in the IPPS rule. The eCQM Validation pilot performed in 2015 was not the same as what is put forth in the current proposed rule. The most notable difference being the inclusion of a "remote-in" process whereby the CDAC validators were directed by the hospital staff to the discrete, encoded fields from which the CEHRT technology sources the data. No such "remoting-in" is included in the proposed validation strategy.

The FAH continues to have operational concerns involving issues such as determinations by the contractor regarding which patient data was available for capture from the EHR. In other words, the proposed validation method involves sending medical records (as hospitals do for Core Measure validation in IQR). Such a method does not identify the fields that are discrete, encoded fields references by the CEHRT tool. The FAH is concerned that validation methodology could negatively impact hospitals because the CMS contractor will look at free text fields, which likely are not reviewed by the CEHRT tool. Our hospitals that participated in the eCQM validation pilot found this to be the case in late 2015. The FAH recommends that the implementation of eCQM data validation be delayed and that CMS convene stakeholders to discuss issues arising from the pilot project, clarify operational validation procedures based on that input, and then implement a larger pilot test before proposing and finalizing a validation process. We believe taking the time to more carefully develop validation standards will result in a more suitable and equitable assessment of hospital eCQM submissions.

VIII.C. Long-Term Care Hospitals Quality Reporting Program (LTCH QRP)

The FAH is very concerned about the number of measures being proposed for the LTCH QRP and the lack of specification and testing of these measures in the long-term care hospital (LTCH) setting. In previous comment letters to CMS and in the FAH comments at the beginning of Section VIII of this letter, the FAH clearly articulates key factors that must be met before a new measure is added to the LTCHQRP. Those factors include specification of the measure for the setting in which it is intended to be used, adequate field testing of the measure in the setting and validation of the results of the measure, endorsement by "NQF" and recommendation by the "MAP". While the FAH recognizes that CMS has statutory deadlines and mandates imposed by the IMPACT Act, the FAH believes that CMS should take the necessary time to ensure that the measures deployed in the LTCHQRP are fit for purpose, are well-specified and tested to ensure sufficient reliability and validity. If these preparatory steps are not carried out fully, our experience in the acute hospital inpatient programs indicates that hospitals and CMS will spend significant resources fixing programs and measures that would have been far less expensive to correct prior to implementation. In addition to these wasted resources, patients and their families will not have access to accurate data that can help to inform their decision making about care.

The IMPACT Act requires that the Secretary use measures endorsed by the NQF with the following exception: "The exception to this general rule is that, "[i]n the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the [NQF], the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary."[3]

In the case of the newly proposed measures for the LTCH QRP, NQF endorsement is of particular importance as well as recommendation by the Measure Applications Partnership ("MAP"). The NQF Consensus Development Process (CDP) ensures that the measures are scientifically sound, feasible to collect and report, and are endorsed after review by a wide range of stakeholders. In addition, the role of the MAP plays a significant role in determining whether or not a specific measure is fit-for-purpose for the program in which it is being considered. The FAH is disappointed that CMS, in proposing a number of measures in this Rule, has ignored a number of the recommendations from the MAP and the NQF. Without NQF endorsement of these measures for use in the LTCH setting, CMS is forced to demonstrate "due consideration" in adopting quality measures. Support of the MAP and use of a technical expert panel (TEP) that includes LTCH community input are important indicators of CMS's requisite due consideration.

In the FY 2017 Proposed Rule, CMS proposes four new quality measures for the LTCH QRP that would also meet certain domains under the IMPACT Act of 2014. Yet, none of these quality measures is endorsed by NQF for the LTCH setting and MAP does not support these measures for the LTCH QRP until the measures are modified and tested specifically for this setting. This is consistent with the FAH concerns about the proposed measures. Rather than adapting standards from different healthcare settings, CMS should develop measures tailored to the unique needs of LTCHs and the patients they serve. For the IMPACT Act measures, CMS should not adopt measures for the LTCH QRP until new or existing measures are developed and

[3] Id. at § 1886(m)(5)(D)(ii).

specified to be appropriate for the LTCH setting, adequately tested, endorsed by NQF and supported by the MAP.

Proposed New Measures

a. Discharge to Community

In the RTI analysis of the Discharge to Community measure, there was no mention of the published fact that discharge destination codes in MedPAR data are not accurate.[4] The study surmised that "the discharge destination field in administrative data can result in misclassification when used to identify patients transferred to [LTCHs]."[5] It tabulated 19,543 false negatives, or LTCH transfers misclassified by the discharge destination field, in the overall United States sample.[6] As such, the errors in coding for the correct discharge destination could impact the validity of the Discharge to Community measure. The accuracy of these discharge destination codes must be remedied prior to the implementation of the Discharge to Community measure in order to prevent further errors.

The validity of the Discharge to Community measure may be further compromised if retrospective data is used to determine a baseline rate prior to initiating processes to improve coding, which will likely occur once the measure is implemented. To avoid this, the FAH suggests that implementation of the Discharge to Community measure begin at the start of the baseline period.

Furthermore, this measure, as presented, should not be applied to patients who could never return to CMS' definition of "community" due to their permanent living setting prior to their acute care hospital stay. It is unreasonable and disingenuous to hold post-acute care to a standard of improving community discharge beyond where a patient had resided prior to the acute hospital stay. "Successful discharges" could be limited by family or economic factors, which do not reflect the quality of the hospital or post-acute care episode of care. In addition, changes over time in the relative proportion of patients with externally mitigating factors affecting their ability to go home could artificially alter the performance scores of the Discharge to Community measure, while not representing the quality provided by the LTCH. For example, if due to economic hardships the number of successful discharges were impacted for a number of years, the measure could inaccurately reflect a change in the LTCH's quality of care. By failing to account for pre-hospitalization living settings, this measure is potentially biased and should be modified to accordingly prior to implementation, or be withdrawn.

b. *Potentially Preventable 30-Day Post-Discharge Readmission Measure*.

Another proposed quality measure is the Potentially Preventable 30-Day Post-Discharge Readmission Measure. The measure is adjusted for mechanical ventilation status; however, it is not clear whether the risk adjustment includes patients with an artificial airway without

[4] Jeremy M. Kahn & Theodore J. Iwashyna, *Accuracy of the Discharge Destination Field in Administrative Data for Identifying Transfer to a Long-Term Acute Care Hospital*, 3 BMC RES. NOTES 205 (2010); Antony M. Grigonis, et al., *Long-Term Acute Care Hospitals Have Low Impact on Medicare Readmissions to Short-Term Acute Care Hospitals*, 28 AM. J. MED. QUALITY 502 (2013).

[5] Jeremy M. Kahn & Theodore J. Iwashyna, *Accuracy of the Discharge Destination Field in Administrative Data for Identifying Transfer to a Long-Term Acute Care Hospital*, 3 BMC RES. NOTES 205 (2010)

[6] Id.

mechanical ventilation. This issue should be clarified in the measure specifications and the final rule.

c. *Drug Regimen Review Conducted with Follow-Up.*

More clarity is needed on this quality measure. This measure includes four sub-measures that when combined into one measure, as proposed, makes it difficult for use in quality improvement activities such as determining what the specific quality issues are and under which sub-measure.

Furthermore, the term "clinically significant medication issue" must be defined. Otherwise, individual hospitals will assign this phrase different meanings, producing a lack of uniformity and yielding results that are not comparable. CMS should also clarify when medication issues are "identified." For example, the appropriate categories of the NCC MERP index for categorizing medication errors could be used for each post-acute care setting to identify medication issues. The definitions of these terms should be clarified in the measure specifications and the final rule.

Proposed Public Display of Quality Measures Data for the LTCH QRP and Procedures for the Opportunity To Review and Correct Data and Information**.**

The FAH recommends that CMS establish a separate LTCH Compare Web site so that LTCHs are only compared to other LTCHs, and the public can make an informed comparison without unnecessary confusion. LTCHs and other post-acute care providers are not currently included on Hospital Compare, which we support due to the differences in setting, measures, and patient populations served. Although LTCHs are certainly a type of acute care hospital, including LTCH quality data on Hospital Compare would be inappropriate because LTCHs treat patients who are sicker, more medically complex, and require longer hospital stays, on average, than short-term care hospitals ("STCHs"). The juxtaposition of LTCH data against STCH data may give the wrong impression that LTCHs provide poor quality of care.

LTCH quality data should be presented to the public on a distinctly separate web page so that patients and their families, as well as providers and insurers who use this data, are only comparing an LTCH's quality performance against that of other LTCHs. In addition, short stay acute care hospitals are not subject to the IMPACT Act; only the four major post-acute care provider types are subject to the IMPACT Act and reporting on quality across these hospital types using Hospital Compare would not prove useful. Moreover, two other post-acute provider types subject to the IMPACT Act have unique quality compare web pages—Nursing Home Compare and Home Health Compare. For these reasons, there should be a separate LTCH Compare Web site.

The FAH also disagrees with the proposed deadline to make changes to quality data reported to CMS. CMS should provide a 30-day preview period for LTCHs before their data are made public. We appreciate CMS's willingness to allow LTCHs to notify CMS during the previous period if there are errors in measure calculations. However, CMS should allow LTCHs to make corrections to their data during the preview period so that only accurate data is released to the public. This is very important, as CDC and CMS systems errors do occur. Therefore, LTCHs should be afforded adequate opportunity to correct reported quality data after the reporting deadline, so that the public is provided accurate data. We believe Congress had the 30-

day preview period in mind for this purpose. A preview period is not very useful if the data cannot be corrected during that time.

Proposal to Extend Timeframe for LTCHs to Submit Extension and Exception Requests**.**

The FAH agrees with the CMS proposal to extend the waiver or extension request from the 30-day timeframe to 90 days for submitting data for the LTCH QRP. When LTCHs are unable to submit timely quality data due to an event that is beyond their control, such as a hurricane or a flood, it may take more than 30 days to gather and report the information or to be in a position to submit a request for a waiver. Therefore, additional time to submit quality data would be extremely helpful. The FAH appreciates that CMS is allowing LTCHs more time to submit such requests for waivers.

VIII. D. Inpatient Psychiatric Facility Quality

D.3 Proposed Update to Previously Finalized Measure: Screening for Metabolic Disorders

The FAH supports the change in the length of stay to exclude patients with a length of stay equal to or greater than 365 days or less than or equal to 3 days. This change will support the intent of the global sample to allow IPFs to use the same sample for as many measures as possible. However, the FAH is concerned that that there is no denominator exclusion for patients who refuse the metabolic screen. Patients have every right to refuse treatment and their refusal does not necessarily correspond to a quality of care issue. The proposed rule currently includes "enduring unstable medical or psychological condition" as exclusion, and the FAH supports this exclusion. However, because patient refusal is different from and not incorporated in the "unstable condition" exclusion, the patient refusal needs to be an added category of exclusion.

The CMS response in the *2015 Inpatient Psychiatric Facilities Prospective Payment System—Update for Fiscal Year Beginning October 1, 2015* to this concern was, "We believe that patient compliance is indicative of quality care," and, "We encourage providers to educate patients about the importance of these screenings, and we, therefore, will not exclude patients who refuse the screening." The FAH takes exception to the sweeping statement that patient compliance is indicative of quality care. Often, behavioral health patients, as part of their medical condition, may not be able to fully comprehend and think through the implications of a decision to refuse the screening. Therefore, our members continue to be very concerned about the CMS inadequate justification for the decision to not include patient refusal as a denominator exclusion.

The FAH also is very concerned that this measure has not been endorsed by the NQF nor has it been pilot-tested. This follows the pattern of concern previously noted at the beginning of Section VIII of this comment letter.

The FAH experience over the past few years in implementing measures in the IQR, IPFQR, LTCHQRP, ASCQRP and measures in other CMS quality reporting programs is that far too often they did not meet the standards of being: 1) fully specified for the program in which they were being used; 2) endorsed by the NQF; 3) and broadly pilot tested, and when they failed to meet those standards, there have been significant implementation issues. The cost of fixing these implementation issues is substantial and falls on the hospitals/facilities, contractors and

CMS. These costs could and should be avoided so that time and resources could more appropriately be devoted to patient care and quality improvement rather than fixing technical issues around implementation that could and should have been avoided.

D.4. Proposed New Quality Measures for the FY 2019 Payment Determination and Subsequent Years

D.4. a SUB-3 (Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge) *and the* ***subset SUB-3a measure (Alcohol & Other Drug Use Disorder Treatment at Discharge)***

CMS proposes to add the third component to the set of substance use disorder measures that are currently part of the IPFQR program. The proposed additional components require that, at discharge, patients who screen positive for drug and alcohol abuse are offered treatment options (specifically a prescription for an FDA-approved medication for alcohol or drug abuse disorder, OR a referral for addictions treatment). The FAH does not support the addition of this measure to the IPFQR. As we have previously stated, the SUB suite of measures does not appropriately address the needs of patients in psychiatric inpatient services. The SUB measures were developed to be population screening measures, not facility measures. Psychiatric hospitals perform an in-depth assessment of patients' alcohol and substance abuse history and current use. This assessment requires far more than a screening question for alcohol use. Patients who are assessed to have an alcohol disorder (which is often co-morbid with other substance use disorders and mental illness) are treated through a multi-disciplinary, multi-model plan.

The FY2016 final rule took the alcohol screening question further by adding the SUB-2 and 2a measures (requiring a brief intervention be offered and provided if the alcohol use screen is positive). The FAH did not support this addition and provided recent literature citations to back our recommendation. The psychiatric literature supports the efficacy of brief intervention in primary care for patients who have screened positive for unhealthy alcohol use. However, it identifies that there is no evidence of efficacy among those with very heavy use or dependence. Brief intervention is not the treatment of choice for persons with severe addictive disorders. They require, as noted above, an intensive, multi-disciplinary plan of care if they are being treated in a psychiatric hospital. CMS disagreed with our comments regarding the efficacy of brief interventions and ruled that there must be a "bedside discussion with the patient" focusing on an extensive list of factors in order to get "credit" for the measure.

The SUB-1 and SUB-2 measures focus on alcohol abuse and SUB-3 focuses on both alcohol and substance abuse. This creates changes in the denominator and raises definitional questions about what constitutes substance use that requires ongoing treatment as distinguished from overall outpatient mental health treatment.

We cannot support adding the proposed SUB-3 and SUB-3a measures to a set about which we have serious concerns and no evidence that they are advancing the quality of the IPF field. CMS states in the proposed rule that there is "value created by the inclusion of the SUB-1 measure and the SUB-2 and 2a measure…" Yet, in our experience, providers are not seeing the value. Referring patients for treatment of their psychiatric and often co-morbid substance abuse conditions is required of IPFs in many other ways and an inherent part of providers' standards of care. The SUB measures are, in many cases, inappropriate and inadequate interventions. Publicly reporting compliance with this specific set of measures does not, in our opinion, further

the CMS goal of evaluating critical processes of care that have significant impact on patient outcomes in order to allow consumers to make informed decisions about providers. In our comments we noted that the SUB measures have not been systematically tested in inpatient psychiatric units and asked that CMS continue to review the usefulness of the SUB for such application. We are not aware that any such review has been conducted.

The FAH does not recommend extension of the SUB measures. We further recommend review of the usefulness of SUB-1 and SUB 2 and 2a, based on the literature and providers' experience with it through the past year. We note that substance abuse screening is part of NQF-endorsed HBIPS-1, which has been available since 2008 and is currently in widespread use in inpatient psychiatric facilities. We recommend that HBIPS-1 be enhanced, if necessary, and adopted for the IPFQR program.

b. Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility (IPF)

The FAH acknowledges that readmission to a psychiatric or acute care hospital within 30 days of hospitalization is an event that deserves careful review. The psychiatric provider field is committed to developing strategies that assist patients to maintain stability at the most appropriate level of care. Because of the widely-reported inadequacies in the mental health infrastructure, we know patients and providers are severely challenged in moving within the continuum of psychiatric services. Readmissions can be life-saving interventions.

We have concerns with the broad characterization presented in the proposed rule of readmissions as a direct reflection of the quality of care received in an IPF. We think the body of literature used to draw the link between quality of inpatient care and rate of readmission is weak. Citations used to build the cause-and-effect relationship are from international journals (from countries with very different healthcare delivery systems such as Great Britain, Israel, Australia), from populations not covered by the IPF quality reporting program (such as veteran administration hospitals, Medicaid patients), and from general medical literature (such as medical discharges of the hospitalized elderly). Issues related to readmission such as length of stay, availability of resources following discharge, and characteristics of the population (age, diagnosis, acuity) were not accounted for in the literature review. Strategies recommended to decrease readmissions (such as medication reconciliation, assigning a transition manager, and connecting patients to services they will need in an outpatient setting prior to discharge) were drawn as examples from studies and have not been systematically studied across large populations. The effectiveness of the interventions that were reported was interesting, but not compelling. The interventions under the control of IPFs for improving readmission rates are limited.

The characteristics of the Medicare beneficiaries cared for in IPFs are significantly different from the general Medicare population. As noted in the "Inpatient Psychiatric Facility All-Cause Unplanned Readmission Measure Draft Technical Report," approximately 65% of patients accounting for index admissions were less than 65 years old on the day of admission. These beneficiaries qualify for Medicare due to disability. Approximately 58% of all IPF admissions also have Medicaid eligibility, indicating poverty status. These combined factors describe beneficiaries with unique challenges in stabilizing their chronic conditions in the midst of an acute psychiatric crisis. The strategies used to reduce readmissions for many Medicare

patients (care in skilled nursing facilities, in-home care) are not available to most of this disabled population.

Because of the relatively small number of IPF discharges meeting the measure inclusion criteria (716,174), we question whether 24 months of data (as proposed in the measure) will provide an adequate facility-level sample size. We know this was chosen for the measure development phase, but because of public reporting, we ask for assurance that the sample is adequate to establish a risk standardized readmission rate for each facility. We also note that, because IPF data is only reported once a year because of limitations to the CMS ability to receive the data, the reported rates lag behind actual rates by a significant amount of time. We anticipate there will be significant public interest in these data, that they will be used for purposes beyond the IPFQR reporting, and their timeliness and accuracy are of great concern.

The HSAG Technical Report discussed the reasons for designing an All-Cause Readmission measure as opposed to limiting the measure to readmissions to IPFs (approximately one quarter of IPF index readmissions are to acute care hospitals). These reasons included among others: 1) determination of the relationship between the principal discharge diagnosis of the index admission and the principal discharge diagnosis of the readmission is complex because similar clinical presentations might be captured with slightly different principal diagnosis codes, and 2) a focus on all-cause readmissions offers the IPF an opportunity to implement a broader range of quality improvement initiatives with promise for greater impact than measures that focus on a specific cause of readmission. While we acknowledge these are the assumptions of CMS, we question if this is the readmission measure that best captures the quality of care provided in IPFs. Patients are admitted to acute care hospitals for many reasons totally unrelated to their index psychiatric admission. The relationship between the psychiatric admission and a subsequent acute care admission has not been systematically explored. Holding IPFs accountable for these admissions could dilute the clarity and actionability of the measure.

The FAH recommends review of the 24-month timeframe for collection of data to determine a facility-level sample size.

We also recommend very careful monitoring of the results of the Medicare claims data review as it relates to readmissions based on our concerns with the strength of empirical evidence of the link between the quality of inpatient care and the rate of readmission.

D.6. Possible IPFQR Program Measures and Topics for Future Consideration

The FAH continues to recommend exploring the development of a patients' perspective-of-care measure. This measure should be constructed with active engagement of the psychiatric provider field. As we know from the data CMS has collected, most providers use a perception of care measure, yet these have not been standardized.

D.7. Public Display and Review Requirements

The FAH supports the CMS objective to publicly display data as soon as possible on the CMS website. We know it is only possible to post IPFQR data annually because of, as we understand it, CMS resource constraints. We continue to be required to report data in more rudimentary ways than other reporting systems. However, it is very important that each IPF have the opportunity to review its data before public display and to identify errors. We support

flexibility rather than regulatory constraints. We think it is imperative that facilities have at least 30 days to review their data, and we would not support any change to that standard.

Outlier Payments FFY 2017

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

For FY 2017, 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 $23,681. The present threshold, which has been in effect since October 1, 2015, is $22,544. CMS indicates that it has used the same methodology to calculate the fixed loss threshold as it has since FY 2014. 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. We expect that this threshold will decrease by the final rule based on updated information, particularly updated cost to charge ratios ("CCRs"). Since 2009, every final outlier threshold has been lower than its related proposed threshold, and on average, the reduction between the proposed and final threshold has exceeded five percent. We address in more detail our concerns below.

The proposed threshold for FY 2017 represents an approximate five-percent increase over the outlier threshold CMS used for FY 2016, without any explanation by CMS that could be justified by data it made available to commenters to explain why the threshold would need to increase by such a large amount 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 for FY 2015, when the threshold was set at $24,626, Watson Policy Analysis ("WPA"), see the attached report *Summary of Research Modeling FY 2017 Proposed Inpatient Prospective Payment System Outlier Payments* (Attachment B) at pp. 4-5[7], indicates that outlier payments as a proportion of DRG payments will be about 4.87%, which falls below the 5.1 target percentage. Given that the threshold applied in FY 2015 appears to result in total outlier payments that fall short of the 5.1% target,[8] it is particularly questionable whether an increase in the threshold is warranted.

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 2017

[7] All of the tables below appear in the WPA report except for the last table in this section of the comment, also prepared by WPA, but supplemental to the WPA report.

[8] CMS declined to estimate the actual outlier payments for FY 2016 in the Proposed Rule, stating that it was unable to do so because MedPAR claims data for the entire FY 2016 will not be available until after September 30, 2016. 81 Fed. Reg. 25,273, col. 3.

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, 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 still believes that CMS has not provided enough specific information and data to allow the underlying numbers used in CMS' calculation of the charge inflation factor to be replicated and/or tested for accuracy. 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 2016 proposed rule, CMS estimated that "using the latest CCRs from the December 2014 update of the PSF, actual outlier payments for FY 2015 will be approximately 4.88 percent of actual total MS-DRG payments, approximately 0.22 percentage point lower than the 5.1 percent we projected when setting the outlier policies for FY 2015." *See* 80 Fed. Reg. at 24634, col.2. In this year's proposed rule, CMS states 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. 25,273.

We are concerned that CMS believed it would hit its 5.1% target amount for FY 2015, only to learn this year, yet again, that its original estimate was overstated. WPA's use of even more current data also indicates that the amount indicated for FY 2015 in the proposed rule for FY 2016 is overstated. See WPA Report at Analysis 3, pp. 4-5. It is critical that CMS not allow the use of incomplete data from prior years to color its calculation of current period thresholds. We set forth below a historical table of the impact of overstating the outlier threshold each year, resulting in an understatement of outlier payment:

Federal Fiscal Year	Number of Cost Reports Beginning in FFY	IPPS Payments Net of IME, DSH and Outlier Amounts ($)	Outlier Payments ($)	Outlier Payment Level (%)	Target Outlier Payments (5.1%)	Shortfall in Outlier Payments ($)
2010	3,072	79,733,087,154	3,660,488,700	4.39	4,284,918,277	-624,429,577
2011	2,973	77,197,362,245	3,707,407,929	4.58	4,148,646,443	-441,238,514
2012	2,716	67,461,311,753	3,137,279,264	4.44	3,625,423,498	-488,144,234
2013	3,047	80,760,714,604	4,270,125,578	5.02	4,340,143,777	-70,018,199
2014	564	14,960,509,393	708,511,061	4.52	803,989,441	-95,478,380
Total (2010-2014)	12,372	320,112,985,149	15,483,812,532	4.61	17,203,121,436	-1,719,308,904

C. Using Most Recent Data To Calculate The Threshold

We also note that with each rulemaking, the final outlier threshold established by CMS is always significantly lower that the threshold set forth in the proposed rule. While the FAH can only speculate as to why this consistently occurs, the FAH believes the decline is most likely due to the use of updated CCRs or other data in calculating the final threshold. This again emphasizes that CMS must use the most recent data available when it calculates the outlier threshold. Table A below expresses this trend graphically.

Table A				
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[9]	$ (1,809)	-7.66%
2014	$ 21,748	$ 24,140	$ (2,392)	-9.90%
2015	$ 24,626	$ 25,799	$ (1,173)	-4.76%
2016	$ 22,544	$ 24,485	$ (1,941)	-7.93%

With regard to the current rule-making, we note, for example, that CMS has used data from the December 2015 PSF file, but that at the time the proposed rule was issued, the March 2016 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 $20, 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%.

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, 81 Fed. Reg at 25272, col. 2, CMS addresses its decision not to consider the impact of outlier reconciliation in its determination of the outlier threshold as follows:

[9] CMS issued a corrected proposed outlier threshold of $26,337 on the 6/11/12 in 77 Fed. Reg. at 34,328, 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 53,696.

As we did in establishing the FY 2009 outlier threshold (73 FR 57891), in our projection of FY 2017 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.

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 ten 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 9.8% over two years, which, if costs were held constant, would suggest that a significant number of hospitals could be subject to reconciliation. WPA also developed the following Table from HCRIS.

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

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)

*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.

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.

The FAH is not proposing a threshold for FY 2017. 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. In addition, we recognize that with the release of the MedPAR Final data with additional claims, which will lead to new weights being calculated, and with updated cost to charge ratios, it is appropriate to recalculate the Fixed Loss Threshold from the data that will be released with the final rule.

The FAH is not proposing a threshold this year. 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 related to the proposed rule. In addition, we recognize that with the release of the MedPAR Final data with additional claims, which will lead to new weights being calculated and with updated cost to charge ratios, it is appropriate to recalculate the Fixed Loss Threshold from the data that will be released with the final rule.

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

Sincerely,