Charles N. Kahn III
President and CEO

June 23, 2020

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: Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing; Proposed Rule (Feb. 24, 2020)

Dear Administrator Verma:

The Federation of American Hospitals (FAH) is the national representative for over 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural America. Our members include teaching and non-teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

The FAH is pleased to provide CMS with our views in response to the above-referenced *Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing* proposed rule.

FAH members appreciate the opportunity to test innovative care models developed by CMS' Center for Medicare & Medicaid Innovation (CMS Innovation Center). The Comprehensive Care for Joint Replacement (CJR) model has promoted high quality care delivery at lower costs, thereby improving outcomes for beneficiaries, the Medicare program, and population health, though it is not without its challenges, as discussed further below.

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Because our members and all health care providers across the country face a health care landscape dominated, appropriately, by responding to the COVID-19 national public health emergency (PHE), it is impossible for the FAH to comment on specific provisions of the proposed rule in isolation, without considering the proper place for the CJR model in the Medicare program during and after the COVID-19 PHE. Therefore, we first provide a set of overall strategic recommendations informed by our experience with the CJR model to date, followed by comments on specific provisions of the proposed rule that should be considered if CMS proceeds with extending the CJR model program.

I. Overall Comments on the Proposed Three-Year Extension and Protecting Participating CJR Hospitals in Performance Year (PY) 5

CMS Should End the CJR Model Without a Three-Year Extension and Hold Participating CJR Hospitals Financially Harmless in PY 5 Given the COVID-19 PHE

Given the COVID-19 PHE, the FAH urges CMS to end the CJR model at the original termination date of December 31, 2020, without the proposed three-year extension. Our member hospitals are using all hands on deck to respond to the PHE and earlier this year suspended elective surgeries in response to CMS' announcement on March 18, 2020.[1] The lasting impacts of this PHE will endure well beyond the currently unknown timeline for the formal declaration of the end of this PHE and PY 5, as it will take time for hospitals to return to normal volumes and processes. As a practical matter, there is no reason for CMS to continue this model for testing purposes at this time. While we understand that CMS cited its primary reason for the extension was to test the impact of Medicare paying for total knee arthroplasty (TKA) and total hip arthroplasty (THA) in the hospital outpatient setting, there are a number of factors that would prove problematic for testing that episode under this program. For example, it would be difficult, if not impossible, to generalize any future findings from CJR that occur over the next several years, as these evaluation results will be confounded by the impact of the COVID-19 pandemic.

Ending the CJR model after 5 years, as scheduled, would allow CMS to more fully evaluate the program, determine lessons learned, and reassess how best to move forward. There is more than sufficient data from prior years to evaluate the effectiveness of the program. Some issues, as discussed below, will need to be addressed as results from 2020 must be used with extreme caution for purposes of evaluating performance of CJR participating hospitals. There are far too many substantive unknowns, beginning with the expected duration of the PHE, for hospitals to participate in an extension of the CJR model currently or for the foreseeable future on a voluntary much less a mandatory basis as proposed by CMS beginning in 2021. **Accordingly, the FAH respectfully urges CMS not to finalize a three-year extension. Alternatively, CMS could establish a simple streamlined pathway by which a hospital could voluntarily become an Episode Initiator (non-convenor participant) for the BPCI-Advanced site-neutral lower extremity joint replacement episode that is already underway.**

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[1] CMS press release available at: https://www.cms.gov/newsroom/press-releases/cms-releases-recommendations-adult-elective-surgeries-non-essential-medical-surgical-and-dental

The FAH also urges CMS to hold providers harmless against financial risk in PY 5 given the COVID-19 PHE by applying the CJR model's extreme and uncontrollable circumstances policy uniformly for all of PY 5. Under the April 6, 2020 COVID-19 PHE interim final rule with comment (IFC), CMS has expanded the applicability of the model's extreme and uncontrollable circumstances policy to all episodes (with or without fracture) that 1) have dates of anchor hospitalization admissions on or within 30 days before the date that the emergency period begins or 2) occur through the termination of the emergency period. Under the revised policy, actual episode payments will be capped during reconciliation calculations at the applicable target price as determined for that episode under §510.300 (85 FR 19263).

We agree with CMS' logic in that it anticipates the volume of procedures performed under CJR will decline during the PHE, as providers have already sharply limited the performance of elective operations, in keeping with guidance from CMS, as well as the CDC and numerous professional societies. Our member hospitals and their physician teams have appropriately postponed substantial numbers of elective TKA and THA surgical procedures to conserve critical resources such as Personal Protective Equipment (PPE) as well as limit exposure of patients and staff to the SARS-CoV-2 virus. Despite previous guidance released by CMS regarding next steps in resuming health care operations in stages[2], the 2020 volume of elective knee and hip surgeries will not reflect the typical spending pattern of a hospital or region in PY 5, and thus cannot be used to judge how a given CJR participating hospital would perform, absent the PHE.

It is very likely that participating CJR hospitals will have very low episode volumes for nearly all of PY 5 given the uncertainty of when the COVID-19 PHE will end. Even in the unlikely scenario where the COVID-19 PHE ends and hospitals have at least 6 months of CJR episodes for PY 5, the spending pattern for these episodes will likely be more resource-intensive and costly compared with prior years. There will be a ramp-up period necessary as hospitals and their providers work to develop more normal staffing patterns and use of hospital resources. In addition, during this PHE, we have seen significant challenges in discharge to post-acute care, in particular in the SNF setting, which further reduces a hospital's ability to manage care across the continuum. Such disruptions in care transitions will not be reflective of the cost or quality of care provided under normal circumstances. **Thus, the FAH urges an equitable solution for PY 5 and recommends that CMS cap actual episode payments at the applicable target price. This would allow participating CJR hospitals that achieved some savings to realize those savings but protect them against potential losses given the PHE.**

<u>CMS Should Mitigate the Effects on CJR Hospitals of Declining Quality Performance in PY 5</u>

Similarly, the FAH also requests that CMS protect participating CJR hospitals from payment reductions based upon their quality scores for the entirety of PY 5. Multiple COVID-19 PHE-related factors are likely to impair performance on quality metrics, interfere with data collection and reporting, or render the measures invalid and be outside of the control of clinicians and hospitals. CJR participants may be particularly vulnerable to perverse effects on quality scoring during PY 5 given the limited number (two) and nature of the model's required

[2] https://www.cms.gov/files/document/covid-flexibility-reopen-essential-non-covid-services.pdf; https://www.cms.gov/files/document/covid-recommendations-reopening-facilities-provide-non-emergent-care.pdf

quality measures. Performance in the THA/TKA complications measure (NQF #1550) inevitably will decline for many participants because the vast majority of CJR procedures performed during the COVID-19 PHE will be THAs done to treat patients with hip fractures. This patient subset is well known to have a complication rate significantly exceeding that for patients undergoing elective THA or TKA for chronic osteoarthritis. The remaining mandatory measure, the hospital-wide HCAHPS Survey measure (NQF #0166), as previously noted by the FAH on several occasions, has a tenuous relationship with the beneficiary experience of care during a CJR episode under normal health care delivery conditions that certainly is not likely improved during a PHE. Further, patient responsiveness and the ratings given are likely to be negatively influenced by the care changes necessary during the COVID-19 PHE (*e.g.*, reduced contact with clinicians intended to limit patient virus exposure), further degrading the validity of the data acquired as a meaningful measure of the CJR patient experience. Finally, minimal case counts as a result of the reduction in total elective surgeries will result in invalid measures.

The FAH recommends that CMS consider actions to mitigate the payment effects on CJR hospitals of declining quality performance during PY 5. The CJR model's extreme and uncontrollable circumstances policy is silent regarding adjustments to CJR quality measurement or performance during events that trigger the policy's application such as the COVID-19 PHE. **We recommend that CMS eliminate the 3 percent quality score-based adjustment entirely during PY 5 reconciliation given the uncertainty of reliable and valid data available to make payment determinations.** Alternatively, CMS could award all participants the same quality adjustment they received for PY 4. If the CJR model were to continue, consideration also should be given to excluding PY 5 data from use in any future quality measurement calculations.

II. FAH Comments on Specific Provisions of the Proposed Rule

As previously stated, the FAH believes that the best course of action given the circumstances of the COVID-19 PHE, is to end the CJR model as initially designed after the conclusion of PY 5. However, if CMS decides to move forward with extending the model, as proposed, we have specific comments, as discussed below.

CMS Should Consider Certain Factors Before Expanding the CJR Episode Definition to Include Procedures Performed in the Hospital Outpatient Department

The FAH requests that CMS should consider certain factors before implementing the CJR episode definition changes proposed by CMS, *i.e.*, incorporating primary, elective TKA and THA procedures performed in the hospital outpatient department setting into the model. CMS should consider that successful inclusion of these outpatient procedures in the model may be variable, depending on the uptake of these procedures in the outpatient setting nationwide. The variation observed reflects multiple factors including surgeon experience and preferences, beneficiary demographics and prevalence of comorbidities, the capabilities of hospitals of various sizes, the availability of multidisciplinary care coordination and discharge planning teams, the types of post-acute care resources present within a region, population dispersion, and rurality within a hospital's referral region. Prematurely including outpatient episodes without

adequate consideration of these factors and with relatively little data to inform the potential impacts on the target price puts providers at significant risk.

We also continue to believe that the choice of the procedure performance setting is a decision that must be left to the treating physician and patient to make together without regulatory interference. The FAH, therefore, urges CMS to uphold its deference to the physician's clinical judgment in deciding on the most appropriate setting for a given patient and allow additional time for clinical practice patterns to become less varied across the nation before we begin to evaluate the impact of these procedures in the CJR model. **In addition, as we have previously commented, we urge CMS to permanently restrict RAC reviews of patient status for total knee and total hip arthroplasties. Absent such moratorium, RAC reviews should only be undertaken upon a referral by a Quality Improvement Organization (QIO).**

CMS Should Delay the PY 6 Start Date until At Least January 1, 2022

Due to the COVID-19 pandemic, the proposed January 1, 2021 start date for the revised CJR model might is not tenable given the ongoing, widespread disruptive effects of the pandemic. The extension of PY 5 through March 31, 2021 recently implemented through the COVID IFC is not tenable either due to the unknown and unpredictable timeframe for resumption of sufficient normal health care operations that would allow performance of major, elective surgical procedures such as TKA and THA. Furthermore, the ramp-up period for FAH member hospital participating in other CMS Innovation Center models has typically been 6-12 months. Although the CJR model design is familiar to participants, there are numerous substantive proposed structural and financial changes that if finalized, will require considerable retooling by participants of the clinical, administrative, and financial teams and processes they used during PYs 1-5 for use in PYs 6-8. Additionally, there are several proposed major revisions about which more information must be provided to participants before model operations can begin (*e.g.*, the site-neutral episode payment category, target price risk adjustment). **The FAH therefore urges that the start date allow for at least a 12-month ramp up period between publication of the final rule and the PY 6 start date, and with a start date no earlier than January 1, 2022.**

CMS Should Modify the Proposed Participant Requirements

CMS is proposing that CJR model participation remain mandatory through PY 8 for all of the hospitals that are currently mandated participants. CMS further proposes to exclude for PYs 6-8 those hospitals who have continued in the model as participants by exercising the opt-in opportunity offered during January 2018. That opportunity was available to the low-volume and rural hospitals located in any of the 67 metropolitan statistical areas (MSAs) originally selected for mandatory model testing and to all other hospitals located in the 33 MSAs for which mandatory participation was dropped beginning with PY 3.
The Federation does not support the proposed participant requirements that limit voluntary participants.[3] We believe excluding voluntary participants interested in remaining

[3] As the FAH has previously commented, we do not believe that CMS has the authority to require model participation by any group of potential participants, and we remain steadfastly opposed conceptually to mandatory models as the best approach for testing innovative models.

for PY 6 and subsequent years would be inequitable. Their exclusion seems to be based on their small total number and the anticipation by CMS that their data will not add importantly to the findings of the model's evaluation. **The FAH believes that the hospitals proposed for exclusion have demonstrated their clear and sustained commitment to value-based care delivery and have earned an opportunity to continue in the revised CJR model if they so desire. Therefore, we urge CMS to rescind the proposed exclusion.**

Reducing the Years Used to Calculate Baseline Data and Modifying the Methodology Used to Determine the High Episode Spending Cap Will Not Likely Result in More Reliably Calculated Initial Target Prices

The FAH questions whether moving to the use of one-year of baseline data instead of a 3-year baseline data would result in a more reliably calculated target price. The CJR model currently uses 3 years of baseline data to calculate initial target prices with the 3-year baseline data updated every other year. CMS chose this policy because it wanted to ensure that it had sufficient historical episode volume to reliably calculate target prices, and because in PYs 1 – 3, CMS incorporated hospital-specific data into target prices. The FAH continues to believe even with the move to aggregated regional episode spending data that it is important to have more than one year of data from which to calculate initial target prices. Year-to-year spending, even at the regional level, can vary and additional volume of data smooths out such anomalies.

In addition, if CMS moves forward with the 3-year extension, CMS will need to reconsider what baseline data to use for PY 7 – its proposal is to use episode baseline data from 2020. Given the COVID-19 PHE, this year of data will not be representative of a typical year. The FAH also does not believe that using 2019 for both PY 6 and PY 7 would be a wise choice given potential difference in the use of TKA and THA in the hospital outpatient setting in those years, and other factors without determining and applying appropriate adjustments. **We recommend that CMS explore this issue further and not finalize how this baseline will be determined for PY 7 at this time.**

The FAH disagrees with CMS' proposal to change its methodology of calculating the high episode spending cap amount applied for purposes of the initial target price by calculating the high episode cap amounts based on the 99th percentile amount. The current method caps costs for those episodes at 2 standard deviations above the regional mean episode price, but CMS expresses concern that the high episode spending cap is being applied too often because these costs cannot be characterized as having a normal statistical distribution. In such a case, 95 percent of episodes would have costs that are within 2 standard deviations of the mean cost. We do not believe, however, that setting the cap at the 99th percentile will be sufficient to protect hospitals from high episode costs for TKA and THA episodes. As CMS has rightfully pointed out, the cost distribution is skewed for TKA and THA episodes with a higher percentage of cases at the extremes. We believe that issue warrants more study. **Thus, the FAH recommends that CMS set the cap at a lower threshold, such as the 98th percentile, to recognize the skewed nature of the distribution and to better protect participating CJR hospitals from observed TKA and THA episode costs.**

CMS Should Reconsider Use of Census-Based Regional Target Pricing

The FAH requests that CMS consider modifying its use of US census-based regional target pricing. 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. This approach does not adequately consider the adverse effect on Medicare heavy states, for example Florida. Medicare populations in these types of states have significantly higher utilization of healthcare resources, resulting in higher post-acute spending than other states in the region. By allowing other states in the census region to affect the THAs/TKAs target prices for higher Medicare-utilization states, hospitals in those states face a far greater challenge than peer hospitals in other states and face inequitable risk of losses.

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 reflect too wide a range of patient severity, practice patterns, and availability of specialized services, with a significant risk of the unintended consequence of over-penalizing hospitals for factors beyond their control. Using MSAs 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.

The FAH Generally Supports Modifications Regarding Reconciliation, Episode-Level Risk Adjustment, Composite Quality Score Adjustment, With Revisions to The Proposed High-Episode Spending Cap Calculation

The FAH generally supports CMS' proposal that for each of PYs 6 through 8, it will conduct one reconciliation 6 months following the end of the PY. We agree with CMS that reconciling payment twice at 2 and 14 months is not necessary and appreciate that this proposed approach will significantly reduce the administrative burden associated with an extra reconciliation calculation on CMS and participant hospitals. We continue to be concerned, however, about a timely feedback loop to providers as there is a long-time between the beginning of the performance year and the reconciliation. We request that CMS develop a tool for participants that would take into account the adjustments CMS makes at reconciliation, such as application of the risk factor multipliers, using the best available data. This will help participants gauge their performance with the understanding that these results are estimates and will vary from the final reconciliation results. Given the 3-month extension of PY 5 in the COVID-19 PHE IFC, which will now end on March 31, 2020, we also recognize that the timing of the reconciliation for PY 5 CMS proposed may be subject to change.

The FAH agrees with much of CMS' proposal to incorporate additional episode-level risk adjustment to account for the variability within the target prices for purposes of reconciliation. As expressed in prior comments, the FAH has recommended that additional risk adjustment is needed to better account for variability within the four categories of target price: MS-DRG 469 and MS-DRG 470 with/without hip fracture. CMS' proposal to incorporate the Hierarchical Condition Category (HCC) condition count and beneficiary age should better reflect the true variation in episode costs. We have few comments on how exactly the model should be specified and whether additional factors should be included in the risk adjustment model. It was

difficult for the FAH to assess and quantify the potential impact of this proposed policy as limited information was made available. The FAH requests that CMS make available a more detailed technical report to inform commenters on CMS conclusions that this modeling approach was the best option. In addition, our member hospitals would have been able to provide more thorough and meaningful comments if CMS had provided a proforma model or other tools to help hospitals determine the financial impact of the proposed target pricing methodology on its particular circumstances. Thus, we agree with this proposal based on our experience that better risk adjustment by controlling for factors such as age and a measure of clinical severity will improve the accuracy of the target prices than maintaining the status quo.

The FAH believes, however, that CMS should consider an alternative approach to calculating coefficients separately for each region (or MSA) instead of uniformly applying risk factor multipliers for CJR for all age bracket and HCC count combinations at the national level. This may also capture unobserved socioeconomic characteristics or other factors that vary by region. CMS did not share this information or did not perform a statistical test to determine whether a "pooled" model (in this case national) is preferred to a "unpooled" approach (in this case regional). This statistical information would have been helpful in judging the necessity of such an approach and could be used by CMS to help decide which approach is best in combination with other qualitative factors.

Given the COVID-19 PHE, CMS will also have to reconsider what baseline data it uses in calculating the age and HCC coefficients for the risk adjustment variables. In PY 7, for example, CMS proposes to use a baseline of January 1, 2020 to December 31, 2020. Given the deferral in elective surgeries, including TKA and THA procedures occurring during this PHE, the 2020 volume of elective hip and knee surgeries will not reflect the typical spending pattern of a hospital or region in PY 5. Similar to the reasons discussed above with the target price, the FAH also does not believe that using 2019 for both PY 6 and PY 7 would be wise choice without some adjustments given potential difference in the use of TKA and THA in the hospital outpatient setting in those years, and other factors. Thus, we recommend that CMS explore this issue further and not finalize how this baseline will be determined for PY 7.

The FAH supports proposed changes to the composite quality score adjustment. Currently, CMS applies a 3 percent discount to establish the episode target price that applies to the participant hospital's episodes during that performance year; this discount serves as Medicare's portion of reduced expenditures from the episode. For PYs 1 through 5, this discount factor is reduced by 1 percentage point for good quality performance and 1.5 percentage points for excellent quality performance. We support CMS's proposal to increase a participant hospital's ability to reduce this discount factor by 1.5 percentage points for good quality performance and by 3 percentage points for excellent quality performance. We believe that this provides an appropriate incentive and reward for hospitals to strive for obtaining excellent quality performance. At the same time, we are concerned that some hospitals will be left with higher risk inpatients (since the lower risk patients may be treated on an outpatient basis), and thus it could be more difficult for hospitals to reach an "excellent" quality score. We ask CMS to monitor this issue moving forward and its impact on hospitals.

As discussed above with respect to setting the initial target price, the FAH disagrees with CMS' proposal to change its methodology of calculating the high episode spending cap amount applied during reconciliation by calculating high episode spending cap amounts based on the 99th percentile of costs. We do not believe given the nature of episode cost distribution, that setting the cap at the 99th percentile will be sufficient to protect hospitals from high episode costs for TKA and THA episodes and warrants further study. **Instead, the FAH recommends that CMS set the high episode spending cap amount at a lower threshold, such as the 98th percentile for reconciliation, to recognize the skewed nature of the distribution and to better protect participating CJR hospitals from observed TKA and THA episode costs.**

CMS Should Eliminate the 50 Percent Cap on Gainsharing, Distribution, and Downstream Distribution Payments

The FAH has previously recommended that the gainsharing cap be eliminated for payments to a physician, non-physician practitioner, physician group practice, or non-physician practitioner group practice. We continue to believe that hospitals must be given flexibility to construct their gainsharing programs in ways most likely to succeed in their local environments. The cap is arbitrary and inhibits otherwise desirable collaboration between hospitals and practitioners. **We fully support this change and we commend CMS for being open to revising this longstanding policy.**

CMS Should Ensure Equitable Beneficiary Discharge Planning Notification Requirements for Outpatient and Inpatient Episodes

CMS appropriately extends the requirement for beneficiary discharge planning notification to outpatient CJR episodes. We remain troubled, however, by the inclusion in the regulation text at §510.405(b)(3) of the language requiring the discharge planning notice for both inpatient and outpatient episodes to be provided "no later than the time that the beneficiary discusses a particular post-acute care option or at the time the beneficiary is discharged from an anchor procedure or anchor hospitalization, **whichever occurs earlier" (**emphasis added).

Outpatient episodes will be classified for payment through the OPPS Ambulatory Payment Classification (APC) system, and all outpatient THA and TKA procedures will fall into C-APC 5115. However, inpatient episodes will be classified under the IPPS MS-DRG system, and the final DRG assignment may be delayed for up to 3 days post-discharge. Because of this difference in applicable payment systems, the "whichever comes earlier" notification language can become problematic for inpatient episodes. Notification challenges for hospitals will be further amplified for those CJR episodes that are triggered during the COVID-19 PHE, as they will nearly all be inpatient episodes.

For outpatient episodes, the notification requirement also can become problematic when a discharge plan is uncertain at the time of procedure scheduling or when a previously discussed plan must be revised on the date of the procedure. **The FAH respectfully requests that CMS consider a revised timing standard for the discharge planning notification, one that requires only "best efforts" to provide notification by the time of discharge from the hospitalization or the procedure for inpatient and outpatient episodes, respectively.**

CMS Should Reconsider the Appropriateness of the Required CJR Model Quality Measures

There are only two quality measures for which reporting is required by participants in the CJR model: the THA/TKA complication rate (NQF #1550) and the HCAHPS survey measure (NQF #0166). The FAH continues to believe that value-based delivery models should adjust payment to reflect the quality of care delivered under the model, and we find both of these measures lacking in that regard. The shortcomings of these measures will be amplified by the expansion of the CJR model to include outpatient THA and TKA episodes, as discussed previously.
The THA/TKA complication rate continues to lack risk adjustment for sociodemographic status (SDS). Such adjustment is particularly important for hospitals serving vulnerable populations and is vitally important for accurately assessing health care provider performance for fair and transparent public reporting. Further, this measure was developed for inpatient use. Not only will this measure fail to measure the quality of outpatient CJR episodes, results for this measure will be skewed for the residual inpatient episodes that inevitably will have more high-risk patients, given that THA for hip fracture treatment will continue to be performed on an inpatient basis. Results for the measure will now reflect a hospital's inpatient versus outpatient CJR episode mix as much or more than it captures quality of care.

The HCAHPS measure is well-known to CJR participants from the hospital quality reporting program. It is a very broad and totally generic hospital-wide measure that has not been updated in over ten years; the survey questions are not tailored to CJR patients or even to surgical patients. Since the vast majority of hospitals collect HCAHPS data on only a randomized sample of their inpatients, it is very possible that the survey sample (and the survey data) contains few and possibly even no THA/TKA patients. The tenuous connection between the HCAHPS survey measure and the CJR patient experience of care will be worsened when outpatient episodes are added to the CJR model as there will be no possibility of the survey measure capturing data from patients who undergo THA or TKA as outpatients.

The FAH acknowledges that reliable quality measures have not yet been established for outpatient THA and TKA. In their absence, however, CMS needs to reconsider how quality scoring is applied to CJR payments. For example, an adjuster for inpatient versus outpatient episode mix may need to be developed and applied to the composite quality score. CMS should not use a measure that was designed and endorsed by the NQF assuming an inpatient population to be used without proper adaptation and validity testing in the outpatient population. Regrettably, until valid quality measures are available to reflect the totality of CJR episodes, the impact of the current measures on payment must be minimized; consideration should be given to further adjustments to the quality-adjustment applied to target prices to reduce the CMS discount applied to all CJR participants. **Finally, the inadequacy of the quality measures, that will be further exacerbated, once CJR is expanded to include outpatient episodes, may alone provide sufficient reason not to proceed with extension of the CJR model for additional performance years.**

Further, the FAH is very troubled by the changes proposed for the single voluntary CJR model measure, the THA/TKA Patient Reported Outcomes (PRO) measure. The FAH acknowledges the potential of PRO measures in general as part of the quality measurement

enterprise for value-based initiatives. However, we have multiple ongoing concerns with this measure. The reporting is overly complex and burdensome. The rapidly escalating data submission thresholds have become increasingly unrealistic and unsustainable for CJR participants, yet CMS proposes to increase those thresholds yet again for PYs 6-8, ending with a requirement for 100 percent submission that is utterly unrealistic for any measure. Those hospitals who have persevered in reporting the THA/TKA PRO measure despite these challenges are further discouraged by having received no feedback about their results, as CMS has not provided any information or analysis based upon the substantial amount of PRO measure data already collected during PYs 1-4. **The FAH recommends, at a minimum, a "reset" of the PRO measure thresholds to their PY 3 levels** or changing this measure to one that generates a bonus for reporting any data during PY 6. Finally, the FAH asks CMS to inform CJR participants if and when data about the PRO measure will be shared with them.

CMS Should Extend Existing CJR Waivers to Outpatient Episodes When Applicable

The FAH agrees with CMS that patients properly selected for outpatient THA or THA will seldom require discharge directly to a skilled nursing facility (SNF) post-procedure. However, we support the proposed extension of the CJR SNF 3-day rule waiver to outpatient CJR episodes so that necessary services are available to all beneficiaries regardless of the site of THA or TKA performance. We restate our understanding that when a beneficiary (inpatient or outpatient) chooses transfer to a non-qualifying SNFs (star rating under 3) despite having received appropriate discharge planning notification about the financial consequences of that choice, the discharging hospital is not financially liable for the SNF admission.

The FAH also supports the extension of the waiver of direct physician supervision of postoperative visits made by clinical staff to the patient's residence. Such visits will be important for smooth and safe transition of many beneficiaries to their communities after either inpatient or outpatient arthroplasties. **The FAH supports these visits being provided using telehealth or other audio/video communication technologies (e.g., internet conferencing applications, smartphone) during the COVID-19 PHE to limit patient and clinical staff viral exposure risk.**

The FAH has commented previously on various aspects of post-acute care delivered after CJR procedures that could be improved by additional waivers. Our comments have generally been directed at maximizing flexibility so that appropriate post-acute care options are available to all CJR beneficiaries despite regional variations in the distribution of various types of post-acute care facilities and services. Many of our prior comments are relevant to both inpatient and outpatient CJR episodes. **We briefly reprise them here and ask that CMS consider creating the requested waivers for application to both inpatient and outpatient CJR episodes when relevant and as determined by the patient's condition and the professional judgment of the treating physician.** We note that any or all of the options below could be initiated as pilot programs at selected CJR hospitals and generalized only if costs are reduced and quality maintained.

- Facilitating value-based care delivery by inpatient rehabilitation facilities (IRFs) who commit to working effectively in coordination with their hospital partners.
    - CMS would establish an upfront discount to be made to the standard payment amount for IRF admissions of CJR beneficiaries.
    - CMS would apply a per-diem payment method for shorter-than-average stay patients (similar to how IRFs are currently paid for certain transfer cases).
    - Waive the 60 Percent Rule for IRFs that accept the discounted standard payment amount and/or the per diem payment amount, as applicable.
    - Waive the 3-Hour Rule, allowing flexibility for therapy provision through multiple modes including group and concurrent therapy, tailored to the needs of the patient.

- Supporting smooth and safe transitions to the community postoperatively without penalizing CJR hospitals by waiving the post-acute care transfer policy when the treating physician determines that it is in a beneficiary's best interest to be discharged after a stay shorter than 3 days to care by the most appropriate post-acute care provider that commits to working effectively in coordination with their hospital partners.
    - Post-acute care eligibility could be restricted to high performing providers using cost and quality criteria.

- Allowing a waiver of beneficiary patient right of choice for selected CJR hospitals to establish post-acute care partner networks that are preferentially recommended to beneficiaries at the time of discharge from the hospital or post-procedure.
    - For beneficiary protection, this waiver should be strictly limited to CJR model "high performers" in terms of both quality and costs; for example, those with two or more consecutive years in which "Excellent" composite quality scores were achieved and in which reconciliation payments were earned.

<u>Extending Bundled Payment For Lower Extremity Joint Replacements to ASCs is Premature</u>

CMS solicits comment on how to conceptualize and design a future bundled payment model focused on lower extremity joint replacements (LEJR) procedures performed in the ambulatory surgical center (ASC) setting. The FAH believes that such a proposal is premature. Medicare coverage of TKA procedures in the ASC setting only began on January 1, 2020. Thus, there is very little data available about performance of these procedures in ASCs, and this lack of data is significantly exacerbated by the fact that very few of these procedures have been performed in ASCS (or other settings) in 2020 due to COVID-19 (as discussed above), which resulted in the closure of many ASCs and performance of elective procedures. Further, without more extensive details for such a proposal and with little actual data available, it is difficult to provide meaningful and thorough comments and thus we request the opportunity to provide comment in the future when more data and details are available.

The FAH appreciates CMS' consideration of our concerns and recommendations. We recognize that the effects of COVID-19 PHE are likely be profound and prolonged for health care delivery nationwide. FAH members are working tirelessly to ensure that they meet the health care needs of their patients during the COVID-19 pandemic and are grateful for the flexibility and support CMS has provided during this serious public health threat. If you have questions about our comments or need further information, please contact me at 202-624-1534.

Sincerely,