

Charles N. Kahn III President and CEO

June 13, 2017

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

SUBJECT: CMS-1677-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 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices; April 28, 2017

Dear Administrator Verma:

The Federation of American Hospitals ("FAH") is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching hospitals in urban and rural 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 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices, April 28, 2017 ("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 notwithstanding some modest changes to Worksheet S-10 that CMS made late last year, those changes fall far short of what is needed. The Agency is moving too quickly to use a form that remains unclear 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 "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. Among other issues, 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 remain; and there is no audit process to guard against data anomalies and address the inconsistencies in the ways that hospitals prepared 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. At a minimum, a transition to the form should be delayed until an audit is conducted, which could be accomplished by FY 2019. In addition, the transition, which we assert is well within CMS authority, should be extended to five years, and initially nominalized to give CMS the time it needs to address its many problems <u>before</u> data from the form is allowed to have a disproportionate impact on the allocation of UC-DSH funds.

ATRA Recoupment

FAH strongly urges CMS to restore in FY 2018 the excess 0.7 percentage point negative adjustment applied in FY 2017. CMS's proposal to only adjust the standardized amount by 0.4588 percentage points in FY 2018 and its plan to increase the adjustment to the standardized amount by 0.5 percentage points in FYs 2019 through 2023 would improperly create a permanent negative reduction to payment rates. This proposal misinterprets the relevant statutory authority under MACRA, which explicitly assumes that the ATRA section 631 recoupment would result in an estimated 3.2 percent adjustment in FY 2017 and requires that adjustments in a particular year not apply to subsequent years. 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, FY 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. Clearly at the time ATRA was passed both Congress and the Secretary recognized that the ATRA recoupment would end by FY 2018. CMS has, and should exercise in FY 2018, its authority to restore the excess 0.7 adjustment and thereby satisfy MACRA's mandate without perpetuating the ATRA adjustment beyond the savings Congress sought to achieve with MACRA.

Long-Term Care Hospitals

The FAH supports the proposal to pay all short-stay outlier cases using the "blended" option at section 412.529(c)(2)(iv) effective for discharges on or after October 1, 2017. The FAH believes this will help address the payment cliff at the SSO threshold and provide a more gradual increase in payment as the patient's length of stay increases. However, the FAH does not support the imposition of a permanent budget neutrality factor to account for this change in SSO policy. A permanent reduction of the standard Federal payment rate by 3.28% is very significant and will place further, undue financial strain on LTCHs that are already grappling with a difficult transition to the two-tiered payment system. The imposition of this budget neutrality factor is not mandated by the original legislation authorizing the LTCH PPS or the dual-rate LTCH PPS system, has not been applied by CMS previously with other changes to SSO payments and will result in less predictability in LTCH PPS payments. The "blended" option is already in the regulation and, therefore, it seems any affect it has on aggregate LTCH payments would have been accounted for previously.

The FAH strongly disagrees with CMS's proposal to apply a budget neutrality factor to LTCH site neutral cases that qualify for high cost outlier payments. 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 MedPAC has shared.

While FAH appreciates CMS's proposal to extend for one year the statutory moratorium on the 25 percent Rule, the FAH believes there are compelling reasons for CMS to completely retire the Rule, effective October 1, 2017. At a minimum, CMS should never 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.

The FAH finds it encouraging that CMS is studying and proposing modifications to the HwH rule in recognition of the limits that these regulations place on the ability of providers to provide seamless care across the continuum of care. The FAH supports modifications to the regulations that remove obstacles to providers collaborating across healthcare settings. Specifically, the FAH supports the proposed modification to the introductory language of 42 C.F.R. § 412.22(e) that would clarify that on and after October 1, 2017, the separateness and control requirements would no longer apply when two or more IPPS-exempt hospitals are colocated. The FAH also supports the proposed sunsetting of the basic hospital functions requirements outlined in 42 C.F.R. § 412.22(e)(1)(v) also beginning October 1, 2017.

Quality Data Reporting

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.

In the proposed rule, CMS seeks comments pertaining to accounting for social risk factors for a variety of quality and payment programs. The FAH has long believed that appropriately accounting for social risk factors, such as sociodemographic status adjustment, is essential for accurately assessing health care provider performance for public reporting and accountability programs, particularly with respect to outcome measurement. The FAH is pleased to offer some guiding principles for implementing social risk factor adjustments. First, while the proposed stratification approach under the Hospital Readmissions Reduction Program (HRRP) is a reasonable first step for addressing social risk factors, stratification should be viewed as a stopgap tool, not a permanent solution. Second, share of dual eligible beneficiaries should also be viewed as a short-term proxy for assessing the extent to which a hospital has patients facing social risk factors. Third, any adjustment for social risk factors must be accompanied by a process in which hospitals and other providers receive confidential reports showing their results. Fourth, public reporting of social risk factor-adjusted information on *Hospital Compare* or similar site must be useful to patients, families, and providers.

In the Hospital Inpatient Quality Reporting Program (IQR), the FAH supports inclusion in the <u>voluntary</u> reporting of the National Quality Forum (NQF)-endorsed hybrid hospital-wide readmission measure. The FAH continues to have concerns about use of a hospital-wide all cause readmissions measure, but believes that improved risk adjustment is potentially a very good use of EHR data, and that testing this approach will develop useful information that could apply to other Medicare claims-based measures, not just this one readmission measure. However, the FAH strongly urges CMS not to finalize the use of this measure in any future payment years at this point. Hospitals and CMS both need several years of experience with this measure – and the measure itself should undergo additional testing and re-review by the NQF and the Measure Applications Partnership (MAP) – before assessing whether it is appropriate to include in a quality payment program.

The FAH also strongly supports alignment of the requirements for reporting of electronic clinical quality measures (eCQMs) in the IQR Program with the Electronic Health Record (EHR) Incentive Program. Our members appreciate CMS's acknowledgement of the difficulties encountered by hospitals implementing eCQM reporting capabilities – and submitting data to CMS. However, the proposed modifications to eCQM reporting for the CY 2017 and CY 2018 reporting periods do not go far enough to alleviate these implementation and reporting

difficulties. As CMS noted in the proposed rule, "certain challenges and issues...may not be fully resolved and as a result, may persist in CY 2018." In order to resolve these challenges, including ensuring that CMS can process the QRDA Category 1 files and confirm for providers that their files have been received and processed, the FAH believes that CMS should maintain the CY 2016 electronic reporting requirements of four measures over one quarter for the CY 2017 and CY 2018 reporting periods.

The FAH also supports the proposed modification to the 2018 EHR reporting period for participants attesting under the Medicare or Medicaid EHR Incentive Programs. We appreciate CMS's recognition that additional time is necessary for testing and implementation of 2015 Edition CEHRT and the associated Stage 3 program requirements, as well as the timely notice CMS provided for this modification. However, even with the modified reporting period, the FAH remains concerned about the readiness of providers to report in 2018 using the 2015 Edition due to deployment delays from vendors and the time necessary for implementation and staff training. At a minimum, we recommend that CMS permit the same flexibility for the 2018 certification requirements as for the 2017 requirements – attestation to objectives and measures using technology certified to the 2014 Edition, the 2015 Edition, or a combination of the two. Ideally, CMS should delay Stage 3 to allow for a meaningful evaluation of how well the Program is meeting its goals and to further align the hospital Program with the Advancing Care Information (ACI) category of the Merit-based Incentive Payment System (MIPS) for physicians, including eliminating the "all-or-nothing" standard.

Survey and Certification Requirements

The FAH has long-supported transparency and public reporting of a variety of data, particularly data that is usable, enhances a patient's ability to make decisions about their health care, and offers fair comparisons of similar facilities facing similar challenges. The FAH is concerned that CMS's proposed changes to the application and re-application procedures for national accrediting organizations (AO) do not meet these benchmark tests. The changes proposed by CMS would require AOs to post to their own websites any deficiencies or conditions of non-compliance found during a survey and to list the plan of correction for achieving compliance with the CMS Conditions of Participation. Having each AO report on a website of its creation, in the format of its choosing, would result in disparate data that is not comparable across providers, and thus not helpful to patients and their families. It is also duplicative, as CMS already makes hospital quality and safety information public through several different websites.

If CMS moves forward with reporting of survey findings, the FAH strongly recommends that such findings be reported to one centralized site and accompanied by an independent right of appeal for the providers to contest findings before anything is published. We also recommend that the agency convene a multi-stakeholder advisory group to work through the many issues around public display.

ATRA Recoupment

II.D.2. Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA)

CMS proposes making a positive adjustment of 0.4588 percentage points to the standardized amount for FY 2018 and expects to propose positive 0.5 percentage point adjustments for FYs 2019 through 2023 in lieu of making the single positive adjustment of 3.9 percentage points in FY 2018 required to offset the adjustments made to implement the American Taxpayer Relief Act of 2012 ("ATRA") section 631 recoupment. This proposal misinterprets the relevant statutory authority, which explicitly assumes that the ATRA section 631 recoupment would result in an estimated 3.2 percent adjustment in FY 2017 and requires that adjustments in a particular year not apply to subsequent years. The FAH therefore urges CMS to apply a positive adjustment of 1.1588 percentage points in FY 2018, reflecting the sum of the 0.4588 percentage point adjustment mandated under section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") as amended by section 15005 of the 21st Century Cures Act (Pub. L. 114-255) and the 0.7 percentage point adjustment required to offset the additional negative adjustment applied in FY 2017 under section 631 of ATRA. In combination with the 0.5 percentage point adjustments for FYs 2019 through 2023, this would result in a 3.6588 percentage point adjustment by FY 2023, leaving 0.242 percentage points to be adjusted in FY 2024 to avoid impermissibly converting the one-time negative adjustments under ATRA into a permanent negative adjustment. In the alternative, if CMS disagrees with our interpretation of the statutory authority, we nonetheless urge CMS to exercise its discretion under section 1886(d)(5)(I) and apply a positive adjustment of 1.1588 percentage points in FY 2018.

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, FY 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.

This is consistent with the requirement under section 7(b)(2) of the TMA, Abstinence Education, and QI Programs Extension Act of 2007 (Public Law 110-90) that any adjustment under section 7(b)(1)(B)—including the ATRA adjustments—"shall not be included in the determination of standardized amounts for discharges occurring in a subsequent year." Clearly at the time ATRA was passed both Congress and the Secretary recognized that the ATRA recoupment would end by FY 2018.

In an effort to generate savings to pay for a permanent fix to the sustainable growth rate for physician payments under Medicare, Congress instructed CMS to delay the restoration of the one-time negative adjustments created by ATRA § 631(b) in FY 2018 by implementing a

schedule of restorative adjustments over 6 years, leaving CMS to implement any final restorative adjustment in FY 2024. 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).

MACRA § 414 (emphasis added). Clearly Congress anticipated in this 2015 legislation that the final adjustment in FY 2017 to implement ATRA § 631 would approximate 3.2 percentage points. Indeed, that percentage is expressly included in the statutory language. The subsequent restorative adjustments are closely tied to that amount, leaving only an estimated 0.2 percentage point adjustment to be implemented by CMS in FY 2024.

After the enactment of MACRA on April 15, 2015, CMS proposed and finalized a significantly higher ATRA adjustment of 3.9% for FY 2017. This marked deviation from CMS' previous statements concerning its intended approach to ATRA adjustments is at odds with Congress' explicit assumption in section 414 of MACRA that the total negative adjustment for FY 2017 would be approximately 3.2 percentage points.

Subsequently, on December 13, 2016, the 21st Century Cures Act (Pub. L. 114-255) was enacted. Section 15005 of the 21st Century Cures Act amends section 414 of MACRA to reduce the FY 2018 standard adjustment by 0.0412 percentage points. Critically, Congress did not amend the parenthetical language in section 414 of MACRA which references the 3.2 percent estimate of ATRA adjustments to be reversed, indicating that Congress was basing the budgetary savings under section 15005 on the delay of an estimated 3.2 percentage point restoration rather than a delay in the restoration of a significantly larger amount. In drafting the 21st Century Cures Act, Congress could have simply amended the parenthetical in section 414 to state that the statue delays a one-time adjustment to the standardized amount that is "estimated to be an increase of 3.9 percent." This approach would have explicitly delayed the additional 0.7 percentage point adjustment necessitated by the FY 2017 ATRA adjustment, capturing additional savings to offset spending under the bill.

Whatever Congress may have intended with the amendment of ATRA § 631(b) by MACRA § 414 and 21st Century Cures § 15005, it is clear that Congress did not intend to create a large permanent negative adjustment to the IPPS standardized amount. Despite amending section 7(b) of the TMA with the passage of ATRA, MACRA, and 21st Century Cures, Congress has retained the requirement that each "adjustment made under [section 7(b)(1)(B)] for discharges occurring in a year . . . not be included in the determination of standardized amounts for discharges occurring in a subsequent year." CMS's proposal to only adjust the standardized amount by 0.4588 percentage points in FY 2018 and its plan to increase the adjustment to the standardized amount by 0.5 percentage points in FYs 2019 through 2023 would improperly create a permanent negative reduction to payment rates in the form of a residual ATRA adjustment of negative 0.9412 in FY 2024. This is contrary to the interpretation of ATRA that CMS has repeatedly advanced and that was left unaltered by Congress in the MACRA and 21st

Century Cures Act amendments. To the contrary, CMS is obligated to fully restore the ATRA adjustment by FY 2024 by applying the positive adjustments specified in section 414 of MACRA as amended by section 15005 of the 21st Century Cures Act, restoring this year the excess 0.7 percentage point negative adjustment applied in FY 2017 and not addressed by Congress, and, in FY 2024, making a final positive adjustment to fully offset the ATRA adjustments (i.e., 0.242 percentage points). Even if CMS takes a contrary view with regard to Congress' intent for the FY 2018 adjustment, we urge CMS to exercise its discretion under section 1886(d)(5)(I) to increase the FY 2018 adjustment by 0.7 percentage points to offset the additional ATRA adjustment applied in FY 2017.

MS-DRG Classifications

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

For this proposed rule, CMS' MS-DRG change analysis is based on ICD-10-CM claims data from the December 2016 update of the FY 2016 MedPAR file, which contains hospital bills received through September 30, 2016 for discharges occurring through September 30, 2016. Based on our review of the rule, FAH agrees overall with the proposed changes being recommended for MS-DRG and/or ICD-10 code classification changes for FY 2018 other than the items noted below.

II.F.2.c MDC 1 (Diseases and Disorders of the Nervous System – Precerebral Occlusion or Transient Ischemic Attack with Thrombolytic)

CMS proposes to add 39 ICD-10-CM diagnosis codes that are currently assigned to MS-DRGs 67 and 68 (Nonspecific CVA and Precerebral Occlusion without Infarction with MCC and without MCC, respectively) and MS-DRG 69 (Transient Ischemia) to the Grouper logic for MS-DRGs 61, 62 and 63 (Acute Ischemic Stroke with the use of Thrombolytic Agent with MCC, with CC and without MCC/CC, respectively) when those conditions are sequenced as the principal diagnosis and reported with an ICD-10-PCS procedure code describing the use of a thrombolytic agent (tPA).

This change is proposed in an effort to better account for:

- the subset of patients who were successfully treated with tPA to prevent a Stroke
- to identify the increasing use of thrombolytics at the onset of the symptoms of a Stroke
- to further encourage appropriate physician documentation for a precerebral occlusion or TIA when patients are treated with tPA
- and to reflect more appropriate payment for the resources involved in evaluating and treating these patients

CMS also proposes to retitle MS-DRGs 61, 62 and 63 as "Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with MCC, with CC and without MCC/CC respectively. And, retitle MS-DRG 69 as TIA without Thrombolytic".

FAH agrees with CMS on the above noted proposed changes for FY 2018. We also agree these changes will better account for this subset of patients and more appropriately reflect payment for the resources involved. However, for future rulemaking, we ask that CMS consider

creation of new MS-DRGs that would specifically distinguish acute ischemic strokes from precerebral occlusions and transient ischemia, with and without thrombolytics, and, with and without MCC/CC respectively.

II.F.9 MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services) Updates to MS-DRGs 945-946 (Rehabilitation with CC/MCC and without CC/MCC)

CMS is not proposing any changes for these MS-DRGs for FY 2018 given the lack of a diagnosis code to capture the principal diagnosis of encounter for rehabilitation. CMS noted that if the CDC creates a new code, it will consider proposing updates to MS-DRGs 945 and 946 in the future.

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 an 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 (MDC 1), Degenerative Nervous System Disorders w/o MCC instead of MS-DRGs 945 or 946.

There is a concern with the lack of continuity with DRG assignment with rehab cases with ICD-9-CM vs ICD-10-CM now being assigned within DRGs associated with the injury or disease process. The further concern is the injury and/or disease process DRGs could be diluted with less severity cases that involve rehab included with more acute care cases. Many hospitals are burdened with inefficient manual workarounds to address the DRG shifts, and reporting needs to accurately reflect the rehab-related patient population.

As provided in comments to the proposed rule for FY 2017, we suggested that a single new ICD-10 CM diagnosis code be created to replicate the ICD-9-CM code category V57, care involving use of rehabilitation procedures. As noted in the FY 2018 proposed rule, creation of this new code for encounters for rehabilitation services has been completed and is pending comment period and approval.

CMS noted in the FY 2018 proposed rule, "if a new ICD-10-CM diagnosis code is created to identify encounters for rehabilitation services, we would address any updates to MS-

DRGs 945 and 946 in the future". FAH supports this new code and we support that the capture of encounters for rehabilitation must be addressed to resolve continuity issues with MS-DRG assignment for these cases. As the proposed Z code states "encounter for rehabilitation services", we additionally support that the Z code be applicable as the first listed/principal diagnosis for cases in which the admission is for rehabilitation. This would be consistent with the application of other Z codes, such as encounter for chemotherapy and radiation.

As further support that the logic for MS-DRGs 945 and 946 must be examined, FAH also provides an alternative approach to address this issue, in the event the new Z code is not approved for future use. We recommend that CMS assemble a technical advisory panel (TEP) made up of industry stakeholders, such as rehab providers and other industry representation. The purpose of this TEP would be to conduct a thorough evaluation and propose recommended DRG logic changes under MDC 23 specific to rehabilitation admissions for FY2019. Please refer to the example provided above involving patients admitted to rehab for hemiplegia and hemiparesis following cerebral infarction affecting right dominant side (I69.351) with gait and/or balance assessment using other equipment (F01ZDYZ). This example supports the notion that there are obvious omissions from this list of diagnosis inclusions under MDC 23.

II.F.10 Medicare Code Editor (MCE) Changes

FAH agrees in general with all proposed MCE changes. However, we recommend that CMS determine if "transgender" considerations need to be addressed as part of the sex conflict edits that exist to detect inconsistencies between a patient's sex and any diagnosis or procedure on the patient's record. Cumbersome workarounds can be required to bypass the applicable edits for this patient population.

II.F.17.a Other Operating Room (O.R.) and Non-O.R. Issues (O.R. to Non-O.R. Procedures)

CMS continues efforts to address the recommendations for consideration received in response to some of the proposals set forth in the FY 2017 proposed rule pertaining to changing the designation of ICD-10 PCS procedure codes from O.R. to Non-O.R. procedures. Based on these recommendations received, CMS proposes to change the designation of 867 ICD-10 PCS procedure codes from OR to Non-OR status for FY 2018.

No data analysis or specific rationale was provided in the proposed rule pertaining to each category in which changes were recommended. The consistent overarching comment provided for each category included the notation that "these procedures generally would not require the resources of an operating room and can be performed at the bedside therefore we are recommending that these procedures be designated as Non-O.R. procedures".

While some of the proposed changes appear logical based on the "approach" of the procedure, CMS should provide, assuming it has been completed, the data analysis and other procedure specific rationale to support these designated changes. The transparency of this analysis is particularly important to support revisions to procedures designated as an "open" approach, and, in some instances, those designated as a "percutaneous" approach. While the

volume of recommended O.R. to Non-O.R. designation changes have historically been low in volume prior to ICD-10 implementation, these have typically been covered in the DRG change section of the proposed rules and provided with more detail and discussion. (Reference IPPS proposed rule FY 2016 published in April 2015; MDC 14 for DRG change section. For example, the commentary included information about a specific procedure code that CMS reviewed for how it was classified under ICD-10-CM and how the designation was affecting MS-DRG assignment based on the logic and that results of analysis by CMS and clinical advisors agreed that a change needed to be made.)

Some examples of procedures represented in Tables 6P.4a thru 6P.4p of the FY 2018 proposed rule are included below. Many of the ICD-10 codes, especially those codes in categories identified in section 17 of the proposes rule as item numbers (2) Percutaneous Insertion Intraluminal or Monitoring Device, (27) External Division and Excision of Skin, (30) Open Drainage, (33) Open Extraction, and (34) Percutaneous and Open Repair, were all recognized O.R. procedures when CMS GEMs (General Equivalence Mappings) are utilized to map between I-9 and I-10 codes.

Open Approach example - Open Drainage Category Table 6P.4i

0J9H0ZZ	Drainage of Left Low Arm Subcutaneous and Fascia, Open Approach	8309	Soft tissue incision NEC
0108077	Drainage of Abdomen Subcutaneous and Fascia, Open Approach	8309	Soft tissue incision NEC

The above procedure code in ICD-9-CM (83.09) backward maps with GEMs to an ICD-9-CM recognized O.R.

Percutaneous Approach example –Stem Cell and Bone Marrow transplant, percutaneous approach - Table 6P. 40

30253G1	Transfusion of Nonautologous Bone Marrow into Peripheral Artery, Percutaneous Approach		Allogeneic bone marrow transplant without purging
			Transplant from live related donor, non-
		00.9x	related donor, cadaver
	Transfusion of Nonautologous		
30263Y1	Hematopoetic Stem Cells into		Allogeneic stem cell transplant without
3020311	Central Artery, Percutaneous		purging
	Approach	41.05	
			Transplant from live related donor, non-
		00.9x	related donor, cadaver

Per the MS-DRG Definitions Manual, Version 32 for ICD-9-CM procedure codes 83.09 and 41.0x were considered O.R. procedures under ICD-9-CM. Additionally, in ICD-9-CM, two codes were required to capture the transplant procedure, i.e., the 41.0x code that was the recognized O.R. procedure and the 00.9x code that identified the donor type. In ICD-10-CM,

only one code is required to capture the transplant and the donor type (see code narrative above).

Cases involving bone marrow or stem cell transplants fall into MS-DRGs 014, 016 and 017, unless another procedure is performed that trumps the surgical hierarchy, i.e., DRG 003. Per Table 5 of the FY 2018 Proposed Rule, MS DRGs 014, 016 and 017 fall into the Pre-MDC category. Cases that fall into this "Pre-MDC" category are grouped by surgical procedure rather than principal diagnosis. Absent grouper logic to test, there is no transparency for these MS-DRGs especially since it is currently impacted by a procedure code as evidenced by its presence in a Pre-MDC which may require a recognized O.R.

MS- DRG	MDC	ТҮРЕ	MS-DRG Title
014	PRE	SURG	Allogeneic Bone Marrow Transplant
016	PRE	SURG	Autologous Bone Marrow Transplant With CC/MCC
017	PRE	SURG	Autologous Bone Marrow Transplant Without CC/MCC

The FAH is concerned that given the volume of proposed changes to Non-O.R. designation for FY 2018, and, in light of the examples provided in this comment letter, it is imperative that more analysis and research be conducted by CMS prior to implementing all of the proposals involving O.R. designation changes for FY 2018, and, future years.

FAH specifically and strongly opposes the changes to all of the O.R. designation changes that relate to percutaneous transfusion of bone marrow and stem cells listed in Table 6P.4o based on the above rationale, and in light of no further analysis provided by CMS.

II.H.5 Proposed FY 2018 Status of Technologies Approved for FY 2017 Add-On Payments

There were eight add-on payment categories approved for FY 2017 that were discussed in the FY 2018 proposed rule. FAH agrees with CMS's proposal for the below 8 add-on payment categories based on rationale provided by CMS for each in which determination to continue or discontinue is based on the anniversary date of entry on the market. Per notation in the proposed rule, CMS extends add-on payments for an additional year only if the 3-year anniversary date of the product's entry into the U.S. market occurs in the latter half of the fiscal year.

- CardioMEMS HF (Heart Failure) monitoring system
 - Discontinue add-on payment for FY 2018 based on anniversary date occurring prior to the beginning of FY 2018
- Defitelio (Defibrotide)
 - o Continue add-on payment for FY 2018 due to 3 year anniversary date not met yet
- GORE EXCLUDER Iliac Branch Endoprosthesis (Gore IBE Device)
 - o Continue add-on payment for FY 2018 due to 3 year anniversary date not met yet
- Praxbind Idarucizumab
 - o Continue add-on payment for FY 2018 due to 3 year anniversary date not met yet
- Lutonix Drug coated Balloon PTA Catheter and In.PACT Admiral Paclitaxel

- Discontinue for FY 2018 based on 3 year anniversary date occurring in the first half of FY 2018
- MAGEC Spinal Bracing and Distraction System (MAGEC Spine)
 - \circ Discontinue for FY 2018 based on 3 year and anniversary occurring prior to the beginning of FY 2018
- Vistogard (Uridine Triacetate)
 - o Continue for FY 2018 due to 3 year anniversary date not met yet
- Blinatumomab (BLINCTYO)
 - Discontinue for FY 2018 due to 3 year anniversary occurring in the first half of FY 2018

II.H.6 Proposed FY 2018 Applications for New Technology and Add-On Payments

There were nine new applications received by CMS for consideration of add-on payments for FY 2018. Three applicants withdrew applications prior to issuance of the proposed rule. FAH agrees with the CMS request for additional comments to determine if these new requests meet CMS clinical and cost criteria.

II.G. Recalibration of the Proposed FY 2018 MS-DRG Relative Weights

The FAH is concerned about the impact of large, negative year-to-year fluctuations in MS-DRG relative weights, which can lead to substantial and unexpected underpayment for critical care. In particular, it is problematic when such significant disruptions occur in the absence of an articulated policy proposal from CMS.

For instance, in the FY 2018 Proposed Rule, the most drastic cut in relative weight to any MS-DRG is unexplained in the preamble. MS-DRG 215 (Other Heart Assist System Implants) faces a proposed relative weight reduction of 34.8%. This MS-DRG includes procedures involving critically ill cardiovascular patients who often require longer hospital stays and treatment in the ICU.

The proposed reduction to MS-DRG 215 seems to be an unintended result of FY 2018 being the initial year in which claims data using ICD-10 diagnosis and procedure codes form the basis for MS-DRG relative weights. We would note that CMS has articulated a policy of ensuring that ICD-10 DRG assignments accurately replicate ICD-9 assignments to avoid "unintended payment redistributions."

The possibility that the relative weight of an MS-DRG could face a reduction of more than a third with no explanation adds an unnecessary element of unpredictability to hospital reimbursement. In the context of MS-DRG 215, this unexpected reduction would lead to significant underpayments because it coincides with FDA approvals and American Hospital Association coding guidance that are projected to increase the acuity of patients and the cost of procedures included in the DRG.

¹ 82 Fed. Reg. 19817 (Apr. 28, 2017).

² 81 Fed. Reg. 56790 (Aug. 22, 2016).

We believe that the proposed reduction to the MS-DRG 215 relative weight illustrates the need to consider limiting the percentage by which an MS-DRG's relative weight can decrease year to year without a specific CMS policy proposal and explanation and an opportunity for the public to comment. For example, CMS could, in this year's final rule, implement either an annual cap of perhaps ten percent on reductions to DRG relative weights in the absence of a specific policy proposal or explanation from CMS, or a multi-year transition period for such reductions when they exceed that percentage.

Wage Index

The FAH appreciates the opportunity to comment on CMS's proposals regarding the Medicare wage index. CMS's ongoing transparency is vital to the successful implementation of wage index policy and regulations.

III.D.2 Method for Computing the Proposed FY 2018 Unadjusted Wage Index

In the FY 2018 IPPS Proposed Rule, CMS is seeking public comment on whether it should, in future rulemaking, propose to only include the wage-related costs on the core list in the calculation of the wage index and exclude any other wage-related cost in the calculation if the wage index. The FAH does not oppose CMS proposing to only include the wage-related costs on the core list in the calculation of the wage index and exclude any other wage-related cost in the calculation of the wage index in future rule making. If CMS adopts this proposal, it should be as transparent as possible with hospitals and provide complete information on the impact on the wage index for all wage areas of the country.

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

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

III.I.2.c Proposed Deadline for Submittal of Documentation of Sole Community Hospital (SCH) and Rural Referral Center (RRC) Classification Status to the MGCRB

CMS is proposing to establish a deadline of the first business day after January 1 for hospitals to submit documentation of Sole Community Hospital ("SCH") or Rural Referral Center ("RRC") status to the Medicare Geographic Classification Review Board ("MGCRB") when seeking geographic reclassification under 42 C.F.R. § 412.230(a)(3). The FAH does not disagree with the establishment of a deadline for submission of documentation related to the

approval of SCH or RRC status, but urges CMS to also establish a deadline by which the agency must respond to hospitals' requests for SCH or RRC status. The proposed deadline will provide clarity to hospitals, the MGCRB and CMS in this process and will ensure adequate time for the MGCRB to include SCH and RRC approvals in its review, but absent a defined timeframe within which CMS must respond to hospitals' requests for SCH or RRC status, hospitals face a disadvantage in complying with this deadline, as described in detail below.

Existing regulations require a hospital seeking to use the special rules for geographic reclassification available to SCHs and RRCs under 42 C.F.R. § 412.230(a)(3) to be an active SCH or an RRC as of the date of the MGCRB's annual review, which usually occurs in early February. Accordingly, the MGCRB currently accepts documentation of SCH or RRC status up until the date of MGCRB's review. In this proposed rule, CMS establishes a deadline of the first business day after January 1 for hospitals to submit to the MGCRB documentation of SCH or RRC status approval, and to require hospitals to submit this approval documentation rather than have SCH or RRC classification that is effective as of the date of MGCRB review. In other words, under the proposed change, a hospital must submit to the MGCRB approval of its status as an SCH or RRC prior to January 1, but its SCH or RRC status may be effective after the date of MGCRB review. FAH is concerned that this proposal to establish a January 1 deadline for submission of documentation of SCH or RRC status approval to MGCRB, without establishing some deadline by which CMS must rule on hospitals' requests for SCH or RRC status, is problematic.

Current regulations provide that a hospital may request classification as an SCH at any time, and the classification is effective 30 days after the date of CMS' written notification of approval of that request. See 82 Fed. Reg. at 19907, col. 2; 42 C.F.R. § 412.92. While the regulation establishes when SCH status becomes effective, it does not establish any timeframe by which CMS must rule on the hospital's request for SCH status. For RRCs, current regulation provides that a hospital must submit its request for RRC status during the last quarter of a cost reporting period for its RRC status to be effective at the beginning of the following cost reporting period. See 82 Fed. Reg. at 19907, col. 2; 42 C.F.R. § 412.230(a). The governing statute and regulation further provide that the hospital's cost reporting period as an RRC must begin on or before the date of the MGRCB's review in order to be considered an RRC by the MGCRB. See 82. Fed. Reg. at 19907, col. 2. Again, as with the SCH approval process, the regulation fails to provide a timeframe by which CMS must rule on a hospital's RRC request.

The absence of a deadline by which CMS must rule on an SCH or RRC request presents a significant issue in connection with CMS' proposal to require hospitals to submit documentation of approval of SCH or RRC status to MGCRB prior to January 1, because there is no guarantee, even if the hospital presents to CMS its request for SCH or RRC status well in advance of January 1, that it will obtain CMS' approval by the January 1 deadline. For example, a hospital with a cost reporting period ending December 31, 2017 may timely submit its request for RRC status to CMS on October 1, 2017 (i.e., at the beginning of the final quarter of the cost reporting period), seeking RRC status to be effective January 1, 2018 (the beginning of the following cost reporting period). Notwithstanding the hospital's timely submission, the hospital is entirely uncertain whether CMS will rule on the request and issue the approval of RRC status prior to January 1. If CMS does not issue the approval by January 1, under CMS' proposal, the

hospital loses its opportunity to seek geographic reclassification from MGCRB because it is unable to provide documentation of CMS' approval of RRC status to MGCRB prior to that date. A hospital that seeks SCH status from CMS via a request dated October 1, 2017, or even earlier, faces the same uncertainty.

To avoid the uncertainty associated with CMS' proposal to establish a January 1 deadline to submit documentation of SCH or RRC status to the MGCRB, FAH urges CMS to establish a deadline by which CMS must respond to a hospital's SCH or RRC requests. Specifically, the FAH urges CMS to adopt a deadline of 30 days from the receipt of the request for SCH or RRC status and all supporting documentation from the hospital. FAH believes this deadline is appropriate because (1) it is a reasonable amount of time for CMS to review the request and issue its approval or denial of SCH or RRC status and (2) it provides hospitals seeking geographic reclassification from MGCRB as SCHs or RRCs with an element of certainty that allows them to appropriately manage the proposed January 1 deadline.

III.I.2.d Clarification of Special Rules for SCHs and RRCs Reclassifying to Geographic Home Area

In the Proposed Rule, CMS states "we believe it is unclear how [the special access rules in 42 C.F.R. § 412.230(a)(3)(ii)] would apply to a hospital with a § 412.103 rural redesignation and SCH or RRC status." Accordingly, CMS is proposing to revise this regulation section to clarify that a hospital with § 412.103 rural redesignation and SCH or RRC approval may reclassify to either its geographic home area or to the closest area outside of its geographic home area.

The FAH appreciates CMS' attempt to provide clarity with respect to SCHs or RRCs with § 412.103 rural redesignation applying for MGCRB reclassification based on the special access rules. Further, the FAH agrees with CMS' proposal to allow SCHs or RRCs with § 412.103 rural redesignation to apply for MGCRB reclassification under the special access rules to either its geographic home area or the closest area outside of its geographic home area. This clarification is consistent with the regulations and past administrative decisions. It is also consistent with CMS' policy through which an urban hospital can obtain § 412.103 reclassification and use that deemed rural status to get wage index redesignation to another urban area.

III.I.4 Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

Certain Medicare regulations specify that hospitals have 45 days from the publication of the annual proposed rule for the hospital IPPS to inform CMS or the MGCRB of requested reclassification/redesignation and out-migration adjustment changes relating to the development of the hospital wage index. In the FY 2018 IPPS Proposed Rule, CMS is proposing to revise those regulations and policies to require notification to the MGCRB or CMS within 45 days from the date of public display of the annual proposed rule for the hospital IPPS at the Office of the Federal Register. The FAH objects to this proposal because it does not give hospitals enough time to review the applicable data and in some cases may require a hospital to submit notification to the MGCRB or CMS prior to decisions on MGCRB appeals.

As an example of how problematic this could be, this year MGCRB decisions were issued around February 16, 2017. Providers wishing to appeal these decisions had to submit an appeal letter within 15 days, or by roughly March 3, 2017. The CMS Administrator then had 90 days to review the appeal, or until June 1. Under the current regulations, providers must submit the notifications described above to the MGCRB within 45 days of the publication of the Proposed Rule in the Federal Register. This year the Proposed Rule was published in the Federal Register on April 28th. Forty-five (45) days after April 28th is June 12, which gives hospitals adequate time after MGCRB appeals are decided. However, 45 days from the date of public display of the Proposed Rule on April 14 would have been two weeks earlier – i.e., May 30. This would have meant that many MGCRB appeals would not even have been decided by the time hospitals are required to provide notice to CMS or the MGCRB.

III.M Process for Wage Data Corrections

Effective beginning with the FY 2019 wage index development cycle, CMS is proposing to use existing appeal deadlines (in place for hospitals to appeal determinations made by the MAC during the desk review process) for hospitals to dispute corrections made by CMS after posting of the January PUF that do not arise from a hospital request for a wage data revision. The FAH is not taking a position on this proposal at this time. However, we do have concerns about the proposal that bear commenting on.

First, we believe that, should this proposal be adopted, the exact language describing the 14-day threshold and the particulars of the appeal process as it stands with finalization of the proposal should be added to the FY 2019 Wage Index Timeline published and made available online each year by CMS. Second, we believe that adjustments to the wage data that do not arise from a hospital request should be performed much earlier in the process than these April and May appeal deadlines. We seek assurances from CMS that adjustments they make to the wage data on a routine basis will still be performed long before these appeal deadlines are implicated and that the adjustments to which they refer will be rare and unusual circumstances requiring CMS' intervention and adjustment to the data. The FAH would oppose a policy that gives CMS the latitude to indiscriminately make adjustments to hospital wage data this late in the process where that adjustment was known of far ahead of time and/or could have easily been made earlier in the process.

III.N Proposed Labor Market Share for the Proposed FY 2018 Wage Index

We fully understand that CMS is obliged to rebase the market basket and reassess labor share every four years, and understand the difficulties in accomplishing this task. Our ability to provide meaningful input this year is hampered by several problems with data transparency from CMS on its calculation of changes to the labor share. While it is now too late for CMS to provide the information necessary for us to review its calculation of the labor share we do ask that in the final rule, or sooner, CMS provide the following information so that we can replicate and verify CMS's determination:

- a. CMS needs to clarify its data sources for the calculation;
- b. Case counts at different points in the assessment, such as the number of providers after trimming;
- c. Provider data such as the impact file identifying what data was used by CMS in the calculation; and
- d. The kinds of checks CMS made during calculations to assess and ensure accuracy.

Sole Community and Medicare Dependent Hospitals

V.C. Proposed Change to Volume Decrease Adjustment for Sole Community Hospitals (SCHs) and Medicare-Dependent, Small Rural Hospitals (MDHs) (§ 412.92)

We very much appreciate CMS's proposal to clarify through an amendment to its existing regulations that its prior informal guidance regarding calculation of the volume decrease adjustment for SCHs and MDHs to its Medicare Administrative Contractors did not withstand scrutiny by the PRRB or CMS Administrator on appeal. CMS is proposing to revise 42 C.F.R. § 412.92(e)(3) so that:

[I]f a hospital's total MS–DRG payment is less than its total Medicare inpatient operating costs, the sum of any resulting volume decrease adjustment payment and its MS–DRG payment would never exceed its total Medicare inpatient operating costs due to the fact that the fixed cost percentage is applied to the MS–DRG payment in calculating the volume decrease adjustment amount. By taking the ratio derived from the subset of fixed costs to total costs and applying that same ratio to the MS–DRG payment, we ensure that the sum of a hospital's IPPS payment and its volume decrease adjustment payment would never exceed its total Medicare inpatient operating costs, thus negating the need for a cap calculation. Thus, the proposed methodology renders the current volume decrease adjustment cap calculation obsolete.

82 Fed. Reg. at 19934, col.2. CMS is proposing to apply this calculation method to SCHs and to MDHs (but only if Congress renews the current MDH program for fiscal periods beginning on or after October 1, 2017).

Our concern with CMS's proposal is its application. CMS would only apply the clarified method prospectively. We believe this is clearly short-sighted given that CMS acknowledges the revised calculation methodology is a result of appeals setting aside the prior calculation methodology and adopting a methodology consistent with what CMS now proposes. CMS indicates in the proposed rule that:

In those adjudications, the PRRB and the CMS Administrator have recognized that: (1) The volume decrease adjustment is intended to compensate qualifying

SCHs for their fixed costs only, and that variable costs are to be excluded from the adjustment; and (2) an SCH's volume decrease adjustment should be reduced to reflect the compensation of fixed costs that has already been made through MS–DRG payments.

Id. at 19933 (citations to the many appeals decisions immediately precede the quote above). We respectfully suggest that as part of this clarification to its existing regulations CMS apply the clarification to pending appeals and NPRs that have yet to be issued. To do otherwise would cause administrative and hospital resources to be expended needlessly through appeals where the results are already known. This application also should apply to existing MDHs.

Disproportionate Share Hospital Payment

V.G.4.c. UC-DSH Calculation of Proposed Factor 3 for FY 2018

FAH appreciates the Centers for Medicare and Medicaid Services (CMS) past engagement of the hospital industry 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"). The accuracy and equity of the methodology CMS develops to calculate each hospital's share of the UC-DSH fund ("Factor 3") is critical to hospital financial stability given that (1) the total fund of UC-DSH payments to hospitals (the product of "Factor 1" and "Factor 2") is fixed for a given year but is a substantial part of hospital Medicare payments, varying from \$10 billion to \$6 billion since 2014,³ (2) the total fund of UC-DSH payments to hospitals is set in advance based on estimates of future year DSH spending and is not revised after the fact if actual data is different than estimates and the calculation of aggregate UC-DSH is precluded from administrative and judicial review, and (3) because hospitals have no administrative recourse to change the calculation of their share of such payments once calculated finally by the Secretary. Because hospitals receiving a portion of the funds from this UC-DSH pool are measured against each other, small variances in the data used to determine a hospital's share can grossly overcompensate a hospital to the detriment of all other hospitals that are DSH eligible. And while we oppose CMS's proposal to begin using Worksheet S-10 as a data source for the Factor 3 calculation beginning in FY 2018, which we discuss in considerable detail below, we do support CMS's proposal to annualize short and long period cost report data for Medicaid days and Medicare with SSI days for the Factor 3 calculation beginning in FY 2018. We continue to request more specific detail on the increase in Factor 1, which is important to the determination of aggregate UC-DSH payments (the product of Factor 1 and Factor 2). We have no additional comments regarding the calculations of Factor 2 under the statute this year, but we note it is unfortunate that CMS did not have the flexibility to calculate Factor 2 in prior years using its new data source for the changes in the insured population.

Medicare payments.

19

³ We also note that because Medicare Advantage is approximately 34% of Medicare, the change in hospital UC-DSH payments will similarly impact Medicare Advantage payments from Medicare Advantage Organizations, because such organizations network contracts with hospital providers almost universally tie their payments to hospitals to a percentage of traditional

For the past four fiscal years, CMS has determined Factor 3 based on the utilization of hospital services by low-income patients defined as inpatient days for Medicaid patients (not entitled to Medicare Part A benefits) plus inpatient days of Medicare SSI patients. Throughout that time period, CMS declined to use Worksheet S-10 data for purposes of determining Factor 3 for several reasons, including because CMS "believe[d] it is important that data used to determine Factor 3 are data that have been historically publicly available, subject to audit, and used for payment purposes (or that the public understands will be used for payment purposes)." 78 Fed. Reg. 50496, 50635 (August 19, 2013). Also, throughout, CMS noted the many specific deficiencies and drawbacks of relying on the Worksheet S-10 data. See, e.g., 78 Fed. Reg. at 50636; 79 Fed. Reg. 49854, 50015-17 (August 22, 2014); 80 Fed. Reg. 49326, 49522-26 (August 17, 2015); 81 Fed. Reg. 56762, 59963-64 (August 22, 2016). CMS went so far in the FY 2017 inpatient prospective payment system (IPPS) Final Rule as to reject its own proposal to start using Worksheet S-10 data for FY 2018, stating:

Instead, we expect to begin to incorporate Worksheet S–10 data into the computation of Factor 3 by FY 2021, once we have taken certain quality control and data improvement measures and also implemented an audit process, as we described above. We believe that postponing our decision regarding when to begin incorporating data from the Worksheet S–10 is necessary to allow us time to consider what changes to the cost report may be necessary and to implement an audit process. When we have determined that it is appropriate to use Worksheet S–10 data, we anticipate proposing to continue to use data from three cost reports, as we are doing for the calculation of Factor 3 for FY 2017, which would have a transitioning effect as we described in the proposed rule. (81 FR 25091).

81 Fed. Reg. at 56965.

We are very concerned that CMS is again moving too quickly to use Worksheet S-10 to distribute UC-DSH funds to eligible hospitals, without having addressed its own articulated concerns with the quality of the data from that form. We are particularly troubled that CMS now premises moving to significant use of that data because it (a) believes the data is the best data available to distribute the UC-DSH funds because of an updated correlation analysis by Dobson | DeVanzo, and (b) it is legally constrained by the relevant statute in its continued use of the data from its current methodology. We address each of these two points below in Section II. Parts A and B of this comment.

Further, CMS posits that information from the FY 2014 Worksheet S-10 improved as a result of allowing hospitals to amend that data in late FY 2016: "The fact that the Worksheet S-10 data changed for such a significant number of hospitals following a review of the cost report data they originally submitted and that the revised Worksheet S-10 information is available to be used in determining uncompensated care costs contributes to our belief that we can no longer conclude that alternative data are available that are a better proxy than the Worksheet S-10 data..." 82 Fed. Reg. at 19949, col.3. We question this assertion of improved accuracy resulting from hospital efforts to amend their Worksheet S-10 data for FY 2014 given that CMS provided

no education, guidance or other insight that may allow hospitals to report S-10 information more accurately or consistently in the time period that CMS gave hospitals to resubmit their FY 2014 S-10. With a transmittal date of July 15, 2016 and an effective date of August 16, 2016, (see R1681OTN), CMS gave hospitals until September 30, 2016 to submit their amended data. Yet on August 22, 2016 in its FY 2017 IPPS Final Rule, CMS stated: "In light of the significant concerns expressed by commenters regarding the Worksheet S-10 data, we are postponing the decision regarding when to begin incorporating data from Worksheet S-10 and proceeding with revisions to the cost report instructions for Worksheet S-10. We expect data from the revised Worksheet S-10 to be available to use in the calculation of Factor 3 in the near future, and no later than FY 2021." 81 Fed. Reg. at 56773, col.1. Thus, CMS acknowledged weeks after asking hospitals to consider submitting amended data, a month before such data was due, that revised reporting instructions had yet to be considered to make such data useable. Our review of the amended Worksheet S-10 data in Part C below continues to identify dramatic shortfalls in the current quality of the Worksheet S-10 data that make it unreliable as a tool to allocate billions of dollars in payments to hospitals. CMS even acknowledges that it will not desk audit Worksheet S-10 data until 2017 cost reports are filed. That means CMS proposes to entirely use unaudited Worksheet S-10 data from the FYs 2014-2016 Medicare cost reports for FY 2020 and two years of such unaudited data for its FY 2019 Factor 3 calculations and one year of unaudited data for its FY 2018 Factor 3 calculations. The statute requires use of "appropriate" data for distribution of UC-DSH funds. We question whether use of unaudited data to distribute billions in UC-DSH funds will be consistent with government accounting principles including those applied by government oversight agencies when doing program reviews. It is difficult to imagine that such oversight agencies would be tolerant of over \$50 million in overpayments to the two hospitals mentioned in Part II.C. below that would occur due to obvious errors in their reported S-10 data. And there appears to be no mechanism to correct or recover those overpayments once Factor 3s for hospitals are finally calculated for a given fiscal year.

In Part II.D. below we address continued problems with the Worksheet S-10 preparation instructions including, for example, their failure to recognize a mandatory element of Section 3133 of ACA, "the amount of uncompensated care...costs of subsection (d) hospitals for treating the uninsured" through non-means tested uninsured discount programs among other definitional problems. 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. In Part II.E. of our comment below, we propose a process to CMS to accomplish that goal, essentially a 5-year phase-in period to begin when CMS preliminarily eliminates significant errors and inconsistencies from the Worksheet S-10 data.

I. FACTOR 1 COMMENTS

We remain extremely concerned with the lack of CMS transparency in calculating the amount that Medicare would pay under traditional disproportionate share payments but for the passage of ACA section 3133, the Factor 1 calculation required by that same statute. Since the inception of this calculation for the FY 2014 fiscal year, our consultants have not been able to

replicate this calculation. This is particularly frustrating because in each subsequent year, when CMS has updated the calculation, the prior year calculation has significantly changed to the benefit of the Medicare Trust Fund at the expense of hospitals. This calculation is very important to the provider community because it sets the limit for the fund available to eligible provider for UC-DSH payments and is not subject to administrative or judicial review.

Our consultants once again were unable to replicate the calculation for FY 2018 because of a lack of data and assumptions from CMS that the Actuary used for its calculation. But we did review the variability of the new estimates of DSH payments for prior years, in particular FYs 2016 and 2017, and the Factor 1 calculations for those years when initially forecast that they are using later data:

Review of CMS Projection for 100% Empirical DSH Payments

FFY 2014 through FFY 2018

Year	Latest Est for Yr.	Estimated for Payment Year (Factor 1)	Variance in Estimates	% Variance in Est.	Source for Latest Estimate
2014	12,790,922,790	12,715,139,572	75,783,217	1%	2017 Final Rule
2015	13,354,993,012	13,383,462,196	(28,469,184)	0%	2018 Proposed Rule
2016	14,433,067,974	13,411,096,528	1,021,971,446	8%	2018 Proposed Rule
2017	15,392,949,466	14,396,635,710	996,313,756	7%	2018 Proposed Rule
2018	16,002,553,460	16,002,553,460	-	0%	2018 Proposed Rule

FAH is very concerned that later data show the Factor 1 estimates would be over \$2 billion higher over that period of time than originally predicted. Incorporating Factor 2, we estimate that the aggregate pool of UC-DSH payments would have been \$832 million higher based on later data.

This \$832 million is an important source of funding that Medicare provides to hospitals that care for a vulnerable patient population. We would hope that CMS will investigate its prior methodology for FYs 2016 and 2017 to identify why its estimates vary so significantly from later information and take steps to improve its estimation methodology in this year's final rule. Additionally, CMS needs to fully identify every aspect of its data sources, methodologies and assumptions of its Factor 1 calculation in future proposed rules (which it did not do this year) so that the provider community, through public comment, can raise issues that CMS can take into account to ensure this calculation occurs accurately.

II. FACTOR 3 COMMENTS

A. FAH Response to "Improvements to Medicare Disproportionate Share Hospital (DSH) Payments -- Benchmarking S-10 Data Using IRS Form 990 Data: An Update" by Dobson | DaVanzo, April 13, 2017

In support of its proposal to utilize Worksheet S-10 data in computing DSH Factor 3 for FY 2018, CMS relies primarily on an April 13, 2017 report prepared by consultants at Dobson | DaVanzo, in conjunction with KNG Health Consulting, entitled "Improvements to Medicare Disproportionate Share Hospital (DSH) Payments -- Benchmarking S-10 Data Using IRS Form 990 Data: An Update" (the "Dobson Report"). See 82 Fed. Reg. at 19,948–49. The Dobson Report compares Worksheet S-10 data with uncompensated care costs reported to the IRS on Form 990 by not-for-profit hospitals, assessing the correlation in the Factor 3 calculations derived from each of the data sources. The April 2017 Dobson Report updates the analysis performed by Dobson | DaVanzo in advance of the FY 2017 IPPS Proposed Rule, using the same methodology, with the only change being the years studied (the previous report used data from 2010 to 2012, while the April 2017 Dobson Report uses data from 2011 to 2013).

In the FY 2018 IPPS Proposed Rule, CMS finds that because the April 2017 Dobson Report "continues to demonstrate a high correlation between the amounts for Factor 3 derived using the IRS 990 data and the Worksheet S-10 data and that this correlation continues to increase over time" it "leads us to believe that we have reached a tipping point with respect to the use of the Worksheet S-10 data." 82 Fed. Reg. at 19949, col. 2. Based on Dobson's previous findings and the public comments received in response, CMS decided not to finalize its proposal to begin incorporating Worksheet S-10 data into the calculation of Factor 3 for FY 2018 in the FY 2017 IPPS Final Rule. Now, using the same methodology challenged by numerous commenters, CMS finds that based on the April 2017 Dobson Report, "we can no longer conclude that alternative data are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured than the data on uncompensated care costs reported on the Worksheet S-10." Id. As discussed in more detail below, CMS did not address the significant weaknesses that remain in the methodology employed in the Dobson Report, and CMS has not explained why the updated Dobson Report's findings merit a reversal of a policy adopted just eight months earlier. In short, the Dobson Report's findings are insufficient to serve as a "tipping point" for use of the Worksheet S-10 to distribute UC-DSH funds. 4

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⁴ Because the Dobson Report involved the use of statistical analysis, the remainder of this section of our comment was prepared by Alex M. Brill. Mr. Brill is the Economic Policy Advisor to Hooper, Lundy & Bookman, PC. Mr. Brill formerly served as the Policy Director and Chief Economist to the House Committee on Ways and Means and as an economist at the White House Council of Economic Advisers (CEA). In 2010, Mr. Brill served as a consultant advisor to the President's Fiscal Commission (Simpson-Bowles Commission). He also currently serves as a research fellow at the American Enterprise Institute.

From multiple perspectives, the hospitals analyzed in the Dobson Report are not representative of the full set of hospitals receiving DSH payments. The Dobson Report authors acknowledge the weaknesses in their study's representativeness, stating "[O]ur analysis is limited to those hospitals that have IRS 990 data (not-for-profit hospital) for 2011-2013. Our findings may not generalize to all IPPS hospital[s]." Dobson Report, at 14. Not only is this analysis restricted to only not-for-profit hospitals, which may not be representative of all hospitals, a significant share of these not-for-profit hospitals that are likely DSH-eligible are then excluded from the sample. In 2011, 32 percent of eligible hospitals are excluded from the analysis for the reason that valid data for these hospitals were not available in 2012 or 2013. This restriction may unduly bias the sample toward a higher positive correlation between S-10 and 990 for the reason that only those hospitals that are most diligent and consistent in reporting are included in the sample.

Further, while 1,061 hospitals may be a sufficiently large sample, the relevant question is if that sample is unbiased. Evidence presented by Dobson | DaVanzo – Exhibits 4, 5, 6, and 7 – indicate that the sample is not reflective of the broader DSH hospital universe. For example, the Dobson | DaVanzo sample skews urban, skews towards larger hospitals (measured by number of beds), skews toward the East North Central and Middle Atlantic regions, and skews towards teaching hospitals. The Dobson | DaVanzo data set is over representative of Illinois, New York, Ohio, and Pennsylvania, among others, and is under representative of Florida, Texas, and others. This is particularly telling given that some of the most significant problems we have identified in the Worksheet S-10 data are for governmental hospitals, excluded from the Dobson analysis because they do not file IRS Form 990s, and that are located in Texas, for example, which is underrepresented. See Part C.1.a of our comment below.

Finally, the question Dobson | DaVanzo is pursuing is the correlation between an estimated "Factor 3" calculation based on IRS 990 data and Factor 3 calculation based on Worksheet S-10 within a single hospital. We question the Dobson Report's decision to exclude hospitals that may not be DSH-eligible in FY 2017 (the Dobson Report's sample is restricted by approximately half due to the self-imposed limitation). Including all of the hospitals that report IRS 990 and Worksheet S-10 data would allow readers to review correlation among all hospitals and separately for hospitals that are DSH eligible relative to those that are not. By preemptively eliminating hospitals that will not likely be DSH-eligible, the Dobson Report does not permit this analysis. A robust analysis should include all hospitals for which there is available data, regardless if those hospitals are expected to be DSH-eligible in FY2017.

The rising correlation between IRS 990 and Worksheet S-10 data in the Dobson Report is actually quite modest. While CMS asserts that the increasing correlation "leads us to believe that we have reached a tipping point with respect to use of the S-10 data," the Dobson Report's authors interpret their findings more modestly: "[T]he correlation coefficient between Factor 3's calculated from the IRS 990 and S-10 has increased *slightly* over time, from 0.7984 in 2011 to 0.8464 in 2013." Dobson Report, at 14 (emphasis added). Moreover, the Dobson Report's findings actually demonstrate that the Worksheet S-10 data's stability is dwindling among the hospitals with the highest Factor 3 calculations. The data in Exhibit 10 (at 11) of Dobson's Report indicates that the hospitals providing the largest share of uncompensated care (e.g. hospitals with high Factor 3s) often report S-10 and IRS 990 data that are wildly variant. The disparity (absolute percent difference) at this tail of the distribution increased over the sample

period. For example, the disparity rises from 89% absolute percent difference at the 90th percentile in 2011 to 98% absolute percent difference at the 90th percentile in 2013. Contrary to the "key finding" reported by Dobson | DaVanzo with respect to correlation, there is no evidence that the S-10 and IRS 990 data is converging over time among hospitals with high Factor 3s and moreover, the disparity among those hospitals with high S-10 values is clearly large.

The Dobson Report utilizes only correlation analysis instead of the more rigorous regression analysis. Given the plentiful amount of data (large number of observations and detailed characteristics about each hospital) the logical analytical framework is a regression analysis. More advanced statistical methods could readily and more appropriately investigate the relationship between S-10 and IRS 990 data sources while adjusting for the potential influence of other factors.

Finally, as we discussed in response to last year's report from Dobson | DaVanzo, even assuming that the correlation is statistically significant, it might simply mean that such data by any given hospital is being reported consistently on the two forms, but still incorrectly. CMS effectively presumes, without support, the accuracy of the IRS Form 990 data by resting its decision to use Worksheet S-10 data on a correlation between the two. In addition, whether these hospitals are reporting consistently between the two federal programs is irrelevant to accurate payments under Factor 3. Because Factor 3 is a hospital relative factor, the absence of hospital to hospital variation is the key to an accurate distribution of these payments. The consistent reporting of relevant data between all participating hospitals remains critical. The Dobson Report may show that an individual hospital is reporting data consistent to the IRS and on Worksheet S-10 but it does not show that hospitals have a consistent understanding of Worksheet S-10 and its instructions and are reporting information consistent with that understanding. It is this consistency that would be necessary to demonstrate that Worksheet S-10 is appropriate data for use in distributing UC-DSH payments.

B. CMS's Concerns About Its Legal Authority to Continue Using Proxy Data Are Unfounded

CMS implicitly questions its continued authority to use proxy data for Factor 3 in the proposed rule, but has shared more directly such concerns during informal meetings with industry representatives. In response to CMS's concerns, FAH on behalf of its members commissioned its outside counsel to undertake an analysis of the statutory framework of 42 U.S.C. § 1395ww(r) to assess the scope of CMS's authority to continue to use proxy data exclusively, blended with other data such as the Worksheet S-10 data, or on an adjusted basis. That review by outside counsel accompanies this comment as Attachment A and is incorporated herein by reference.

We share our counsels' view that CMS has statutory authority to continue using its pre-FY 2018 data sources until Worksheet S-10 data becomes "appropriate" either alone, adjusted or in a hybrid with Worksheet S-10 data weighted at a very low level until robust reporting and auditing of S-10 data has occurred. In a single paragraph of the IPPS 2017 Final Rule, CMS acknowledged: (1) that it had the authority to continue to use Medicaid and Medicare with SSI days data to calculate Factor 3, because the data from S-10 was not "appropriate" data, (2) under

what conditions S-10 data would become "appropriate" to use under the statute, (3) that it was appropriate in FY 2017 to use multiple years of data sources to smooth the impact of relative changes in hospital data and, (4) even when Worksheet S-10 data would be appropriate to use, CMS would continue to use 3 years of data, which would necessarily include initially two years of Medicaid and Medicare with SSI days data for a "transitioning effect." 81 Fed. Reg. at 56961, col.1.

CMS's legal concerns about continuing to use low-income patient days as the data source for distributing UC-DSH payment appear to be motivated by the timing of the Medicaid expansion (see, for example 81 Fed. Reg. at 56955). That is, CMS is concerned about the appropriateness of distributing uncompensated care payments once it begins using FY 2014 data in the distribution methodology that reflects the Medicaid expansion occurring under the ACA beginning in FY 2014. Following this logic, CMS would then face the dilemma of whether to use low-income patient days reflecting the Medicaid expansion in FY 2014 or Worksheet S-10 data from FY 2014 going forward that, as outlined below, are clearly faulty. We think this choice is a false one and suggest alternatives below that CMS could adopt that would allow it to continue to use pre-2014 low income patient days in the distribution of UC-DSH payments while it works to make improvements to the Worksheet S-10 and its instructions as well as develop audit protocols that will make the Worksheet S-10 usable for this purpose. CMS has authority to fashion an "appropriate" calculation using proxy data as it has already been doing for three years, adjusted proxy data or blended data as we suggest in section E. 2. below.

We acknowledge that CMS would have little authority to avoid using Worksheet S-10 data for the Factor 3 calculations if CMS had been diligent in taking the steps it has acknowledged must be taken before that data is reasonably usable for Factor 3 purposes. But for all of the reasons we set forth in Part C below, the Worksheet S-10 data available for FY 2014 is neither accurate or consistent for that purpose.

C. The Currently Available Worksheet S-10 Data from FY 2014 and Subsequent Cost Reports Is Highly Inaccurate and Would Lead to a Distribution of UC-DSH Payments Under Factor 3 that is Irrational, Grossly Overpaying Some to the Detriment of Many

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 the FY 2017 proposed rule CMS said:

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 instead of following its proposal, in the FY 2017 IPPS Final Rule, CMS recanted the usability and accuracy of the Worksheet S-10 data when it provided:

Instead, we expect to begin to incorporate Worksheet S–10 data into the computation of Factor 3 by FY 2021, once we have taken certain quality control and data improvement measures and also implemented an audit process, as we described above. We believe that postponing our decision regarding when to begin incorporating data from the Worksheet S–10 is necessary to allow us time to consider what changes to the cost report may be necessary and to implement an audit process. [81 Fed. Reg. at 56965.]

CMS makes the same statement in this FY 2018 IPPS proposed rule to move to using Worksheet S-10 data, a "belief" that hospitals have been reporting the data more accurately and consistently. CMS provides no support for that belief through any audit of the data and is not proposing any audit of the data at all from FYs 2014 through 2016 cost report submissions. The proposed rule provides no evidence that CMS's assertions in this regard are more accurate than they have been in the past, which ultimately led to CMS not finalizing the proposal it made in the FY 2017 IPPS proposed rule. Our review of the Worksheet S-10 data, conducted both internally and by an outside consulting firm (DeBrunner and Associates, Challenges with the Use of S-10 Data in the Calculation of Medicare DSH Uncompensated Care Payments, June 2, 2017," Attachment B hereto) continue to establish that Worksheet S-10 data is not appropriate at this time to use to allocate billions of dollars in funds to hospitals that serve low income patients. We present those findings below.

1. FAH Study on the Accuracy of Worksheet S-10 Data

Our internal study focused on the data quality of hospitals that CMS projects in the FY 2018 IPPS proposed rule would actually receive UC-DSH payments in 2018 and excludes hospitals where CMS is not proposing to use S-10 data such as hospitals in Puerto Rico, and IHS hospitals.⁵ The data for the study was developed using CMS's "FY 2018 IPPS Proposed Rule: Medicare DSH Supplemental Data File" and 3/31/2017 HCRIS File. By focusing only on hospitals that were indicated as receiving DSH, and also excluding IHS and Puerto Rico hospitals, as indicated above, we were able to reduce the number of hospitals in the file to 2,347. For these hospitals, the reported Worksheet S-10 data would have a direct impact on UC-DSH payments under the CMS proposal. Our findings from this review of the remaining data are as follows:

a) Obvious Aberrations in Reported Hospital Charity Charges

⁵ The work performed for this internal study was provided by a single individual over the course of two weeks. We are therefore troubled that CMS has not at least performed a similar analysis of the S-10 data to identify and then rectify those problems after contacting the involved hospitals to correct those aberrations.

To identify hospitals where we have major concerns with reported charges, we compared charges indicated on S-10 to Worksheet C, line 202. The items included as charges on S-10 are as follows: Medicaid Line 6, CHIP Line 10, Other State Line 14, Charity Line 20, Col. 3 and Bad Debts Line 26. This comparison yielded the following information:

- i. The national average of S-10 charges to gross charges for all hospital mentioned above is 24%.
- ii. 116 hospitals had an S-10 percentage of charges that exceeded 50%, double the national average. 46% of these 116 hospitals are governmental hospitals, while 15% of the hospitals in the study are governmental. These 116 hospitals are expected to receive \$942 million in UC-DSH payments in FY 2018. This amount will likely triple by 2020 if Worksheet S-10 is the sole data source.
- iii. 37 of the 116 hospitals had S-10 charges of 70% or greater than total charges and would account for \$374 million in UC-DSH payments in FY 2018.
 - o 70% seems high when considering that Grady Memorial in Atlanta is at 57%, Metro Nashville General Hospital is at 59% and OU Medical Center is at 38%. These are 3 well-known, large urban, indigent careheavy hospitals.
 - o 26 of the 37 hospitals are governmental (public).
- 7 hospitals exceed 100% of charges, with 4 exceeding 1000%. The hospitals exceeding 1000% would receive \$76 million in UC-DSH payments in 2018. One of the hospitals appears to have a major input error on bad debts.

We tested the above findings to determine if this aberrant charge information is an indicator of the magnitude of increase in UC-DSH payments as a result of moving to Worksheet S-10 data to calculate Factor 3. The table below calculates the percentage of S-10 charges to Worksheet C charges for the twenty hospitals with the largest increase in UC-DSH payments from 2017 to 2018. Many of these hospitals are identified as being high S-10 to Worksheet C-charge ratio hospitals.

Top 20 Hospitals with Increases in UC DSH Payments in FY 2018
S-10 Charges as a Percentage of Worksheet C Charges For Hospitals Expected to Receive UC DSH Payments for FY 2018

PROV	Hospital Name	18 Proposed UC DSH Payments	17 UC DSH Calculated Payments	17 to 18 Change	S-10 Charges Compared to Worksheet C
450289	HARRIS HEALTH SYSTEM	71,187,737	16,911,314	54,276,423	83%
450080	TITUS REGIONAL MEDICAL CENTER	48,048,936	474,706	47,574,230	1020%

450015	DALLAS CO. HOSP. DIST.	54,567,673	22,928,309	31,639,364	69%
100022	JACKSON MEMORIAL	59,904,662	32,921,868	26,982,794	70%
140124	JOHN H. STROGER JR. HOSP OF COOK CTY	28,597,869	9,518,912	19,078,957	74%
450213	UNIVERSITY HEALTH SYSTEM	26,700,184	8,253,114	18,447,070	60%
100001	SHANDS JACKSONVILLE MEDICAL CENTER	28,860,046	13,346,300	15,513,746	62%
110079	GRADY MEMORIAL HOSPITAL	27,611,259	12,545,615	15,065,644	57%
150024	ESKENAZI HEALTH	18,999,849	6,499,807	12,500,042	66%
450039	TCHD D/B/A JPS HEALTH NETWORK	21,532,313	9,535,552	11,996,761	53%
190005	MEDICAL CTR. OF LA AT NEW ORLEANS	13,930,283	4,064,964	9,865,319	80%
190098	UNIVERSITY HEALTH SHREVEPORT	14,350,409	6,381,774	7,968,635	59%
450124	UNIVERSITY MED CENTER BRACKENRIDGE	12,527,380	4,622,368	7,905,012	56%
220031	BOSTON MEDICAL CENTER	17,894,247	10,580,922	7,313,325	60%
450024	UNIVERSITY MEDICAL CENTER OF EL PASO	11,757,318	4,788,670	6,968,649	93%
340047	NORTH CAROLINA BAPTIST HOSPITAL	17,227,964	10,378,984	6,848,980	26%
460009	U OF U HOSPITALS & CLINICS	12,587,515	5,973,036	6,614,479	20%
10033	UNIVERSITY OF ALABAMA HOSPITAL	21,143,275	14,665,535	6,477,740	25%
310119	UH - UNIVERSITY HOSPITAL	14,225,439	7,834,258	6,391,181	62%
50038	SANTA CLARA VALLEY MEDICAL CENTER	15,345,770	8,987,610	6,358,160	65%
		537,000,130	211,213,617	325,786,512	

Data Sources:

FY 2018 IPPS Proposed Rule: Medicare DSH Supplemental Data File

CMS 3/31/2017 HCRIS File

The table above shows that many of the hospitals scheduled to receive the largest increases in UC-DSH payments have unusually high charity charges compared to total charges. It also shows a lot of variability between these hospitals and an obvious error for Provider No. 45-0080. Because Worksheet C charges are total hospital charges, the ratio of S-10 to Worksheet C charges should represent the portion of a hospital's business that is essentially charity care and bad debt. The national average of S-10 Charges to Worksheet C is 24% as noted above. Only 3 of the above twenty hospitals fell within that range. The ratios for the other hospitals could not seemingly be true or these hospitals would not be financially viable.

b) Many Hospitals Have Obviously Overstated Charity Charges for Insured Patients

The Worksheet S-10 instructions are very clear that only deductible and coinsurance amounts are to be included in the column designed to capture charity care provided to insured patients. Given that clarity, we would expect that the amounts on line 20 column 2 would always be less than the amounts on line 20, column 1. That is, waived deductibles and coinsurance for charity care insured patients would always be expected to be less than, and a fraction of full charges for charity care uninsured patients. However, that is not what we found. To identify hospitals for our focused review, we compared the insured charity charges in column 2 line 20 with uninsured charity charges in column 1 line 20 on Worksheet S-10. We also reduced the insured charity charges in column 2 for charges for patient days that exceed a program's length of stay limit (line 25), if the hospital indicated that these charges were included in column 2 per line 24 of S-10. From our review, we developed the following findings:

- i. The calculation above indicated a national average of 16% for all DSH hospitals. FAH hospitals average approximately 7% insured charity to uninsured charity.
- ii. 375 hospitals had a percentage greater than 50% and 185 had a percentage of equal to or greater than 100%. The 185 hospitals would receive \$521 million in UC DSH payments in 2018 and the 375 hospitals would receive \$961 million in UC DSH payments in 2018.
- iii. 14 hospitals with insured charity charges did not report any uninsured charity charges
- iv. 51 that had negative insured charges when line 25 was subtracted from column 2 of line 20. These negative amounts likely indicate that the hospital did not follow the S-10 instructions.

To assess the impact of the above findings on UC-DSH payments, the table below shows the top ten hospitals with reported insured charity charges. Only 1 of these 10 hospitals have a ratio of insured to uninsured charity charges of under 173% and the top hospital has the 7 highest increases in UC DSH payments when comparing FY 2017 to FY 2018. We believe these data suggest incorrect reporting and hospitals reporting more than deductibles and coinsurance amounts on line 20 column 2 of the Worksheet S-10 despite the clear instructions for how to report these items. This incorrect reporting results in substantial redistribution of UC-DSH payments to these hospitals.

Top 10 Hospitals Insured Charity Charges For Hospitals Expected to Receive UC DSH Payments for FY 2018

Prov #	Hospital Name	Charity Charges Insured	Charity Charges Uninsured	Insured Charity as a % of Uninsured
100001	SHANDS JACKSONVILLE MEDICAL CENTER	657,713,181	329,232,570	199.77%
490009	UNIVERSITY OF VIRGINIA MEDICAL CENTE	611,623,181	49,242,043	1242.08%
390115	ARIA HEALTH	206,249,014	40,527,661	508.91%
450289	HARRIS HEALTH SYSTEM	169,728,289	1,440,578,853	11.78%
490022	MARY WASHINGTON HOSPITAL	160,737,024	92,886,944	173.05%
450040	COVENANT HEALTH SYSTEM	116,177,122	46,198,072	251.48%
50599	UC DAVIS MEDICAL CENTER	112,721,229	1,280,771	8801.04%
450209	NORTHWEST TEXAS HOSPITAL	106,917,391	4,107,118	2603.22%
360163	THE CHRIST HOSPITAL	106,658,869	5,395,431	1976.84%
110087	GWINNETT HOSPITAL SYSTEM INC	99,772,143	55,235,677	180.63%

Data Sources:

FY 2018 IPPS Proposed Rule: Medicare DSH Supplemental Data File

CMS 3/31/2017 HCRIS File

c) <u>Many Hospitals Are Reporting Unsupportable Cost to Charge Ratios</u> that are Inflating Their Uncompensated Care Costs

A review of the cost to charge ratio ("CCR") data for the hospitals under study continues to reveal that too many hospitals still appear to have aberrant CCRs. Forty-seven hospitals are using a CCR of greater than 60% to calculate uncompensated care costs. Eleven of these hospitals use a CCR greater than or equal to 100%. We do not agree that CMS's trimming methodology adequately addresses this problem. We believe an edit of 3 standard deviations above the mean captures too few problems in this area. Further, replacing such a CCR with the

statewide average CCR may disadvantage these hospitals relative to what they are otherwise entitled. A number of these hospitals may be a no-charge structure or all-inclusive rate public providers whose equivalent CCR is a significantly higher than the statewide average because their equivalent charge is much closer to their costs. Arbitrarily assigning a statewide average 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.

d) Reported Bad Debt Information Is Overly Variable and Aberrational to be Accurate

We have monitored Worksheet S-10 data on bad debts as reported on line 28 on S-10 since FY 2014 and continue to observe significant variability within a given provider. We reviewed this data for hospitals that are expected to receive DSH payments in 2018 for cost report years beginning between 2013 and 2015 in the CMS 3/31/17 HCRIS File. The majority of hospitals had over a 20% change in Bad Debts between FY 2013 and 2014 as well as FY 2014 and 2015. 26% had a change of greater than 50% between FY 2013 and 2014 and 23% had greater than a 50% change between FY 2014 and 2015. See following table for additional detail:

Threshold	Change GT 10%		Change GT 20%		Change GT 50%	
Years Compared	13 to 14	14 to 15	13 to 14	14 to 15	13 to 14	14 to 15
Hospital with Change over Threshold	1,757	1,770	1,346	1,308	622	562
Hospitals Scheduled to Receive DSH	2,418	2,418	2,418	2,418	2,418	2,418
% of Hospitals over Threshold	73%	73%	56%	54%	26%	23%

Data Sources:

FY 2018 IPPS Proposed Rule: Medicare DSH Supplemental Data File

CMS 3/31/2017 HCRIS File

We tested to see if the extent of such variability could predict large increases in UC-DSH payments. To test for payment impact, we reviewed the ten hospitals with the largest increase in UC-DSH payments from 2017 to 2018 (see table below).

Top 10 Hospitals with Increases in UC DSH Payments in FY 2018

Variation in Bad Debt Reported on Worksheet S-10 For Hospitals Expected to Receive UC DSH Payments for FY 2018

PROV	Hospital Name	2018 Proposed UC DSH Payments	2017 UC DSH Calculated Payments	17' to 18' Change in UC DSH Payments	2013 Bad Debt	2014 Bad Debt	2015 Bad Debt
450289	HARRIS HEALTH SYSTEM	71,187,737	16,911,314	54,276,423	122,617,763	351,126,596	46,915,379
450080	TITUS REGIONAL MEDICAL CENTER	48,048,936	474,706	47,574,230	13,206,040	1,342,635,975	24,174,603
450015	DALLAS CO. HOSP. DIST.	54,567,673	22,928,309	31,639,364	366,316,381	310,977,162	260,342,655
100022	JACKSON MEMORIAL	59,904,662	32,921,868	26,982,794	441,014,031	470,240,280	552,410,860
140124	JOHN H. STROGER JR. HOSP OF COOK CTY	28,597,869	9,518,912	19,078,957	325,868,028	181,026,235	171,736,530
450213	UNIVERSITY HEALTH SYSTEM	26,700,184	8,253,114	18,447,070	92,492,076	101,804,416	117,373,233
100001	SHANDS JACKSONVILLE MEDICAL CENTER	28,860,046	13,346,300	15,513,746	78,268,336	77,543,455	100,062,858
110079	GRADY MEMORIAL HOSPITAL	27,611,259	12,545,615	15,065,644	262,352,653	352,471,721	253,118,099
150024	ESKENAZI HEALTH	18,999,849	6,499,807	12,500,042	40,670,859	60,526,138	109,986,562
450039	TCHD D/B/A JPS HEALTH NETWORK	21,532,313	9,535,552	11,996,761	(248,780)	56,756,868	5,662,406

Data Sources:

FY 2018 IPPS Proposed Rule: Medicare DSH Supplemental Data File

CMS 3/31/2017 HCRIS File

This data appears to indicate the Titus Regional Medical Center had a keypunch error in entering Bad Debts on Worksheet S-10 for their FY 2014 cost report since it is showing a 10,000% increase from 2013 to 2014. Titus may have added two decimals places (keyed cents as dollars) when they entered bad debts onto their 2014 cost report. If the actual bad debts for 2014 is \$13,426,369, the 2018 proposed UC-DSH payments would decline from \$48,048,936 to \$849,982. Similarly, it appears Harris County may have overstated its bad debt amounts by over \$200 million in FY 2014, and this would have overstated its proposed FY 2018 UC-DSH payments by \$6,029,007. Six of the ten hospitals had changes greater than 20% in comparing 2013 to 2014 and/or 2014 to 2015.

Volatility in bad debt reporting indicates that this data is not being accurately or consistently reported by many hospitals. In some cases, significant errors are being made in reporting these amounts. For example, Titus and Harris County errors in bad debt reporting may be overstating their UC-DSH reimbursement by over \$50 million, and thereby understating every other hospitals UC-DSH payments. Thirteen hospitals expected to receive UC-DSH payments actually had negative bad debt expense indicated on line 28 of S-10 for FY 2014 cost reports, even after last year's opportunity to amend their S-10 data. This bad debt information clearly shows the need for an audit and review process period to S-10 data before utilized for payment distribution between hospitals. Further, the systemic increase in the bad debt reporting further argues for an audit of these data before the data is used for payment. If hospitals increased their bad debt reporting knowing that these data would affect the amount of UC-DSH payments they are receiving, these increases need to be reviewed so that hospitals are not advantaged by reporting more bad debt than other hospitals when those amounts cannot be supported under audit. Compliant hospitals should not under any circumstances be disadvantaged by noncompliant hospitals with regard to reporting data in Worksheet S-10.

2. The DeBrunner Study

The DeBrunner study referenced earlier was commissioned by the FAH and three other hospital associations to review the FYs 2014 and 2015 cost report data from Worksheet S-10 and related worksheets using the March 2017 update to HCRIS. This HCRIS update included for FY 2014 any amended data a hospital may have submitted in response to the CMS Transmittal R1681OTN by September 30, 2016, to account for the new trigger date to claim charity care cost for a hospital account.

DeBrunner's data findings were reasonably consistent with those of the FAH internal study of the same HCRIS data. DeBrunner at p. 3 sets forth the significant variances in the FYs 2014 and 2015 data, as follows:

- 210 hospitals reported providing at least 50 percent less uncompensated care during FY 2015 than in FY 2014,
- 150 hospitals reported providing at least 50 percent more uncompensated care in FY 2015 than in 2014 and seventy reported that their uncompensated care more than doubled,

- Titus Regional Medical Center, in Texas, reported \$534 million in uncompensated care in FY 2014 but only \$9.8 million in FY 2015,
- The University of Virginia Medical Center reported \$17.5 million in uncompensated care during FY 2014, and \$141 million during FY 2015,
- Martin Medical Center, in Florida, reported \$6.9 million in uncompensated care during FY 2014 and \$44.1 million in FY 2015, and
- Swedish Covenant Hospital reported \$8.7 million in uncompensated care in FY 2014 and \$31.4 million during FY 2015, even though Illinois, where it is located, expanded its Medicaid program.

Additionally, DeBrunner identified numerous incidents of reported charity costs that could not reasonably be sustained at the reported levels, strongly suggesting the reported data is incorrect. For example, in the same data source, DeBrunner found:

- Eight hospitals reported providing more than \$500,000 in uncompensated care per bed in FY 2014,
- One hospital reported charity care and bad debt costs that were greater than eight times its total operating expenses for the year in FY 2014,
- The average percentage of total operating expenses represented by charity care and bad debt ranges from four to five percent depending on how it is calculated, yet 18 hospitals reported ratios greater than 25 percent and three reported ratios greater than 50 percent in FY 2014, and
- In FY 2015, nine hospitals reported ratios of charity care and bad debt costs to total operating expenses greater than 25 percent.

DeBrunner notes that some of these issues with incorrect reporting appear to be systemic. As noted in the FAH study above, a higher incidence of aberrational data appears at public hospitals. For example, from the above 18 hospitals reporting bad debt and charity care ratios above 25% of operating expenses, 10 hospitals are from Texas and Louisiana, and two thirds of those are public hospitals. DeBrunner at p.3 concludes from this that: "this suggests that the S-10 itself is not adequately directing hospitals to report a significant source of compensation that offsets the charity care and bad debt costs these hospitals incur."

From this data, and the definitional issues it identified with the instruction to Worksheet S-10, DeBrunner at p.2, made the following key findings:

- Clear inconsistencies remained in the data in the 2014 and 2015 reporting periods, indicating that confusion regarding what could or should be reported on the S-10 has not yet been resolved.
- It is not clear that the charity care and bad debt costs reported on the S-10 can accurately be described as "uncompensated care" in all cases.
- To a significant degree, FY 2014 S-10 data reported by hospitals is questionable in far too many cases for it to be a credible tool for use in determining Medicare reimbursement.

- Because S-10 data has never been audited and is collected in a manner that leaves no outside sources against which it can be benchmarked, validation of this data is extremely difficult.
- Using UC data reported by hospitals on their S-10 for computing Medicare DSH UC payments would be highly redistributive, with many hospitals experiencing significant swings in their payments. In this zero-sum redistribution, winners would gain \$2.3 billion and losers would lose \$2.3 billion. The ten percent of hospitals that would see the greatest gains from a shift to basing Medicare DSH UC payments entirely on the S-10 would find their share of the overall Medicare DSH pool rise from 18.8 percent to 44.5 percent of the pool an increase of \$1.8 billion. This means that 10% of hospitals would experience 77% of the total gains among all hospitals. Others would suffer significant losses, with no assurance that the underlying data is accurate enough to support such changes for either the winners or the losers.

Our own internal study in combination with the DeBrunner report clearly establishes that the quality of the data reported through Worksheet S-10 is not "appropriate" for purposes of the Factor 3 calculation as required by the applicable statute, and consequently, CMS should continue to use the proxy data for that purpose until CMS can remedy the quality issues associated with Worksheet S-10 reporting and data.

D. Worksheet S-10 Preparation Instructions Are Inconsistent with the Statutory Mandate and Continue to Create the Inconsistent Reporting of Critical Data Elements By Hospitals

In every FAH comment since the FY 2014 IPPS Proposed Rule, we have identified problems with the Worksheet S-10 instructions that have caused inconsistent and inaccurate reporting of critical data elements from that form that CMS now proposes to use to allocate almost \$7 billion in funding to DSH eligible hospitals. To date, CMS has not addressed the specific problems with the Worksheet S-10 and instructions we have identified.

We have identified in Part C of this comment above a sampling of the impact on the quality of data caused by inconsistent compliance with Worksheet S-10 instructions. We have included as Attachment C, a discussion of the problems associated with the instructions that apply to both pre-October 1, 2016 cost reports, and cost reports that will be submitted under the CMS slightly revised set of instructions to Worksheet S-10 for cost reporting periods beginning on and after October 1, 2016. All of our prior concerns apply to the now current set of instructions. Below however, we again address our concerns about Worksheet S-10 not capturing the cost of uninsured discounts that are not means tested and we identify problems created by the few amendments to the Worksheet S-10 instructions CMS made available in November 2016. There is still time for CMS to modify the S-10 instruction set to fix these

problems before hospitals begin to prepare cost reports for periods that begin on and after October 1, 2016.

Indeed, CMS need not wait to address the uninsured discount issue, described in detail below. Curing S-10 instructions for uninsured discounts is easily rectified in the same fashion that CMS used last year to allow hospitals to correct data in the 2014 S-10 and refile it. CMS simply needs to delete definitional references that exclude discounts from uncompensated care, ability to pay, and the instruction that reads "Do not include charges of uninsured patients who do not meet the hospital's charity care criteria for a full or partial discount." Then it simply needs to instruct hospitals to file amended Worksheet S-10s for FY 2014 and forward to include the costs of discounts provided to uninsured patients.

1. 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 had a dual purpose. First, it 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 costlier 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. Second, it provided compensation to hospitals for their uncompensated care costs on the assumption that hospitals with a high proportion of low-income insured patients would also have significant numbers of uninsured or otherwise uncompensated patients. Neither of these purposes were explicit in the statute prior to the Affordable Care Act but have been generally accepted as the underlying goals of Medicare DSH. 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 post-Affordable Care Act 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.

In proposing a transition from the current proxy measure used to distribute UC-DSH payments, CMS proposes to use data from a 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.

a) <u>The Current Worksheet S-10 Frustrates Rather than Furthers the Purpose of ACA Section 3133</u>

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 instructions then clearly go on to say not to include charges for "uninsured patients with or without full or partial discounts who do not meet the hospital's charity care criteria". Clearly such discounts are not bad debt, but the definition of "charity care" indicates 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 explicitly exclude it.

The current version of the worksheet was first used for purposes completely unrelated to Section 3133. It was used to capture data necessary to make Electronic Health Record (EHR) incentive payments under section 4102 of the American Recovery and Reinvestment Act (ARRA) 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.

CMS modified the Medicare cost report 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 not to report them.

b) 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 could define uncompensated care for the uninsured to achieve that purpose. CMS could develop the same definition for Medicaid and Medicare purposes adopting a consistent approach to implement ACA Section 3133 as it has for Medicaid. 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 would serve Section 3133's purpose to measure 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.

c) 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 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.

		Discounting	Exar	пріе					
From CMS 2552-10 Worksheet C									
Total Costs	Line (200, Col 3)	\$ 243,437,92	29						
Total Hospital Charges (Gross Charges)	Line (200, Col 8)	\$ 1,137,011,0	76						
Cost to Charge Ratio (Worksheet S-10, Line 1)		0.214	11						
		I. Patient I							
		No Dis	counti	ng	Discounting				
		Self-Pay		Charity	Self-Pay	Charity	Charity		
		Example A.1 - Hospital Does Not		Example A.2 -	Example B.1 - Hospital Discounts	Example B-2 - Hospital Charity 75%	Example B-3 - Hospital Charity 75%		
		DiscountUninsured		ospital Provides	Uninsured Self-Pay	& Reports Net Charity			
	S-10 Ref	Self-Pay		100% Charity	75%	on S-10	Charity on 5-10		
Charity	0 20 110	ocii ru,		20070 01121117	****	0110 20	and try on a 20		
Gross Charges for Services Rendered			Ś	50,000		\$ 50,000	\$ 50,00		
harity Discount				(50,000)		(37,500			
elf-Pay Amount				-		12,500	12,5		
harity Charges Reported on S-10	Line 20			50,000		37,500	50,0		
ost to Charge Ratio	Line 1			0.2141		0.2141	0.21		
Cost of Charity Care	Line 21		\$	10,705		\$ 8,029	\$ 10,70		
aid By Patient (S-10 Line 22)	Line 22			- [-			
-10 Net Cost of Charity Care	Line 23		\$	10,705		\$ 8,029	\$ 10,70		
lad Debt									
Gross Charges for Services Rendered		\$ 50,0	00		\$ 50,000	50,000	50,00		
harit _i Discount						(37,500	(37,5)		
Ininsulred Discount			-	-	(37,500)				
harges net of Discount		50,0	00	-	12,500	12,500	12,5		
aid By Patient			-	-					
Ion-Medicare Bad Debt - Reported on S-10	Line 28	50,0		-	12,500	12,500	12,50		
ost to Charge Ratio	Line 1	0.21		0.2141	0.2141	0.2141			
Cost of non-Medicare Uncompensated Care	Line 29		5 \$	-	\$ 2,676				
Total Uncompensated Cost S-10 (Ln. 23 + Ln 29)	Line 30	\$ 10,70)5 S	10.705	\$ 2.676	\$ 10,705	\$ 13.31		

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

		No Discounting				Discounting					
		Self-Pay	Charity Example A.2 - Hospital Provides 100% Charity		Self-Pay Example B.1 - Hospital Discounts Uninsured Self-Pay 75%		Example B-2 - Hospital Charity 75% & Reports Net Charity on 5-10		Charity Example B-3 - Hospital Charity 75% & Reports Gross Charity on 5-10		
	S-10 Ref	Example A.1 - Hospital Does Not DiscountUninsured Self-Pay									
Charity											
Gross Charges for Services Rendered			\$	50,000			\$ 50,	000	\$ 50,0		
Charity Discount				(50,000)			(37,	500)	(37,5		
Self-Pay Amount				-			12,	500	12,5		
Charity Charges Reported on S-10	Line 20			50,000			37,	500	50,0		
Cost to Charge Ratio	Line 1			0.2141			0.2	141	0.21		
Cost of Charity Care	Line 21		\$	10,705			\$ 8,	029	\$ 10,7		
Paid By Patient (S-10 Line 22)	Line 22			- [2,	000	2,0		
S-10 Net Cost of Charity Care	Line 23		\$	10,705			\$ 6,	029	\$ 8,7		
Bad Debt											
Gross Charges for Services Rendered		\$ 50,000		-	\$	50,000	50,	000	50,0		
Charity Discount							(37,	500)	(37,5		
Uninsured Discount		-		-		(37,500)					
Charge net of Discount		50,000		-		12,500	12,	500	12,5		
Paid By Patient		2,000		-		2,000	2,	000	2,0		
Non-Medicare Bad Debt - Reported on S-10	Line 28	48,000		-		10,500	10,	500	10,5		
Cost to Charge Ratio	Line 1	0.2141		0.2141		0.2141	0.2	141	0.21		
Cost of non-Medicare Uncompensated Care	Line 29	\$ 10,277		-	\$	2,248	\$ 2,	248	\$ 2,2		
Total (ncompensated Cost S-10 (Ln. 23 + Ln 29)	Line 30	\$ 10,277	\$	10,705	\$	2,248	\$ 8,	277	\$ 10,9		
1 Total costs - Allowable costs for all patients as deter	mined under the Medic	are principles of reimburse	ment.								
² Total charges - this is the sum of colums 6 and 7.											
Columns 6 and 7—Enter on each cost center list patients and, where applicable, standard cust orthotics). Also include the total inpatient and column 26 and, therefore, do not contain "cost Source: CMS Pub. 15-2 84023	omary charges for item outpatient gross charg	s reimbursed on a fee sche es for cost centers which h	dule (e ave a c	.g., DME, oxyger	n, prosthetic	s, and					

In Example 2 above, all of the scenarios for payment involve a patient with \$50,000 in charges that pays \$2,000 of the 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.

As we have established above, Worksheet S-10 has only been used 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 there is already a regulatory protocol in place to recognize the cost of uncompensated care to the uninsured under Medicaid. CMS could implement that protocol for Medicare, which hospitals already are obliged to follow now in reporting such data to state Medicaid programs.

2. CMS's Slightly Amended Worksheet S-10 Instructions Issued November 2016 Create the Same Inconsistent and Inaccurate Reporting by Hospitals as Prior Instructions

In addition to our concerns with the way the Form S-10 instructions exclude uninsured discounts from uncompensated care, we also have concerns with several revised instructions from the November 25, 2016 amendments to Section 4012 of PRM-II. We believe that the instructions set forth below create additional confusion for providers and will result in the inconsistent reporting of relevant cost data. Given these instructions will be used with current period cost report filings we believe CMS should make every effort to institute corrections immediately.

a) Offsetting partial payment patients approved for charity care (Line 22)

We believe the instructions released on November 16, 2016 may have been in error with respect to offsetting partial payment patients approved for charity care (line 22) for cost reporting periods beginning on or after October 1, 2016. For these cost reports, line 22 subtracts from charity care charges payments received or expected to be received from patients who have been approved for charity care for services delivered during the cost reporting period. For cost reporting periods beginning prior to October 1, 2016, the line 20 instructions direct the hospital to enter the total initial payment obligation measured at FULL CHARGES (emphasis added). The term "full charges" was added with the November 25, 2016 instructions to clarify the meaning of "total initial payment obligation." In this case, "partial payments received for patients approved for charity care" would be subtracted from full charges adjusted to cost for those same patients. For example, assume full charges are \$100 and \$70 of those charges are written off to charity care and the hospital has a cost-to-charge ratio (CCR) of 0.5 and the patient is uninsured. The patient owes and pays \$30. For cost reporting periods beginning prior to October 1, 2016, the hospital would report \$100 on line 20, column 1 (full charges). The \$100 would be adjusted by the hospital's CCR of 0.5 and \$50 would be entered in line 21, column 1. The hospital would then subtract \$30 received from the patient and its uncompensated care costs would be \$20. If the hospital did not receive the \$30 balance from the patient, the amount would be recorded as bad debt if the amount was not expected as a balance due from the patient or recorded charity care if waived by the hospital under its charity care policy. In either circumstance, after adjusted by the hospital's CCR, the result would be the same.

With the same example applied to cost reporting periods beginning on or after October 1, 2016, the instructions produce a different result. The instructions now indicate "enter the actual charge amounts...written off to charity care..." on line 20, column 1. The hospital is instructed to report only those charges written off to charity care on line 20, not full charges as occurs for the cost reporting periods beginning prior to October 1, 2016. The hospital reports \$70 instead of \$100 on line 20, column 1. On line 21, the hospital adjusts the \$70 in charges by the hospital's CCR of 0.5 and reports \$35. The instructions for line 22 now say "if payment is received during this cost reporting period, regardless of when the services were provided, from patients who have approved for charity care, enter such payments for the entire facility." This sentence instructs that the \$30 owed and paid by the patient in the above example is to be subtracted from the hospital's \$35 cost. The hospital now has \$5 (\$35 - \$30) in uncompensated care costs rather than \$20 in the above example. If the hospital did not receive the \$30 balance from the patient, the hospital's charity care costs would be \$35 under the instructions rather than the \$50 in the above example.

These two examples have the same circumstances but produce different results. In our view, the first example is an analytically correct way of accounting of charity care costs. In the second example, we believe the instructions err in requiring that the amount due and paid from the patient be subtracted from charity charge costs that are derived from charges that are waived and not expected to be paid by the patient. In our view, once the hospital waives charges under its charity care policy, there is no expectation of payment on those charges and the costs

associated with those charges should be fully realized as charity care costs. The amount due from the patient could then either be paid by the patient or be recognized as bad debt.

Taking the second example further and consistent with this point, the hospital's charity care costs would be the \$70 in charity care charges adjusted by the CCR of 0.5 or \$35. Even though charity care costs are higher in this example than the first one (\$35 versus \$20), we believe the second example also produces an analytically correct way of accounting for charity care costs. In our view, it would not matter whether the patient paid or did not pay the \$30 in charges expected to be paid to determine the hospital's charity care costs as the hospital waived charges associated with those costs and is not expecting payment. If the patient does not pay the \$30 in charges that are due, we believe this amount in the second example would be reported as bad debt on lines 26 and 28 using the instructions for cost reporting periods beginning on or after October 1, 2016. Bad debt is then adjusted by the CCR (\$30 * 0.50 or \$15) and reported on line 29. The hospital's uncompensated care costs (charity care plus bad debt) are \$50 or the same as the amount in the first example.

One complication in the instructions that may have resulted in producing these results is that the pre-October 1, 2016 cost reports include charity care and bad debt write-offs in the cost reporting period when the services were provided while the cost reporting periods beginning on or after October 1, 2016 instruct making these write-offs in the cost reporting period when the write-off is made. For the cost reporting periods beginning on or after October 1, 2016, there may not be symmetry for a given patient between when charges are written off to charity care on line 20 and when payment is received on line 22. It makes sense that charges will often be written off to charity care in the cost reporting period where the services are being provided as the patient will be indicating at the point of service or discharge whether he or she can afford to pay. It seems unlikely, if it ever happens at all, that a hardship patient would make a payment on charges that have been waived. However, on line 22, the patient may be making a partial payment at some later point when his/her financial circumstances change, which could be in a different cost reporting period from when services were provided. In our view, that is more likely to be a payment for an amount the patient is still expected to pay than an offset to waived charges adjusted to costs. If the patient makes a payment at some later point, we would recommend that it be an offset to an obligation owed, and potentially reduce an amount that was or would be written off as a bad debt.

b) Adjusting Insured Patient Deductible and Coinsurance Written Off to Charity Care.

For the instructions to lines 20 - 23 of Form S-10, we agree with distinguishing how charity care is handled for insured versus non-insured patients. We further believe that charges reduced to costs using the CCR is a sensible concept when trying to determine hospital costs for uninsured patients. However, we are less certain about the analytical validity of reducing charges to costs in the context of insured patients. An uninsured patient will be either paying full charges or a percent of full charges if charges are waived under a charity care policy. There is no contractual or IPPS amount like there is with a private payer or a governmental payer like Medicare or Medicaid. Historically (prior to the advent of IPPS), third-party payers typically paid a percent of charges which is conceptually analogous to a CCR to identify hospital

costs. As there is no contractual or IPPS amount for an uninsured patient like there is for an insured patient, adjusting waived charges by the CCR approximates the costs of caring for that patient. However, for an insured patient, we do not believe the concept applies, as the contracted or IPPS amount will already represent a percentage of full charges likely to be above a hospital's costs as the hospital's payments in total must be above its costs for it to remain financially viable. Once the insured patient's liability is determined, those costs are split between the patient (deductible and coinsurance) and the payer.

We agree with accumulating charges written off to charity care on line 20, column 1 for uninsured patients and adjusting those charges for the CCR on line 21, column 1. As stated above, we do not believe the subtraction on line 23 (partial payment by patients approved for charity care) should be occurring as an offset to only the portion of charges waived for charity care reduced to costs. For insured patients (line 20 and line 21, column 2), we find the labeling of the line to be inconsistent with the instructions. Line 20 is labeled "charity care charges for the entire facility." However, the instructions for line 20, column 2 tell the hospital to enter "the deductible and coinsurance payment required by the payer for insured patients" which we find confusing and believe our members will as well.

To address these issues, we recommend:

- <u>a)</u> Changing line 20 to "Uninsured patients: Charity care charges for the entire facility." The instructions for this line would be similar to those that exist now but would be limited to uninsured patients or other patients that do not have a specific source of payment from a third-party (such as state or local indigent care programs like those reported on lines 13-16).
- b) Eliminating line 22 so there is no longer a subtraction from charity care costs for "partial payment by patients approved for charity care."
- <u>c)</u> Eliminating column 2 (and therefore the need for column 1 and 3) and creating a new line in its place that parallel the lines for charity care that would read:
 - Line x.1:" Insured patients: Deductible and coinsurance written off to charity care"
 - Line x.2:" Cost of deductible and coinsurance written off to charity care" (line 1 times line x.1)
- <u>d</u>) Charity care would equal (Charity care charges X CCR) + Deductibles and coinsurance written off to charity care.
- e) Add to the instructions that charges that remain due from uninsured patients after charges are waived under the charity care policy are to be reported on the current lines 26 and 28.

CMS has time now to rectify these problems with its new Worksheet S-10 instructions, and the previously identified problems with vast portion of the instructions it has not amended, along with amending the instructions to allow providers to include the cost on uninsured discounts that are not means tested. Providers have not begun to prepare cost reports for periods that begin on and after October 1, 2016 and will not until sometime in early 2018. Fixing these

problems now will insure that CMS has a more robust data set from which to calculate Factor 3 after it audits such data.

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

To move the use of Worksheet S-10 data forward so that it can become appropriate data to use under the statutory standard applicable here, CMS needs to take steps to audit the available data, and to phase-in the use of that data as it becomes more reliably useful for its intended purpose over time. We propose a plan to address each of these steps below.

1. 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 Part D-1 above, the uncompensated care costs for uninsured patients (a concept defined for 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. Because hospitals have an even greater interest in the correctness of such audit than for the wage index, the process for hospital feedback in such audits should at least equal the process for the wage index.

We suggest in the initial year of such audits that CMS focus on FY 2014 data and identify at a high level, as we did in Part C of this comment, highly aberrant data reported by hospitals. In particular, just as we noted in Part C, CMS should focus on the major items that skew the Factor 3 calculation heavily in a provider's favor that are well out of normal ranges such as charity charges at some hospitals, or claimed bad debt at others. Hospitals reporting such aberrant data should be given a reasonable period of time to justify or replace their reported data with the understanding that if they cannot satisfy CMS with a reliable data element, for example, the amount of their non-Medicare bad debt, such data may be rejected entirely in the Factor 3 calculation, or subject to some local average replacement. As there is no administrative or judicial review of a hospital's UC-DSH payment, we believe the policy decision CMS makes on this issue—whether to reject the hospital's data entirely or substitute alternative data in its place—should be addressed through rulemaking. Because there is no time to do this work before this rule becomes final, we believe CMS should use the existing Factor 3 calculation data sources and methods for FY 2018.

2. CMS Should Use a Five-Year Phase-in Beginning in FY 2019 for Worksheet S-10 Data That Has Been Preliminarily Audited.

Assuming the above audit suggestions are implemented during FY 2018, we believe the first year of the S-10 data phase-in could start in FY 2019, but that the weight accorded to the S-10 data be limited to 10 percent, using FY 2014 S-10 reports. We would limit the first year S-10 data to a 10 percent weight because we think it likely that fewer than 100 of the almost 2500 DSH eligible hospitals will have aberrant data that rise to the level of CMS's preliminary inquiry.

In Year 2 of the phase-in, FY 2020, the S-10 data should be subject to a broader wage index survey like inquiry for FYs 2014 and 2015 S-10 data, for a larger population of hospitals. During that period, hospitals should be encouraged to amend their FY 2015 S-10 data consistent with the problems identified during the prior year data reviews. The two years of S-10 data should be averaged and should equal 20 percent, with the remaining 80 percent weight accorded to the current data source from FYs 2012 and 2013.

In Year 3 of the phase-in, FY 2021, S-10 data from FYs 2015 and 2016 should be averaged and weighted at 40 percent, with 60 percent weight accorded to the current data source.

The phase-in process should continue in Year 4, FY 2022, with the use of averaged FY 2016 and FY 2017 S-10 data with an 80 percent of weight, the remainder accorded to the current data source.

In FY 2023, year 5 of the phase-in, S-10 data would be the sole data source for the Factor 3 calculation, with an average of audited data from FYs 2016 through 2018.

Quality Payment Program

Accounting for Social Risk Factors

In the proposed rule CMS seeks comments pertaining to accounting for social risk factors for the Hospital Readmissions Reduction Program (HRRP), the Hospital Acquired Condition (HAC) Reduction program, the Inpatient Hospital Value-Based Purchasing (VBP) Program, and the Hospital Inpatient Quality Reporting (IQR) Program. The following comments are intended to respond to each of the separate requests for comment on social risk factors, both for these programs as well as the quality proposals in section IX.

The FAH has long believed that appropriately accounting for social risk factors, such as sociodemographic status adjustment, is essential for accurately assessing health care provider performance for public reporting and accountability programs, particularly with respect to outcome measurement. All beneficiaries, including those with social risk factors, should receive the best possible care. At the same time, where social risk factors affect patient outcomes in ways that are beyond the control of healthcare providers, providers should not be penalized for nor discouraged from treating these patients. The metrics used for holding hospitals accountable need to properly balance these goals.

The 21st Century Cures legislation focused on share of dual eligible as a patient-level proxy for assessing the extent to which a hospital has patients at risk for readmissions. While this is a widely-available proxy, it provides only a partial picture of patients' social risk factors, and thus should not be viewed as long-term or permanent solution. For example, it excludes other important patient-level information such as education and language proficiency. The FAH also believes that CMS should consider social risk factors beyond patient-level information. A growing body of evidence shows that community characteristics, such as availability of healthcare providers and access to pharmacies and transportation, are associated with patient outcomes. For instance, in an April 23, 2016 interview with Modern Healthcare, Cara James, Ph.D., Director of the CMS Office of Minority Health (OMH), noted that there are estimates that as much as 80 percent of health disparities are derived from social determinants and that structural barriers are in place to prevent the health care system from effectively addressing these conditions. The impact of social determinants is supported by an OMH-commissioned report released in January 2016 entitled, "Guide to Preventing Readmissions Among Racially and Ethnically Diverse Medicare Beneficiaries." ⁶ The report acknowledges higher readmission rates for socially complex patients that are not explained by clinical differences. This suggests that two hospitals of equal quality, but unequal sociodemographic-status mix, will experience different penalties under the Hospital Readmission Reduction Program.

As noted in the December 2016 report of the HHS Assistant Secretary for Planning and Evaluation (ASPE), patients with social risk factors have worse outcomes and providers who treat them have poorer performance and greater financial penalties in the pay-for-performance programs. In considering various strategies for addressing this issue, the ASPE considered the need for measure developers to develop measures or statistical approaches that are suitable for reporting performance for beneficiaries with social risk factors; the need to study the relationship between social risk factors and health status to determine whether improved medical risk adjustment is part of the solution for recognizing differences in these patient populations; and the potential for targeted assistance to hospitals that disproportionately serve beneficiaries with social risk factors.

The FAH agrees with these strategies. The FAH also agrees with the ASPE report's further conclusion that, with respect to social risk factors, the pay-for-performance programs should not be looked at in isolation. Instead, the cumulative penalties across the three hospital programs for providers that serve patients with social risk factors should be tracked. This includes prospective monitoring of how changes in one program would affect these hospitals and their financial penalties across all three programs.

The 21st Century Cures legislation calls for stratifying hospital performance on the pneumonia mortality and readmission measures by percent of dual eligibles. The FAH agrees that stratification can be a useful tool in identifying and understanding disparities in hospital

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⁶ Betancourt, J., Tan-McGrory, A. & Kenst, KS. (2015, September). *Guide to preventing readmissions among racially and ethnically diverse Medicare beneficiaries*. Prepared by the Disparities Solutions Center, Mongan Institute for Health Policy at Massachusetts General Hospital. Baltimore, MD: Centers for Medicare & Medicaid Services Office of Minority Health.

performance by patient income. However, the FAH sees the stratification process for payment purposes as a stop-gap approach allowing time to reconfigure the payment programs to take into consideration the full results of the ASPE work. Additionally, any proposals in this area — whether stratification or future adjustments — will require CMS to provide hospitals with data in a timely manner. Only then can stakeholders evaluate the bet approach for addressing social risk factors.

With regard to the stratification proposals outlined by CMS in the rule, the FAH supports the proposed approach to first provide hospitals with confidential reports showing stratified results, which would raise awareness of any disparities in care within the hospital and in comparison, to other hospitals. This step is essential for stratification – or any other social risk factor adjustments. The FAH agrees that public reporting on *Hospital Compare* should be contemplated for the future and careful consideration should be given to what type of information display would be most useful to the public. Any public reporting of information adjusted for social risk factors, regardless of the method for adjustment, must be presented in a format that is most helpful to patients, their families, and providers. The FAH strongly urges CMS to undertake focus groups to test messaging and understanding of the data; similar focus groups were very helpful when *Hospital Compare* was first being established.

V.I. Hospital Readmissions Reduction Program

CMS proposes for the HRRP beginning in FY 2019, that hospitals would be stratified into peer groups based on the percentage of patients who are Medicare-Medicaid dual eligible, as directed by section 15002 of the 21st Century Cures Act (P.L. 114-255), which calls for stratification of hospitals into peer groups based on the percentage of patients who are Medicare-Medicaid dual eligible. The current HRRP formula would be modified so that a hospital's HRRP payment adjustment would be calculated based on a comparison to its peer group instead of a national average comparison. Specifically, CMS proposes to use five peer groups and to adjust the readmission formula to include the difference between the hospital's excess readmissions ratio and the median ratio for its peer group.

As discussed in more detail in the addressing social risk factors section of this comment letter, in moving forward with stratification under the HRRP, the FAH offers some guiding principles for implementation and future social risk factor adjustments. First, while the proposed stratification approach is a reasonable first step for addressing social risk factors, it should be viewed as a stop-gap tool, not a permanent solution. Our members urge CMS to reexamine and reform the payment programs to take into consideration the full results of the ASPE work. Second, share of dual eligible beneficiaries should also be viewed as a short-term proxy for assessing the extent to which a hospital has patients facing social risk factors. It is not a complete solution. CMS should continue analyzing the impact of social risk factors on hospital readmission rates, as well on other payment programs, and to seek improved risk adjustment of the readmission measures and other outcome measures to account for social risk factors beyond dual eligibility status. Third, any adjustment for social risk factors must be accompanied by a process in which hospitals and other providers receive confidential reports showing their results. This will allow providers to see disparities both within their systems and compared to other systems and providers, as well as to address any concerns with the data or results. Fourth, public

reporting of social risk factor-adjusted information on *Hospital Compare* or other similar site must be useful to patients, families, and providers. Our members encourage CMS to utilize focus groups to test the display and comprehension of the data, similar to what was done during the development of *Hospital Compare*.

V.J. Hospital Value-Based Purchasing Program

Proposed Removal of PSI 90 Measure

The FAH welcomes removal of the current PSI 90 patient safety composite measure from the Hospital VBP Program for FY 2019, but, at this time, we do not support the proposal to add back the modified PSI 90 Patient Safety and Adverse Events Composite for FY 2023. The FAH believes consideration of this proposal should be postponed until hospitals have experience with the measure using ICD-10-CM claims. While we are pleased that CMS sought NQF endorsement for the modified measure, hospitals have not yet received any performance data on it. Therefore, our members are not able to comment on the addition of this measure until they can receive and better understand their own data and how the measure changes impact their score. In addition, the data that will be provided to hospitals in the summer of 2017 for purposes of the FY 2018 IQR Program will still be based on ICD-9-CM claims. The first performance period using ICD-10-CM data for the PSI 90 measure will end in June 2017. The CMS has previously said that the necessary claims data will not be available until later in 2017. Additionally, the AHRQ software update hospitals need to do their own calculations of the modified PSI 90 measure using claims coded in ICD-10 is currently unavailable. Taken together, these timing and operational difficulties currently make it impossible for hospitals to use this measure for internal quality improvement activities or to thoroughly comment on it at this time. We urge CMS to delay this proposal until these concerns are addressed.

Considering the impending removal of the PSI-90 measure, we agree with the proposal to reduce from three to two the number of measures needed for a hospital to receive a score for the safety domain.

Efficiency and Cost Reduction Domain

The FAH does not support the proposed addition of the pneumonia episode payment measure to the VBP Program efficiency domain in FY 2022. While the measure has undergone NQF review and endorsement, the Measure Applications Partnership (MAP) did not support the pneumonia episode payment measure's inclusion. The FAH agrees with the concerns that MAP raised. First, the FAH continues to believe that the inclusion of condition-specific episode payment measures overlaps with the existing total Medicare Spending per Beneficiary (MSPB) measure. CMS should adjust the MSPB measure to remove the cases that overlap with any of the condition-specific measures included in the efficiency domain. Secondly, all the episode payment measures, including MSPB, should be reconsidered for sociodemographic risk adjustment. The FAH believes that the steps that were taken with NQF on this matter were inadequate. The models the measure developer used for testing of sociodemographic factors in these measures was not robust and did not include many of the factors described earlier in this letter in the section on accounting for social risk factors.

The FAH supports the proposals to establish 36-month performance and baseline periods for the heart failure and acute myocardial infarction (AMI) efficiency measures beginning in FY 2023. If CMS elects to finalize addition of the proposed pneumonia episode payment measure, the FAH encourages a delay in implementation until a 36-month period can be adopted for this measure as well. A 23-month performance period is proposed for the initial year (FY 2022) of inclusion for this measure in the VBP Program. Having different performance periods for similar measures is confusing for providers and patients.

With respect to changes in efficiency measure scoring, the FAH opposes the proposal to weight the MSPB measure at 50 percent of the efficiency domain score. Since the inception of the VBP Program, measures have been equally weighted in calculating domain scores, and the FAH sees no reason to make an exception in this case. The FAH does agree that an efficiency domain score should be calculated if a hospital has a score on any one of the efficiency measures, rather than requiring a score on the MSPB measure.

V.K. Hospital Acquired Condition Reduction Program

Proposed Data Collection Time Periods for the FY 2020 HAC Reduction Program

The FAH supports the proposals to return to a 24-month performance period for all HAC measures for FY 2020. CMS previously shortened the performance period for the patient safety composite measure to adapt to the switch from ICD-9-CM claims to ICD-10-CM claims in calculating hospital performance on the measure. The FAH also supports proposed changes to align extraordinary circumstances exceptions policies across the various Medicare hospital quality reporting and pay-for-performance programs.

Request for Comments on Inclusion on Disability and Medical Complexity for CDC NHSN Measures

Additionally, the FAH supports the possible future adjustment of the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network infection measures and the Agency for Healthcare Research and Quality (AHRQ) patient safety measures to account for patient medical complexity. Appropriate evidence-based adjustments of these measures to take into account factors that increase risk of infection or patient safety events will only improve the validity of the measures in assessing differences in hospital performance. We agree that patients with certain medical conditions (e.g., diabetes, pulmonary disease, adrenal failure) are at higher risk of infection, and that frailty and functional limitations are risk factors for some patient safety events. CMS also acknowledges that exposure to nursing homes is a risk factor for infection, and we urge that social risk factors also be considered. The ASPE report discusses the limitations of the current hospital-level approach of the CDC measures, and describes work it has underway to use electronic health record (EHR)-based data that would better capture clinical and laboratory results to support risk adjustment. Any work that measure stewards at CDC and AHRQ undertake to make these improvements should be transparent and involve input from technical expert panels and stakeholders. Future risk-adjusted measures should undergo NQF review and

endorsement and review by the MAP before adoption in this program or any of the other reporting and value-based purchasing programs.

Request for Comments on Additional Measures for Potential Future Adoption

CMS notes that the NQF has identified several topic areas for potential outcome-based patient safety measures for future addition to the HAC Reduction Program (falls with injury, glycemic events, adverse drug events, and ventilator associated events). The FAH recommends that as CMS considers possible measures for addition to this program, that the measures be endorsed by the NQF and recommended for the program by the MAP. Additionally, measures adopted for the HAC Program should not be considered for addition to the VBP Program patient safety domain to avoid even more measure overlap than is already in effect. Lastly, given the very large penalties imposed under the HAC Reduction Program, we also recommend that brand new measures not be considered for addition to the program. That is, measures for this program should be drawn from among those with which hospitals and CMS have gained considerable experience under the IQR Program.

Payment for Inpatient and Outpatient Services

V.M.2 Eliminating Inappropriate Medicare Payment Differentials for Similar Services in the Inpatient and Outpatient Settings

In the FY 2018 proposed rule, CMS states its commitment to "eliminating inappropriate Medicare payment differentials for similar services in the inpatient and outpatient settings," citing MedPAC's June 2015 report raising concerns about the appropriateness of inpatient one-day stays. See 82 Fed. Reg. at 20,001, col. 1–2. CMS then requests public comment on ways to identify and eliminate such payment differentials. In response to the policy challenges around clearly defining inpatient versus outpatient hospital services, the FAH has long stated that a payment solution that more suitably compensates for hospital resource utilization and recognizes the central role of the admitting physician in determining the medical needs of the patient is more appropriate than an arbitrary policy that seeks to draw a bright line between inpatient and outpatient services. While the FAH supports CMS's efforts to "prudently pay for high quality care," the FAH rejects the presumption that payment differences between services provided in the inpatient and outpatient settings are per se "inappropriate" and must be eliminated. See 82 Fed. Reg. at 20,001, col. 1. For the reasons set forth below, the FAH generally opposes any short-stay payment policy requiring absolute site neutrality, without any regard for hospital resource utilization, physician judgment, or the unique medical needs of a patient.

First, CMS has not identified any specific statutory authority for altering the prescribed inpatient payment rate calculation for medically necessary inpatient services. CMS has long recognized that the "methodology for arriving at the appropriate rate structure is essentially prescribed" in 42 U.S.C. §1395ww(d)(2). *See* 48 Fed. Reg. 39,752, 39,763 (Sept. 1, 1983)). This Medicare statute defines payments for acute care hospital inpatient services using DRG prospective payment rates, and the statute only allows a Medicare exception to the MS-DRG payment methodology for post-acute care transfers. Short-stay inpatient cases (i.e., inpatient stays lasting less than two midnights) are cases for which, in a physician's judgment, the

condition of the patient justifies the provision of services on an inpatient basis. Absent the applicability of the post-acute care transfer exception, the Medicare Act does not provide for payment for inpatient services under any system other than the inpatient MS-DRG payment methodology.

Second, CMS's longstanding policy recognizes that physicians determine whether and when to admit a patient to or discharge a patient from inpatient care. Because the determination of when to admit and discharge patients lies with physicians, and not with hospitals, it would be fundamentally unfair to reduce hospitals' payments purely on the perceived inappropriateness of a short inpatient stay, given hospitals' limited involvement with that determination.

The FAH urges CMS to reject the assumption that short inpatient hospital stays and any payment differences as compared with outpatient services are *per se* inappropriate. As we and other stakeholders have explained previously, inpatient hospital services differ materially in terms of resource utilization compared to services rendered in an outpatient setting. In particular, inpatient services tend to be more resource intensive early in a patient's stay. The FAH believes that establishing a per diem or similar system would not appropriately recognize the intensity of resources used early in a patient stay. In its evaluation of short-stay models using a per-diem approach (modeled after CMS's existing transfer policy), the American Hospital Association concluded that this per-diem approach would not be a viable option for reimbursing short inpatient stays because it would not account appropriately for resource use. See, Ltr. from the American Hospital Association to Sean Cavanaugh, CMS, Re: Two-Midnight Policy and Potential Short Stay Payment Solutions (Feb. 13, 2015). The FAH has not identified any model or data that could appropriately measure resource intensity such that one-day stay resource use could be matched uniformly to an accurate payment amount.

Finally, CMS's concern about overpaying for inpatient hospital services in short-stay cases rings hollow in the face of the overall negative Medicare margins incurred by hospitals. For example, MedPAC projects that in 2017, Medicare will pay hospitals at a rate 10 percent lower than hospitals' costs. *See*, MedPAC, *Report to the Congress: Medicare Payment Policy* (March 2017), 63–64. Moreover, this aggregate Medicare shortfall continues to increase over time, up from –7.1 percent in 2015. Id. at 64.

Physician-Owned Hospitals

V.O. Request for Information Regarding Physician-Owned Hospitals

The FAH appreciates your request for information on the appropriate role of physicianowned hospitals in the delivery system. There is a substantial history of congressional policy development and underlying research on the impact of self-referral to physician-owned hospitals. The empirical record is clear that these conflict-of-interest arrangements of hospital ownership and self-referral by physicians result in cherry-picking of the healthiest and wealthiest patients, excessive utilization of care, and patient safety concerns. This policy development includes 15 years of work by Congress, involving numerous hearings, as well as analyses by the Health and Human Services Office of Inspector General, the GAO, and the Medicare Payment Advisory Commission (MedPAC). Seven years ago, after a decade of studies and congressional hearings showing the adverse impact of these arrangements, Congress acted to protect the Medicare and Medicaid programs and the taxpayers that fund them by imposing a prospective ban on self-referral to new physician-owned hospitals.

In 2016, using the most recent publicly available data, Dobson | DaVanzo reinforced the findings of Congress, MedPAC, CMS and others. Their analysis in Attachment D compared the performance of non-physician owned full-service community hospitals with physician-owned hospitals identified on the Physician Hospitals of America's (PHA) public-facing website. It provides a clear picture that the characteristics of these PHA hospitals virtually mirror the findings and data collected in the early-to-mid 2000s that drove Congress to enact the law prospectively banning self-referral to new facilities. Among those findings, physician-owned hospitals:

- cherry-pick patients by avoiding Medicaid and uninsured patients;
- treat fewer medically complex patients;
- enjoy all-payer margins nearly three times those of non-physician owned hospitals;
- provide few emergency services an important community benefit; and
- are penalized for unnecessary readmissions at 10 times the rate of non-physician owned hospitals.

Along the same lines, in its comment letter responding to CMS's request for public comments, MedPAC noted that its previous findings regarding the risks of patient selection practices as well as the financial risks to the Medicare program from physician-owned hospitals "are still relevant today."

Concerns about physician-ownership of hospitals extends beyond full-service community hospitals. Physician-owned rehabilitation hospitals are also afforded an unfair competitive advantage over non-physician owned IRFs operating in the same market through the effects of the IRF 60% Rule. The 60% Rule requires that at least 60% of an IRF's cases must be derived from a list of 13 medical categories specified by CMS (known as "CMS-13"). If an IRF does not meet this requirement there are dire consequences – it is not recognized by CMS as an IRF and is ineligible for Medicare's IRF payment rates. The dynamics of physician-owned IRFs are disadvantageous to other non-physician owned IRFs in a given market, because there are a finite number of CMS-13 cases in that market.

Allowing physicians to own IRFs without accounting for the effects of the 60% Rule exacerbates the arbitrary nature of the 60% Rule. An underlying characteristic of the 60% Rule is that it effectively ignores the judgment and opinion of physicians who believe a particular patient suffering from the debilitating effects of an illness or condition that is not a CMS-13 diagnosis, such as cancer or cardiac, should receive rehabilitative care in an IRF. In that way, the Rule is akin to centralized decision-making and functions as a direct limitation on, or even rationing of, IRFs' services. In any case, the Rule is not patient-centered. Yet a physician owner of an IRF is able to gain considerable advantage over other non-physician owned IRFs in a given market by virtue of the Rule's effects in that market, because the Rule encourages and incentivizes the physician owner to refer as many CMS-13 cases to their IRF as possible. This, in turn, means other IRFs in that market will have more difficulty satisfying the Rule, especially

if the physician owners derive their patient referrals from the same general acute care hospital or hospitals as other non-physician owned IRFs.

The FAH strongly believes that the foundation for current law must be fortified, not weakened. It is noteworthy that Congressional Budget Office scoring of proposals to modify existing law consistently demonstrate that self-referral to physician-owned hospitals increases utilization, which increases Medicare costs and health care costs generally. This is a key reason why the <u>U.S. Chamber of Commerce</u> has long supported the ban on self-referral to physician-owned hospitals.

In November 2014, the U.S. Chamber wrote to congressional leadership describing the devastating effects of self-referral to physician-owned hospitals. The letter explains:

"Unbridled, spiraling health care costs is one of the most important challenges facing our health care system today. One legal protection that currently helps combat unnecessary cost increases is a safeguard against certain self-referral practices. When the most profitable patient cases are referred to hospitals where physicians have a financial interest, "cherry-picking" occurs. While this referral practice increases profits for these physician-owned hospitals, such cherry-picking also has the negative impact of leaving the more complicated and poorly reimbursed cases to be treated by neighboring community hospitals.

The Chamber urges Congress to not take a step backward on this policy which has historically enjoyed strong bipartisan support dating back over a decade. Although the Chamber and many lawmakers strongly opposed the Affordable Care Act (ACA) generally in 2010, the Chamber and many bipartisan lawmakers have for years supported the protections and safeguards codified in §6001 of the ACA. This provision is working by appropriately limiting the practice of self-referral to physician-owned hospitals, which increases utilization and costs to businesses and taxpayers, as well as distorting health care markets. The Chamber supports the current self-referral law and opposes any effort to unwind or weaken it."

Efforts to weaken or overturn the prospective ban would harm patients, community hospitals and local businesses. Fortunately, since the enactment of this ban, the system has stabilized. The instability created by the proliferation of self-referral has calmed. Patients can choose the appropriate facility for the procedures and treatments they need, and health care spending has been kept in check. In those instances where grandfathered arrangements have met the law's conditions, they have been permitted to grow.

To be clear, the 2010 law is working exactly as planned to protect taxpayers and ensure a more level playing field – one that promotes fair competition. It is a carefully crafted policy with an important safeguard that permits limited expansion of grandfathered hospitals to meet demonstrated community need. Several physician-owned hospitals, in fact, have met the requirements and are currently on the path to expand.

The FAH agrees with the Chamber that, "Balancing entrepreneurial spirit and sound public policy is no easy feat, but Congress achieved the right balance when it prohibited self-referral prospectively while grandfathering current arrangements...."

The law as it stands protects patients, businesses and taxpayers. It also helps ensure that full-service hospitals can continue to meet their mission to provide quality care to all the patients in their communities.

Hospital-Within-Hospital Regulations

VII.B. Proposed Changes to Hospital-Within-Hospital Regulations

Currently, IPPS-exempt hospitals like LTCHs, inpatient psychiatric facilities and inpatient rehabilitation facilities must comply with the regulations for hospitals-within-hospitals ("HwHs") at 42 C.F.R. § 412.22(e) when they are co-located with another hospital. For cost reporting periods beginning after October 1, 1997, hospitals that met the definition of a HwH must comply with various requirements, including requirements governing the separateness of the two co-located hospitals in order to maintain their IPPS-exempt status.

In recent years, the Center for Medicare and Medicaid Innovation ("CMMI") has introduced initiatives such as bundling and accountable care organizations that are changing the way patient care is provided across care settings and by extension, how hospitals and other care providers are paid. As the healthcare system continues to evolve, providers in the acute care and post-acute care settings will be expected to better coordinate care transitions among care settings and manage care over episodes of care. For these new models to be successful, providers will need support from CMS to remove regulatory burdens and obstacles that impact how they coordinate care across care settings and over the course of care episodes.

CMS is proposing to amend the HwH rule to clarify that an IPPS-exempt hospital colocated with another IPPS-exempt hospital, while still a HwH, would not need to comply with the separateness requirements of the rule. In addition, because of overlap between the performance of the basic hospital functions requirements of the HwH rule and the Medicare conditions of participation and related interpretive guidelines, CMS is also proposing to sunset the basic hospital functions requirements on October 1, 2017.

The FAH finds it encouraging that CMS is studying and proposing modifications to the HwH rule in recognition of the limits that these regulations place on the ability of providers to provide seamless care across the continuum of care. The FAH supports modifications to the regulations that remove obstacles to providers collaborating across healthcare settings. Specifically, the FAH supports the proposed modification to the introductory language of 42 C.F.R. § 412.22(e) that would clarify that on and after October 1, 2017, the separateness and control requirements would no longer apply when two or more IPPS-exempt hospitals are colocated. The FAH also supports the proposed sunsetting of the basic hospital functions requirements outlined in 42 C.F.R. § 412.22(e)(1)(v) also beginning October 1, 2017.

However, the FAH believes the proposed modification to \$412.22(e)(1)(v) is ambiguous and subject to different interpretations. The FAH requests CMS's clarification and confirmation

that the basic hospital function requirements outlined in 42 C.F.R. § 412.22(e)(v) will not apply to any HwHs beginning on October 1, 2017 and that the proposed revision to 412.22(e)(v) should not be interpreted to mean that a HwH must have satisfied one of the basic hospital functions tests prior to October 1, 2017 in order to maintain a PPS exemption. CMS's preamble discussion at 82 Fed. Reg. 20005 only mentions the "sunsetting" and "removal" of §422.22(e)(v)(A) and (v)(B) does not mention the application of (v)(C). If §422.22(e)(v)(C) would remain a requirement, many IPPS-excluded HwHs would lose their status. We do not believe this was CMS intent, but the FAH requests that CMS clarify this in the final rule.

While CMS re-evaluated HwHs in the proposed rule, the FAH would encourage CMS to also revisit hospital co-locations more generally. As outlined above, with the advent of new payment models and various bundled and coordinated care initiatives, healthcare providers are encouraged if not required to work together more now than ever before. Furthermore, in light of the ever-changing payor environment, and the move to more community-based care and fewer inpatient hospital admissions, hospitals are increasingly required to be flexible, nimble and forward thinking. In this landscape, the FAH requests that CMS adopt a more flexible, open approach to hospital co-locations.

For many of the same reasons outlined in the preamble in the discussion on revisions to the HwH rule, the Medicare conditions of participation and interpretive guidelines establish the basic set of rules that all hospitals must satisfy, whether freestanding or co-located with other providers. The FAH believes these requirements can reasonably be satisfied in environments when multiple providers are located in the same building or on the same hospital campus. However, the FAH has learned that in the absence of formal guidance or rules addressing hospital co-location, different CMS regional offices and state agencies are interpreting the existing rules and regulations differently, sometimes in restrictive or limited ways that seem antico-location. At a time when patient care is increasingly moving out of the hospital setting, hospitals need the flexibility and opportunity to use hospital space in creative or different ways, which may mean allowing other providers to operate within the four walls of a hospital or on a hospital campus. The FAH believes that CMS should universally be open to thoughtful hospital co-location arrangements when co-located providers are sufficiently separate and segregated to independently satisfy the existing, applicable regulatory requirements (including, for example, when two co-located hospitals are located in the same building but are completely separate other than common paths of public travel like entrances, corridors and elevators). The FAH does not believe that CMS should be adopting or imposing additional regulatory requirements or interpreting existing requirements in a restrictive or limiting way.

Long-Term Care Hospital PPS

VIII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System ("LTCH PPS") for FY 2018

1. VIII.D. Proposed Changes to the Short-Stay Outlier Adjustment Policy (42 C.F.R. § 412.529)

CMS is proposing to streamline the short-stay outlier (SSO) payment policy at 42 C.F.R. § 412.529 by moving to a single payment methodology, the "blended" option at section 412.529(c)(2)(iv). Under this option, a SSO case is paid based on a blend of the IPPS comparable amount (determined under section 412.529(d)(4)(i)) and the MS-LTC-DRG per diem amount (determined under section 412.529(d)(1) in conjunction with section 412.503). As the patient's length of stay increases, more of the blended payment would be comprised of the LTCH PPS amount. This change would be effective for LTCH discharges on or after October 1, 2017. To ensure this change does not increase aggregate LTCH PPS payments, CMS is also proposing to adjust FY 2018 LTCH PPS payments by a one-time, permanent budget neutrality factor of 0.9672 (i.e., -3.28%).

The FAH supports the proposal to pay all SSO cases using the "blended" option at section 412.529(c)(2)(iv) effective for discharges on or after October 1, 2017. The FAH believes this will help address the payment cliff at the SSO threshold and provide a more gradual increase in payment as the patient's length of stay increases. We understand that CMS is retiring the other three payment options, and the very short-stay outlier policy, as a result. We ask CMS to confirm this in the final rule.

However, the FAH does not support the imposition of a permanent budget neutrality factor to account for this change in SSO policy. A permanent reduction of the standard Federal payment rate by 3.28% is very significant and will place further, undue financial strain on LTCHs that are already grappling with a difficult transition to the two-tiered payment system. The imposition of this budget neutrality factor is not mandated by the original legislation authorizing the LTCH PPS or the dual-rate LTCH PPS system, has not been applied by CMS previously with other changes to SSO payments and will result in less predictability in LTCH PPS payments. The "blended" option is already in the regulation and, therefore, it seems any affect it has on aggregate LTCH payments would have been accounted for previously.

2. VIII.G. Moratorium and Proposed Regulatory Delay of the Full Implementation of the "25-Percent" Threshold Policy

The "25% Rule" is a set of regulatory payment adjustment policies under the LTCH PPS, originally established in the FY 2005 IPPS final rule. In the FY 2017 IPPS/LTCH PPS final rule, CMS adopted a new 25% Rule regulation at 42 C.F.R. § 412.538, effective for discharges in cost reporting periods beginning on or after October 1, 2016. The new regulation is based upon the two existing regulations at sections 412.534 and 412.536, with some notable differences. The default percentage threshold remains 25%, and higher percentage thresholds for rural LTCHs and MSA-dominant referring hospitals are still available. The regulation further provides that multi-campus hospitals must meet the exception at each location. The original 25% Rule regulations at 42 C.F.R. §§ 412.534 and 412.536 continue to apply to LTCH cost reporting periods beginning before October 1, 2016.

59

⁷ 72 Fed. Reg. 26,870, 26,904-19 (May 11, 2007) (adopting the very short-stay outlier policy codified at 42 C.F.R. § 412.529(c)(3)(i)).

⁸ 69 Fed. Reg. 48,916, 49,191 (Aug. 11, 2004).

CMS is proposing to make conforming changes to the 25% Rule regulation at section 412.538 in order to implement the 21st Century Cures Act relief. For LTCHs that may fall in the "gap" period where relief was unavailable (namely, from July 1, 2016 through September 30, 2016) CMS has indicated that it does not expect LTCHs will receive a payment adjustment as a result of this "gap" period. CMS is also proposing to extend the 1-year statutory relief period under section 412.538 by an additional year through regulation, effective until October 1, 2018, so that it will have more data to analyze LTCH admissions practices under the dual rate payment system and "avoid creating any additional confusion by having the 25-percent threshold policy become effective for a period of time when future analysis of LTCH claims data may indicate the policy concerns underlying the 25-percent threshold policy have been moderated." 10

The FAH strongly believes that CMS should completely retire the 25% Rule, no later than October 1, 2017. The new LTCH patient criteria and two-tiered payment system address the same policy concerns 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 25% Rule no longer serves a legitimate purpose (if it ever did).

To the contrary, Congress specified in the Pathway for Sustainable Growth Rate Reform Act of 2013 (Pub L. 113-67) ("PSRA") that patient discharges meeting the new patient criteria would be paid at the standard LTCH PPS payment rate. The 25% Rule policies run afoul of this statutory mandate by reducing payments to otherwise qualified LTCH PPS payment rate cases arbitrarily based on the number of patients discharged from a particular hospital. If a 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. CMS should once and for all retire the "blunt" and "flawed" policy regulated through the 25% Rule and its various regulatory iterations effective immediately, and in no event later than October 1, 2017, the date the statutory moratorium expires for LTCH discharges and when all LTCHs will be subject to the patient criteria and site neutral payment.¹¹

If CMS does not retire the 25% rule in its entirety, the FAH supports CMS's proposal to implement section 15006 of the 21st Century Cures Act and to extend the 1-year statutory relief under section 412.538 by another year by regulation. The FAH requests that CMS confirm that it does not intend to enforce the 25% Rule for the "gap" period in relief between the effective dates of the old and new regulations as it has done before. Importantly, this support is based on the FAH's understanding that all LTCHs will be equally exempt from the 25% Rule regulations

⁹ 82 Fed. Reg. at 20,028.

¹⁰ *Id.* at 20,029.

¹¹ Report to the Congress: Medicare Payment Policy, MedPAC, Ch. 10, at 237 (March 2011). These statements contradict MedPAC's statement in their current comment letter that they have historically supported the 25% Rule. MedPAC comment letter to FY 2018 IPPS/LTCH PPS proposed rule (May 23, 2017), pg. 16.

for both on-campus and off-campus referrals from the date the previous 25% Rule regulations at sections 412.534 and 412.536 no longer apply through discharges on September 30, 2018. The FAH requests that CMS confirm this in the final rule.

3. VIII.I Proposed Changes to the Average Length of Stay Criterion under the 21st Century Cures Act

Section 15007 of the 21st Century Cures Act (Pub. L. 114–255) amended section 1206(a)(3) of the PSRA by excluding Medicare Advantage and site neutral payment rate discharges from the calculation of the average length of stay ("ALOS") for all LTCHs, effective for discharges in cost reporting periods beginning on or after October 1, 2015. To implement this provision, CMS is proposing to remove the final sentence of the regulation at 42 C.F.R. § 412.23(e)(2)(vi). This sentence included site neutral payment rate and Medicare Advantage discharges in the calculation of the ALOS for hospitals classified as LTCHs after December 10, 2013.

In order to initially qualify as an LTCH, a general short-term acute care ("subsection (d)") hospital paid under IPPS must demonstrate to Medicare that after a qualifying period of at least 6 months, it has an average length of stay for Medicare patients of greater than 25 days. In addition, once certified as such, each LTCH must continue to maintain an average length of stay for Medicare inpatients of greater than 25 days.

Section 1206(a) of the PSRA changed the way that LTCHs will be paid by establishing a dual-rate payment system pursuant to which some patients treated in an LTCH will not be eligible for payment at the LTCH PPS standard Federal payment rate and instead, will be reimbursed at a lower "site neutral" payment rate that is closer to the payment that general short-term care hospitals receive. PSRA recognized that, with these changes to the payment system, it would be inappropriate to require site neutral patients to be included in the calculation of whether the LTCH mains the requisite ALOS. As a result, the PSRA provided that, beginning on October 1, 2015, and with a few limited exceptions, both site neutral and Medicare Advantage patients would no longer be included in an LTCH's average length of stay. Under the PSRA, this does not apply to hospitals that were short-term care (subsection (d)) hospitals as of December 10, 2013. It was amended by the PAMA so that only hospitals that were LTCHs as of December 10, 2013 will exclude site neutral and Medicare Advantage patients from their average length of stay.

Inadvertently, the PSRA, as amended, created two different classes of LTCHs around the ALOS requirement—(1) hospitals that were still in their qualifying period to become LTCHs on December 10, 2013, and (2) hospitals that were already LTCHs on December 10, 2013. After the PAMA, there were still two different classes of LTCHs held to two different ALOS standards—(1) all pre-December 10, 2013 LTCHs that exclude these patients from their ALOS, and (2) all post-December 10, 2013 LTCHs that do not. LTCHs established after December 10, 2013 are at a significant disadvantage because of this.

Section 15007 of the 21st Century Cures Act eliminated the exception to the revised ALOS requirement that prevented newer LTCHs (established after December 10, 2013) from excluding site neutral and Medicare Advantage patients from their ALOS. This amended the

PSRA so the revised LTCH payment system would be aligned with the LTCH ALOS requirement for all LTCHs. Site neutral and Medicare Advantage patients are now excluded from an LTCH's ALOS calculation for all LTCHs effective with their discharges in cost reporting periods that began on or after October 1, 2015. The FAH agrees with CMS's proposal to implement this provision by removing the last sentence of the regulation at 42 C.F.R. § 412.23(e)(2)(vi), which included site neutral and Medicare Advantage discharges in the calculation of the ALOS for hospitals classified as LTCHs after December 10, 2013.

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

a. HCO Target Amounts and Fixed-Loss Thresholds

CMS is proposing to continue to use the current high-cost outlier policies for standard Federal payment rate cases and site neutral payment rate cases, as modified in the FY 2016 IPPS/LTCH PPS final rule. Specifically, CMS has indicated it plans to maintain separate HCO targets, one for LTCH PPS standard Federal payment rate cases and one for cases paid at the site neutral payment rate. CMS is modifying the current LTCH PPS HCO payment methodology for LTCH PPS standard Federal payment rate cases in FY 2018, reducing the 8% outlier "pool" to 7.975% pursuant to section 15004 of the 21st Century Cures Act. CMS also is proposing to continue to use the target that is used for IPPS HCO payment of 5.1% for HCO payments to cases paid at the site neutral payment rate.

CMS is proposing a FY 2018 fixed-loss amount for LTCH PPS standard Federal payment rate cases of \$30,081, based upon only cases that meet the new patient criteria; this represents a very significant increase from \$21,943 in FY 2017 and \$16,423 in FY 2016. CMS is proposing a \$26,713 FY 2018 fixed-loss amount for cases paid at the site neutral payment rate, which is the same as the proposed FY 2018 IPPS fixed-loss amount.

While the FAH generally supports using a target amount of 8% (now 7.975%) for HCOs paid using the LTCH PPS standard Federal payment rate, it is once again concerned about another significant increase in the proposed FY 2018 fixed-loss amount of \$30,081 for LTCH PPS standard Federal payment rate cases. This represents a 37% increase from the FY 2017 fixed-loss amount of \$21,943, which also represented a significant increase from 2016. These large increases two years in a row are concerning and not consistent with CMS's policy goal of mitigating instability in the HCO fixed-loss amounts for LTCH PPS standard Federal payment rate cases.

The FAH supports CMS' proposal to use the proposed FY 2018 IPPS fixed-loss amount of \$26,713 for cases paid at the site neutral payment rate in FY 2018, and the same 5.1% target as the IPPS for HCO payments for these cases in FY 2018.

b. Budget Neutrality Adjustment for Site Neutral HCO Cases

CMS also is proposing to continue to apply a budget neutrality adjustment factor under section 412.522(c)(2)(i) to all cases paid at the site neutral payment rate (including the site neutral payment rate portion of blended rate payments during the transition period) so that HCO

payments for site neutral cases will not result in any change in estimated aggregate LTCH PPS payments. The FAH strongly disagrees with the CMS proposal to apply an additional 5.1% budget neutrality adjustment for site neutral cases that qualify as high-cost outliers. As discussed in our comment letter from last year, this BNA is duplicative and unwarranted because CMS has already applied budget neutrality adjustments to reduce the operating and capital portions of the IPPS standard Federal payment rate by the same 5.1%, before using that rate to determine the IPPS comparable per diem amount for site neutral payment cases.

In MedPAC's prior May 31, 2016 comment letter, it 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." The FAH agrees with MedPAC that this BNA is duplicative and should not be applied. CMS should only adjust LTCH site neutral payments once for outlier budget neutrality. The FAH is raising this issue again this year because of CMS's failure to address the issue directly. Since this budget neutrality adjustment has already been applied to site neutral HCO cases in FY 2016 and FY 2017, the FAH urges CMS to reverse these adjustments to all impacted FY 2016 and FY 2017 payments or make a prospective increase in payments for FY 2018 site neutral rate cases to account for this historic underpayment.

5. Other Comments/Considerations: LTCH Patient Criteria & Site-Neutral Payment

a. Clarification of the "Immediately Preceded" Standard

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." In the FY 2017 IPPS/LTCH PPS final rule, CMS amended this definition to fix an incorrect cross-reference. It now 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 did not propose any changes to the definition of a "subsection (d) hospital" in this Proposed Rule.

The FAH recommends that CMS amend the definition of a subsection (d) hospital at section 412.503 to clarify that: (i) a subsection (d) hospital is not required to submit a Medicare claim, and (ii) a subsection (d) hospital need not be enrolled in Medicare as an IPPS hospital. CMS also should re-issue Transmittal 1544 to make conforming changes and to instruct the MACs of these clarifications. The LTCH is responsible for submitting its claim correctly, and the MAC should be responsible for paying the LTCH's claim correctly and promptly.

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¹² MedPAC Comment Letter to CMS re: File Code CMS-1655-P at 16 (May 31, 2016).

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 from proper LTCH payment 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 must 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. By way of example, military and VA hospitals 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, even if the hospital is not Medicare certified as an IPPS hospital. 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.

Based on prior comments submitted in response to the FY 2017 LTCH PPS proposed rule, CMS agreed that the Transmittal 1544 instructions were too narrow. Unfortunately, instead of revising the regulation and Transmittal 1544, CMS issued separate guidance in MLN Matters SE1627 on October 18, 2016 stating that patients may have had an immediately preceding inpatient stay at a subsection (d) hospital that is not present in the Medicare claims processing system (e.g., VA or military hospital). CMS instructed LTCHs who receive a site neutral payment in this situation to contact their MAC who will "work with the LTCH to obtain the documentation it finds sufficient to demonstrate that the applicable criteria for exclusion from the site neutral payment rate have been met and adjust the applicable LTCH claim to make any

appropriate adjustments to payment." This guidance was a step in the right direction, but it does not go far enough to address the issues discussed above.

The FAH understands that a number of LTCHs are still experiencing problems getting claims paid correctly for patients that qualify for LTCH patient criteria. The SE1627 guidance unfairly places the entire burden on the LTCH to contact the MAC, obtain "documentation" to substantiate the immediately preceding subsection (d) hospital stay, and convince the MAC to accept the documentation so that the LTCH can be paid correctly. Moreover, the guidance does not specify the documentation needed of the prior hospital stay. This results in too much subjectivity, inconsistency, and unnecessary regulatory burden. Instead, the appropriate solution is for CMS to clarify, as recommended above, that a subsection (d) hospital patient stay does not need to result in the submission of a Medicare claim under the IPPS, and to revise and reissue Transmittal 1554 accordingly.

b. The impact of Site Neutral Payment on Access to Care

Under the regulation at 42 C.F.R. § 412.522(c)(3), the site neutral payment rate is being phased-in over three years for discharges that do not meet the new patient criteria. For discharges in cost reporting periods beginning on or after October 1, 2015 and on or before September 30, 2017 (i.e., FYs 2016 and 2017) that are site neutral, LTCHs are paid a blended rate of one-half the site neutral payment rate and one-half the standard LTCH PPS standard Federal payment rate. For discharges in cost reporting periods beginning on or after October 1, 2017, LTCHs will be paid at the full site neutral payment rate. Therefore, all LTCHs will begin receiving a full site neutral payment for such cases beginning some time in FY 2018.

CMS has stated repeatedly that it does not expect any changes in the quality of care or access to care as a result of the move to a site neutral payment system. ¹³ This simply cannot be the case. Site neutral payment is the most significant change in the LTCH payment system since the implementation of the LTCH PPS almost 15 years ago. The FAH anticipates real patient access issues as LTCHs adjust to the new dual-rate payment system, especially when the 50% patient criteria "discharge payment percentage" requirement takes effect.

Further, the FAH would expect the costs and resource utilization for LTCH site neutral cases to be very different from IPPS cases assigned to the same DRG, with the LTCH cases involving longer lengths of stay and much higher average costs. By their very nature, the FAH would anticipate that LTCH patients who are admitted directly from short term acute care hospitals where the patients have already received acute care, but continue to have a severe or medically complex enough condition to require an LTCH admission are likely to be much more expensive patients to treat than those assigned to the same DRG upon an initial admission to a short term acute care hospital. As a result, the FAH believes CMS should revise its statements in the final rule so that LTCHs and Medicare beneficiaries are not misled about the impact of the site neutral policies on their health care decisions or access to care.

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¹³ See, e.g., 82 Fed. Reg. at 20,222.

c. 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. For cost reporting periods beginning on or after October 1, 2020, Section 1886(m)(6)(C)(ii) of the Social Security Act requires 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. CMS developed a notification process through sub-regulatory guidance, ¹⁴ but the model notice does not yet specify the process for reinstatement or appeal.

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 an 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.

The FAH believes that CMS should implement a "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, which 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)). If, however, the LTCH does not have a discharge payment percentage of at least 50% for this cure period, 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)). Under the existing statute and regulations, the LTCH would have the right to appeal this agency determination to the Provider Reimbursement Review Board ("PRRB") and obtain subsequent administrative and judicial review. 15

Further, 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.

¹⁴ Transmittal 3373 (Change Request 9253) (Oct. 14, 2015), pgs. 14-15.

 $^{^{15}}$ 42 U.S.C. \S 139500; 42 C.F.R. \S 405.1835 et seq.

Quality Data Reporting

IX.A. Hospital Inpatient Quality Reporting Program

Refinements to Existing Measures in the Hospital IQR Program for the FY 2020 Payment Determination and Subsequent Years

The FAH supports the concept of replacing the pain management questions with questions regarding communication about pain. However, when the MAP considered the revised pain question, it recommended that the measure be refined and resubmitted with testing results. The current language is not NQF endorsed, and the FAH urges that the proposed replacement questions not be implemented until the MAP has had an opportunity to review the testing results and decides whether to recommend to CMS going forward with the replacement questions. The FAH surmises that the proposed new questions are better than the current questions, however, our members would like to see unambiguous evidence that the new questions are proven effective in addressing pain.

The FAH also reiterates our previous comments that the HCAHPS survey needs other changes. In general, the HCAHPS measurement tool has been in use for more than a decade, and has not been considered for overall re-evaluation in a very long time. In particular, the data collecting and reporting modes should be adapted for the 21st century. Our members encounter difficulties in obtaining completed surveys due to the survey length and the limitations of a telephone or paper interview. Allowing beneficiaries to choose to reply to the survey electronically via the web or a phone application would increase survey participation. In addition, the FAH believes that greater participation would result from a shorter survey, which could be accomplished by randomly rotating questions.

Refinement of the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke Hospitalization Measure for the FY 2023 Payment Determination and Subsequent Years

The CMS proposes refinement of the stroke mortality measure to include the NIH Stroke Scale in the measure risk adjustment. The modification has a clinical rationale and was developed with the American Heart Association and the American Stroke Association. The FAH supports this important risk adjustment. However, while the measure is endorsed by the NQF, there are continued concerns on whether the measure can truly be implemented by hospitals since registry data was used as a proxy for EHR data. In addition, the MAP did not support this measure when it was under reviewed in 2016. CMS should retest the measure to ensure that it truly captures data that is valid when extracted from an EHR and submit a revised measure with testing results to the MAP prior to further rule making.

Proposed Voluntary Hybrid Hospital-Wide Readmission Measure

The FAH supports inclusion in the IQR of <u>voluntary</u> reporting of the NQF-endorsed hybrid readmission measure, which is a claims-based measure that draws additional patient-level information for risk adjustment purposes from EHR data. The FAH continues to have concerns

about use of a hospital-wide all cause readmissions measure, but we believe that improved risk adjustment is potentially a very good use of EHR data, and that testing this approach will develop useful information that could apply to other Medicare claims-based measures, not just this one readmission measure. CMS indicates that it may propose this hybrid readmission measure in the future as a mandatory measure. The FAH strongly urges CMS not to finalize the use of this measure in any future payment years at this point. Hospitals and CMS both need several years of experience with this measure before assessing whether it is appropriate to include in a quality payment program. Among other concerns, there are ongoing issues regarding inconsistent specifications of electronic clinical quality measures (eCQMs) across vendors that would need to be evaluated/resolved before EHR data are used for risk adjustment. FAH further believes that EHR data used for measure risk adjustment should be subject to data validation. Any further consideration of this measure should be postponed until additional testing and analysis is completed and a data validation component has been adopted. After these steps are completed, NQF and the MAP should again review the measure for use in public reporting and consequential payment programs.

Given the potential importance of this hybrid approach, we urge CMS to be transparent about its analysis of voluntary reporting and make the results public as soon as they are completed. In addition, the FAH urges CMS to make public the results of the voluntary pilot program for reporting core clinical data elements drawn from the EHR. Public reporting of this data allows all stakeholders to learn from that experience as they work to employ EHR data to measure and improve clinical care.

Proposed Modifications to the eCQM Reporting Requirements for the Hospital IQR Program

The proposals to reduce the reporting burden associated with eCQMs are welcome. The FAH appreciates that CMS proposes for the CY 2017 reporting period/FY 2019 payment determination to reduce the number of reported eCQMs from eight (8) to six (6) for any two calendar quarters. However, the FAH strongly recommends that CMS simply continue the current reporting requirements of four (4) eCQMs for any calendar quarter in CY 2017. It is unclear CMS has the capacity to accept even a modest increase in submitted measures. Rather than expanding the number of measures to be submitted, the FAH encourages CMS to focus its own internal efforts on strengthening CMS's technical capacity for accepting eCQM reporting. As such, the FAH also recommends that CMS maintain the same requirements for CY 2018 reporting period/FY 2020 payment determination.

The FAH also encourages CMS to give higher priority to implementing data validation of eCQMs. The eCQMs pull from set fields of structured data, but there is often significant variation among hospitals and EHR vendors that could complicate validation efforts. This was evidenced in the eCQM validation pilot, where hospitals volunteering in the pilot often found discrepancies between their data and what the CMS contractors determined based on their review of the broader medical record. Unfortunately, these concerns were not addressed due to the limited length of the pilot, and the FAH is concerned that these discrepancies will continue to be a problem in any CMS validation efforts going forward. To properly address these concerns, the FAH suggests that CMS first develop a detailed plan for how validation will be done, including which fields of structured data will be used for validation and how that will compare with

medical record review. The hospital and vendor community should have an opportunity to comment on this detailed plan, and then CMS should undertake a second, expanded pilot to test and further the refine the plan in collaboration with stakeholders. The information garnered during this pilot can then be used to determine what constitutes "successful" eCQM-specific data validation. The specified percentage of category assignment agreement required for successful non-eCQM validation is likely not the appropriate metric of success for eCQM validation due to the variability in eCQM data. However, due to limited experience with eCQM validation, neither CMS nor hospitals or vendors can currently posit on the appropriate metric. Finally, only after ensuring effective data submission and validation systems should CMS consider expanding the number of eCQMs to be reported.

The CMS and The Joint Commission (TJC) also should work collaboratively to better align their systems for compatibility so that hospitals reporting eCQMs to TJC for accreditation purposes are aligned with the CMS eCQM reporting. Both organizations currently provide answers to hospitals' questions and interpretations of the specifications. These inconsistencies between CMS and TJC result in inconsistent data reporting, which increases hospitals' time and cost burdens.

Further, CMS should ensure that eCQM requirements for the IQR Program are aligned with the meaningful use requirements of the Medicare EHR Incentive Program operationally. Our members have reported glitches in how the eCQM reporting works between the programs in practice. Specifically, it is not always possible to confirm eCQM reporting for the IQR Program for purposes of meaningful use because the eCQM submission remains in "pending" status as the meaningful use deadline approaches. Some hospitals have then chosen to attest to meaningful use in order to avoid a penalty. The FAH suggests that CMS extend the meaningful use reporting deadline if eCQM submissions are pending to align with the IQR reporting requirements.

Potential Inclusion of the Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures Measure

Regarding the potential new eCQMs identified in the proposed rule, the FAH strongly objects to consideration of the proposed informed consent eCQM. If the purpose of the measure is to assess patient understanding of the informed consent process, this proposed measure does not get at the root of the issue of understanding. The proposed measure is a structural measure that would be very burdensome to report, requiring abstractors to consistently rate hospital informed consent documents. The FAH is willing to work with CMS to address any concerns about implementation of informed consent requirements; however, this eCQM approach is not the most productive way to address the issue. In general, as noted above, instead of creating new eCQMs the FAH strongly recommends that CMS first focus resources on ensuring consistent measure standards across vendors and enhanced CMS capacity for accepting hospital reporting of eCQMs.

Proposed Changes to the Hospital IQR Program Extraordinary Circumstances Exceptions Policy

As noted earlier, FAH supports proposed changes that would align extraordinary circumstances exceptions policies across the various hospital quality reporting and pay-for-performance programs.

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

IX.C.2. General Considerations Used for Selection of Quality Measures for the LTCH QRP

In general, the FAH has commented previously that the quality measures used for the LTCH Quality Reporting specifically should be tested in the LTCH setting, endorsed by the NQF for the LTCH setting, and recommended by the MAP prior to implementation in the LTCH QRP. To that end, the FAH supports the work CMS has undertaken with Technical Expert Panels for consideration of possible new measures. The FAH encourages CMS to use these panels for advice <u>prior</u> to the development of new measures so that the unique perspective and practical experience of the LTCH community can be factored into the specifications for the measures <u>prior</u> to the measures being fully developed and considered by the NQF for endorsement and the MAP for pre-rulemaking review.

Unfortunately, many of the quality measures CMS proposes for the LTCH QRP are not endorsed by NQF and have not been tested in the LTCH setting. As discussed above, the FAH strongly encourages CMS to ensure that all LTCH measures have been fully specified for the LTCH setting and gone through the full NQF endorsement process; the expedited review using the Time-Limited Endorsement is insufficient. The full review often addresses concerns that are unique to the collection of data in the LTCH setting or to the characteristics of the LTCH patient population, which is very different from other settings in the inpatient and post-acute environments.

Additionally, each measure must be completely specified and appropriate cross-walks provided prior to implementation of the measure. Lack of clear specifications and cross-walks make it very difficult for staff to appropriately implement measures and use the data to improve the care delivered to patients. The FAH requests that the cross-walks be included in the final rule or in a separate publication with significant lead time prior to a measure's implementation.

Lastly, FAH appreciates that CMS has taken steps to reduce the reporting burden for the LTCH QRP. Our members support the removal of the interrupted stay items from the LTCH Care Data Set. However, CMS should consider several other factors when looking at burden in the LTCH setting. Each additional measure requires additional staff time and training, and this training takes time away from patients, particularly when the measure is complex such as the Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay measure.

IX.C.3. Proposed Collection of Standardized Patient Assessment Data Under the LTCH QRP

The *Improving Medicare Post-Acute Care Transformation Act of 2014* (Pub. L. 113-185) (IMPACT Act) requires that CMS collect standardized patient assessment data from LTCHs beginning in FY 2019 on the following categories: functional status; cognitive function; special services, treatments, and interventions; medical conditions and comorbidities; impairments; and other appropriate categories. CMS is proposing to define standardized patient assessment data as patient assessment questions and response options that are identical in all four post-acute care assessment instruments (LTCH, IRF, SNF, and HHA), and to which identical standards and definitions apply.

The LTCH community begins reporting standardized patient assessment data in the FY 2020 program year for these five specified patient assessment categories. For new LTCHs, CMS is proposing that reporting begin no later than the first day of the calendar quarter that begins 30 days after the date on the facility's CMS Certification Number (CCN). CMS also proposes two separate data completeness thresholds: 80 percent completion of measure data and patient standardized assessment collected through the LTCH CARE Data Set and 100 percent completion for measure data collected and submitted using the CDC NHSN tool.

The FAH is concerned about the significant number of data elements required for patient assessment. Our members indicate that at least 32 new data collection points will be required for each patient, and that number jumps to 58 when the sub-points are included. This reporting increases burden on providers by necessitating the hiring and training of new staff, as well as the establishment of new mechanisms to verify the accuracy of the data. The FAH strongly encourages CMS to reconsider the necessity of these data collection points, particularly when data currently reported under the LTCH QRP goes unused. Regardless of the data collection requirements CMS finalizes, the specific data points and reporting requirements must be clearly defined so that LTCHs know exactly what is expected of them.

IX.C.7.b. Proposed Mechanical Ventilation Process Quality Measure: Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay

The FAH is concerned about the inclusion of the SBT by Day 2 of the LTCH Stay measure, as it is not supported by consistent research findings. Many factors influence a patient's ability to be weaned from a ventilator, not the least of which is how a move from one clinical care setting to another may affect a patient overall. LTCH patients are complex medical cases, and the staff may need more than two days to appropriately assess a patient and determine the best course of care for weaning the patient from a ventilator. The FAH strongly encourages CMS not to finalize the SBT by Day 2 of the LTCH stay for the FY 2020 reporting period. The LTCH community needs time to work with the measure to determine if the specifications are truly appropriate prior to the measure's finalization in the LTCH QRP.

IX.C.8. Proposed Removal of the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs from the LTCH QRP

The FAH is pleased that CMS proposed removal of the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from the LTCH QRP. The FAH agrees that removing the measure would reduce duplication with other measures.

IX.C.17. Proposals and Policies Regarding Public Display of Measure Data for the LTCH ORP

The public display of LTCH data began in 2016, and LTCHs have a 30-day preview period to review their data before it is posted to LTCH Compare. As a general principle for public reporting, data for similar measures should not be displayed on LTCH Compare at the same time. For example, when the current Pressure Ulcer measure (NQF #0678) is removed from the program, it should also be removed from the Compare site. This will ensure that there is not any overlap on LTCH Compare between the old measure and the new Skin Integrity: Pressure Ulcer/Injury measure.

The FAH also encourages CMS to focus on making LTCH Compare a useful tool for patients, their families, and providers. This means including enough information on LTCH Compare for users to understand the context of the data and why measures were removed or replaced. Additionally, CMS should consider creating graphics that further explain measure results, such as comparisons with national rates; a raw rate presented in isolation can be misleading. CMS should also convene multi-stakeholder groups to review and provide guidance on the current display of the various Compare websites, including LTCH Compare.

IX.D. Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

IX.D.2. Factors for Removal or Retention of IPFQR Program Measures

The FAH supports the work CMS is undertaking to re-evaluate the current IPFQR measures. The measure set has been in use for several years and has not been evaluated by CMS to assess whether it meets the objectives listed. As CMS has tried to align the IPFQR measures with other quality programs, at times, it has resulted in the adoption of measures that do not meet the needs of patients served through the IPFQR program. Population screening measures and measures drawn and adopted from other programs without appropriate consideration of how they evaluate critical aspects of psychiatric care are an ongoing concern. The FAH strongly recommends that an evaluation of the IPFQR measure set be done before more measures are added to the set. The measure set should focus on the areas that are actionable by providers and demonstrate quality of psychiatric care. While there might value in some circumstances in choosing measures that align with other programs, measures that do not contribute to the demonstration of the value of psychiatric specialty care should not be adopted. The FAH looks forward to working with CMS and the psychiatric field in looking at specific measures to determine whether they meet criteria for removal or retention from the IPFQR program.

IX.D.3. Proposed New Quality Measure for the 2020 Payment Determination and Subsequent Years – Medication Continuation Following Inpatient Psychiatric Discharge

For the FY 2020 payment year, CMS is proposing adoption of the Medication Continuation Following Inpatient Psychiatric Discharge measure. The FAH supports the value of appropriate medication in the follow-up care of psychiatric patients. This measure identifies patients in the Medicare fee-for-service database who have Medicare Parts A, B, and D with a diagnosis of schizophrenia, major depression, or bipolar disorder. Data is collected on whether the patient has filled a prescription for a psychotropic medication within 30 days of discharge from a psychiatric hospital. Data will be publicly reported on individual hospitals and on a small percentage of discharged patients (Medicare fee-for-service patients with Medicare Part A, B, and D). Our members estimate this will be about 20-25 percent of discharges.

The literature supports that medication adherence is an important component of a patient's ability to remain stable in the community. As part of patient care and in anticipation of discharge, IPFs work individually with patients to help them understand the importance of medication in their treatment plan. Patients are taught the effects and potential side effects and dosing schedules of the drugs they will be prescribed. The clinicians work with the patients' Part D plans to assure that patients have access to the medication. When appropriate, they work with the patients' families and caregivers to engage them in post-discharge activities.

Unfortunately, the proposed measure assesses whether a patient filled a prescription. While that is the first step, the measure does not assess whether the patient actually took the medication, which is a far more important measurement. Our members recognize it is a function of outpatient treatment to assess whether a patient is taking their medication. The FAH suggests that this measure be reconsidered prior to implementation and a reworked measure focus on what factors and strategies influence patient behavior in this area. In its current form, this measure is unlikely to be useful to the public in determining the quality of psychiatric care delivered by a given hospital.

IX.D.4. Summary of Proposed and Previously Finalized Measures for the FY 2020 Payment Determination and Subsequent Years

<u>Substance Abuse and Tobacco Measures</u> – The FAH recognizes that many of our members' patients have challenges with alcohol and other substances. As the FAH has stated in previous comment letters, the Alcohol and Other Drug Use Disorder (SUB) measures included in the IPF measure set were developed for broad population screening and do not adequately capture the kind of alcohol and substance use data that is required as the basis for treatment of persons with serious disorders. The modalities (such as brief intervention for alcohol use) have not been tested with patients demonstrating the high levels of alcohol and substance abuse that would justify treatment in inpatient facilities.

Some patients when admitted to an inpatient psychiatric facility are at a point of readiness to quit alcohol or tobacco dependence at the time of inpatient treatment (patients are generally tobacco-free during their hospitalization because of regulatory requirements), yet others are not at a point or readiness. The current quality measures require that treatment is provided (or offered) to all patients during their inpatient stay and at discharge. The FAH has not been able to

document the need for such intervention requirements for all patients who are seriously psychiatrically impaired, during a very brief, stabilizing hospitalization. The FAH finds it difficult to justify the use of very limited resources in ways that are not demonstrated to be effective. There is significant burden to both patients and staff in the application of the measures and the data recording and retrieval processes. It is not clear to our members that the collection of the Tobacco and Alcohol information truly distinguishes high and low performers among providers of psychiatric inpatient services or if the information is helpful in informing the public about the quality of the psychiatric care.

The level of concern about the lack of data to support the use of these measures in the IPFQR program is demonstrated in the MAP's recommendation to delete both the SUB and Tobacco (TOB) measures from the IPFQR set. The MAP noted in its 2017 pre-rulemaking report ("MAP 2017 Considerations for Implementing Measures in Federal Programs") recommendations on the "importance of addressing both substance abuse and tobacco cessation but recommended that CMS prioritize measures that will better address the quality of mental health care." The FAH supports the MAP's recommendation and requests that these measures be deleted.

IX.E. Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the EHR Incentive Programs

As discussed in more detail in the section of this letter addressing IQR and eCQM alignment, the FAH supports alignment of these programs. And, while the FAH appreciates CMS' acknowledgement of the difficulties encountered by hospitals implementing eCQM reporting capabilities – and submitting data to CMS – the proposed modifications to eCQM reporting for the CY 2017 and CY 2018 reporting periods do not go far enough to alleviate these implementation and reporting difficulties. As CMS noted in the proposed rule, "certain challenges and issues (for example, EHR upgrade and system transition challenges associated with the development cycle of technology and the timeframe to develop and execute work flows and processes and train staff based on EHR upgrades and system transitions) may not be fully resolved and as a result, may persist in CY 2018." In order to resolve these challenges, including ensuring that CMS can process the QRDA Category 1 files and confirm for providers that their files have been received and processed, the FAH believes that CMS should maintain the CY 2016 electronic reporting requirements of four measures over one quarter for the CY 2017 and CY 2018 reporting periods.

IX.G. Proposed Changes to the Medicare and Medicaid EHR Incentive Programs

2018 Reporting Period

The FAH supports the proposed modification to the 2018 EHR reporting period for participants attesting under the Medicare or Medicaid EHR Incentive Programs. We appreciate CMS' recognition that additional time is necessary for testing and implementation of 2015 Edition CEHRT and the associated Stage 3 program requirements. The proposed "any continuous 90-day period within CY 2018" is essential for providers struggling to install updates,

test systems, and train staff. The FAH is also appreciative of the timely notice CMS provided for this modification and supports timely notification for any future modifications as well.

Reporting Periods for Providers Undergoing EHR Vendor Transitions

While CMS did not address this in the proposed rule, the FAH recommends that the Agency adopt a permanent 90-day reporting period for providers undergoing an EHR vendor transition in any given year. Transitioning providers have difficulty obtaining and combining data from one certified EHR with data from another certified EHR. For example, vendors are reluctant to provide data once a provider determines it will no longer utilize that vendor's system, or may provide the data in a format that is not combinable with another certified EHR. Should CMS increase the reporting period in future years, we are concerned that these data retrieval difficulties could prevent providers from successfully attesting as meaningful users. Therefore, if an EHR transition occurs, a 90-day reporting period utilizing the new EHR vendor would allow the provider to successfully report on all MIPS performance categories. Additionally, as discussed in the section of this letter addressing IQR and eCQM alignment, the FAH also supports a permanent 90-day (or one quarter) reporting period for eCQMs for eligible providers undergoing an EHR vendor transition in any given year.

Exception for Decertified EHR Technology

CMS is proposing to implement Sections 4002(b)(1) and 4002(b)(2) of the 21st Century Cures Act (Pub. L. 114-255), which provide exceptions to the EHR Incentive Program downward payment adjustment for eligible professionals, eligible hospitals, and CAHs that cannot be "meaningful EHR users" because their EHR technology has been decertified by the Office of the National Coordinator for Health Information Technology (ONC). The FAH supports the two eligibility timeframes CMS has proposed for these exceptions: the 12-month look-back period preceding the applicable EHR reporting period for the payment adjustment year; and during the applicable EHR reporting period for the payment adjustment year. The FAH also supports CMS' proposals for application deadlines for eligible hospitals seeking these exemptions. It is unclear from the preamble, however, what form the application will take (e.g., a standard form created by CMS; a letter from the affected provider; etc.). We encourage CMS to release timely guidance on the application to ensure affected providers are able to avail themselves of these important exceptions.

Certification Requirements for 2018

For 2017 reporting, providers may attest to objectives and measures using EHR technology certified to the 2014 Edition, the 2015 Edition, or a combination of the two. For reporting in 2018, CMS plans to require providers to use technology certified to the 2015 Edition and the associated Stage 3 requirements. The FAH appreciates CMS' acknowledgement in the proposed rule that some providers and eligible professionals may not be ready, and the Agency's solicitation of comments on allowing reporting flexibility should CMS identify "significant issues" with the implementation of the 2015 Edition. The FAH remains concerned about the readiness of providers to report in 2018 using the 2015 Edition due to deployment delays from vendors and the time necessary for implementation and staff training. Thus, at a minimum, we

recommend that CMS permit the same flexibility for the 2018 certification requirements as for the 2017 requirements – attestation to objectives and measures using technology certified to the 2014 Edition, the 2015 Edition, or a combination of the two. Should CMS move solely to the 2015 Edition in a future year, that should be accompanied by a 90-day reporting period – with timely notice to affected stakeholders.

Delay Stage 3 to Re-evaluate and Re-align the Meaningful Use Program

While we support the use of health information technology to improve health care, the current burdens imposed on providers by the Meaningful Use Program - (e.g., increased costs, time, and workflow disruptions) continue to exceed the benefits (e.g., efficiencies and patient care improvements). Several requirements for providers under Stage 3 are dependent upon immature technology, operationally difficult to implement, or requiring the building and use of functionality that is of limited value to patients and providers alike. Delaying Stage 3 would allow for a meaningful evaluation of how well the Program is meeting its goals and to further align the hospital Program with the Advancing Care Information (ACI) category of the MIPS for physicians, including eliminating the "all-or-nothing" standard. Although FAH was pleased with CMS' progress in the OPPS final rule to provide some flexibility for hospitals and CAHs under the Meaningful Use Program, there remains a lack of alignment between those requirements and the more flexible requirements for eligible professionals under MIPS. The FAH urges CMS to make similar modifications with respect to the requirements for hospitals under the Medicare and Medicaid EHR Incentive Programs, and to eliminate the "all-or-nothing" standards that remain there, which would provide for a more meaningful assessment of hospitals as meaningful users of certified EHR technology. In doing so, CMS should seek the greatest alignment possible between ACI category requirements for eligible professionals under MIPS and the hospital meaningful use requirements.

Prevention of Data Blocking

Starting April 16, 2016, MACRA requires that an eligible professional, eligible hospital, or CAH seeking to be a meaningful EHR user must demonstrate that they have not "knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology." Last year, CMS finalized an attestation with three parts, paraphrased as follows:

- Did not knowingly and willfully take action (*i.e.*, disable functionality) to limit compatibility or interoperability of CEHRT;
- Implemented technology and standards to ensure CEHRT was at all times connected, compliant with standards related to information exchange, and implemented in a way that allows for timely patient access; and
- Responded in timely manner to requests made by patients and providers for medical records.

The attestations are overly broad and providers are concerned that even reasonable actions could result in them being inappropriately labeled as "data blockers." The FAH encourages CMS to modify the attestations or provide clear guidance on how these requirements

will be enforced so that all providers understand what actions they need to take and/or avoid in order to be found in compliance.

Survey and Certification Requirements

XI. Proposed Changes Relating to Survey and Certification Requirements

The CMS proposes to make changes in the application and re-application procedures for national accrediting organizations (AO) that are approved by the Secretary. To receive Medicare payments, health care facilities must demonstrate compliance with the Medicare Conditions of Participation (CoPs), Conditions for Coverage, or Conditions for Certification. The FAH member hospital companies generally engage private accrediting organizations, which are deemed by CMS as meeting the standards set forth by CMS and able to perform evaluation of the facilities to assure they meet the CoPs. The private national AOs must demonstrate the ability to effectively evaluate a facility's compliance using accreditation standards that meet or exceed the applicable Medicare conditions, as well as survey processes that are comparable to those survey methods, procedures, and forms required by CMS for conducting Federal surveys for the same health care facility type. These standards generally are outlined in regulations and specified in the State Operations Manual. If a deficiency is found, a facility must submit to CMS an acceptable plan of correction (PoC) for achieving compliance describing how and when, within a reasonable timeframe, the issue will be corrected. The form for submitting the finding of non-compliance is Form 2567. CMS makes public through several different websites hospital quality and safety information. In the proposed rule, CMS also notes that several websites already publicly display survey findings.

In addition, CMS articulates plans to require AOs to post to their own websites any deficiencies or conditions of non-compliance found during a survey and to list the PoC for achieving compliance with the CMS CoPs. CMS would require AOs to post these documents within 90 days of providing the information to the applicable facility.

The FAH has long-supported transparency and public reporting of a variety of data. Our members support providing data that is usable and will enhance a patient's ability to make decisions about their healthcare. The FAH also supports posting of data that offers fair comparisons of similar facilities facing similar challenges. The FAH is concerned, however, that the proposal CMS outlines in the proposed rule does not meet these benchmark tests.

As currently proposed, each AO would be required to report on a website of its creation, in a format of its choosing, the results of its survey of a particular facility. Having disparate data that is not comparable across providers is not helpful to patients and their families. Survey reports can be confusing and the implications of the information presented may not be easily understood. The FAH believes that the public display of such information is beneficial only when presented consistently, with explanations and definitions of critical issues and dangerous non-compliance findings, as well as the process for corrective plans of action. If each AO is permitted to create its own independent display, the public will not benefit from the clear ease and usability of similar data for comparison purposes.

The FAH strongly recommends that, if CMS moves forward with reporting of survey findings that such findings be reported to one centralized site and accompanied by an independent right of appeal for the providers to contest findings before anything is published. We also recommend that the agency convene a multi-stakeholder advisory group to work through the many issues around public display, including the development of a standardized format and language that is consumer-friendly and easily understood by a layperson. The multi-stakeholder advisory group should also discuss which survey findings should be publicly available (e.g., all issues vs. only open issues). For example, if a condition level violation is found and is corrected before the survey agency leaves the location, does that need to be publicly reported?

The survey process is a multi-faceted process and improvement is continuous within healthcare facilities. Frequently, the AOs offer enhanced educational and learning opportunities for best practices that go beyond the CoPs. The FAH recommends that any public display of information be limited only to those issues that are strictly related to federal CoPs; these additional educational opportunities should not be required for public display purposes. This will help users of the data to better understand what is displayed and to compare the same information across facilities. It also will enhance educational opportunities within facilities on new topics added by private accrediting agencies without the fear that a user of the publicly-displayed data could misinterpret such information as a violation.

CMS Flexibilities and Efficiencies

XIII. C. Request for Information on CMS Flexibilities and Efficiencies

We appreciate CMS's request for comments on regulatory, subregulatory, policy, practice and procedural changes that would assist providers in improving the quality of care we provide to our patients. Improvements to items such as the regulatory structure, a rethinking of the framework for delivery system reform efforts, and attention to quality measurement programs would greatly enhance hospitals' ability to fulfill their mission of patient-centered care.

In mid-May, the FAH submitted to HHS an extensive list of regulatory reform items that we believe warrant review and action by CMS. That list is attached as Attachment E to this comment letter, and includes a broad range of issues, *e.g.*, proposed reforms to CMS's post-acute care (PAC) payment policies, Medicaid DSH and supplemental payment policies, and Medicare compliance policies.

We believe the regulatory items on this list would make important improvements to a number of CMS's priority initiatives. For example, HHS should ensure that the Center for Medicare & Medicaid Innovation (CMMI) acts only within its designated authority to voluntarily test alternative payment models (APM), not make permanent or mandatory changes to the Medicare program. Additionally, HHS should indefinitely suspend the troubled Hospital Star Ratings system while the Agency collaborates with stakeholders on appropriate risk adjustment. Additionally, HHS should provide hospitals with flexibility to relocate their provider-based departments to meet community needs and still retain hospital outpatient payments. These items,

and additional regulatory relief and program reform items included in the FAH list, are highlighted further below.

Delivery System Reform

The Important and Appropriate Role for CMMI

The FAH supports the purpose of the CMMI to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing quality of care, with an emphasis on models that improve coordination, quality, and efficiency of health care furnished to Medicare and Medicaid beneficiaries. Such models could, for example, include a voluntary population-based demonstration project under which networks are paid prospective monthly capitated payments for coordinated care furnished to Medicare beneficiaries. Episode payment models, when realistically constructed with sufficient stakeholder preparation time, hold promise as part of CMS's strategy to move from volume to value, and we appreciate the opportunity to be involved with testing these innovative care models.

However, the FAH shares concerns expressed by Secretary Price and others that CMS has overstepped its authority with respect to mandatory demonstrations. We believe that any proposed or finalized requirement for such mandatory provider and supplier participation runs counter to both the letter and spirit of the law that established the CMMI and the scope of its authority to test and expand models under section 1115A.

Any permanent or mandatory changes to Medicare payment systems must be enacted by Congress after taking into account results of models that have been tested. CMS may not impute that Congress granted the agency this authority. The Agency's aggressive and incorrect interpretation of the statute raises issues of impermissible delegation of lawmaking authority where none was intended. This is especially true because Congress precluded administrative or judicial review of a substantial number of matters of CMMI demonstration authority. CMS has successfully demonstrated that it is fully capable of testing models under section 1115A solely through providers of services and suppliers that volunteer to participate in those models. Experience with the Bundled Payment for Care Improvement (BPCI) program shows a substantial number and range of providers and suppliers willing to participate in carefully crafted models. Encouraging voluntary participation by providers and suppliers was the intent of Congress in enacting section 1115A, the manner in which previous demonstrations were conducted, and is the proper and appropriate use of legislatively granted demonstration authority.

CMS's policy mandate under the Comprehensive Care for Joint Replacement (CJR) and the Episode Payment Models (EPM), however, are imposed on providers and suppliers without any testing, as required under section 1115A, and fails to account for difference in types of providers or suppliers, or their particular circumstances. Many hospitals will be challenged significantly in developing these capabilities, such as small hospitals that often have limited financial resources, those that are located in lower income geographic regions, or that incur high amounts of uncompensated care, have low case volume on which to spread financial risk, do not yet have experience with episode-based payment, or lack existing networks with physicians and other providers. The potential consequences for patient care are real.

Keys to Delivery System Reform

Provider investment and payment adequacy. APMs need to have the ability to recover their significant investment in infrastructure necessary for providers to coordinate and manage care for beneficiaries with chronic illnesses (e.g., clinical staff, case managers, upgrades in health information technology and exchange), while at the same time providing some level of predictability and certainty in prices and payments. Medicare beneficiaries with chronic conditions have an expectation that hospitals will continue to provide them with access to a broad range of services, and hospital investment in new infrastructure as well as the rehabilitation of aging infrastructure will be necessary in order for hospitals to continue serving the community adequately. Thus, delivery system reform program must be structured to ensure providers have the opportunity to offset their up-front investment costs.

<u>Transition period</u>. Transformative policies should be adopted incrementally, beginning with voluntary participation and broadening as more providers gain experience with managing financial risk and patient care across the continuum. The transition must be measured and orderly so that the marketplace can adjust to the new incentives of value based purchasing and a culture oriented more towards social and community services and population health. The financial viability of providers participating in APMs needs to be protected through this transition in order to maintain beneficiary access to necessary care.

<u>Flexibility</u>. APMs should continue to offer providers the flexibility to choose different levels of risk-taking—in terms of the types of patients and services at financial risk, the length of time over which care is delivered, and the amount of financial risk—in order to promote broad participation.

Need for Appropriate Administrative Waivers to Allow Hospitals the Needed Flexibility to Delivery System Reform Goals While Managing Legal and Regulatory Risk

As the FAH has noted in commenting on past CMMI bundled payment proposals, the need for protection from various legal and regulatory risks that are inherent in developing coordinated care arrangements between hospitals, physicians and post-hospital providers are necessary for payment model success. Thus, CMMI or other similar CMS-led models must include waivers of program integrity laws, such as the federal anti-kickback (AKS), physician self-referral (Stark Law), and civil monetary penalties (CMP) laws to ensure the integrity of gainsharing and preferred provider network arrangements. Further, these waivers must be coordinated through both CMS and the HHS Office of Inspector General (OIG).

In the absence of such waivers, hospitals and their partners could be exposed to significant risks, and law enforcement and whistleblowers are not likely to be swayed from taking action by the public policy goals of these bundled payment programs. If providers do not have legal certainty in their arrangements to share risk or reward with physicians and post-hospital suppliers, then lawsuits are a distinct possibility.

Accordingly, the FAH recommends that CMS set aside its current piecemeal approach to bundled payment fraud and abuse waivers and develop a single, overarching waiver, a "Bundled

Payment Waiver" of the Stark law and AKS, applicable to all gainsharing arrangements, developed and administered pursuant to the terms of any CMS-led bundled payment program. The Bundled Payment Waiver would apply to models such as CJR, the EPM model, and any future CMS-led, bundled payment programs, with the understanding that CMS could issue program-specific waivers where circumstances warrant a different approach. We have noted in detail, most recently in our comments to the Proposed EPM Rule, how such a Bundled Payment Waiver could be constructed.

In addition to such an all-inclusive program-specific waiver, we encourage CMS to evaluate other waivers that would remove barriers and help level the competitive playing field among PAC providers, and would furnish these providers with the incentives and tools needed to be able to offer PAC care in a manner that contributes to improved quality and efficiencies, while containing costs.

Existing COPs and other regulatory requirements restrict fair competition across PAC providers.

Timely and Regular Data Sharing is Required to Achieve Program Goals

Prior to implementation of a new payment model, it is critical that providers receive relevant and timely historical data, be permitted enough time to analyze the data, and take appropriate action with participant partners. The data must be provided prior to the start of the program, and at regular intervals (*e.g.*, monthly) throughout the program.

To successfully manage risk, hospitals must have sufficient time and data to analyze and understand the composition, characteristics, and needs of their patient population. If healthcare providers are expected to improve patient care and outcomes and enhance their value to other healthcare providers, then they must have greater access to information and data about their patients following their treatment of them. Otherwise, they will not have a meaningful baseline on which to improve.

Appropriate Quality Measurement

In a value-based healthcare delivery model, payment is adjusted to reflect the quality of care delivered under the model. As such, the quality measures used for adjusting payments should have clear links to the condition or treatment upon which the model is focused. Additionally, the measures must be aligned with the parameters of the model. For instance, in the EPM mandatory bundled payment model, CMS proposed using at least two clinical measures that are 30-day measures while the payment model pays for 90-day episodes. This misalignment creates potential issues such as how to generalize results to the 90-day episode. The models should also incorporate measures that are relevant to each part of the delivery model, avoiding measurement gaps. Importantly, prior to implementation of any model, participants need full access to their historical quality data, some of which is available to them only through CMS. Meaningful, collaborative, quality improvement initiatives do not happen overnight, and implementation should not be undertaken until providers have had sufficient time to analyze and act upon their data. Further, quality improvement programs are most likely to succeed when

frequent, actionable feedback is provided to program participants. Participants should be provided with automatic performance updates at least quarterly.

Supporting Post-Acute Hospital Care

PAC providers are an essential component of episodic-based care delivery and reimbursement models and is a key ingredient toward improving and expanding care coordination and provider collaboration activities.

In order for these models to fully succeed, PAC providers must be provided reimbursement flexibility and regulatory relief, including within APMs. As the FAH has argued in comments to both the CJR and EPM rules, PAC hospitals should have the choice of receiving optional lower reimbursement from Medicare in APMs where they are primary or secondary risk holders, such as serving as a participant in the BPCI program or as a "collaborator" under the CJR model. PAC providers electing to be reimbursed with lower rates than what they otherwise would receive from Medicare should receive relief from the effects of burdensome rules and regulations that were designed in the 1980's and early 1990's in the era of fee-for-service reimbursement. These rules include the "60 percent rule," which is intended to distinguish IRFs from acute hospitals and to justify Inpatient Rehabilitation Facility (IRF) Prospective Payment System (PPS) rates, and the "3-hour rule," which requires that each patient must receive at least 3 hours of therapy per day for at least 5 days per week.

Achieving the Promise of HIT

The FAH encourages greater flexibility in the Meaningful Use Program. This will help ensure improvements in technology align with the real-world practice of medicine and includes alignment of the hospital and physician programs. We encourage CMS to delay implementation of Stage 3 to allow a meaningful evaluation of the Program to determine whether it is meeting its intended goals of better patient care, reduced provider and patient burden, and reduced medical costs. Delaying Stage 3 would also give CMS time to further align the hospital Program with the ACI category of the MIPS for physicians, including eliminating the "all-or-nothing" standard. The FAH supports the proposed 90-day reporting period in 2018, and appreciates the timely notification from CMS. This modified reporting period in 2018 is essential for hospitals and other providers to implement system updates and undertake staff training.

Making the Hospital Quality Programs Work

The FAH believes public reporting of provider quality data that is reliable, valid, and meaningful to consumers is vital to creating the patient-centered health care delivery system that we strive to achieve. Numerous studies have shown patient care improvement and greater efficiencies in care provided by acute and post-acute care hospitals through the public reporting and payment programs. However, the three major value-based purchasing programs: Hospital Value-base Purchasing (HVBP), Hospital Readmission Reduction program (HRRP), and the Hospital Acquired Condition Reduction Program (HACRP) have significant overlap and are ripe for reconsideration, including the addition of appropriate risk adjustment for critical

sociodemographic status (SDS). The FAH believes these programs should be refined to focus on rewarding both improvement and attainment of established goals.

The FAH supports the CMS work to make provider quality measurement and payment data more transparent, reliable, and useful for patients and their families. Unfortunately, the latest CMS transparency effort - the Hospital Star Ratings system - suffers from significant deficiencies, including the lack of SDS adjustment, resulting in unintended consequences and misleading information that could do more harm to consumers than good. These deficiencies should be addressed.

Further, for the federal quality payment programs to work well, providers need quick and complete access to their own data as well as patient data post-discharge in order to use it for quality improvement. Providing acute and post-acute hospitals with timely and complete patient level data for outcomes measures such as readmissions is essential.

In a refined quality payment structure the number of quality measures should be reduced and only those measures that truly make a difference in patient health and are predictors of value should be implemented. Hospitals also must be able calculate their own measure performance, which currently is not possible with many of the claims-based outcomes measures. In the evolving world of quality payment, the FAH is hopeful that quality measurement data eventually will be drawn directly from the electronic medical record ("EMR"). However, much additional work is needed before that will become an effective quality measurement tool.

In addition, integral to meeting the goals of the CMS pay-for-value programs is the role of the National Quality Forum (NQF) and its public-private partnership, the Measure Applications Partnership, which provides input into the quality and performance metrics used in those programs for hospitals and other health care providers. The role of the NQF in this process is now well established and accepted and has assisted with providing greater transparency in measure selection for the wide variety of federal payment programs.

An efficiently functioning infrastructure to support federal quality data collection and reporting is essential to producing valid data to inform payment adjustments. The FAH strongly encourages CMS to ensure there are sufficient resources available for appropriate oversight and testing of all data collection and reporting systems to ensure full functionality of the CMS and Centers for Disease Control and Prevention (CDC) data system and warehouses. The hospitals represented by the FAH regularly experience system failures at both CMS and CDC, adding considerable and avoidable costs, in resources and time, to both HHS and the reporting hospitals, and eroding trust and confidence. The payment and quality programs are ineffective if the data being used to inform consumers and calculate payment are inaccurate or incomplete.

Evaluating CMS Regulations

Hospitals are committed to ensuring patients receive high-quality care and believe a comprehensive review and repeal or revision of regulations that are outdated, ineffective, or otherwise overly burdensome will further our shared goals of improving health outcomes and efficiencies in care delivery. As noted earlier, we submitted an extensive list of items, which we

believe warrant CMS review and action. Listed below are just three examples of regulations which deserve attention.

Permit Hospital Provider-Based Departments to Relocate to Meet Community Health Needs

CMS should provide hospitals with broad flexibility to relocate provider-based departments, whether on- or off-campus, and retain hospital outpatient payments. At minimum, a number of exceptions, such as lease expiration and organic growth and community needs, are necessary for hospitals to deliver efficient, high quality care in a safe location. In addition, this flexibility would enable hospitals to successfully renegotiate favorable lease terms, comply with local building codes, and preserve access to care in the aftermath of a natural disaster. Rural hospitals, for example, serve communities spread across larger geographic areas, making off-campus outpatient departments an important avenue to providing services needed by the community. As new employers arrive, expand, and contract or new housing developments are constructed, a rural community's needs can shift dramatically, and hospitals ought to be in a position to adapt to meet those needs. CMS regulations, however, unreasonably restrict a hospital's ability to do so by stipulating that under most circumstances an existing provider-based department that relocates would forfeit its ability to be paid as a hospital outpatient department.

Ensure Meaningful MIPS Measurement and Maximize Advanced APM Participation

CMS should set a path for the Quality Payment Program (QPP) for 2018 and beyond that ensures meaningful measurement in the Merit-Based Incentive Payment System (MIPS) reporting and that maximizes participation in Advanced APMs. As CMS transitions to the OPP. so far the Agency has chosen a large set of potentially reportable measures from which clinicians can choose. Instead, FAH encourages CMS to rapidly move to a streamlined set of standardized high-priority measures that would align incentives and actions across the health care system. The move to streamlined measures should include allowing hospital based clinicians to utilize hospital quality measures for measurement under MIPS, as envisioned in the Medicare Access and CHIP Reauthorization Act (MACRA). In last year's final QPP rule, CMS projected that the vast majority of physicians would not reach Advanced APM Qualifying Participant (QP) status and thus would not be eligible for the five percent bonus. CMS should allow more APMs to be designated as Advanced APMs. Additionally, as the CJR model is currently underway, CMS should, as we commented in our letter to CMS regarding the delay of the EPM bundling program, implement the finalized changes to the model on July 1, 2017 in order for CJR to qualify as an Advanced APM. Adopting additional options – other than payment amount and patient count – for use in determining the Advanced APM Threshold Score will also increase Advanced APM participation by not disadvantaging multispecialty practices. Finally, CMS should revise the financial risk definitions: to provide Advanced APM status to APMs transitioning from one-sided to two-sided risk; and begin at lower levels of financial risk that gradually increase over time.

CMS should delay the January 1, 2018 implementation date for ordering providers to consult appropriate use criteria (AUC) and for furnishing providers to submit claims based documentation. Specifically, CMS should allow a 12 to 18 month implementation timeframe after CMS approval of the clinical decision support mechanisms (CDSMs) providers can use to consult AUCs. The list of approved CDSMs is not expected until this summer, leaving very little time for providers to work with their health information technology vendors to implement these new requirements under the Protecting Access to Medicare Act of 2014 (PAMA). Additionally, in order to enable beneficiaries to receive necessary, timely services, CMS should develop a pathway for a furnishing provider to perform and receive reimbursement for advanced imaging when the ordering physician does not consult CDSM.

Maximizing the Potential of Telehealth

The recent advancements in medical technology have greatly expanded the opportunities for patients to receive care in settings that are convenient to them, and in a timely manner, while being responsive to individual needs. Early health interventions, often accessible only through telehealth technologies, can help curb the growth of health care costs by preventing long-term costly catastrophic health events from occurring. From remote patient monitoring for chronic care management to access to care from specialists, telehealth is an expanding field that is dramatically improving the way health care is provided and can accelerate ongoing efforts to clinically integrate care. Unfortunately, patients are unnecessarily denied access to the use of telehealth technologies because the federal government has not kept pace with the advancement of health care technology.

The FAH believes CMS should more aggressively expand patient access to medical and behavioral health care using telehealth technologies. Currently, Medicare covers only a very limited set of services, and CMS must approve new services for telehealth coverage on a case-by-case basis – a cumbersome and costly process. The FAH encourages CMS to exercise its authority, including CMMI's demonstration authority, to reform current coverage and payment rules for telehealth and remote monitoring technologies. Considering the use of Medicare's innovation authority to loosen originating site restrictions is one way to spur the future use of these technologies. Increasing access to care – primary, behavioral health, specialty and subspecialty – through telehealth is an efficient way, to improve health outcomes for beneficiaries in both rural and underserved urban areas.

Outlier Payments FFY 2018

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

For FY 2018, CMS has proposed a case be eligible for high cost outlier payments when the cost of the case exceeds the sum of the of the prospective payment rate for the diagnosis related group ("DRG"), any indirect medical education ("IME") and disproportionate share hospital ("DSH") and Uncompensated Care payments, any add-on payments for new technology and the proposed fixed loss threshold of \$26,713. The present threshold, which has been in effect since October 1, 2016, is \$23,573. 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 still exceeds five percent. We do note that the reduction between the proposed and final rule's outlier threshold for FY 2017 was well below that average and we continue to be concerned that threshold was set too high. We address in more detail our concerns below.

The proposed threshold for FY 2018 represents an increase of more than \$3,000 over the outlier threshold CMS used for FY 2017, with no clear basis in the data made available to commenters to explain why such a dramatic increase in the threshold would be required to approximate the 5.1% target for outlier payments as a portion of total DRG payments. We are particularly concerned about the magnitude of the increase given that for FY 2016, when the threshold was set at \$22,544, Watson Policy Analysis ("WPA"), see the attached report *Summary of Research Modeling FY 2018 Proposed Inpatient Prospective Payment System Outlier Payments* (Attachment F) at pp. 4-5¹⁶, indicates that outlier payments as a proportion of DRG payments will be about 5.27%, which is still lower than CMS' estimate of 5.37%. See 82 Fed. Reg. at 20175, col. 1. Given that the threshold applied in FY 2016 appears to result in total outlier payments only nominally above the 5.1% target, ¹⁷ it is particularly questionable whether such a significant 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 2018 proposed rule, CMS again offers a table with quarterly total charges and claims data for the eight quarters used to calculate the charge inflation factor. In addition, this year, like last year, CMS offers a more detailed summary table by provider with the monthly charges that were used to compute the charge inflation factor. The FAH appreciates the additional data, but maintains that CMS has not provided enough specific information and data to allow the underlying numbers used in CMS' calculation of the charge inflation factor to be replicated

¹⁷ CMS declined to estimate the actual outlier payments for FY 2017 in the Proposed Rule, stating that it was unable to do so because MedPAR claims data for the entire FY 2017 will not be available until after September 30, 2017. 82 Fed. Reg. at 20,175, col. 2.

¹⁶ All of the tables herein appear in the WPA report except for the table in section D of the comment, also prepared by WPA, but supplemental to the WPA report.

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 2017 proposed rule, CMS estimated that its "current estimate, using available FY 2015 claims data, is that actual outlier payments for FY 2015 were approximately 4.68 percent of actual total MS-DRG payments." See 81 Fed. Reg. at 25,273, col.3. We are concerned that CMS believed it would hit its 5.1% target amount for FY 2015, only to learn later that its original estimate was overstated, and, notwithstanding, still raise the threshold for the subsequent year.

In this year's proposed rule, CMS states that its "current estimate, using available FY 2016 claims data, is that actual outlier payments for FY 2016 were approximately 5.37 percent of actual total MS-DRG payments." See 82 Fed. Reg. 20,175 at col. 1. However, WPA's analysis concludes this figure is overstated. See WPA Report at Analysis 3, pp. 4-5. Specifically, WPA concluded that the outlier payments for FY 2016 amount to 5.27% of total DRG payments, as illustrated below:

Data Source	Operating IPPS Payments Net of IME, DSH and Outlier Amounts (\$) (Does not include Capital	Outlier Payments (\$)	Outlier Payment Level (%)	Total Medicare Payment (\$)
MedPAR 2016 Actual Outlier Payments, FY 2016 Final Rule Impact File Adjustment Factors.	81,767,595,191	4,552,819,444	5.27%	\$108,795,465,363

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

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

Federal Fiscal Year (Month of HCRIS release)	Number of cost reports	IPPS Payments Net of IME, DSH and Outlier amounts	Outlier Payments	Outlier Payment Level (%)	Target Outlier Payments (5.1%)	Shortfall in Outlier Payments
FY 2013 (December)	2,875	\$75,513,803,937	\$3,820,292,807	4.82%	\$ 4,058,170,707	(\$237,877,900)
FY 2013 (March)	3,047	\$80,760,714,604	\$4,270,125,578	5.02%	\$ 4,340,143,777	(\$70,018,199)
FY 2014 (December)	2,388	\$63,505,784,324	\$3,085,415,408	4.63%	\$3,412,850,369	(\$327,434,961)
FY 2014 (March)	3,054	\$82,479,662,313	\$4,343,131,876	5.00%	\$4,432,521,368	(\$89,389,492)
FY 2015 (December)	2,850	\$78,849,610,927	\$3,847,264,205	4.65%	\$4,238,185,938	(\$390,921,733)
FY 2015 (March)	3,036	\$84,552,076,553	\$4,283,484,754	4.82%	\$4,543,853,974	(\$260,369,220)

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

C. Using Most Recent Data To Calculate The Threshold

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

FY	Final	Proposed	Variance	%
				Variance
2009	\$ 20,045	\$ 21,025	\$ (980)	-4.66%
2010	\$ 23,140	\$ 24,240	\$ (1,100)	-4.54%
2011	\$ 23,075	\$ 24,165	\$ (1,090)	-4.51%
2012	\$ 22,385	\$ 23,375	\$ (990)	-4.24%
2013	\$ 21,821	\$ 23,63018	\$ (1,809)	-7.66%
2014	\$ 21,748	\$ 24,140	\$ (2,392)	-9.90%
2015	\$ 24,626	\$ 25,799	\$ (1,173)	-4.55%

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¹⁸ 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.

2016	\$ 22,544	\$ 24,485	\$ (1,941)	-7.93%
2017	\$ 23,573	\$ 23,681	\$ (108)	-0.46%

While the FAH can only speculate as to why this drop in the threshold occurs, the FAH believes the decline is most likely due to the use of updated CCRs and/or additional/other data in calculating the final threshold. This again emphasizes that CMS must use the most recent data in order to appropriately calculate the outlier threshold.

With regard to the current rule-making, we note, for example, that CMS has used data from the December 2016 PSF file, but that at the time the proposed rule was issued, the March 2017 PSF file was available. We had WPA attempt to replicate CMS's methodology in setting the threshold using the same data CMS indicates it used for the proposed threshold. Correcting for the revised transfer weights, WPA was able to replicate the threshold within \$75, accepting CMS's charge inflation factor as accurate only because it could not replicate that factor due to a lack of supporting information for CMS's calculation. Thus, we have high confidence that WPA understands CMS's methodology and has accurately modeled that methodology such that inputting more current data will yield a threshold that will be more likely to meet the target percentage of 5.1%.

We are particularly interested in whether, for the FY 2017 and FY 2018 proposed rule, CMS used more updated data than it had used in prior years to calculate the proposed threshold. If that is the case, then CMS' use of more updated data to calculate the proposed threshold may explain why the variance between the proposed and final threshold for FY 2017 was much smaller than the variance we had seen in prior years, and why we may see a significantly smaller variance between the proposed and final threshold for FY 2018 as well.

D. Accounting For Outlier Reconciliation

The FAH has repeatedly requested that CMS release information on the outlier reconciliation process and data showing the amounts recovered so that it can evaluate the impact of the reconciliation process on the outlier threshold. In the Proposed Rule, 82 Fed. Reg at 20,173, col. 3, CMS addresses its decision not to consider the impact of outlier reconciliation in its determination of the outlier threshold as follows:

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

The FAH has concerns regarding CMS's decision not to consider outlier reconciliation in developing the outlier threshold and its failure to provide any objective data concerning the number of hospitals that have been subjected to reconciliation and the amounts recovered during this process. We are certainly aware that in February 2003, the Secretary signed an emergency interim final regulation that would have corrected the outlier threshold to account for reconciliation, but that the rule was not issued because of objections from the Office of Management and Budget. If it was possible to correct the outlier threshold at the time reconciliation was first being proposed, it is difficult to understand why, with fourteen years of reconciliation experience, that cannot be accomplished. We are particularly concerned with CMS's failure to consider adjusting for reconciliation this year given CMS's projected charge inflation factor of 10.4% over two years, which, if costs were held constant, would suggest that a significant number of hospitals could be subject to reconciliation.

Historical Outlier Reconciliation Payments Using the 1996 and 2010 HCRIS File¹⁹

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

The FAH again requests that CMS disclose in the final IPPS rule and future proposed and final IPPS rulemaking 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

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

¹⁹ Outlier reconciliation from 1996 and 2010 format HCRIS cost reports Using Worksheet E,

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 rulemaking and to be transparent about the amounts involved in that process.

E. Extreme Cases Significantly Skew the Fixed Loss Threshold

The FAH also asks CMS to consider whether it is appropriate to include extreme cases when calculating the threshold. WPA conducted various examinations and probing of data to understand the factors that drove CMS to increase the threshold over \$3,000 between FY 2017 and FY 2018, and observed that the inclusion of extreme cases in the calculation of the threshold significantly impacts its determination.

In the IPPS rate-setting process, statistical outliers (i.e., extreme cases) are generally removed from calculations on the basis that they improperly skew those calculations. In calculating the outlier threshold, however, those statistical outliers are not excluded from the calculation. To observe the impact of these statistical outliers on the calculation of the threshold, WPA calculated how the threshold would differ after the removal of cases that had total charges above particular trim points. The results of WPA's analysis are included in the table below:

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

The table illustrates that the removal of a relatively small number of extremely high cost (using total charges as a proxy for cost) cases from the calculation significantly decreases the threshold. For example, removing all cases with total charges above \$2,000,000 (738 cases) drives the threshold down over \$1,000. Removing all cases at certain other thresholds, lower than \$2,000,000, but still high enough to be considered extreme high cost cases, drives the threshold down even further. For example, removing all cases with total charges above \$1,000,000 (5,679 cases) drives the threshold down over \$3,000, and removing all cases with charges above \$500,000 (38,637 cases) drives the threshold down over \$8,000.

WPA also noted that the number of extreme cases has been steadily increasing over time. To demonstrate this trend, WPA created the following table illustrating the number of cases with a covered charges above \$1.5 million for each of the past several years:

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

If this trend continues (that is, if the number (and proportion) of extreme cases continues to increase each year), the impact of this population of cases on the threshold will likewise increase. Thus, it is imperative that CMS carefully consider whether the inclusion of these cases in the calculation of the threshold is appropriate.

The FAH urges CMS to consider the removal of extremely high cost cases from its calculation of the threshold. Not only is this consistent with the calculation process used for IPPS rate setting generally, but it will also produce a threshold that more accurately reflects the universe of cases.

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The FAH is not proposing a threshold for FY 2018. While we have confidence in the work of WPA, its work is dependent on a large variable in the outlier calculation, charge inflation, that we cannot verify from the limited information that CMS has provided. We also note that the impact of the inclusion of extreme cases in the calculation of the Fixed Loss Threshold is significant, and urge CMS to consider whether the inclusion of these cases is appropriate. Finally, we recognize that with the release of the MedPAR Final data with additional claims, which will lead to new weights being calculated, and with updated cost to charge ratios, it is appropriate to recalculate the Fixed Loss Threshold from the data that will be released with the final rule.

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

Sincerely,