Charles N. Kahn III
President & CEO

October 16, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

SUBJECT: ***CMS-5524-P, Medicare Program; Cancelation of Advancing Care Coordination Through Episode Payment Models; Changes to Comprehensive Care for Joint Replacement Payment Model, August 17, 2017.***

Dear Administrator Verma:

The Federation of American Hospitals (FAH) appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) on the above notice of proposed rulemaking (Proposed Rule), published in the *Federal Register* on August 17, 2017 (82 FR 39310). The FAH is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members are diverse, including teaching and non-teaching, short-stay, rehabilitation, long-term acute care, psychiatric, and cancer hospitals in urban and rural America, and they provide a wide range of acute, post-acute, and ambulatory services.

I. FAH Supports CMS's Proposal to Cancel the Episode Payment Models

The FAH supports CMS's proposal to cancel the Episode Payment Models (EPM). CMS's reasoning for canceling the models is largely in line with the FAH's comments when the models were originally proposed. In those comments, the FAH noted that our member hospitals have become increasingly concerned about the pace of change proposed 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. The FAH suggested then that a better approach would be for CMS, prior to advancing additional bundled

payment models, to evaluate and learn from hospitals' Comprehensive Care for Joint Replacement Model (CJR) experience and from the Bundled Payments for Care Improvement (BPCI) initiative Model 2 results. Establishing a "proof of concept" is a very important tool to utilize before implementing new mandatory episode payment models that could affect large numbers of Medicare beneficiaries and potentially have significant and adverse unintended consequences if not implemented in a reasonable, thoughtful, and deliberate manner.

As noted in the proposed rule, CMS received comments from many stakeholders, including the FAH, noting that the models contain many design flaws that undermine their success and could harm patients, providers, and the Medicare program overall. Further, CMS discussed that many stakeholders expressed opposition to the mandatory nature of the models. The FAH also opposes the mandatory nature of the EPM. While we will provide additional explanation below, we strongly believe that Center for Medicare and Medicaid Innovation (CMMI) models should only be implemented on a voluntary basis, and we appreciate CMS acknowledging in this proposed rule that this view is shared by many stakeholders.

FAH members believe that episode payment models, when realistically constructed with sufficient stakeholder preparation time, hold promise as part of CMS's strategy to move from volume to value. Unfortunately, we believe the EPM models finalized on January 3, 2017, did not meet this standard. As such, we strongly support CMS's proposal to cancel the EPM models.

II. FAH Encourages CMS to Move Forward with the Cardiac Rehabilitation Incentive Payment Model

We respectfully request that CMS not finalize its proposal to cancel the cardiac rehabilitation (CR) incentive payment model. We believe the CR model is an important test of how intensive cardiac rehabilitation (ICR) can significantly improve long-term outcomes for patients following acute myocardial infarction (AMI) or coronary artery bypass grafting (CABG).

We believe the CR model remains valuable even after the cancelation of the EPM. By continuing the implementation of the model, patients of participating providers will experience the benefit of testing new ways to enhance coordination of care and patient adherence to that care. Continuing the model could result in nationwide patient benefit through the dissemination of new practice of care for cardiac patients.

III. FAH Appreciates CMS's Proposal to Scale Back CJR's Mandatory Participation Areas and Encourages CMS to Operate all CJR and other CMMI Models through a Voluntary Process

CMS also is proposing certain revisions to the mandatory participation requirements for the CJR model to allow CMS to continue to evaluate the effects of the model while limiting the geographic reach of the current mandatory model. Again, we appreciate CMS's scaling back the mandatory reach of this model amidst its concerns about, and desire to evaluate, its effects. We also appreciate CMS retaining the provisions of the model that make CJR Advanced Alternative Payment Model (APM)-eligible. Nevertheless, we have strong concerns about the mandatory

nature of the CJR, or any other similar model. **The FAH does not believe the statute authorizes CMS to mandate provider participation in any 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. 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. 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 maintain or 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). Lastly, 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.

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.

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.

Any Agency interpretation that the statute permits mandatory models 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. An Agency determination allowing mandatory participation of providers of services and/or suppliers is an overreach in interpretation that 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 of providers of suppliers, we do not believe CMS may implement a policy that requires such mandatory participation. We appreciate that CMS is proposing to cancel the mandatory EPM models and reduce the mandatory reach of CJR, and further urge CMS to take this policy a step further to fully eliminate the mandatory nature of the CJR model, while ensuring that this is solely a voluntary model. We also believe any future CMMI models are statutorily required to be voluntary as well.**

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).

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 jumps over this process and imposes a mandatory program on affected hospitals (and the EPM model would do the same). There was no Phase I or Phase II of testing CJR, nor the EPM models, before these models were mandated. **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.**

A policy of imposing mandated models on providers and suppliers without any testing 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). In addition, it assumes that 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. We note that CMS discusses these practical concerns in the proposed rule, which appears to be a key factor the Agency's proposal to cancel the EPM models. **We urge CMS to similarly cancel the CJR models on this basis as well.**

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

We appreciate and support CMS's proposal to cancel the EPM. 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 it meets the requisite conditions, including that it is expected to maintain or reduce spending while maintaining or improving the quality of patient care.

We support CMS's proposal to cancel the EPM precisely because it is a prohibited expansion in scope of the CJR model. **Additionally, even the CJR model has not met the Phase I requirements.** CMS has not evaluated the CJR model as required under section §1115A(b)(4) of the SSA. Further, CMS did not make 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.

IV. FAH Supports CMS's Proposal to Allow Low-Volume and Rural Hospitals to Opt-In to CJR Participation in Mandatory Markets and for all Hospitals in Voluntary Markets to Opt-In

The FAH supports the CMS proposal to exclude and automatically withdraw low-volume and rural hospitals in the proposed 34 mandatory participation metropolitan statistical areas (MSAs), as identified by CMS from participation in the CJR model (effective February 1, 2018). We are pleased that CMS recognizes the challenges that low-volume and rural hospitals face participating in CJR. As shared in previous comments, these hospitals often have limited financial resources, have low case-volume on which to spread financial risk, or lack existing networks with physicians and other providers.

Per the Proposed Rule, CMS intends to define a low-volume hospital as a "hospital identified by CMS as having fewer than 20 LEJR episodes in total across the 3 historical years of

data used to calculate the performance year 1 CJR episode target prices." **While the FAH appreciates that CMS recognizes the challenge low-volume hospitals have in participating in CJR, we believe a more appropriate low-volume threshold would be 100 LEJR episodes and encourage CMS to adopt this standard rather than the 20 LEJR episode standard proposed.** A higher threshold is warranted given these hospitals have lower risk tolerance, are subject to the results of wide variation in costs and acuity in small numbers of episodes, and are less capable of supporting needed infrastructure to achieve efficiency for high cost episodes.

CMS also proposes that all hospitals in a voluntary MSA and low-volume and rural hospitals in a mandatory MSA be able to opt-in to the program on a one-time voluntary basis by January 31, 2018. The FAH supports the CMS proposal to allow these hospitals to participate on a voluntary basis. This recognizes that certain hospitals in this group may benefit from the CJR model and have already made substantial investments specific to implementing the CJR model. The requirement to initially opt-in is less burdensome compared with an initial opt-out approach, and its voluntary design is consistent with the FAH's belief that participation in CMMI models should be voluntary. However, we would encourage CMS to make an important adjustment to the voluntary opt-in proposal. **The FAH believes that all hospitals in the voluntary MSAs and low-volume and rural hospitals in the mandatory MSAs should also be allowed an annual opt-out provision.** Given that hospitals have only been through one reconciliation, it is too early for hospitals to make a decision about whether to opt-in, likely resulting in many of these hospitals remaining outside the program. If they were provided an opportunity to opt-out on an annual basis, hospitals in the voluntary MSAs and low-volume and rural hospitals in the mandatory MSAs may be more likely to remain participants in CJR.

V. The FAH Urges CMS to Provide Additional Detail on Changes to its CJR Model Evaluation Design

The FAH is concerned that the modification of the evaluation plan based on the proposed changes was not explained in sufficient detail in the proposed rule. It is not transparent that the changes to the evaluation design will be rigorous enough to address the substantial design changes in the CJR model. In particular, we are concerned about the generalizability of the findings of the CJR model given the design changes. While we anticipate that there will be sufficient variation in characteristics and experiences of the hospitals remaining in the CJR model, CMS needs to lay out additional detail and analysis demonstrating this assertion in the final rule to ensure that its evaluation plan and approach are sufficiently rigorous.

Moreover, should CMS remove total knee arthroplasty (TKA) from the CMS inpatient list – as proposed in the 2018 Hospital Outpatient Prospective Payment System rule – this would also substantially complicate the study design and the methods used to assess the impact of the CJR model on costs and health care outcomes. In particular, the analysis and evaluation of the model's results may be negatively impacted as:

- Fewer patients would result in fewer episodes available for analysis for both cost and quality outcomes,
- Some statistical methods may not be feasible and subset analysis could be limited, and
- The power of the model to detect significant changes in cost or quality may be lowered.

CMS should provide in the final rule a detailed evaluation plan including a process/timeline so that it can be reviewed by external stakeholders and evaluation experts. We believe that it is prudent to develop an evaluation plan that has been fully vetted by external stakeholders and experts on evaluation design to ensure that the conclusions drawn from the CJR model are reasonable, empirically-supported, and valid.

VI. FAH Encourages CMS to Make Additional Changes to the CJR Model

- ***Gainsharing***

Allow Participant Hospitals to Increase the Frequency of Their Gainsharing Payments

The FAH believes CJR's requirement that 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 distribute payments monthly and quarterly. 42 C.F.R. §§ 512.500(c)(1)(ii); 510.500 (c)(1)(ii). CJR participating 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.[1]

The FAH does not dispute that the above poses 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 CJR to permit a quarterly gainsharing payment schedule, consistent with most BPCI models.

Increase the Gainsharing Cap

The FAH requests that CMS consider increasing the total amount physicians and/or physician group practices (PGPs) may be eligible to receive under CJR. CMS has entrusted hospitals with the responsibility to oversee and implement care redesign. Accordingly, the

[1] 80 Fed. Reg. 73274, 73385 (November 24, 2015).

FAH believes that CMS should likewise entrust hospitals with, and grant them 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 percent 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.

- ***CMS Should Use Metropolitan Statistical Areas Instead of Census Divisions to Establish Regional Prices***

Further, the use of the nine census divisions to establish regional prices in CJR 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.

- ***CMS Should Evaluate Its Continued Use of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Measure***

As we noted when commenting on the CJR Proposed Rule in 2015, the HCAHPS measure is well-known to hospitals. However, it is a broad assessment of care across an entire hospital, not just total hip arthroplasty (THA)/TKA patients. Given that the vast majority of hospitals collect HCAHPS data on only a sample of patients, it is very possible that the sample contains few and possibly even no THA/TKA patients. **As such, CMS should evaluate whether the HCAHPS measure is appropriate for continued use in CJR**.

VII. The FAH urges CMS to Provide a Clear and Transparent Plan for Adjusting the CJR Model for the Anticipated Effects of Removing TKA from the Inpatient Only List, Should CMS Elect to Proceed with Removal

As noted above, the FAH strongly supports the CMS proposals to decrease the geographic reach of the CJR model and to scale back mandatory hospital participation. However, as detailed in our recent OPPS Proposed Rule comments opposing TKA removal from the inpatient only list for CY 2018, the FAH has serious concerns about the overlap between the proposed major revisions to the CJR model with the CMS proposal for TKA removal.

In addition to the evaluation design effects described above, potential CJR impacts include:

- variable and unpredictable reduction in the number of CJR patients and episodes,
- increased complexity and frailty of CJR TKA patients,
- increased volume and intensity of post-acute services needed for good clinical outcomes,
- quality and cost targets that are not realistic for the residual CJR patient population, and
- excess financial risks and competitive disadvantages imposed upon the remaining mandatory participant hospitals.

At a minimum, should CMS move forward with its OPPS proposal, the Agency should acknowledge the impact on CJR target prices and agree to update those target prices on a more frequent basis than currently done under the demonstration. Failing to do so will likely have negative consequences for those hospitals that remain in the program.

VIII. The FAH Supports Use of the Amended CJR Composite Quality Score during Performance Year 1 Subsequent Reconciliation

During reconciliation, a CJR participant hospital's episode target price is adjusted using the hospital's composite quality score. For the CJR Performance Year 1 (PY 1) initial reconciliation, CMS intended to apply the composite quality score methodology as revised and finalized ("amended") in the Episode Payment Model final rule,[2] rather than the original methodology from the CJR final rule.[3] However, CMS was unable to do so because the revision's effective date was delayed until May 20, 2017, past the scheduled CY 2017 first quarter initial reconciliation time period. CMS proposes to apply the revised scoring methodology beginning with the PY 1 subsequent reconciliation, but also discusses an alternative to begin instead with the PY 2 initial reconciliation.

The FAH supports the CMS proposal to apply the amended CJR composite quality score methodology beginning with the PY 1 subsequent reconciliation. The revised scoring adds improvement points to the composite score for a 2-decile percentile performance increase year-over-year, rather than the original 3-decile requirement. The resulting higher composite scores will allow more CJR participants to be eligible for reconciliation payments or to owe smaller repayments, at least partially offsetting the unfunded infrastructure and care coordination investments that successful CJR participation requires. The revised scoring also preserves the ability for high-performing hospitals to earn reconciliation payments that more accurately reflect their performance and investments in the program. Finally, the revised methodology also uses a more appropriate national peer group as the reference population when computing quality performance points for each quality measure.

Transitioning to the revised composite quality score methodology between the PY 1 initial and subsequent reconciliation calculations may increase the differences between the results of the two calculations than would otherwise have occurred during subsequent

[2] 82 Fed. Reg. 524 through 526
[3] 80 Fed. Reg. 73381 (November 24, 2015).

reconciliation due to the anticipated longer claims runout, model overlap accounting, and post-episode spending adjustments. The differences will vary by hospital and may be positive or negative. The impact of any larger downward adjustments, however, should be least in PY 1, during which hospitals are not responsible for repayments to CMS if their costs exceed their quality-adjusted episode target prices. **The FAH urges CMS to conduct the PY 1 subsequent reconciliation and share results with participant hospitals as early as feasible in 2018 to minimize the uncertainty for hospitals about potential downward adjustments.**

Delaying implementation of the revised quality scoring until CJR PY 2, in which model participants begin to bear risk for repayments, would amplify the reconciliation financial risk for hospitals. Further, delayed implementation would increase CJR operational complexity and would complicate evaluation of the CJR model results, since having different quality scoring for PY 1 versus subsequent years would require developing a mechanism such as a crosswalk to validly compare performance across all years of the model. **The FAH opposes delaying the implementation of the amended quality scoring until the initial reconciliation for PY 2.**

IX. The FAH Supports CMS's Proposal to Create a "Clinician Engagement List"

The FAH supports CMS's proposal to create a "clinician engagement list" to allow additional providers contributing to the quality and/or cost goals of an Advanced APM Track 1 CJR to count their participation toward Qualifying APM Participant (QP) status under the Quality Payment Program (QPP).

CMS uses an Affiliated Practitioner List to "identify the eligible clinicians who will be assessed as Qualifying APM Participants (QPs) for the year."[4] Currently, only clinicians that have a financial arrangement with the Advanced APM Entity (e.g., the CJR-participating hospital) to support the Advanced APM Entity's quality or cost are eligible for inclusion on a clinician financial arrangement list, which CMS considers an Affiliated Practitioner List.

In the Proposed Rule, CMS proposes to permit clinicians who do not have a financial arrangement under the CJR model but who "have a contractual relationship with the participant hospital based at least in part on supporting the participant hospital's quality or cost goals under the CJR model"[5] to be included on a clinician engagement list that, together with the clinician financial arrangement list, would be considered an Affiliated Practitioner List for purposes of QP determinations.

The FAH agrees with CMS that these clinicians "should have their contributions to the Advanced APM Entity's participation in the Advanced APM recognized under the Quality Payment Program,"[6] and encourages CMS to finalize this proposal.

[4] 82 Fed. Reg. 39324 (August 17, 2017).
[5] 82 Fed. Reg. 39325 (August 17, 2017).
[6] 82 Fed. Reg. 39324 (August 17, 2017).

X. FAH Supports Providing Flexibility for Post-Acute Care Providers to Participate in Bundling Programs

Bundled payment programs should encourage high quality patient outcomes through incentivizing more collaborative and coordinated decision-making around the efficient utilization of care and services, including post-acute care (PAC) services. **As CMS continues to develop and implement bundled payment programs, which place financial risk on acute care hospitals for PAC spending, it is important to provide payment flexibility to PAC hospitals to allow them to achieve efficiencies and better coordinate care with acute care hospitals that are at financial risk under these bundled payment models.** This is an issue that the FAH has brought to the attention of CMS in our previous comments related to the EPM model and which we reiterate here.

Optimal efficiencies for PAC utilization requires involvement of PAC providers in bundling arrangements. For example, inpatient rehabilitation facilities (IRFs) could test a CMMI bundling program that would not be derived from the IRF prospective payment system (PPS), but instead would permit IRFs to assume the risk of caring for certain patients over a defined period of time and with sufficient regulatory relief, such as rescinding the 60 percent rule and three-hour rule.

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.[7]

Unlike SNFs and HHAs, there is no flexibility for IRFs to reduce their Medicare

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

payments for the benefit of hospitals participating in the bundled payment models, regardless of the cost-efficiencies an IRF may generate. This is because episode target prices and performance period spending in Medicare's bundled payment programs are based on Medicare payments, and Medicare payments to IRFs are per-discharge (not per diem) and diagnosis based (not therapy based). Thus, IRFs need additional flexibility to participate in bundled payment programs 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).

A voluntary CMMI bundling program that would allow IRFs to assume the risk of caring for certain patients over a defined period of time and with sufficient regulatory relief would enable IRFs to more fully and robustly share in the potential risks and rewards of these bundled payment programs. It would also 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 the need for payment flexibility as Medicare reimbursement moves towards alternative payment models and away from fee-for-service.

Bundled payment and delivery programs require hospitals and other providers to be more accountable for their referral decisions for post-acute care services, including both outcomes and spending. These shifting dynamics have obviated the need for stringent rules, such as the 60 percent and three-hour rules. Acute-care hospitals and physicians should have broader flexibility to discharge their patients to the most appropriate level of post-acute care needed to meet their patients' needs, focusing on what is best for the patient, not on whether a patient's diagnosis satisfies the 60 percent rule.

Further, the three-hour rule undermines patient-centered care, especially in a bundled payment and coordinated care environment. This intensive therapy requirement should be aligned with the IRF patient's unique medical and therapy needs and rehabilitation physicians' and therapists' clinical judgment, rather than a cookie cutter approach. Flexibility is needed to address patient need, while ensuring the quality of care and cost efficiencies needed for success in a bundled payment program.

The FAH urges CMMI to provide the opportunity for IRFs to carry more risk in bundling programs, while rescinding the 60 percent and three-hour rules. Permitting greater shared accountability between hospitals and IRFs would strengthen their relationship, leading to improved patient care and reduced costs.

XI. Implement an Advanced Alternative Payment Model (APM)-Eligible Voluntary Bundled Payment Model

The FAH applauds the commitment CMS made in January 2017 and in the August 2017 Proposed Rule to build on the BPCI model to "design a new voluntary bundled

payment model" that would "meet the criteria to be an Advanced APM."[8] However, as we approach CY2018, this new model is not yet available to clinicians, and CMS has not released a timeline for its development.

It is important that CMS act soon on its intention. There are more than 1200 participants in Phase 2 of BPCI awaiting guidance from CMS on the new framework. As CMS is aware, current BPCI participants and new participants alike will require substantial lead time to do the advance work required prior to participate in any new CMS model. Providing prospective participants with information now will likely lead to greater success of the model in the future.

As noted in the FAH comments on the CY2018 QPP Proposed Rule, CMS has identified a limited number of models that merit designations as Advanced APMs and whose participating clinicians could reach QP status. While the success of APMs rests on allowing different payment models to compete on value and efficiency and allowing the marketplace to determine success among the models, under the statute, the Advanced APM incentive bonus lasts for only six years (2019-2024). As we move into QPP performance year two, limited availability of Advanced APMs leaves a narrow window for CMS to use the MACRA-established incentive payments to encourage providers to shift into these models. The FAH is concerned that clinicians and their hospital partners ultimately may be unlikely to join together in APMs, and clinicians will instead choose the predictability of remaining in MIPS. The net result will be that Medicare's movement from volume to value will be considerably slower and much less robust than CMS desires for its beneficiaries. **To improve participation in Advanced APMs, the FAH encourages CMS to implement the new voluntary bundled payment model as soon as possible.**

XII. CMS Should Consider Providing CJR Program Waivers for Hospitals Facing Natural Disasters or Public Health Emergencies

CMS should consider implementing a policy offering CJR hospitals facing public health emergencies or natural disasters, such as the recent hurricanes, the option of obtaining a program participation waiver. Such a waiver would ensure that these hospitals are not unfairly penalized by circumstances that are outside of their control. Hospitals in these areas face unanticipated challenges that require shifts from normal operations to meet the clinical needs of their impacted communities. Additionally, given that the impact on a hospital in such an area will likely last well after the on-set of the emergency or disaster, a waiver of program participation is appropriate.

****

[8] 82 Fed. Reg. 215 (January 3, 2017). "However, building on the BPCI initiative, the Innovation Center intends to implement [a] new bundled payment model for CY 2018 where the model(s) would be designed to meet the criteria to be an Advanced APM." And, in response to stakeholder comments, "We appreciate these considerations as we design a new voluntary bundled payment model." *See* also 82 Fed Reg. 39313 (August 17, 2017). "…providers interested in participating in bundled payment models may still have an opportunity to do so during calendar year (CY) 2018 via new voluntary bundled payment models. Building on the BPCI initiative, the Innovation Center expects to develop new voluntary bundled payment model(s) during CY 2018 that would be designed to meet the criteria to be an Advanced APM."

The FAH appreciates the opportunity to comment on the Proposed Rule. We look forward to continued partnership with the CMS as we strive for a continuously improving health care system. If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1500.

Sincerely,