Federation of American Hospitals®

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April 19, 2017

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

Re: CMS-5519-IFC; Medicare Program; Advancing Care Coordination Through Episode Payment Models (EPMs) Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model; Delay of Effective Date

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, short-stay acute, inpatient rehabilitation, long-term acute care, psychiatric and cancer hospitals in urban and rural America, and provide a wide range of acute, post-acute and ambulatory services. The FAH appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services ("CMS") on the above notice of rulemaking, published in the *Federal Register* (81 FR 14464-14466) on March 21, 2017.

We appreciate CMS's action to delay the implementation of the program as it will give the Agency more time to review the model and implement necessary changes important to its success. Given that CMS has indicated it will thoroughly review the model, the FAH has provided below not only our comments on the proposed implementation timeline but also on changes we believe should be made to the model prior to its implementation.

COMMENTS ON PROPOSED DELAY

I. The FAH Urges CMS to Delay the Start Date of the Episode Payment Models Until at Least January 1, 2018

FAH members appreciate the opportunity to test innovative care models developed by CMS's Center for Medicare & Medicaid Innovation ("CMMI"), and believe that the three new EPMs ―acute myocardial infarction ("AMI"), coronary artery bypass graft ("CABG"), and surgical hip/femur fracture treatment ("SHFFT")―and the new cardiac rehabilitation ("CR") and intensive cardiac rehabilitation ("ICR") incentive payment model could hold significant promise. We also appreciate the critical and central role that hospitals will play in these models and look forward to working with CMS to help build and implement effective and successful payment models.

The FAH and its members, however, have become increasingly concerned about the pace of change mandated by CMS and the unreasonable expectations and burden that such rapid and multiple changes in the delivery system and related payment structure place on hospitals and their work forces. Simply put, this is too fast and too soon. We strongly believe that, at a minimum, CMS first needs to evaluate and learn both from hospitals' Comprehensive Care for Joint Replacement Model ("CJR") experience before even considering expanding that model, and from the Bundled Payments for Care Improvement ("BPCI") initiative Model 2 results. Establishing "proof of concept" is a very important tool to utilize before implementing new mandatory EPMs that could affect large numbers of Medicare beneficiaries and potentially have significant and adverse unintended consequences if not implemented using a reasonable, thoughtful, and deliberate approach.

The BPCI Model 2 is most analogous to the EPM approach, as the BPCI Model 2 design includes the anchor admitting hospital stay and all related professional services for a chosen episode length of 30, 60, or 90 days. In August 2016, CMS released the BPCI Year 2 evaluation and monitoring report, which raises questions, in particular, about the cardiac models[1]. Results from the evaluation of year 2 results showed no statistically significant difference in Medicare payments and an increase in mortality for the cardiovascular surgical episodes between the BPCI and comparison groups. While CMS states that subsequent results do not show a statistically significant increase in mortality between the comparison and BPCI groups, the initial increased mortality findings are very concerning. Moreover, while there was a significant reduction in utilization of institutional post-acute care settings, there were instances where BPCI patients exhibited less functional improvement. This suggests that hospitals will need more time to do more work developing effective collaborative relationships in determining optimal sites of post-acute care and establishing effective transitions to appropriate home health care. Also, additional work in developing collaborative relationships is predicated on having appropriate legal waivers under the fraud and abuse laws, which were not released in conjunction with the January 3 EPM final rule, and this has a significantly chilling effect on these efforts.

FAH members believe that EPMs, when realistically constructed with sufficient stakeholder preparation time, hold promise as part of CMS's strategy to move from volume to value. FAH members also appreciate the opportunity to be involved with testing these innovative care models. **However, given the challenges outlined and the lack of preparation time for hospitals, the FAH strongly recommends that CMS delay the start date of the EPMs until**

[1] The Lewin Group. (August 2016). CMS Bundled Payments for Care Improvement Initiative Models 2-4: Year 2 Evaluation & Monitoring Annual Report. Prepared for the Centers for Medicare & Medicaid Services.

no earlier than January 1, 2018, and no sooner than six months following the date the final rule is posted. If the final rule is delayed beyond July 1, 2017, we urge CMS to provide hospitals with at least six months of preparation time from the date the final rule is finalized before its provisions take effect.

Based on our members' experience with implementing CJR, BPCI, and the Medicare Shared Savings Program ("MSSP") program, hospitals and their collaborating partners have ideally needed at least 12 months to transition to episode payment models. This time was needed to build the clinical, legal, financial, and quality infrastructure; analyze and understand the clinical and cost data; educate providers and staff; and develop capabilities and networks required to successfully launch the model. Most importantly, our hospitals stressed that most of the time was needed to do the hard work necessary to redesign the clinical care patient care model in a manner that ensures patients receive the most appropriate and optimal care.

The BPCI initiative experience, in particular, is very informative to what is necessary and what is a realistic implementation timeline to position hospitals and their patients for success, and this experience suggests that the proposed timeline will be very difficult to meet. BPCI participants were largely enthusiastic volunteers who seemingly were well positioned to adopt and adapt to the new model, yet many still found the program and timing demands very challenging, as evidenced by the significant departures from that program. Mandating this, especially for unprepared participants, brings even greater challenges and increases the chance of failure and disruption of health care services for Medicare beneficiaries.

Moreover, the June 9, 2015 MSSP final rule recognized that an even longer timeline may be required by providers to transition from traditional fee-for-service to a value-based alternative payment model ("APM"). This timeline allowed Track 1 Accountable Care Organizations ("ACOs") to continue participating under Track 1 for an additional three-year agreement period. The Track 1 option is a one-sided model with no down-side risk, and the vast majority of MSSP ACOs are enrolled in Track 1. We believe the recognition that time is needed for providers to gain experience and manage and analyze claims data in the MSSP ACO context is also appropriate for these episode payments models, especially given it is a mandatory program, and with two-sided risk.

In addition, there are several other reasons that support the FAH's request for a further delayed start date:

- ***A Hospital's Pre-implementation Administrative Work and Data Analysis for these EPM Models is Very Significant and Vital to the Success of the Program.***

Similar to our concerns with the implementation of the CJR model, the experience of our hospital members has shown that there will likely be considerable administrative burden and time necessary to establish physician arrangements, provider networks, and other business arrangements to operationalize and train staff on how to handle patients in these new EPM models. Hospitals need sufficient time to conduct preparatory market analyses, understand the clinical and financial risk of their patient populations, form networks with select physicians and other providers, and establish the needed organizational capabilities to manage payment bundles.

- ***The Variation in Hospital Preparedness and Capabilities for Managing Health Care Episodes Means that Many Hospitals Will Not be Prepared on the Proposed Timeline.***

Given the mandatory nature of the demonstration, as well as the number of and variation across hospitals that will be participating in this program, it is imperative that CMS proceed with caution. As discussed in more detail below, the FAH believes that these EPMs must be structured in a manner that adopts a more gradual and phased approach that facilitates success and rewards improvement. In other words, the EPMs should be implemented such that participating providers are allowed adequate time to learn about and improve their care delivery structures, and for CMS to measure the impact of the model on patient outcomes, program spending, and provider financial stability without unnecessarily causing broad systemic failure in transitioning to these models. This approach will help enable the health care industry to achieve the program goals while preserving access to care.

The EPMs, and in particular the cardiac models, will require sufficient lead time, broad-based clinical experience with continuity-of-care across episodes, appropriate workforce capacity and technology infrastructure, and significant investment by both the public and private sectors in order to succeed. 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 tasks at hand are formidable.

Overall, the FAH believes it is imperative that CMS carefully consider the variability of preparedness of hospitals with different levels of experience, especially under a mandatory model. CMS should ensure that hospitals are fairly protected from severe financial dislocation and that patient access to care is preserved under these models.

- ***The Quality Measurement Framework is Problematic and Needs to be Overhauled Before these EPMs Begin.***

As noted below in detail, there are significant problems with the quality infrastructure. We have serious concerns about the quality framework for the EPMs. Our concerns relate to measure relevance, measure overlap, measure misalignment, measure gaps, composite scoring methodology flaws, risk adjustment and risk stratification, data availability, and attribution of responsibility for quality. Given these concerns, the FAH believes that major revisions to the quality framework and/or the EPM models themselves are needed before any of the EPMs are implemented.

For the foregoing reasons, the FAH strongly believes that Medicare beneficiaries, hospitals, physicians, post-hospital suppliers, and the program itself would all benefit from a delayed start date of no sooner than January 1, 2018 for the three episode payments model (SHFFT, AMI/AMI-PCI, CABG).

II. Only Voluntary Provider Participation in CMMI Models is Permissible, as the Statute Does Not Grant CMS the Authority to Mandate Provider Participation

In implementing mandatory demonstrations, CMS has cited its authority under §1115A of the Social Security Act ("SSA") to implement its EPM programs as well as to modify its existing CJR model. The FAH agrees that section 1115A authorizes demonstration projects carried out by the CMMI and that section 1115A sets forth the scope, parameters and requirements under which those projects are to be implemented. These include requirements for selection of models to be tested as well as a two-phase testing requirement for each model. Under Phase I (§1115A(b) of the SSA), a model is tested in certain geographic areas (but not on a nationwide basis) and under Phase II (§1115A(c) of the SSA), the model may be expanded, including on a nationwide basis, if certain criteria for quality and or efficiencies are met.

As discussed below, however, the FAH does not believe that section 1115A authorizes CMS to mandate provider participation in the EPMs or other CMMI models. Thus, provider participation in these or any other CMMI models is required to be voluntary. Further, to the extent that CMS has previously implemented mandatory models, and now considers implementing these EPMs, under its CMMI authority, we do not believe that these models meet the requirements of section 1115A.

III. The FAH supports retaining the implementation by CMS of the CJR model revisions making the model Advanced Alternative Payment Model eligible and the CR/ICR Payment Model on July 1, 2017.

- ***The FAH Supports Establishing a Pathway for Participants in the CJR to Qualify as an Advanced APM***

The FAH supports the CMS effort to establish a pathway for participants in the CJR to qualify as an advanced APM. We urge CMS to implement the CJR changes as scheduled on July 1, 2017, rather than delay the implementation of those changes to October 1, 2017. While the FAH remains concerned about the CJR, including the mandatory nature of the model, it is already underway. The delayed implementation date in the IFR does not pause the model, but instead only delays needed modifications that could enable CJR participants to qualify for the 5 percent MACRA bonus payment in the 2019 payment year (based on the 2017 performance year).

- ***FAH Supports the CR/ICR Payment Model***

CMS finalized the implementation of a CR incentive payment model that integrates with the AMI and CABG EPMs. CMS believes the evidence supports that CR and ICR can significantly improve long-term outcomes for patients following AMI or CABG. Therefore, the FAH supports the implementation of this model on July 1, 2017 for all AMI and CABG cases regardless of whether those cases are included as part of a bundled payment program.

IV. The FAH urges CMS to hold providers harmless against downside financial risk in the first fifteen months of the model implementation in keeping with the final rule.

Under the final rule, downside risk for all model participants is scheduled to begin on October 1, 2018 with voluntary opt-in downside risk beginning on January 1, 2018. For those participants that do not opt-in to downside risk, the final rule holds them harmless from downside risk for a full fifteen months (July 1, 2017-October 1, 2018). We encourage CMS to maintain a minimum fifteen-month hold harmless standard should it finalize a delay of the models. For example, should CMS delay the model until January 1, 2018, then the Agency should hold providers harmless from downside risk until at least April 1, 2019.

GENERAL COMMENTS

I. The Statute Does Not Authorize CMS to Mandate Provider Participation in the EPMs or Other CMMI Models

- ***CMS Lacks the Authority to Mandate Provider Participation in CMMI Models***

The FAH has repeatedly expressed significant legal and policy concerns over any proposal to implement a CMMI model under which provider and supplier participation would be mandatory. Notwithstanding those concerns, we believe that CMS has incorrectly interpreted that it may require mandatory participation of providers in a CMMI demonstration, as first evidenced by the CJR demonstration as well as the EPM demonstration. The FAH disagrees that §1115A of the SSA provides CMS with the authority to mandate provider and supplier participation in CMMI models. We also believe that 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 models under section 1115A and make recommendations to Congress for permanent or mandatory changes to the Medicare program.

The purpose of the CMMI is 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 (§1115A(a)(1) of the SSA). The statute directs the Secretary to select "from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures" (§1115A(b)(1)(A) of the SSA). The law further directs CMS to evaluate each Phase I CMMI model, and only after taking into account this evaluation, if appropriate, the model may continue to be tested in Phase II to expand "the scope and duration," provided certain requirements are met (§1115A(c) of the SSA), including a requirement for a separate notice and comment rulemaking for any expansion. CMS is required to report periodically to Congress on CMMI models and make proposals for legislative action on models it deems appropriate (§1115A(g) of the SSA).

The language, structure and requirements of section 1115A of the SSA clearly indicate

that Congress did not delegate its lawmaking authority to CMS. 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. Congress is the branch of the Federal government responsible for enacting changes to Medicare payment systems through legislation; CMS is granted limited authority under specific provisions of law to make specific changes to those payment systems or to test new models. There is no language in the statute or any legislative history that supports the interpretation that Congress delegated its authority to make permanent changes to the program to the Secretary through the CMMI. In fact, the limited legislative history on this provision indicates the exact opposite. Notably, nowhere does the law expressly state that CMS can make models mandatory.

Again, mandates on providers of services and suppliers are made through individual legislative enactment; section 1115A of the SSA does not grant CMS the authority to usurp the role of Congress with respect to permanent or mandatory changes to the law. Because delegations of lawmaking authority to the agencies may be constitutionally suspect, Congress would have had to include specific statements in the legislation indicating that it both intended to and actually was delegating its lawmaking role to the Agency. Any such delegation would have had to include clear standards for the administration of duties to limit the scope of Agency discretion as well as procedural safeguards from arbitrariness or abuses. In other words, Congress would have had to specifically permit CMS to require participation of providers of services and suppliers in a model tested by the CMMI in the language of the authorizing statute. CMS may not impute that Congress granted the Agency this authority.

The Agency's aggressive and incorrect interpretation of the statute, as exhibited through implementation of the CJR and the EPM final rule, 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 under section 1115A(d)(2) of the SSA to permit the testing of models. The waivers of administrative or judicial review require that the scope of delegation to the Agency be read in the narrowest terms, meaning that the Agency may not infer additional grants of authority absent specific language in the statute. The Agency's determination to mandate participation of providers of services and/or suppliers is precisely the type of aggressive overreach in interpretation that both contradicts the statutory mandate and raises concerns about impermissible delegation of lawmaking authority to the executive branch. **Absent specific language in section 1115A authorizing the mandatory participation or providers of suppliers, CMS may not implement a policy that requires such mandatory participation.**

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 BPCI 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 and is the proper and appropriate use of legislatively granted demonstration authority. It was the manner in which previous demonstrations were conducted pursuant to section 402(a) of the Social Security Amendments of 1967 (P.L. 90–248), as amended by section 222(a) of the Social

Security Amendments of 1972 (P.L. 92-603).

The inclusion of waiver authority under section 1115A(d)(1) of the SSA was intended to provide the Agency some flexibility with respect to conflicts among the various provider and supplier payment systems and associated requirements for claims submissions; however, the presence of that waiver authority does not vest wholesale authority in the Agency to make the type of policy decisions that are reserved to Congress, such as mandatory participation of all providers of services and/or suppliers in a model being tested in a particular geographic area. No reasonable reading of the statute vests in CMS any authority to take unilateral administrative action to make provider or supplier participation mandatory as part of its authority to test models, either at a regional or national level.

As noted above, CMS must periodically report to Congress on CMMI models and make proposals for legislative action on models the Congress determines to be appropriate using its lawmaking authority. (SSA §1115A(g)). The CJR model and, far more worrisome, the EPM model jump over this process and impose a mandatory program on affected hospitals. There was no Phase I or Phase II of testing CJR before the model became mandatory nor will there be any substantive testing or assessment by the Agency or any review by Congress of the various EPM models that are to be tested in the future. Yet, these programs require mandatory hospital participation which effectively usurps Congress's discretion to study the results of a demonstration project and use its deliberative lawmaking authority to decide if the model should become the basis for a mandatory change in Medicare policy. **The FAH is very concerned with this approach to Medicare payment policymaking and believes that it is contrary to both the language and intent of section 1115A authority. Under this approach, the Agency grants to itself broad lawmaking authority; and that authority was never granted to the Agency.**

Under the CJR and EPM models, hospitals are required to change the way they manage services and will be financially at risk for health care services they do not provide. The intent and impact of the CJR model was clear; it represented a major change in Medicare payment policy. The EPM model presumably is a template for a vast number of future payment models. Thus, CMS has established as a de facto rule that participation of providers of services and suppliers in EPM models is mandatory. This policy mandate would be imposed on providers and suppliers without any testing; this is neither permitted nor contemplated by the language of the statute or any expression of congressional intent. It also fails to account for difference in types of providers or suppliers, or their particular circumstances (for example, size or ability to contract with other providers or suppliers). It also assumes all hospitals will be able properly to manage the risk and patient flow, despite that many hospitals may have little to no previous experience with respect to development of care re-design programs.

- ***The SHFFT EPM is a Prohibited Expansion of the CJR Model***

As noted above, the Secretary must evaluate each model. The evaluation must address: (i) the quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria determined appropriate by the Secretary; and (ii) the

changes in spending under Medicare and Medicaid due to the model. The Secretary must make the results of each evaluation available to the public and may establish requirements for States and other entities participating in model testing to collect and report information that the Secretary determines is necessary to monitor and evaluate the models.

Taking into account the required evaluation, the Secretary may expand the duration and the scope of a model through rulemaking if all of the following conditions are met:

(1) The Secretary determines that such expansion is expected to—
    (A) reduce spending under Medicare or Medicaid without reducing the quality of care; or
    (B) improve the quality of patient care without increasing spending.
(2) The CMS Chief Actuary certifies that such expansion would reduce (or would not result in any increase in) net program spending under [Medicare or Medicaid]; and
(3) The Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under Medicare or Medicaid.

In determining which models or demonstration projects to expand, the Secretary is directed to focus on models and demonstration projects that improve the quality of patient care and reduce spending.

The SHFFT EPM is a prohibited expansion in scope of the CJR model, which appears to be a Phase I CMMI model, although as discussed above, we do not believe the CJR model has met the Phase I requirements. The SHFFT EPM will be tested in the same hospitals already chosen for the CJR model and is intended to permit all hip fracture surgical treatment options at the selected sites to be captured within a model. Procedures under the SHFFT EPM may involve many of the same surgeons, clinicians, and provider participants as well as similar resource use for an expanded scope of hip fracture surgeries. More specifically, the CJR and SHFFT EPM models address the same patient populations with diseases limited to the hip/proximal femur region. The diseases significantly restrict patient mobility and require a major operative procedure performed only by orthopedic surgeons and usually under general anesthesia. The procedures include implantation of a medical device or medical hardware and require inpatient hospitalization and associated post-acute care following hospital discharge, including inpatient and outpatient physical therapy services.

CMS has not evaluated the CJR model as required under section §1115A(b)(4) of the SSA or, if it has, it has not made such evaluation available to the public as required under §1115A(b)(4)(B). Further, CMS has not made either of the requisite determinations (under paragraphs (1) and (3) of §1115A(c)) with respect to the CJR model, and the CMS Chief Actuary has not made the certification required under §1115A(c)(2) for savings under the CJR model. All of these steps are required before a model may be expanded in duration or scope, and none of these steps have been accomplished. **Before implementing the SHFFT EPM, CMS must first complete the evaluation of the CJR model required under section 1115A(b)(4); make the determinations required under section 1115A(c); and receive the attestation from the Chief Actuary as required under 1115A(c)(2). Because CMS has not met any of the requirements for expansion under**

section 1115A, the Agency should not implement the SHFFT EPM.

- ***EPM and Other CMMI Models Must Address a Deficit in Care for a Distinct Population***

As noted earlier, CMMI models are to be selected from among models "where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." (§1115A(b)(1)(A)).

CMS did not examine in any detail the impact mandatory provider participation will have on the hospitals upon which the requirement would be imposed. CMMI authority is intended to test the impact of various innovative payment models on quality and efficiency in the delivery of care for defined populations with deficits of care leading to poor outcomes or avoidable expenditures. Thus, CMMI must first conduct these tests to understand the impact of the models on beneficiary care for these populations as well as on those providers and suppliers that furnish the care. CMS must then report to Congress on the results and permit Congress to determine whether a permanent change to the Medicare program is warranted based on the findings of the model.

The EPM model establishes a set of rules and requirements without taking into consideration the special features of each model or whether the model will meet the statutory requirement to address the defined populations. In addition, this is a dangerous precedent particularly because the EPM rules and requirements could serve as the basis for an undetermined number of future proposals.

Accordingly, CMS must adhere to the language and intent of section 1115A authority. That authority precludes requiring participation of providers or suppliers and requires that models tested must be for certain defined populations and must satisfy meaningful APA notice and comment rulemaking requirements.

II. The FAH Urges CMS Not to Mandate the SHFFT Model

The FAH urges CMS not to mandate the SHFFT model at this time. As stated above, CMS only has limited experience with CJR and does not have sufficient evidence on which to expand this model. In addition, CMS has not provided any protections to beneficiaries with respect to monitoring quality as none of the quality measure specifically target SHFFT models. Also, as we noted earlier, SHFFT patients will be older and in poorer baseline health than their CJR counterparts. SHFFT patients are more likely to be unplanned and seen on an emergent basis. The most common treatment for hip fracture (internal fixation) is a materially different operation than those provided as part of CJR. Finally, discharge planning for a patient who has sustained an unexpected major decrease in mobility (hip fracture) is distinctly different than for someone who has knowingly chosen total hip arthroplasty (THA) and its associated postoperative rehabilitation.

Importantly, and as was described in greater detail earlier, CMS has not evaluated the

CJR model as required under section §1115A(b)(4) of the SSA or, if it has, it has not made such evaluation available to the public as required under §1115A(b)(4)(B). Thus, we are concerned about the potential unintended consequences to Medicare beneficiaries.

If CMS decides to move forward with mandating the SHFFT model, the FAH recommends that CMS phase-in the EPMs by first implementing the SHFFT model no sooner than January 1, 2018 and then implementing the cardiac EPM models six months later (no sooner than July 1, 2018). If the final rule is delayed beyond January 1, 2018, we urge CMS to provide hospitals with at least six months of preparation time from the date the final rule is finalized for implementing the SHFFT model and an additional six months to prepare for the cardiac EPMs. Of the models under review, SHFFT and CJR is the model pair with the most overlap and while we believe it is not advisable to proceed with SHFFT without better understanding the CJR outcomes, there are some operational advantages in beginning with this model. For instance, some of the patient care redesign process and clinical care pathways will be partially transferrable to some SHFFT patients. Moreover, some of the collaborator relationships already established may be applicable to the SHFFT model, and the selection of high-quality post-acute care ("PAC") collaborators for SHFFT is more likely to be more informed by the CJR experience than selection of PAC providers for cardiac disease.

SPECIFIC COMMENTS TO THE STRUCTURE OF EPISODE PAYMENT MODELS

I. Hospitals Need Timely and Relevant Historical Claims Data to Achieve Program Goals and Manage Financial Risk

Because these EPMs require acute care hospitals to be the ultimate bearers of financial risk, hospitals must be given the tools needed to manage patient care and achieve program goals. Specifically, it is critical that hospitals receive relevant and timely historical claims data, be permitted enough time to analyze the data, and take appropriate action with participant partners on a timely basis. The data must be provided prior to the start of the program, and at regular monthly intervals throughout the program. **We urge CMS, regardless of the final delay in implementation, to provide providers with relevant and timely data in keeping with CMS's timeline of providing the data in the spring of 2017.**

To successfully manage risk, hospitals must have sufficient time and data to analyze and understand the composition, characteristics, and needs of their patient population, as well as the quality of local providers. As indicated by experience with the BPCI models and our members experience with CJR in its initial months, comprehensive management and analysis of data is the foundation for hospitals to redesign and coordinate care, select and form networks with the right partners, and establish the necessary organizational and technological infrastructure to manage bundled payments under these models.

Given our member hospital experience in receiving data from CMS on the CJR model, we have concerns about the timeliness of the data received and its quality. For

example, the CJR Final Rule was announced in November of 2015, however, participant hospitals did not receive their performance year claims experience until September 2016. In many cases, our members did not find the data helpful, as it was produced in a "raw" format that was difficult for our smaller hospitals to analyze. Those hospitals that could analyze the data found the data to be incomplete in many cases and not consistent with the hospital's own data. **The FAH urges CMS to work more closely with hospitals to better define the data parameters and the format(s) of episode data that would be most helpful to hospitals and its collaborators**. **This should include considering consolidation of the data by episode prior to its transmittal to hospital participants.** This would allow them to more effectively examine their own cost and quality data, and act on these data to improve the care provided to beneficiaries in a cost-effective manner.

- ***Data Must Be Available Prior to the Start Date of the EPM Models***

The experience of our members' hospitals in CJR and the BPCI initiative demonstrate that hospitals must put into place various organizational capabilities in order to manage payment bundles, including:

- Capabilities to manage care delivery and coordination, payments, and financial risk;
- Clinical and administrative infrastructure for care delivery and coordination;
- Data analytic infrastructure to manage, analyze, and share claims data in "real- time";
- Carefully developed affiliated networks of physicians and other providers; and
- Quality data collection and submission to CMS.

To achieve these goals, hospitals must be provided with historical claims data well in advance of the start date. Consistent with its practice for the CJR model, CMS will provide to an EPM participant, upon request, aggregate expenditure data available for all claims in which the EPM participant is located. Comprehensive analysis of claims data prior to the assumption of risk is a critical step in the preparation process. It serves as a foundation for hospitals to formulate processes and protocols to redesign care; develop networks with physicians, physician groups, and PAC providers; and establish necessary clinical and administrative infrastructure during the pre-implementation period.

Under BPCI and Medicare ACO programs, participants received both historical and monthly (with only a few months data lag) claims data feeds prior to start, and had approximately twelve months from receiving the data prior to enrollment in the program. Inadequate time for preparation and lack of data for preparatory analysis, prior to start, will hinder hospitals' ability to effectively coordinate and ensure smooth transitions across the continuum of care for beneficiaries. **EPM participants must be provided data with at least as much preparatory time as BPCI participants.**

- ***Summary Claims Data Must Be Updated Monthly and Automatically***

The BPCI initiative also indicates that ongoing data analysis is a crucial part of

hospitals' ability to manage care under an APM. Having frequently updated data for analysis, such as trend monitoring and risk identification, lays the foundation for hospitals to understand and manage risk across the full continuum of care under these episodes.

CMS proposed that claims data for EPM hospitals be updated on a quarterly basis. CMS states it has received requests in other initiatives to make data available on a more frequent basis, and proposed to eventually make these data available on as frequently as a monthly basis if practicable. We urge CMS to follow-through with this plan in an expedited manner. We continue to believe that a quarterly timeline would significantly delay hospitals in identifying inefficiencies arising with regard to beneficiary utilization and spending or other issues that could occur in the continuum of care delivery and coordination. Such a delay in data analysis will hinder hospitals' capacity to devise and implement strategies for continued process improvement. We appreciate that hospitals only need to make an initial single request rather than multiple periodic requests for data as this will create less of an administrative burden on hospitals. **The FAH urges CMS to provide disaggregated claims data updates on a monthly basis and automatically.**

- ***Availability of Patient Claims Data Is Critical Due to Lack of Availability of Real-Time Clinical Data***

Although claims data provided on a monthly basis is critical for hospitals to help meet program goals of these EPMs, ultimately it can only provide a part of the data picture needed for hospitals to best manage patient care and financial risk. Real-time clinical data is the other part of the picture, and currently the technological capability to make this data available to providers is very limited and takes significant financial investment. Due to these limitations, it is even more incumbent on CMS to provide hospitals with as much claims data as possible, and as quickly as possible, to help minimize the current gap between claims data and the availability of needed real-time clinical data.

Further, hospitals will face substantial challenges in being able to manage the data and exchange information with hospital partner providers and physicians, which is vital for hospitals in understanding and managing patient "pathways" and clinical/financial risk on a "real-time" basis. Experience under BPCI shows that many providers do not yet have the infrastructure to manage clinical data electronically**.** The establishment of electronic health records ("EHRs") could be an important step toward allowing hospitals to manage, analyze, share, and interpret data in their current day-to-day operations in a timely manner—a capability that is essential for bundling success. According to the Medicare Payment Advisory Commission ("MedPAC"), the ability to track data on service use, costs, and payments over time and across settings is necessary for providers to implement bundled payment.[2] **CMS should recognize that these data challenges – including the significant financial investment, time, and complexities involved in developing and using the necessary**

[2] Medicare Payment Advisory Commission (2010, March). Report to Congress: Medicare payment policy. (Washington, DC: MedPAC)

infrastructure to achieve these goals, along with substantial transaction fees for sharing health information – necessitate a delay in the start of the program.

Additionally, CMS must ensure that the EPMs support the adoption of EHRs and facilitate making the use of EHRs sustainable for providers with regard to financial costs and administrative barriers currently borne by user organizations.

II. CMS Should Consider Reducing the Episode Period from 90 days

Our hospitals' experience in both BPCI and CJR reflects that the 90-day episode period is unmanageable and not feasible for hospitals as they follow the patient through the care continuum. In fact, our experience reflects that after 30 days it becomes difficult for the hospital to track the patient, contact the patient and impact patient behavior. Post 30 days, hospitals find themselves at risk for a great deal more than the anchor admission and often become responsible for chronic care management and for conditions unrelated to the episode of care. In mandating a 90-day episode period, CMS is, in effect, making hospitals managers of population health. Yet most hospitals, today, lack the resources, skill set and infrastructure to engage in the mission of managing population health, and the requirements are much different and much more complex and demanding than what is needed to implement reasonable episode-based payments.

In addition, CMS also has adopted quality and performance metrics that do not align with the episode length. While CMS is requiring the episode length to extend for 90 days, the quality and performance metrics are based on the much more logical 30-day time period.

III. Appropriate Risk Adjustment is Needed to Reflect Participant Hospital Characteristics and Socio-Demographic Conditions

The FAH continues to be concerned about the choice not to use a standard risk adjustment approach to adjust for patient-specific clinical indicators or differentiation within a given DRG. While CMS has controlled some variation in target prices among hospitals by creating different target prices by DRG and condition, this may not be sufficient. CMS continues to believe that the CMS Hierarchical Condition Categories ("HCC") used to adjust for risk in the Medicare Advantage program would not be appropriate for risk adjusting EPM episodes. CMS is proposing, however, EPM quality measures that incorporate HCC risk scoring. The FAH has serious concerns about the failure to properly risk adjust and this could be a significant limitation of the approach. These concerns are supported by a recent analysis published in *Health Affairs* in September 2016[3]. The authors found that failure to risk adjust for comprehensive joint replacement episodes produces wide swings in reconciliation payments and that relying just on region-based target pricing led to reduced reconciliation payments to hospitals that treat medically complex patients. Using CMS-HCC risk scores, on the other hand, appears to have controlled for much of this variation and has certain

[3] Ellimoottil C, Ryan AM, Hou H, Dupree J, Hallstrom B, and Miller DC. Medicare's new bundled payment for joint replacement may penalize hospitals that treat medically complex patients. Health Aff (Millwood). 2016;35(9):1651-1657.

advantages. Specifically, this approach currently is used in a number of other performance programs, can be computed from administrative claims with minimal burden, and factors that comprise the HCC- risk score have independently been shown to affect expenditures**.**

In addition, the FAH believes that CMS should explore and incorporate, as appropriate, additional risk adjustment to address socio-demographic factors, in order to reflect more accurately the level of financial risk that hospitals have to bear with regard to differences in the population socio-demographic status of the market areas where they deliver care. On hospital readmissions, for example, nearly 60 percent of the variation in national hospital readmission rates was found to be explained by the characteristics of the counties where hospitals are located. Local factors such as income, employment levels and nursing home quality were the major factors underlying county-level variation, or amounts of risk that hospitals could not mitigate in delivering and managing care[4].

Thus, the FAH urges CMS to incorporate a standard risk adjustment approach, such as the CMS-HCC risk scores, to risk adjust EPM target prices. The FAH also urges CMS to examine and consider incorporating other important risk-adjustment variables such as sociodemographic status, as appropriate.

IV. CMS Should Use Metropolitan Statistical Areas Instead of Census Divisions to Establish Regional Prices

Further, while the transition from historical to regional prices is an important feature of the EPM models, the use of the nine census divisions to establish regional prices is too broad, as there can be great variation across health care market areas and other sub-regions within the census divisions. **Setting regional target prices by MSAs in which hospitals are located would better account for these differences.** The census divisions are too large to allow for true differences across regions, and will reflect too wide a range of patient severity, practice patterns, and availability of specialized services (such as quaternary care), and risk the unintended consequence of over-penalizing hospitals for factors beyond their control. Using metropolitan statistical areas better reflects the health care provided in that area and the use of MSAs is already commonly used for other purposes, such as adjusting for differences in hospital wage levels.

V. Limits or Adjustments to Participants' Financial Responsibility Should Be Adjusted to Reflect Hospital Challenges and Specific Market Areas

CMS will test the EPM models for five performance years during which hospitals, and others providing services subject to the bundle, will continue to be paid according to the Medicare fee-for-service payment systems. However, after the completion of a performance year, the Medicare claims payments for services furnished to the beneficiary during the episode would be combined to calculate an actual episode payment. The actual episode payment then would be reconciled against an established EPM model target price, which is based on a 3

[4] Herrin, J, St. Andre, J., Kenward, K., Joshi, M.S., Audet, A.-M.J. and Hines, S.C. (2015), Community Factors and Hospital Readmission Rates. Health Services Research, 50:20-39. Doi: 10.1111/1475-6773.12177

percent discount factor, which would be scaled downward from there to reflect high quality performance. The amount of this calculation, if positive, would be paid to the participant EPM hospital subject to satisfactory quality performance and stop-gain limits. This would apply for PYs 1 through 5. If negative, the participant hospital would be required to repay the difference, subject to stop-loss limits. CMS will be responsible for repaying Medicare when their actual EPM-episode payments exceed their quality-adjusted target prices beginning in the second quarter of PY 2 and extending through PYs 3 through 5 (a nine-month period given that PY1 is six-months.)

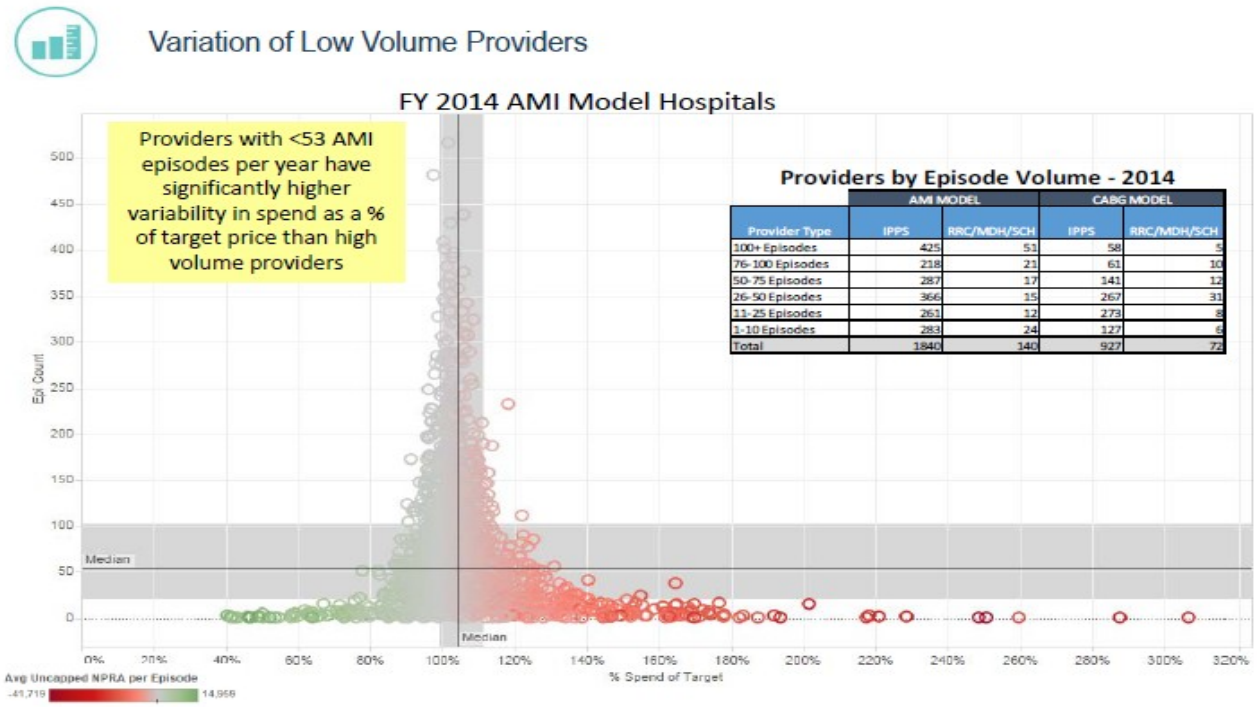
- ***With respect to the discount factor applied to the target price, the FAH recommends that CMS apply a 2 percent discount factor for all performance periods and scale downward from there to reflect high quality performance.***

As discussed extensively above, the EPM models are mandatory and we know from the experience of our member hospitals participating in CJR, BPCI, MSSP, and the Pioneer ACO Model that participation in the models requires significant and costly up-front investment to develop the legal, clinical, financial, and quality infrastructure needed to achieve goals, including technology, data analyses, and development of provider networks. Further, these models will apply to many hospitals with little experience with episode-based payments, and there could be a great degree of variation in episode spending outside the control of the hospital, which is not adequately addressed through risk adjustment. CMS could monitor this program over time and re-propose a target price that reflects hospitals' experience in meeting the many unique challenges they face in achieving the program's goals.

- ***Regarding CMS's stop-gain and stop-loss limits policy, FAH urges CMS to consider a different approach that would apply stop-loss limits at the individual episode level.***

CMS considered two options for setting stop-gain and stop-loss limits for hospitals participating in more than one of the AMI, CABG, SHFFT, and CJR models in the proposed rule. Under the first option, CMS would determine stop-loss and stop-gain limits, in total, at the participant level by calculating a single weighted stop-loss/gain threshold based on the total spending under each model. Under the second option and the one CMS adopted, CMS would establish stop-loss and stop-gain thresholds at the model level; that is, separately for each of the AMI, CABG, and SHFFT models, in addition to the limits that already exist for the CJR model.

In general, we prefer an option that is applied separately on an individual episode level (case-by-case). An analysis performed for the FAH and others raises questions about applying the stop-loss thresholds uniformly across all hospitals, regardless of the number of episodes attributed to each hospital. The analysis shows that variation in spending is too great, particularly for low volume hospitals over a 90-day episode period; this has the effect of shifting health insurance risk to smaller hospitals, which are not in a position to manage such risk (see figure 1).



Source: DHG Healthcare, September 2016.

Given the variation in spending, there is a great potential for "bundles busters," defined as episodes with negative net payment reconciliation amount (NPRA) greater than 100 percent of the target price. For example, the analysis found that providers with less than 53 AMI episodes per year have significantly higher variability in spending as a percentage of target prices than high volume providers. Their analysis showed that the optimal episode-level stop-loss threshold (percent of target) would vary among low and high volume episodes for the AMI model. For example, the analysis shows that for hospitals with medium volume of episodes (>20 episodes and <=53 episodes), the estimated episode level stop-loss threshold (% of target) should be 175 percent. Likewise, for hospitals with greater than 53 episodes the stop-loss should be 200%.

We recommend, based on our analysis, that CMS impose a per episode (case-by-case) stop-loss threshold of 125 percent, which would acknowledge that given the lack of experience with these episodes, hospitals should be protected from one case negatively impacting a hospital's overall experience in the program. We would be happy to discuss this proposal and analysis in more detail, at the convenience of CMS.

Moreover, given the differences in provider capacity to manage risk under episode-based payments in a relatively short period of time, as well as wide variation in episode spending that may be outside the control of the hospital, CMS should, after the period in which hospitals are held harmless, more gradually phase-in and reduce the stop-loss limit that is applied to all hospitals. **If CMS continues its current approach in applying stop-loss limits rather than CMS should cap the stop-loss limit for hospitals at 10 percent by PY5.**

- ***FAH urges CMS to consider eliminating stop-gain limits.***

Hospital experience with BPCI and CJR show the considerable investment hospitals have to make in order to successfully implement these new bundled payment models. The EPMs in the model, will also require significant resource allocation. We appreciate CMS including a stop-loss limit in the final rule and encourage CMS to adjust their proposal with our recommendations, as outlined above, in mind. In addition, we encourage CMS to consider simply eliminating stop-gain thresholds. First, CMS has already built savings into the program by applying a discount factor into the target price. Second, as noted throughout this comment letter, the success hospitals achieve in implementing these bundles depends on making new, significant infrastructure investments, managing risk, and redesigning care delivery for these patients. The potential savings hospitals achieve are needed to help offset these considerable expenses, which will be incurred by providers across the continuum of care and to permit additional investments. CMS is undertaking a "demonstration" program, and the incentives need to reflect these goals and help hospitals provide proof of concept. Limiting savings through the application of stop-gain thresholds, however, is counterproductive to the success of this program and the long-term goal of transforming health care delivery and advancing population health.

VI. A Shared Accountability Payment Model for IRFs Would Increase Efficiency and Competition for PAC Services

As CMS moves forward with its mandatory bundled payment programs, which places financial risk on acute care hospitals for PAC spending, it is important to provide payment flexibility to PAC hospitals in order to allow them to achieve efficiencies that inure to the benefit of acute care hospitals that are at financial risk under these bundled payment models. This is an issue that the FAH brought to the attention of CMS in our comments to the EPM proposed rule and one which we reiterate and update here. It is disappointing that CMS missed the opportunity to address this issue as part of the EPM final rule as it would have undoubtedly strengthened the EPM program. Importantly, CMS has an opportunity in this rule-making to act on a recommendation that will help improve the odds of success for these models.

These additional mandatory bundled payment programs will encompass a larger portion of the patients that Inpatient Rehabilitation Facilities ("IRF") currently treat. Also, acute care hospitals have historically relied on IRF care for a large portion of patients that will be in mandatory bundled payment programs (over 9 percent of CJR and CABG patients and more than 18 percent of SHFFT patients). Options for acute care hospitals to reduce PAC spending are currently limited to encouraging patients to receive PAC in settings that receive lower Medicare payments or encouraging PAC providers that have the ability to reduce payments through efficiencies to do so. Thus, providing payment flexibility to PAC hospitals is important to allow them to effectively compete in a changing environment and to continue to provide beneficiaries with PAC options that best meet their needs.

In this environment, PAC providers such as skilled nursing facilities ("SNF") or home health agencies ("HHA") have the ability under existing regulations to modify their practice or

utilization patterns in a manner that produces lower Medicare payments for patient care. SNFs can reduce their Medicare payments within the current prospective payment rules by simply providing fewer days of care. In addition, SNFs can also reduce the level of therapies provided, which would put patients into lower-paid Resource Utilization Group categories. Similarly, HHAs can reduce the number of therapy encounters during a home health episode with the result of receiving less Medicare payment.

The second year evaluation of BPCI found that SNFs reduced the amount of Medicare spending for SNF services during an episode of care primarily through reduced length of stay (*i.e.,* reducing the number of days patients were in SNFs). The study found a statistically significant reduction in SNF length of stay both when the SNF was an episode initiator itself as well as when the SNF was a downstream PAC provider for a BPCI participating acute care hospital[5].

The purpose of the IRF shared accountability payment model is to provide a similar level of payment flexibility to IRFs in order to reduce Medicare spending for Medicare bundled payment patients, which is not available under the current Medicare IRF prospective payment system ("IRF PPS"). Since episode target prices and performance period spending in Medicare's bundled payment programs are based on Medicare payments, and because Medicare payments to IRFs are per-discharge (not per diem) and diagnosis based (not therapy based), there is no flexibility for IRFs to reduce their Medicare payments for the benefit of hospitals participating in the bundled payment models, regardless of the cost-efficiencies an IRF may generate. The IRF shared accountability payment model would allow acute care hospitals to benefit from being able to maintain or enhance their relationships with IRFs under these programs by permitting IRFs to generate Medicare savings for patients attributed to the bundled payment programs.

The proposed approach would enable IRFs to more fully and robustly share in the potential risks and rewards of these bundled payment programs and allow hospitals participating in the bundled payment program to benefit from savings achieved by IRFs under the alternative payment model, which is similar to how acute care hospitals now benefit from SNFs' reduced length of stay. Thus, this voluntary alternative payment model would permit greater accountability among and between acute care hospitals and IRFs. This approach directly aligns with CMS's recognition of need for payment flexibility as Medicare reimbursement moves towards alternative payment models and away from fee-for-service.

As indicated earlier, we have provided the Agency in earlier comments with a brief report prepared by Dobson-DaVanzo, which provides more details and analysis regarding a prototype version of such a "shared accountability" payment model and encourage the Agency to revisit those comments[6].

VII. CMS Should Provide Appropriate Waivers to Allow Hospitals the

[5] Dummit et.al., "CMS Bundled Payments for Care Improvement Initiative Models 2-4: Year 2 Evaluation & Monitoring Annual Report", August 2016

[6] https://www.regulations.gov/document?D=CMS-2016-0135-0115

Needed Flexibility to Achieve Program Goals of the EPM Payment Models, While Managing Their Legal and Regulatory Risk

- ***Gainsharing Fraud and Abuse Waivers***

As with its bundled payment predecessors, gainsharing stands at the heart of the EPM rule. It is, undoubtedly, the most critical component of the EPM model, serving to align participating providers' otherwise disparate financial interests, and creating the potential to realize CMS's Triple Aim.

Yet, to facilitate such gainsharing arrangements under the EPM model, FAH members need legal certainty that such efforts will not run afoul of federal fraud and abuse laws. To date, no such legal certainty has been provided. EPM model fraud and abuse waivers of the Stark law and the AKS remain conspicuously absent.

The FAH understands that the initial delay in waivers may have simply been the result of CMS's need to fine tune the EPM model. Such was the case for CJR; however, such waivers were issued in conjunction with the CJR final rule, but were not issued when the EPM final rule was issued in January. This approach creates substantial and significant legal uncertainty for our participant hospital members.

Indeed, gainsharing programs are not developed overnight. Rather, they take careful deliberation on the part of numerous stakeholders, involve painstaking drafting of sharing arrangements, and further entail drawn out negotiations with potential gainsharing partners.

Accordingly, the FAH urges CMS to reject this piecemeal approach to bundled payment fraud and abuse waivers and develop a single, overarching waiver applicable to all gainsharing arrangements under a CMS-led bundled payment program. In the alternative, and as outlined below, the FAH urges CMS to consider a new, bundled payment program exception to the Stark law, or revisit and modify current Stark law exceptions to permit gainsharing under CMS-led bundled payment programs. We recognize that CMS has previously noted that certain Stark exceptions can apply to gainsharing arrangements, and we agree with CMS's view. However, to remove any uncertainty for providers and incentivize continued development of innovative models, we encourage CMS to develop a specific Stark exception for CMS-led bundled payment programs.

<u>Bundled Payment Program Waiver</u>

The FAH asserts that CMS should develop a single, overarching waiver ("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 ("Bundled Payment Program"). The Bundled Payment Waiver would apply to 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.

The FAH submits that its proposal, as outlined below, would not represent a dramatic overhaul of current bundled payment fraud and abuse waiver processes. **Rather, the FAH believes that the development of a single waiver would simply: (a) streamline the process for both CMS and the Department of Health and Human Services, OIG; and (b) create additional legal certainty for program participants.**

A. Considering ACO Fraud and Abuse Waivers as a Model

The FAH urges CMS to adopt a comprehensive Bundled Payment Waiver, and outlines potential waiver parameters, below.

The FAH first notes that, in developing its proposed Bundled Payment Waiver, we have drawn heavily upon existing BPCI Model 2, CJR, and EPM model program safeguards. That being said, we also sought to incorporate CMS's approach to, and the structure of, ACO fraud and abuse waivers. The FAH believes ACO fraud and abuse waivers have achieved a delicate and difficult balance: pairing critical program integrity safeguards with adequate flexibility for program participants.

Thus, the FAH's Bundled Payment Waiver proposed below reflects an amalgam of what the FAH believes is the best of current CMS coordinated care models: ACO fraud and abuse waiver flexibility, paired with BPCI and CJR program-specific safeguards.

B. Bundled Payment Waiver: Proposed Requirements

The FAH proposes the following requirements for a new Bundled Payment Waiver:

- Any amounts gainshared by a participant hospital are earned by the participant hospital: (a) solely pursuant to the terms of the Bundled Payment Program; and (b) during the term of the Bundled Payment Program, even if the actual distribution or use of the gainsharing payments occur after the expiration of the Bundled Payment Program;
- The participant hospital has selected its collaborators: (a) based upon criteria related to the quality of care to be delivered to Bundled Payment Program beneficiaries; and (b) in a manner not related directly or indirectly to the volume or value of referrals or other business generated between the parties;
- The participant hospital's sharing arrangement with each collaborator is set forth in writing, is signed by the parties, and specifies both the care redesign services to be provided by the collaborator and the Bundled Payment Program compliant gainsharing methodology;
- The participant hospital's gainsharing methodology is set in advance of any earned amounts from CMS for that specific performance period;
- Any gainsharing payment made to a collaborator by the participant hospital is for actual care redesign services provided;
- The receipt or payment of a gainsharing payment between a participant hospital and its collaborator is not conditioned, directly or indirectly, on the volume or value of referrals

or other business generated between the parties; and

- Any gainsharing payment made by a participant hospital to a collaborator is not knowingly made to induce the collaborator to reduce or limit medically necessary items or services to Bundled Payment Program patients under his or her care.

The FAH acknowledges that, and depending on the applicable Bundled Payment Program, CMS may wish to add or subtract from the requirements of the above Bundled Payment Waiver. However, the FAH suggests for CMS's consideration, that the core tenets of the waiver would remain the same across all such Bundled Payment Programs. In addition, as noted previously, CMS and the OIG would continue to have the ability to issue program specific waivers, where warranted.

An Alternative: Create a New Stark Exception or Revisit Existing Stark Exceptions

In the alternative to a Bundled Payment Waiver, the FAH suggests that CMS consider revising the Stark law exceptions in order to facilitate, with appropriate program oversight, CMS-led bundled payment gainsharing arrangements.

Accordingly, the FAH proposes a new bundled payment program ("BPM") Stark law exception, and, in the alternative, a modification to the current Stark law risk sharing exception.

A. The Bundled Payment Program Exception

The FAH urges CMS to develop a new, BPM Stark law exception. The FAH previously proposed a similar exception in response to CMS's request for comments to the 2016 Physician Fee Schedule Proposed Rule (referred to by FAH in its comments as an "Alternative Payment Exception").

Pursuant to the BPM exception, to the extent that CMS leads and/or administers a Bundled Payment Program, the provision of direct or indirect monetary remuneration ("Incentive Payment") by a designated health services ("DHS") entity to a physician or physician practice group participating in the Bundled Payment Program (referred to collectively, as "Physician") will be deemed protected by the BPM Exception, provided certain program and patient safeguards are met. FAH proposes such safeguards below. Notably, they are similar to FAH's Bundled Payment Waiver program safeguards, as detailed earlier in this comment letter.

- The Incentive Payment arrangement is set forth in writing, is signed by the parties, and specifies both the services to be provided and the Incentive Payment compensation methodology;
- Any Incentive Payments made to a Physician, by a DHS entity is for actual care redesign services provided;
- Only those Physicians who meet quality measures established by the DHS entity in advance of the Incentive Payment arrangement are eligible to receive an Incentive Payment; furthermore, such quality measures must be reasonably related to improving quality outcomes for the DHS' entity's patient population**;**
- The receipt or payment of any Incentive Payment is not conditioned by either party on the volume or value of referrals or other business generated;

- Any Incentive Payment made directly or indirectly from a DHS entity to a Physician must not be made knowingly to induce that Physician to reduce or limit medically necessary items or services to patients under the direct care of that Physician;
- The total amount of Incentive Payment that a Physician may receive is capped at 75 percent of the Medicare physician fee schedule for services provided by that Physician to applicable beneficiaries, for a given calendar year;
- The Incentive Payment methodology is set in advance; and
- Irrespective of any care redesign measure undertaken, physicians retain the ability to make decisions that are in the best interest of their patients.

The FAH believes that the scope of the above BPM Exception, the inherent protections that come with a CMS-issued program, and the substantial program safeguards outlined above, will ensure Incentive Payment Arrangements evolve consistent with CMS's program goals to promote transparency, improve quality, and safeguard against payments for referrals.

B. Revisit the Risk Sharing Exception

CMS may also wish to consider modifying the existing risk sharing exception to apply not only to compensation arrangements between a managed care organization or an independent physician's association and a physician (either directly or indirectly through a subcontractor), but also to Bundled Payment Program arrangements. That is, compensation arrangements between CMS and a Bundled Payment Program participating physician (either directly or indirectly through a downstream contractor, like a hospital), would be protected under the Stark law, risk sharing exception. The FAH notes that it likewise made such a proposal in response to CMS's 2016 Physician Fee Schedule Proposed Rule.

The FAH believes this proposed modification to the risk sharing exception aligns with prior statements made by CMS in the preamble to the Stark Phase II regulations. Specifically, in response to a request for clarification relating to the definition of "managed care organization," CMS stated that it "purposefully declined to define the term 'managed care organization' so as to create a broad exception with maximum flexibility." 69 Fed. Reg. 16054, 16114 (March 26, 2005). It is the FAH's contention that CMS's statement regarding "maximum flexibility" serves as a natural springboard to allow for a more expansive risk sharing exception, one that encompasses CMS-led Bundled Payment Program arrangements. Also, and simply from an operational perspective, hospitals – as the leader and coordinator of any Bundled Payment Program – act similarly to that of their managed care organization counterparts.

We further note that here, as with the proposed BPM Exception, CMS may wish to consider instituting specific safeguards to protect against patient and program abuse. We refer CMS to the "The Bundled Payment Program Exception" for our discussion of such program safeguards.

A Second Alternative: EPM Specific Fraud and Abuse Waivers

While urging CMS to develop a single Bundled Payment Waiver or developing a Bundled

Payment Program specific exception, in the alternative, should CMS and the OIG issue EPM specific fraud and abuse waivers, the FAH seeks to ensure that any such waivers offer participants sufficient flexibility and are *not* based solely upon CJR.

The FAH believes that the CJR fraud and abuse waivers are highly technical in nature, and as a result, fail to appropriately incentivize gainsharing. For example, and because the CJR "Waiver for Distribution of Gainsharing Payments and Payment of Alignment Payments under Sharing Arrangements" requires that participant hospitals meet each and every requirement of 42 CFR §510.500 in order to receive waiver protection, participant hospitals must adhere to the following, technical requirements (among others) in any gainsharing arrangement, or risk foregoing Stark law and AKS waiver protection:

- Collaborator agreements must include "management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out changes to care under the CJR model";
- Participant hospitals must update their list of CJR collaborators on "at least a quarterly basis and publicly report the current and historical lists of CJR collaborators on a public-facing Web page on the participant hospital's Web site"; and
- Participant hospitals must keep records of, among other requirements, "information confirming the organizational readiness of the participant hospital to measure and track internal cost savings."

42 CFR § 510.500. Further, to the extent that a participant hospital's collaborator may inadvertently miss just one of the plethora of program requirements (*e.g.*, a CJR collaborator fails to provide, in a single instance, a CJR beneficiary with the appropriate notice), the participant hospital likewise risks losing waiver protection and faces the potential for both criminal and massive financial penalties. *See* § 510.500(a)(4).

The FAH submits that the above requirements, while potentially of import from a program compliance perspective, are not appropriate to include in fraud and abuse waivers. That is, for example, were a collaborator agreement to not include management and staffing information, the FAH believes such an omission poses *no* fraud and abuse risk to any federal health care program, and accordingly, should not govern whether a participant hospital receives waiver protection.

In sum, the FAH asserts that the CJR fraud and abuse waivers have in fact *hindered* gainsharing arrangements. FAH members remain concerned that they may lose waiver protection as a result of minor technical infractions that, in reality, are not aimed at protecting against patient and program abuse. Indeed, the behemoth mountain of technical requirements that FAH members must wade through do not appropriately balance CMS's program integrity interest with the need for meaningful change.

As noted above, and consistent with CMS's approach to waivers in the ACO context, the FAH urges CMS to take a different approach should it decide to develop EPM specific fraud and abuse waivers.

- ***Waivers Designed to Facilitate the Provision of Pre-Operative Care Management Items and Services***

The FAH recognizes that CMS has not been inclined to start the episode of care prior to the date of the hospital admission. However, we strongly encourage CMS to evaluate the significant benefits to both patients and overall care redesign efforts that could result from more comprehensive pre- operative care management services. Specifically, CMS should consider extending any bundled payment fraud and abuse waivers (including any potential patient engagement incentive waiver) to permit participating hospitals to provide care management tools and services to beneficiaries and providers participating in care redesign efforts, prior to the start of the episode of care. For example, the following pre-episode services have proven to not only improve patient outcomes and satisfaction, but also result in the delivery of more efficient and higher quality care: comprehensive patient evaluations to assess a beneficiary's overall condition and chronic comorbid conditions, patient education videos and materials, discharge planning review and counseling, home safety reviews, and patient and caregiver education. As further evidence of such services value, FAH notes that the aforementioned activities would be consistent with the activities contemplated by the Medicare Shared Savings Program, ACO participation waiver.

- ***Gainsharing***

Allow Participant Hospitals to Increase the Frequency of Their Gainsharing Payments Under Both CJR and EPM

The FAH believes the current requirement that both CJR and EPM participant hospitals limit gainsharing payments to "no more than once per calendar year" is too restrictive and creates an unintended advantage for BPCI program participants who distributed payments monthly and quarterly. 42 C.F.R. §§ 512.500(c)(1)(ii); 510.500 (c)(1)(ii). A practice that could adversely impact EPM and CJR hospital participants. Participant hospitals must be able to share savings with their collaborators on a more frequent schedule, such as quarterly.

The FAH acknowledges that CMS considered and ultimately rejected such an approach in the CJR final rule. However, in doing so, CMS placed significant emphasis on operational concerns – namely, that an annual reconciliation process is necessary to (a) limit the number of subsequent reconciliations and potential fluctuation in financial results for participants, (b) prevent the otherwise constant engagement of participants in the reconciliation and appeals process, and (c) align with the CMS-mandated composite quality score process. *See* 80 Fed. Reg. 73274, 73385 (Nov. 24, 2015).

The FAH does note dispute that the above pose real, operational challenges for CMS. However, they should not be resolved at the expense of an effective gainsharing program. In fact, some BPCI Models allow for monthly gainshare distribution.

Current CJR participant hospitals choosing to gainshare net payment reconciliation amounts are prohibited from making any gainsharing payment until *after* the annual reconciliation process – a time-consuming process that may take up to 18 months from the start of a performance year. FAH members believe this lengthy process is stifling meaningful change and ultimately is

reducing the quality and cost savings potential of the CJR model. Indeed, it is questionable whether any collaborator would be motivated to improve quality and reduce costs, when their potential financial reward is so far removed. **Accordingly, the FAH urges CMS to revise both CJR and EPM to permit a quarterly gainsharing payment schedule, consistent with most BPCI models.**

In the alternative, the FAH requests that CMS consider a modified gainsharing payment schedule, limiting gainsharing payments to no more than once per performance year for the *initial* performance year, and then thereafter allowing for quarterly payments. This may serve to alleviate any operational concerns, while also allowing participants the flexibility to create a more impactful, long-term gainsharing strategy.

Gainsharing Cap

The FAH acknowledges the importance of many of the conditions and restrictions concerning gainsharing payments, as finalized by CMS in CJR and EPM. In particular, the FAH agrees that the total amount of Gainsharing Payments for a calendar year provided to participating *physicians* should be subject to a cap.

That being said, we urge CMS to (1) reconsider application of the gainsharing cap to physician group practices ("PGPs") and (2) relax current gainsharing cap parameters.

A. Remove the PGP Gainsharing Cap

The FAH urges CMS to remove the gainsharing cap for PGP collaborators under both CJR and EPM. While acknowledging that CMS rejected such a suggestion in its CJR final rule, the FAH believes that new facts warrant CMS's reconsideration.

In the CJR final rule, CMS noted that a PGP gainsharing cap was necessary because CJR had simply one episode – LEJR procedures – versus the multitude of potential episodes in the BPCI Model 2 program. *See* 80 Fed. Reg. 73274, 73421 (Nov. 24, 2015). As such, CMS believed it was likely that most services furnished to CJR beneficiaries during an episode would be provided by an "identifiable subset of physicians and non-physician practitioners within a PGP." *Id.*

The FAH respectfully believes that the above rationale is inapplicable to the EPM model, which applies to not just one episode, but three. Further, treatment of the three EPM episodes – AMI, CABG, and SHFFT – assuredly will not all draw on the same subset of physician expertise. Consequently, services furnished to EPM beneficiaries are likely to no longer be furnished by an "identifiable subset" of physicians, 80 Fed. Reg. at 73421, and participating multi-specialty PGPs will look to draw upon additional members to facilitate care redesign efforts.

As a result of this shift, the FAH believes it is appropriate to allow EPM participant hospitals, as in BPCI Model 2, the opportunity to gainshare with PGPs without

gainshare cap limitations. The FAH submits this argument likewise now applies to CJR because (a) a large

number of hospitals will be participants in both CJR and EPM, and may seek to gainshare with a single, multispecialty PGP under both programs; and (b) given the inevitable (and, indeed, intentional) overlap across the two programs, uniformity will be imperative.

B. Increase the Gainsharing Cap

The FAH further requests that CMS consider increasing the total amount physicians and/or PGPs may be eligible to receive under both CJR and EPM. CMS has entrusted hospitals with the responsibility to oversee and implement care redesign. Accordingly, the FAH believes that CMS should likewise entrust, and grant hospitals increased flexibility in designing their respective gainsharing programs and determining the amount of savings to share with their collaborators.

That is, the FAH believes that CMS should consider allowing participant hospitals the opportunity to raise the gainsharing cap, *i.e.*, increase the total amount of gainsharing dollars a physician or PGP is eligible to receive. This increase could be accomplished by applying the cap to the total episode savings up to 50% rather than limiting it only to the Medicare physician fee schedule payment. By doing so, the FAH believes CMS will enhance the effectiveness of any participant hospital's gainsharing program and provide more meaningful financial incentives with limited additional fraud and abuse risk.

Additional Guidance is Needed for the Collaborator, Compliance Plan Requirement

The FAH understands that all EPM collaborators, like their CJR collaborator counterparts, must have a compliance program that includes "oversight of the sharing arrangement and compliance with the requirements of the EPM." 81 Fed Reg. 50921, 50794 (Aug. 2, 2016).

The FAH appreciates CMS's previous comments that a collaborator's compliance program need not take any one particular form and further, that there is no "one size fits all" compliance program. *Id.* That being said, the FAH believes additional guidance is needed.

A requirement that a collaborator include oversight of not only the sharing arrangement, but compliance with the requirements of the *entire EPM or CJR program* is assuredly a large undertaking for any one collaborator, let alone a solo practitioner. We also urge CMS to consider the practical implications of this compliance plan requirement in the event a participant hospital contracts with a physician individually, and that physician is also a member of a PGP not otherwise involved in the EPM or CJR program.

Remove Duplicative and Technical Requirements from CJR and EPM Sharing Arrangements

We note that the regulations lack a clear section laying out each and every requirement to be included in a sharing arrangement. For example, and while the proposed 42 C.F.R. § 512.500(b)(7)

(relating to EPM) and § 510.500(b)(7) (relating to CJR), states "The written agreement memorializing a sharing arrangement must specify the following . . . ," the enumerated list does *not* capture every item that a participant hospital must ensure is included in the agreement. As a simple illustration of this fact, the FAH notes the following (non-exhaustive list of) sharing arrangement requirements scattered throughout the proposed, regulations:

- Sharing arrangements must require its collaborators and downstream contracts to comply with all applicable laws and beneficiary notification requirements. *See* §§ 512.500(b)(3), 510.500(b)(3);
- Sharing arrangements must require the collaborator to have an appropriate compliance program. *See* §§ 512.500(b)(4), 510.500(b)(4);
- Sharing arrangements must specify a participant hospital's recoupment rights. *See* §§ 512.500(c)(9), 510.500(c)(9); and
- Participant hospitals must require each EPM collaborator (presumably, via the sharing arrangement) to maintain contemporaneous documentation with respect to the payment or receipt of any gainsharing payment or alignment payment. *See* §§ 512.500(d)(1)(iii), 510.500(d)(1)(iii).

A comprehensive list of the sharing arrangement requirements, as set forth clearly in any final CJR and EPM sharing arrangement regulations, would assist participant hospitals in ensuring that they remain compliant with the EPM rule.

Second, the required contents of the sharing arrangement may be overly inclusive. For example, we question whether it is necessary to mandate that a participant hospital's sharing arrangement include "management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out EPM activities." *See* proposed 42 § 512.500(b)(7)(iv). Similarly, and while the FAH understands the requirement that all gainsharing payments be only comprised of NPRA and/or *actual* ICS savings realized, without regard to any "paper savings" from accounting conventions, the FAH questions whether the requirement that gainsharing payments be administered in accordance with generally accepted accounting principles and Government Auditing Standards ("The Yellow Book") is necessary. *See* proposed §§ 512.500(c)(15); 510.500(c)(15). (CJR has similar requirements.) The FAH believes such a requirement is overly technical, burdensome, and confusing for physicians, and does not lesson the fraud and abuse risk posed by any sharing arrangement. Finally, and as noted previously, failure of the hospital and/or its downstream contractors to fully satisfy these requirements results in the loss of waiver protection.

Finally, the FAH requests guidance from CMS regarding the impact of the changes to the terminology under the CJR program. Recognizing that CMS's efforts are aimed at providing consistency between the Bundled Payment Programs, it is unclear whether hospitals will need to revisit existing gainsharing arrangements and modify the terminology to reflect these changes. The FAH would appreciate clarification on this point from CMS and further notes any required revisions to existing arrangements would constitute a significant burden on hospitals.

- ***Patient Choice and Beneficiary Notification***

The Development of Preferred Provider Networks Continues to be Hampered by Current Law

In recent years, CMS has increasingly recognized the importance and value of preferred provider networks in care coordinated models. Indeed, in the EPM proposed rule, CMS suggested preferred provider networks may help facilitate both the "coordination of care and optimization of care." 81 Fed Reg. 50921, 50915 (Aug. 2, 2016).

Yet, within all coordinated care models, CMS has continued to require that participants develop preferred provider networks "within the constraints created by current law." *Id.* The FAH urges that such patient choice constraints, specifically as set forth in SSA §1861(ee)(2)(H) and 42 C.F.R. §482.43(c), be waived to truly effect change under Bundled Payment Programs, like CJR and EPM.

While we believe that patient choice must continue to be respected, we also believe that CJR and EPM participant hospitals simply require additional flexibility above and beyond that currently permitted.

Presenting the full list of home health and/or skilled nursing facilities to a CJR or EPM beneficiary provides, in and of itself, little value. It is lengthy, offers no information to beneficiaries on the quality of care of such post-acute providers, and may ultimately serve to only confuse beneficiaries when paired with a "preferred provider" list. To that end, beneficiaries would benefit from receiving a "preferred provider" list only, provided that such list was based on objective, quality based metrics appropriately communicated to beneficiaries. In addition, beneficiaries could be informed that a full list of post-acute care providers is available upon request.

The FAH contends that this approach is consistent with and satisfies the statutory requirement found at Section 1861(ee) of the SSA. Specifically, Section 1861(ee) sets forth a hospital's obligations related to discharge planning, and specifically requires that hospitals may "not specify or otherwise limit the qualified provider which may provide post-hospital home health services, and identify any entity to whom the individual is referred in which the hospital has a disclosable financial interest or which has such an interest in the hospital." SSA §1861(ee)(2)(H). **The FAH urges CMS to adopt an interpretation of "qualified provider" that would permit hospitals to develop a more meaningful discharge planning process that will promote better care and patient experience.**

In the alternative, and again in the interest of ensuring patients receive high quality care post- discharge, we urge that participant hospitals be afforded the opportunity to *exclude* from the full list of home health and/or skilled nursing facilities presented to a CJR or EPM beneficiary, certain post-acute care providers with objectively poor quality scores. In this circumstance, the patient's choice would be respected if he or she expressly requested such a facility, but the hospital would not be required to include the facility in the full list of post-acute care providers in the first instance.

Lastly, the FAH notes that current patient choice requirements may not only serve to confuse beneficiaries, they also may hamper preferred provider network, continuity of care efforts. To the extent a CJR or EPM beneficiary selects a preferred post-acute care facility upon discharge, the discharging participant hospital will be limited in its ability to ensure the EPM beneficiary returns to the hospital in the event a readmission is deemed medically necessary. To facilitate data sharing, improve patient outcomes, and reduce costs, such a process is necessary, yet is currently impeded by both patient choice limitations and AKS concerns.

Beneficiary notice

A. Current Beneficiary Notice Requirements Are Unnecessary

The FAH questions the necessity for a CJR and EPM hospital admission beneficiary notice. We understand and appreciate CMS's sentiment, as expressed in the CJR final rule, that "beneficiary notification and engagement is essential because there will be a change in the way participating hospitals are paid." 80 Fed. Reg. 73517 (Nov. 24, 2015). Yet, historically, CMS has not always engaged beneficiaries in such a manner. Indeed, under the current DRG system – where hospitals are already motivated to contain costs during the hospital stay – CMS imposes no such notice requirements. The FAH believes beneficiary protections afforded by current law are sufficient and that the CJR and proposed EPM notice requirement serve only to burden participating providers and confuse beneficiaries.

B. In the Alternative, Beneficiary Notice Requirements are Duplicative at Best

As CMS has aimed to move towards the Triple Aim goal and unveil new coordinated care models, participating beneficiaries have been inundated with notices. Indeed, were a beneficiary to participate in BPCI Model 2, CJR, and EPM (a distinct possibility), they would receive *at least* three different notices from the participant hospital or Awardee, with the potential to receive additional notices from collaborators. Separate and apart from whether any of such notices are warranted in the first place, the sheer volume of notices is duplicative and may ultimately confuse beneficiaries (particularly those beneficiaries that are later determined by a participant hospital at the time of discharge to be outside of such programs).

Accordingly, the FAH urges CMS to develop one streamlined notice applicable to all beneficiaries that may participate in a Bundled Payment Program, like BPCI Model 2, CJR, or EPM, or incorporate this notice into existing CMS notices. For example, CMS could utilize the Important Message notice as the mechanism for conveying this information to beneficiaries. **Further, we urge CMS to assume responsibility for such notice processes.** CMS, as an objective and trusted voice, could detail the roles and potential conflicts of interest of the multiple Bundled Payment Program participants – *e.g.*, participant hospitals, collaborators, and preferred providers.

C. Hospitals Require Additional Flexibility With Respect to the Timing ofNotices

Provided CMS continues to place beneficiary admission notification requirements on participant hospitals, the FAH urges additional flexibility with respect to the timing of such notices is required. We appreciate the new standard required by CMS under both the CJR and EPM programs – which allows participant hospitals to provide patient notice as late as upon discharge where, due to the patient's condition, it is not otherwise feasible to provide earlier notice. *See* proposed 42 C.F.R. §§ 512.450 (b)(1), 510.450(b)(1). However, and because a beneficiary's DRG may not be assigned until three days post-discharge, there may be circumstances where a participant hospital is not able to identify a CJR or EPM beneficiary until *after* discharge. This will be a more likely occurrence in EPM, as it covers episodes of care that involve non-elective, unplanned treatments and transfers to other facilities for higher levels of care. The FAH urges CMS to design a beneficiary notice process that protects the beneficiary without penalizing the hospital for clinical circumstances that are beyond the hospital's control.

As a result, the FAH respectfully requests that CMS consider a revised timing standard for participant hospital notification, one that requires only "best efforts" prior to the time of discharge. In the alternative, the FAH would appreciate guidance in the event a participant hospital, despite best efforts, is unable to timely deliver notice to a CJR or EPM beneficiary prior to discharge.

- ***Other Waivers Are Needed to Level the Playing Field Among PAC Providers***

Other waivers 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. EPM episode costs will vary dramatically depending on the PAC placement of the patient following the acute hospital stay. Many of these cost differences, for what could be essentially the same types of patients, may be due more to the "siloed" nature of Medicare's PAC payment systems and conditions of participation ("COP") requirements, rather than a reflection of efficient patient treatment rendered by providers.

The EPM model and other APMs should provide strong incentives in the form of regulatory waivers for the clinically appropriate and cost effective placement of patients into PAC settings, and allow PAC providers to compete fairly with one another on the basis of costs and quality. **For example, as discussed earlier, CMS should provide waivers to allow pricing flexibility for IRFs, which are paid on a bundled payment basis, so that IRFs can compete on an even playing field with other PAC providers who are paid on a per diem basis.** IRFs are well-suited to help acute care hospitals succeed under these models through their high-quality outcomes (including lower readmission rates compared to SNFs), ongoing medical management of patients, constant nursing care, and goal-oriented approach of restoring patients' functional deficits or impairments

Further, existing COPs and other regulatory requirements restrict fair competition across PAC providers. **They would not only adversely impact hospitals' ability to**

manage patient care in terms of spending and quality, but would negatively impact patient referral patterns and patient access to clinically appropriate care in certain types of settings.

One example, already noted, is the 3-Hour Rule for IRFs. Another, also described above, is the 60% Rule, which **should be modified for these models**, especially for those IRFs that participate in the shared accountability payment model.

CMS needs to consider the effects of the 60% rule on IRFs in this environment, and take appropriate steps to ensure that the program's effects do not have unintended negative consequences for IRFs and patients who need their services. This rule has historically functioned to distinguish IRFs from acute care hospitals and other PAC providers in a fee-for- service environment where the post-acute care "payment silos" and the rules and regulations governing those silos function in isolation, without the dynamic effects of care coordination/collaboration and accountability for expenditures incurred well beyond a prior hospital episode. However, as Medicare moves away from the traditional fee-for-service model and toward bundled payment and similar models, the IRF 60% rule needs to be appropriately modified –and ultimately, dispensed with – so that IRFs remain a viable component of our healthcare delivery system.

- ***CMS Should Expand Certain Proposed Waivers, Including the SNF 3-Day Rule Proposed Waiver***

The FAH recommends refinement and expansion of some of the EPM proposed waivers. For example, waiver of the SNF three-day rule only applies to the anchor hospitalization, is limited to episodes in the AMI model, and does not apply throughout the 90- day episode. Further, this waiver begins in the second quarter of PY2 (April 1, 2018), rather than in the first year. **The SNF 3-day waiver should be expanded to incorporate all of the proposed EPM models including CABG and SHFFT, apply throughout the 90-day episode and apply at the inception of this program.**

Hospitals and other providers need the tools necessary to maximize efficiencies and cost savings, as well as quality. Limiting the 3-day SNF waiver to the anchor episode is problematic if a patient is re-admitted to a hospital during the 90-day episode and subsequently needs SNF care. This could result in reduced quality of care or substantially increased costs for the patient if the patient cannot receive coverage for SNF care, or has to pay out-of-pocket for this care. We also do not believe it is necessary to limit the waiver only to the AMI models, as physicians should have the discretion to determine the most appropriate treatment and place of service for beneficiaries.

Further, the waiver should apply to the beginning of the program so that hospitals and other providers understand the applicable rules; otherwise, if the rules begin changing mid-stream, *i.e.*, in PY2, this creates too much confusion. More importantly, although hospitals are not at risk for repayment during the first year, they do have the opportunity to share in any upside savings in PY1, and thus should have the full range of tools needed to create as

much savings as possible during the first year, while also improving quality and efficiencies.

CMS Should Modify the SNF 3-day Waiver Beneficiary Protections to Ensure that Hospitals Receive Timely Information on SNF's Quality Rating and Beneficiary Eligibility

CMS would require that if a participant hospital discharges a beneficiary without a qualifying 3-day inpatient stay to a SNF that is not on the published list of SNFs that meet the CJR SNF waiver quality requirements as of the date of admission to the SNF, then the hospital will be financially liable for the SNF stay if no discharge planning notice is provided to the beneficiary, alerting them of potential financial liability. If the participant hospital provides a discharge planning notice in compliance with the revised requirements of §510.405(b)(4), the participant hospital will not be financially liable for the cost of the SNF stay and the normal Medicare FFS rules for coverage of SNF services will apply. CMS would implement this provision for CJR episodes beginning on January 1, 2017 and April 1, 2018 for AMI episodes. The FAH believes this is unreasonable, as this puts too much of the burden on hospitals, with the potential for significant hospital penalties, despite that the information needed to identify beneficiaries to whom a notice must be provided may not be available.

Specifically, too much burden would be placed on hospitals to continually check the list of qualifying SNFs to ensure that they meet the three stars or higher quality rating, as this list can change, and to ensure that the discharge planning notice distribution is targeted specifically to those patients in an EPM bundle. Further, it is extremely difficult for participant hospitals to timely identify bundled payment beneficiaries. Often, participating hospitals do not know that a beneficiary is in fact a bundled payment or shared savings beneficiary until post-discharge. Therefore, it would be extremely unfair to penalize participant hospitals for the cost of a particular beneficiary's SNF stay. CMS is in a better position to update the list of eligible SNFs, and as such, we urge CMS to assume this responsibility for providing the beneficiary notice, as an objective, informed and trusted voice in this process.

If CMS moves forward with this requirement, at a minimum, we urge CMS to provide a list of eligible SNFs to hospitals on a quarterly or periodic basis, and not rely on hospitals to constantly check the website to ensure that the status of a particular SNF has changed. Because beneficiary eligibility also can change, we support the concept that participant hospital knowledge of beneficiary eligibility for a given EPM model should be determined by Medicare coverage status at the time the services under the waiver were furnished.

Finally, we reiterate our earlier comments regarding the need to revise patient choice requirements, as this would help address the proposed SNF 3-day waiver policy. With this proposal, CMS in essence is mandating that certain Medicare beneficiaries select high quality providers. Participant hospitals in bundled payment programs can more effectively assist CMS in this policy goal, were the patient choice rules revised.

VIII. CMS Should Revise the Quality Framework under these EPM Models

The FAH has multiple, serious concerns with the quality framework for the Episode Payment Models (EPMs). The FAH concerns relate to quality measure relevance, measure overlap, measure misalignment, measure gaps, composite scoring methodology flaws, risk adjustment and risk stratification, data availability, and attribution of responsibility for quality.

- ***Measure relevance***

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. In the EPMs, however, CMS proposed to require the reporting of several measures with, at best, tenuous linkages to their associated models.

First, CMS proposed the Hospital Consumer Assessment of Healthcare Providers and Systems ("HCAPHS") Survey as a required measure for all three new EPMs (AMI, CABG, and SHFFT). HCAPHS is very familiar to the provider community as a general measure of patient experience and satisfaction during an acute care hospitalization, but there is nothing about HCAPHS that specifically addresses patient experience and satisfaction from the perspectives of patients having acute myocardial infarctions, undergoing coronary artery surgery, or being treated for hip fractures. These are the very patients, however, who would be receiving their care under the EPMs. Further, unless these patients choose to seek care for these conditions well outside of their home communities, these patients will have no option but to receive care under the mandatory MSA-based EPM models. Therefore, the FAH encourages CMS to consider substituting CG-CAHPS for HCAHPS in the EPM model. Experience within ACO programs indicates that CG-CAHPS better target attributed patients than HCAHPS. The CG- CAHPS are more targeted due to the connection between the patients' care and the physicians and care intervention programs

Secondly, one of the two clinical outcome measures proposed by CMS for the AMI model is AMI Excess Days (Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction). This measure is not NQF-endorsed. In the proposed rule discussion of this measure, CMS stated "In order to address the rising use of observation stays amongst Medicare beneficiaries CMS proposed the Excess Days in Acute Care after Hospitalization for AMI (AMI Excess Days) measure for use in the AMI model". Absent clear evidence as to what number of ED, observation, and/or readmission days are in fact "excess" and preventable rather than clinically justified as appropriate, inclusion of this measure seems to be all about costs of care rather than quality of care. In addition, the measures assess unplanned readmissions, emergency department services and observation days but does not look at the cost of care. The FAH does not support the use of this untested measure in this payment model.

Thirdly, the sole clinical outcome measure in the CABG model, CABG mortality, (Hospital-level 30-Day Risk-Standardized Mortality Rate ("RSMR") following Coronary Artery Bypass Graft Surgery), already is part of the Hospital Inpatient Quality Reporting

program ("HIQR"). By using it in this program, a hospital will be measured on this measure twice in two different payment/reporting programs. The FAH strongly recommends that CMS refrain from duplication of measures in multiple programs. The FAH encourages CMS to rethink the measures proposed for new CABG model since the measures do little to characterize the quality performance of CABG model participant hospitals beyond what it already being done through existing CMS programs.

CMS is already measuring mortality after CABG, perhaps, CMS could consider developing a measure of morbidity in terms of major complications after CABG, analogous to the complications measure used in the CJR model. Utilizing one or more individual complication measures that are known, serious, potential complications of CABG operations, such as deep sternal wound infection or acute renal failure possibly could add value.

Finally, neither the two required nor the one voluntary measures for the SHFFT model have any specificity for the hip fracture patient population. While the FAH appreciates the administrative simplification offered by identical measure profiles for the CJR and SHFFT models, the trade-off of accepting measures for SHFFT that have nothing to do with the model under trial is of highly questionable worth to the Medicare program in its quest for value over volume.

- ***Measure overlap***

Several of the EPM quality measures currently are utilized in one or more CMS hospital payment adjustment programs (e.g., see CABG mortality comments above). The FAH appreciates the attempt by CMS to utilize measures familiar to the provider community. However, there are potential unintended consequences of repeated use of the same measures in multiple Medicare hospital payment programs as reported last year in *Health Affairs*[7].

- ***Measure misalignment***

The bundled care episodes will extend 90 days after hospital discharge for each of the new EPMs. The duration of this bundle presumably allows for capture of nearly all of the care typically delivered for the targeted disease/treatment of each model and incentivizes hospital-led collaboration across sites of service to reduce costs and to improve quality. However, the two clinical measures for the AMI and CABG models, (AMI mortality, CABG mortality) are 30-day measures. Such misalignment creates potential issues such as how to generalize the results to the 90-day EPM episode when planning cost and quality initiatives and how to publicly explain the 30-day results for a 90-day episode in a way that helps inform beneficiary choices about their care.

- ***Measure gaps***

[7] Charles N. Kahn III, Thomas Ault, Lisa Potetz, Thomas Walke, Jayne Hart Chambers and Samantah Burch, "Assessing Medicare's Hospital Pay-For-Performance Programs And Whether They Are Achieving Their Goals"; Health Affairs, 34, no.8(2015):1281-1288.

As noted above, major morbidity after CABG surgery is not addressed by the CABG model. Similarly, major complications after AMI treatment (with or without percutaneous coronary intervention, PCI) are not addressed in the AMI model; instead, only mortality is measured, duplicating a measure already in use in other CMS hospital payment programs. None of the measures for any of the new EPMs reflect post-acute care (PAC), despite the 90-day post-discharge episode duration during which a substantial majority of EPM patients will receive services from at least one type of PAC provider. The lack of attention to the interface between PAC and acute quality paints an incomplete picture of the services a patient receives, and does little to encourage provider collaboration across the care continuum.

- ***Composite scoring methodology flaws***

Hospital Compare data demonstrate that the overwhelming majority of hospitals (96-97%) perform at levels indistinguishable from national averages for all of the three NQF-endorsed clinical outcome measures proposed for EPM use (AMI mortality, CABG mortality, THA/TKA complications), so it is unclear that the performance deciles describe importantly different quality achievement levels. A composite score that converts these deciles to points then uses very small incremental point differences to define four performance categories for payment adjustments to the effective discount factor (Below Acceptable, Acceptable, Good, and Excellent) as proposed by CMS for all three EPMs. This methodology imputes an unjustified precision to these measures, given their national performance distributions.

Another flaw in the methodology arises from the 3-year rolling average performance period used for these measures. It would not be until performance year 3 (PY3), well into the downside risk period of the models, that the 3-year rolling average actually reflects performance under the model rather than historical, pre-EPM performance.

Additionally, the use of a rolling average blurs recognition of improvement by a hospital from its baseline at the inception of the model, when summative, sustained improvement over the course of the model should be the desired goal. Further, the proposed reward for year-over-year improvement is very small -- at best, one point for the most heavily weighted measures -- and offers limited motivation for undertaking complex, costly care redesign.

Finally, CMS proposed that additional composite score points can be accrued through submission of voluntary measure data. Both of the voluntary measures are hybrid measures that require sophisticated health information technology resources to document and to submit. These hybrid measures have not been proven to be effective, are not endorsed and are new to hospitals. The playing field for quality rewards should be level across EPM participants.

- ***Risk-adjustment and risk-stratification***

Risk adjustment and risk stratification in the models are limited and inadequate. Risk adjustment is done only for age, sex, and comorbidities present at admission (as captured by

CMS Hierarchical Condition Categories, HCC), by virtue of being built into the three NQF-endorsed EPM clinical outcome measures (AMI mortality, CABG mortality, THA/TKA complications). No adjustment reflects the population differences inherent between patients undergoing totally elective, discretionary operations (THA/TKA) and urgent operations for major illnesses that present acutely (hip fracture fixation, urgent CABG). For example, it seems intuitive that patients sustaining acute, major illnesses often associated with functional status declines (e.g., acute myocardial infarction, hip fracture) will assess their experiences of care quite differently from patients undergoing discretionary or planned treatment (e.g. THA/TKA, non- emergent CABG). Further, CMS once again fails to make <u>any</u> adjustments for socioeconomic/demographic status (SDS factors). The FAH has commented to CMS on numerous occasions on the need for SDS adjustment and continues to strongly advocate for appropriate SDS adjustment for <u>all</u> outcomes measures. The FAH also notes that without robust risk adjustment, the precedence for BPCI episodes over EPM episodes may incentivize steering of lower-risk patients to BPCI and higher-risk patients to EPMs for cardiac care and lower extremity joint replacement. Risk-stratification is captured only through MS-DRG assignment (i.e., with or without major complications), a methodology designed to reflect typical costs of care rather than quality, and no attention is given to individual, patient-specific characteristics (e.g., delay in seeking treatment, extent of myocardial infarction, pre-existing osteoporosis) that may significantly influence clinical outcomes. The financial pressures associated with new bundled payments may combine with this limited risk-stratification to create an unintended impetus to MS-DRG upcoding.

- ***Data availability***

Prior to EPM implementation, participant hospitals need full access to their historical quality data, some of which is available to them only through CMS (e.g., 90-day THA/TKA complications). CMS states that data release will precede EPM start dates. Meaningful, collaborative, quality improvement initiatives do not happen overnight, and EPM implementation should not be undertaken until hospitals 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. **Participant hospitals should be provided with automatic performance updates at least quarterly.** For hospital systems, data should be provided at the individual subunit and the system-wide levels.

Additionally, CMS will use the HCAHPS Linear Mean Roll-up ("HLMR") score for scoring hospitals' performance. Currently the HLMR score is available to hospitals only through the annual preview reports released to hospitals on Quality Net ("QNet"). **The HLMR score is not made publicly available. CMS must release this value publicly** in order to allow hospitals to not only know their HLMR score, but that of other hospitals in order to understand their percentile levels. These data should also be released automatically and at least quarterly to facilitate hospitals' ability to rapidly improve their performances and assess financial risks.

Finally, CMS has said relatively little about public reporting of EPM-related performance data. The value of quality data is maximized when easily-understood data are

made readily accessible to beneficiaries and their families as they make choices about where and by whom their health care will be delivered. The data also must be reliable, and there must be a transparent process through which hospitals can preview and offer corrections to CMS- provided data before the data are reported on *Hospital Compare*.

- ***Attribution of responsibility for quality***

The FAH believes that major revisions to the quality framework and/or the EPM models themselves are needed before <u>any</u> of the EPMs are implemented. First, the time available before the proposed October 1, 2017 implementation of all of the new EPMs is clearly insufficient to resolve the identified quality framework issues through a process that appropriately takes into account the input of all stakeholders. The **FAH believes that that quality issues outlined above support our recommendation that CMS delay EPM implementation until no earlier than January 1, 2018.** While the FAH supports the evolution of the Medicare program from volume to value, the EPM quality framework as proposed is inconsistent with a true value-based payment system.

The FAH recommends that CMS consider an EPM approach similar to that taken previously by CMS to MSSP ACO quality reporting. In the first year of the EPMs, as was true for MSSP ACOs, there should be no penalty for quality performance, and EPM participants should only be accountable for reporting necessary quality data in a timely and accurate manner and establishing internal systems for analyzing quarterly claims reports to be received from CMS. Instead, EPM participants can use their PY1 quality results as an indication of whether they are at, below, or above the national average. If an EPM participant is below the national average, it could be required to work with its local quality improvement organization ("QIO") to implement a plan of action for improvement. During PY2, results would be compared with PY1 and participant hospitals performing at or above the national average would be able to receive a full reconciliation payment. If a participant hospital that fell below the national average in PY1 followed its plan of action and improved, even though it did not reach the national average, it should be eligible to receive a portion of the reconciliation payment it otherwise earned. However, if a participant hospital fell below the national average in PY1, and did not follow the plan of correction established by their local QIO, its reconciliation payment would be reduced. This would allow PY1 and PY2 to serve as a testing ground for EPM participating hospitals and would encourage individual improvement. There is insufficient congruity between the existing CJR model (itself still in its first year of implementation) and the cardiac care EPMs to think that preparations made by hospitals for the CJR will transfer seamlessly to the new EPMs and will be sufficient to enable the likelihood of EPM success. An approach similar to that of the well-established MSSP ACO program offers a pragmatic solution to the EPM composite scoring methodology issues.

The FAH strongly believes that CMS must address measure modification to maximize the chances that the EPM models are successful. While, as stated above, the FAH does not support moving forward with the SHFFT model, should CMS choose to do so, to achieve face validity with the provider and beneficiary communities, the SHFFT

model must incorporate one or more measures relevant to hip fracture patients. Modification to the 30-day duration of the AMI mortality and CABG mortality measures to align them with the 90-day EPM episode duration should be undertaken; alternatively, consideration should be given to shortening the AMI and CABG episodes. Measures should be sought to fill the identified gaps such as CABG complications and PAC functional outcomes. Measure overlap with other CMS hospital payment programs should be limited or avoided to reduce the resulting financial double jeopardy. If the HCAPHS Survey measure is to be used, CMS should filter the results by MS-DRGs or ICD-10 diagnoses and use only results matched to the EPM patient populations. Consideration could be given to using other CAPHS versions such as the surgical CAPHS (S-CAPHS). In keeping with prior comments, the FAH recommends that the THA/TKA PRO measure should not be included in the EPM program until this complex and complicated measure has been significantly refined to streamline the associated reporting burden.

The FAH once again strongly endorses the application of risk adjustment for SDS factors. Such adjustment is particularly important for small and rural hospitals and those serving vulnerable populations, the same group that is disadvantaged in reporting the voluntary measures. Socio-demographic status adjustment and stratification are also vitally important tools for accurately assessing health care provider performance for fair and transparent public reporting. Further, SDS adjustment is critical for measures that address readmissions, such as AMI Excess Days, as evidenced by a recent study reporting that nearly 60 percent of the variation in national hospital readmission rates was explained by the county in which the hospital is located rather than hospital characteristics. Local factors such as income, employment levels, access to services and nursing home quality were the major factors underlying county-level variation[8].

IX. CMS Should Ensure a Level Playing Field to Avoid Market Distortions and Inappropriate Patient Steering

CMS believes that it is important to simultaneously allow beneficiaries to participate in broader population-based and total cost of care models, as well as models that target specific episodes of care. The rule suggests that, given the overlap in CMS APMs that reward providers with shared savings, an order of precedence must be established to determine which program savings are attributed to which program participants (and to avoid double-counting). Entities that participate in shared savings programs and total cost of care models stand to benefit, at least in part, from the cost savings that accrue under these episode models.

BPCI is an example of a care redesign model that has the potential to overlap with these models. According to CMS, ensuring that BPCI and EPM models do not overlap allows CMS to accurately apply the payment policies in both models. **The FAH is concerned, however, that cases in which BPCI takes precedence over CJR and these EPMs, there exists the potential for patient steering. As CJR and these EPM models are mandatory for hospitals, giving precedence to voluntary BPCI participants, including physician**

[8] Herrin, J., St. Andre, J., Kenward, K., Joshi, M. S., Audet, A.-M. J. and Hines, S.C. (2015), Community Factors and Hospital Readmission Rates. Health Services Research, 50: 20-39. doi: 10.1111/1475-6773.12177

group practices, could create market distortions by incentivizing BPCI participants to select lower severity cardiac cases to initiate in a BPCI episode while leaving high severity orthopedic and cardiac cases to be initiated under CJR and the EPM models in the hospital. Better risk adjustment, which we recommend, might be a mitigating factor, but would not eliminate the financial risk to hospitals participating in the mandatory models. In addition, such patient selection behaviors would distort an evaluation of the program and undermine its ultimate success. **The FAH urges CMS to ensure that CJR and these EPM models are on a level playing field with BPCI and other similar programs, for example, by granting appropriate program waivers, as discussed above. Further, once a level playing field is established, these EPM models and CJR should take precedence over BPCI cases to avoid market distortions and patient steering.**

Given CMS's quick pace in developing and implementing new models of care, it is also imperative that CMS understand the impacts the models have on each other. While it is understandable that CMS would venture to test varying care delivery models, the efficacy of each of those models will hinge on how the model is impacted by other CMS models. It is important that CMS not unintentionally undermine one model due to a lack of understanding of model overlap and impact.

To that end, the FAH believes that CMS could improve the success of its ACO models by allowing ACO participating hospitals to opt-out of the mandatory bundled payment programs. Given the resources required to participate in any of CMS's models, voluntary exclusion by the ACO participating hospitals would allow them to devote resources to success in the ACO model.

We appreciate your consideration of our recommendations that are vital to ensuring this program provides hospitals the ability to achieve program goals, while managing their financial, legal, and regulatory risk. If you have any questions about our comments or need further information, please contact me or my staff at (202) 621-1500.

Sincerely,