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Via Electronic Submission (www.regulations.gov)

September 4, 2015

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
ATTN: CMS-5516-P
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Comprehensive Care for Joint Replacement Payment Model Proposed Rule, File Code CMS-5516-P

Dear Acting Administrator Slavitt:

The Association of American Medical Colleges (AAMC or Association) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's or the Agency's) proposed rule entitled, *Medicare Program, Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services; Proposed Rule*, 80 Fed Reg. 41198 (July 14, 2015). The AAMC is a not-for-profit association representing all 144 accredited U.S. accredited medical schools; nearly 400 major teaching hospitals and health systems, and 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 148,000 faculty members, 83,000 medical students, and 115,000 resident physicians.

AAMC is committed to improving quality and cost of care by breaking down silos of care, aligning providers' incentives, and applying best practice to reduce variation. As a facilitator convenor under the Bundled Payments for Care Improvement (BPCI) initiative, we have a deep interest in the promise of bundled payments to create the right incentives for the provision of high-quality, efficient care. We believe that voluntary expansion of BPCI is the next best step in delivery system reform. The success of BPCI to date demonstrates that there are hundreds of hospitals who are proactively engaged in clinical redesign. Changing the model that is working, while proposing a mandatory program, risks prolonged disruption for patients and providers. While AAMC is pleased to see that the proposed Comprehensive Care for Joint Replacement (CCJR) model is similar to Model 2 BPCI in many respects, the program's mandatory nature, and the substantive and problematic way in which CCJR differs from Model 2, will make this program less successful than it could be.

At the same time, the Agency's proposal raises important questions about the design of a mandatory program for hospitals of many different sizes and types, and at very different points in the "re-design" process. AAMC believes that many aspects of the proposed program must be

altered to ensure that hospitals that invest in care interventions have a fair opportunity to realize savings under CCJR. Specifically, the AAMC strongly urges CMS to make the following changes:

- Delay the program start date;
- Provide historical Medicare claims data and target prices to hospitals in advance of the program start date;
- Not implement regional pricing as proposed;
- Revise the MSA selection methodology to accurately reflect current BPCI participation in lower extremity joint replacement (LEJR) episodes; and
- Change the quality performance requirements to ensure program success and standardize quality of care.

The comments in this letter are heavily informed by our observations as a BPCI facilitator convener and the experiences of our academic medical centers (AMCs).

PROGRAM START DATE MUST BE DELAYED

CMS proposes that the CCJR performance period would last five years, and begin on January 1, 2016. AAMC firmly recommends that this start date be pushed back to October 2016, at the earliest. Many hospitals in the 75 Metropolitan Statistical Areas (MSAs) have no prior experience operating under risk-based models. In order to appropriately direct the resources to thoughtfully implement a bundled payment program, hospital administrative and clinical staff must undertake many activities, including but not limited to the following:

- Learn CCJR program rules and policies;
- Understand the mechanics of bundled payment;
- Review Medicare claims data to identify risks and opportunities and expertly target customized care interventions;
- Educate and engage clinical staff;
- Inform and educate Medicare beneficiaries;
- Develop and execute new contracts with physicians and all providers that address gainsharing;
- Identify and contract with key post-acute care (PAC) partners;
- Develop specific CCJR pathways and quality metric tracking systems in electronic medical records (EMRs); and
- Create accounts and financial systems to track reconciliation and gainsharing payments.

The AMCs with whom we partner needed six to 12 months to prepare for BPCI. Sites that are new to CCJR deserve the same timeline in order to assure success. A rushed start date may lead to unintended consequences that would be prevented with a deliberate planning process. The CCJR start date must be delayed to maximize the benefit of clinical transformation for patients. Therefore, the AAMC recommends that CCJR launch no sooner than October 2016.

DATA SHARING

Claims Data Should Be Updated Monthly and Provided in Additional Formats

CMS proposes to make hospital-specific data available in two formats: 1) summary claims data and 2) beneficiary-level raw claims data. AAMC appreciates CMS's recognition of the fact that hospitals are at different stages in their level of understanding and ability to manipulate beneficiary-level data, and supports this proposal. In order to target care intervention strategies, hospitals must be given the opportunity and resources to learn to analyze beneficiary-level data. The Association believes that CMS should deliver both data formats to hospitals, instead of only providing one format.

AAMC supports the CMS proposal to provide three-year baseline data and regular data updates; however, monthly data, rather than quarterly, is essential for tracking patients whose highest utilization is in the first 30 days after their surgery.

Hospitals Must Be Provided With Data At Least 6 Months Prior to Go-Live

CMS proposes that hospitals must request baseline data, and that Agency will provide the data no sooner than 60 days following the start of performance year 1. AAMC strongly opposes this timeline and believes that it poses an untenable challenge to CCJR participants. Baseline data must be provided to hospitals at least six months prior to go-live, and target price data at least 60 days in advance in order to identify high risk patients early and mitigate risks to patients and program goals.

CMS has previously recognized the importance of participants receiving baseline data prior to entering a bundled payment program and should do so for this program as well. For example, when baseline data delivery was delayed under BPCI, the Center for Medicare and Medicaid Innovation (CMMI) created additional go-live opportunities and applied the same precedence rules regardless of timing of program entry in 2015. This action helped to ensure that BPCI participants had adequate time to review data, identify clinical areas of risk and opportunity, and were not penalized for delays.

The fact that the first year carries no downside risk does not diminish the need for access to data in advance of the CCJR performance period. It is unreasonable to mandate that hospitals enter a risk-based bundled payment program without advanced access to claims data.

CMS Should Ensure that Beneficiary-Identifiable Claims Data Is Shared

CMS proposes to enable beneficiaries to opt out of having their data shared with CCJR hospitals. AAMC opposes this proposal. CCJR is a mandatory program for hospitals and beneficiaries and does not alter beneficiary freedom of choice regarding selection of providers. However, if providers do not have access to all beneficiary information, it may have an impact on the care that beneficiaries receive. Members of AAMC's convened group rely on data on a daily basis, and

regularly scrutinize single patient's episodes to identify clinical and financial opportunities for improvement.

AAMC's concerns are buttressed by the fact that when hospital episode volume is small, the impact of a single episode increases. In such scenarios, lack of access to even a single patient's data can leave a hospital with unanswerable questions and unexpected losses. Access to complete data is also important during the reconciliation process. During the BPCI reconciliation process, rules surrounding precedence, beneficiary eligibility, and episode definitions often cause claims, and at times entire episodes, to be dropped. Not only does this alter a hospital's savings, but the change carries implications for gainsharing arrangements. Hospitals must have the data necessary to validate changes in savings and gainsharing payments as they transform their clinical design.

AAMC SUPPORTS A RETROSPECTIVE PAYMENT METHODOLOGY AND ELIMINATION OF DOWN-SIDE RISK IN YEAR 1

Retrospective Payment

AAMC supports CMS's proposal to utilize a retrospective reconciliation methodology under CCJR. As evidenced by the poor uptake of BPCI Model 4, few providers are ready to assume the role of a third party administrator that is capable of distributing payments to all providers involved in the care of a patient in a prospectively paid bundle.

Payment Adjustments

AAMC strongly supports CMS's proposal to exclude special Medicare payment provisions, such as the indirect medical education adjustment (IME) and disproportionate share hospital (DSH) payments, from target price and performance period spending calculations.

CMS proposes that target prices would not include Medicare repayments or reconciliation payments. This would mean that CCJR savings realized in the first year of the program would not be incorporated into target prices for years 3 through 5 when the target price is rebased to include claims data from later years. This policy is inconsistent with rebasing methodologies utilized under other alternative payment models. For example, the Medicare Shared Savings Program (MSSP) Final Rule provided for a rebasing methodology that would account for savings generated by accountable care organizations (ACOs) during the previous performance period (80 *Fed Reg.* at 32788 - 32791). This provision slows "the race to the bottom", in which efficient providers see their target price continuously decrease to a point where patient safety is at risk and identifiable efficiencies are greatly diminished. AAMC encourages CMS to utilize a similar rebasing methodology in CCJR to provide a fair and sustainable target price for providers.

AAMC supports CMS's proposal to apply a ceiling to high episode payments by capping payments at two standard deviations above the regional mean. Similarly structured risk tracks represent a helpful risk mitigation tool under BPCI.

Regional Pricing Adoption is Premature

AAMC has serious concerns regarding the CMS proposal to incorporate regional data into CCJR target prices. Many hospitals in the 75 MSAs do not have adequate time to implement a bundled payment program, let alone be subject to regional pricing. However, AAMC recognizes that a subset of high volume AMCs may perform well under regional pricing. These AMCs have realized economies of scale by serving a large volume of total joint replacement patients and have been able to deploy intensive improvement strategies for many years. These efficient providers will thrive under a regional model. AAMC recommends that CMS adopt a target price methodology that assigns a hospital a target price that is the higher of the hospital-specific methodology or the proposed blended hospital-specific/regional methodology.

AAMC also notes that while a blend of historical and regional pricing may present a tenable pricing model for LEJR episodes for some institutions, such a model could create serious issues if applied to medical conditions such as chronic obstructive pulmonary disorder (COPD). Episode payments for such conditions vary drastically both within and between different providers' patient populations. It is incumbent upon the Agency to study regional pricing methodologies, broadly disseminate the finds, and utilize those methodologies that are less likely to penalize both efficient providers and those that may be high cost in their regions due to factors that they cannot reasonably control, such as patient risks and the provision of quaternary services.

Census Regions Should Not Be Used as Geographic Regions

CMS proposes to use the 9 census regions as the geographic component of regional pricing. The proposed regional definitions appear impractically large; the size of the census regions suggests that markets that differ drastically in terms of provider type and supply will be compared to one another. For example, an AMC hospital in New York City would face the same regional target price component as a community hospital in Elk County, Pennsylvania. AAMC encourages CMS to study a series of alternative geographic regions when examining the impact of regional pricing in order to understand the impact of unintended consequences on access to care. The lack of known impact on AMCs within census regions further supports the need to delay the start of the program.

Analyses completed by AAMC and DataGen further augment the Association's concerns regarding regional pricing. Using the CCJR proposed rule episode and payment specifications, DataGen modeled hospital-specific DRG 470 episode target prices within the 9 census regions. Data sources included the 2013 100 percent Medicare Standard Analytic Files (SAFs) for inpatient Prospective Payment System (PPS), hospital outpatient PPS, home health PPS, skilled nursing facility PPS, and inpatient rehab PPS, as well as the 2013 5 percent SAF for carrier (physician and other Part B) services. In order to confine their analyses to completed episodes, we only examined episodes that began on or before August 3, 2013.

AAMC is concerned that due to the size of the proposed census regions, the regions will contain extremely large differences in care patterns and payments. As a result, some providers will be extremely disadvantaged while others are tremendously advantaged by the regional component of target prices. The substantial variation in provider type and LEJR volume within the proposed

regions enhances this concern. While there are 371 hospitals in the 9 proposed regions, only 5 teaching hospitals are in the New England region and 108 teaching hospitals are in the mid-Atlantic region. Analysis of hospitals in the 75 mandatory MSAs showed that for 2013, teaching hospital-specific average episode payments ranged from approximately 205 percent greater than the regional average, to 39 percent less than the regional average for teaching hospitals with annual LEJR volume of fewer than 100 episodes (N=222 hospitals). Even for teaching hospitals with LEJR volume of 100 episodes or greater (N=149 hospitals) the variation was +30 percent to -21 percent. The average teaching hospital episode count in mandatory MSAs is higher than for all hospitals (107 cases/year in teaching hospitals as compared with 89 cases for all hospitals). Yet for many teaching hospitals in mandatory MSAs, the break point for payment levels greater than their regions is about 300 cases/year, meaning that the larger the surgical volume, the lower the payment compared with regional price, offering opportunities for significant savings for CMS and providers. Volume below 100 cases/year puts hospitals at great risk of achieving no savings based solely on price (not accounting for quality).

RECONCILIATION SHOULD BE PROVIDED EITHER QUARTERLY OR ANNUALLY

CMS proposes that performance period payments would be reconciled on an annual basis. This extended time frame would mitigate some of the claims run out issues experienced under BPCI. However, it is important to balance this concern with the need for timely data regarding financial performance. As a result, AAMC recommends that CMS give CCJR participants the option to receive reconciliation results on either a quarterly or annual basis.

CCJR HOSPITAL QUALITY PERFORMANCE

The AAMC believes that it is appropriate to develop standards to ensure that all patients receive high quality of care. Overall, AAMC supports the BPCI model, in which the receipt of savings is not predicated on achieving certain quality metrics. Should CMS implement quality thresholds, the proposed methodology must be amended. Association is concerned that the proposed metrics and scoring methodology for the CCJR Program may lead to negative and unintended consequences for beneficiaries. Quality measures and performance scoring thresholds should be used to encourage improvement, not to block a majority of hospitals from participating. We include recommendations below to address these shortcomings and ultimately strengthen the CCJR program moving forward.

Changes Should Be Made to the Quality Measures; HCAHPS Should Not Be Included

CMS has proposed that hospitals in the CCJR program cohort would be eligible for potential savings as long as performance metrics are met on the three measures below:

- Total Hip Arthroplasty (THA)/Total Knee Arthroplasty (TKA) 30 Day Readmissions Rate
- THA/TKA 90 Day Complications Rate
- Hospital Consumer Assessment of Healthcare Provider Systems (HCAHPS) survey

The AAMC appreciates that the proposed quality measures are currently being reported for the Inpatient Quality Reporting (IQR) program, thereby reducing additional quality burden for

hospital staff. However, quality measures that do not directly relate to the care provided should not be included in a payment program. Therefore, the AAMC agrees with CMS that the THA/TKA readmissions and THA/TKA complications measures are appropriate; however, for these claims-based measures, CMS should also apply a socio-demographic status (SDS) adjustment as these measures are tied to community factors that are typically outside of the direct control of providers. As the AAMC suggests in its CY 2016 Medicare Physician Fee Schedule (PFS) comments, CMS should use feedback from the IMPACT Act (which requires a study on SDS), as well as feedback from the National Quality Forum (NQF) trial period on SDS to inform the Agency about which variables should be used.

While AAMC supports the use of patient feedback to assess the overall quality of care, the HCAHPS is simply too broad for this program as it includes all patients with an inpatient admission, not just those Medicare beneficiaries who experience a 90 day THA/TKA episode. Furthermore, HCAHPS only reflects a patient's inpatient experience, a small part of the patient's experience throughout a 90-day episode. The HCAHPS star rating methodology is also biased against major teaching institutions, as evidenced by Figure 1 (appendix). Approximately half of teaching hospitals would be ineligible for savings due to the inclusion of this measure. In addition, hospitals are already being assessed on the HCAHPS, which encompasses 25 percent of the total score of a hospital's performance in the Value Based Purchasing Program. **AAMC recommends that CMS remove the HCAHPS survey from the CCJR quality performance measurement methodology.**

Substantial Changes Are Needed In the Method for Establishing Reconciliation Payment Eligibility

CMS proposes that in order to be eligible to receive savings, hospital performance on all three measures must meet or exceed the 30th percentile for performance years 1 through 3, and the 40th percentile for performance years 4 and 5. The AAMC has serious concerns with the proposed scoring thresholds. CMS does not provide a rationale for utilizing a 30th percentile threshold for performance years 1 through 3 other than noting that the benchmark is currently used in MSSP. The MSSP, however, is a voluntary program and incorporates improvement on quality metrics in the payment methodology, which this program does not.

The proposed methodology would also utilize a hospital's risk-adjusted point estimate to calculate the national percentiles, instead of assessing individual hospital performance within a confidence interval, as the measure was originally designed, tested, and endorsed to do by the NQF. While the Affordable Care Act statutory requirements necessitate that point estimates be used to calculate hospital performance under the Hospital Readmissions Reduction Program (HRRP), no such requirement exists for the CCJR Program.

The AAMC modeled the overall impact of the proposed quality scoring methodology in Figure 2 (appendix) and found that over half of all mandated providers and over 70 percent of major teaching hospitals would not meet all three quality thresholds as proposed. As stated earlier, this program should not block the majority of hospitals, or overwhelmingly disadvantage a subset of

hospitals such as teaching hospitals, from successfully participating. Rather, CMS should provide incentives for hospitals to continuously improve quality of care under this program.

Furthermore, AAMC is very concerned that given the limited performance variation in both the readmissions and complications measures nationally, the proposed methodology would result in hospitals losing reconciliation payments based on clinically and statistically insignificant differences in performance. As CMS itself has acknowledged in other Medicare quality measurement programs, it is problematic to pay providers based on very small differences in performance that are not meaningful. Yet, a recent American Hospital Association (AHA) analysis of the readmissions and complications measures based on July 2015 *Hospital Compare* data (Figure 3 in appendix) shows that there is only a *1.6 percentage point* difference between the 10th and 90th percentile of national performance for both the complications and readmissions measures. There is only a 0.2 percentage point difference in performance on the complications measure between the 20th percentile, which would make a hospital ineligible for reconciliation payments, and the 30th percentile, which would allow a hospital to qualify for reconciliation payments.

In fact, the level of performance on the readmissions measure appears to be very close to the level CMS would deem to be “topped out” in the hospital value-based purchasing (VBP) program. In the context of the hospital VBP program, CMS applies another set of tests to determine whether a measure has reached “topped out” levels of performance. CMS deems measures to have topped out when national measure data meet the following criteria:

- The difference in performance between the 75th and 90th percentile is statistically insignificant (the difference between the 75th and 90th percentile differs by less than two standard deviations)
- The truncated coefficient of variation (TCV) is less than 0.10

The July 2015 AHA analysis of *Hospital Compare* data shows that the TCV for the readmissions measure is 0.096, and that the 75th and 90th percentiles are less than 2 standard deviations different in performance.¹

As a result of these analyses, AAMC recommends that performance be placed into one of three categories: “no different than the national rate,” “better than the national rate,” or “worse than the national rate.” Hospitals that are “no different than the national rate” or “better than the national rate” should automatically be deemed eligible for any potential savings. In addition, hospital performance on the THA/TKA readmissions and complications measures should be assessed using confidence intervals, and should not be scored using a single point estimate.

The AAMC also believes that any quality performance requirement must account for improvement. **Rather than exclude hospitals that perform “worse than the national rate” from savings pools, AAMC recommends that CMS ensure that those providers be allowed to accept savings and simultaneously submit a corrective action plan.** Hospitals that undertake

¹ The standard deviation for the July 2015 data is 0.6. The 75th percentile score is 4.5 percent, while the 90th percentile is 4.1 percent.

a corrective action plan should be provided with technical assistance and should be monitored for improvement. Savings could be linked to investment in the necessary tools to achieve greater improvements in subsequent performance years.

Finally, AAMC is troubled by the fact that measure performance periods are a rolling three year average, which means that any steps undertaken by a hospital to improve care will take considerable time to materialize as measureable results. This methodology means that many of the hospitals that are penalized the first year will continue to be penalized in future years, without an opportunity to improve and qualify for corresponding savings. As proposed, hospitals would have approximately three months to improve on measures during the first payment year. Hospitals must be given more time to implement quality improvement strategies before they are held accountable. **Therefore, the AAMC recommends that CMS make the first two performance years pay-for-reporting, allowing those hospitals who successfully submit data to be eligible for savings.**

Payment Adjustment for Voluntary Submission of PRO Measure

CMS proposes a voluntary THA/TKA patient reported outcome (PRO) measure to encourage hospitals to submit data that is not readily available from other sources. Hospitals that report PRO data on 80 percent of patients would be eligible for a 0.3 percentage point reduction to their target price discount factor.

The AAMC recognizes the importance of patient reported outcomes and appreciates that the measure is voluntary for hospitals. However, the Association is concerned that the 80 percent reporting requirement is too high. AAMC recommends that CMS should only set the thresholds once the Agency has sufficient data to determine an appropriate number. CMS should consider allowing hospitals to report this data directly from their clinical registries in order to receive credit. This measure should also be tested, reviewed, and endorsed by the NQF as soon as possible.

Finally, we ask that CMS take steps to avoid potential problems with the PRO measure that were evident in the attempted roll-out of the B-CARE tool in BPCI. The tool required a manual electronic process to complete, resulting in a significant rework that was inefficient and a misallocation of limited resources. The AAMC is ready to partner with CMS to ensure that the challenges associated with the B-CARE tool do not occur with the voluntary PRO measure.

PARTICIPATION IN BPCI SHOULD TAKE PRECEDENCE OVER OVERLAPPING PROGRAMS

Consistent with the Association's mission to improve the health of all Americans, AAMC supports the continued development and adoption of episode-based payment and population health programs. AAMC recognizes that providers are at different stages in their ability to manage risk, and believe that the varied models enable providers to elect models appropriately suited to their individual capabilities and constraints. However, with the mandated CCJR model, the growing number of different risk-based payment models within the same markets presents challenges. Providers are at risk of losing volume and seeing their savings siphoned off to other programs. These challenges could increase in the next few years as physicians move to adopt alternative

payment to achieve incentives created by the recently passed Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

The table below summarizes the proposed methodology for accounting for overlap between CCJR with both BPCI and MSSP.

CMS Proposed Program Overlap Policies

CCJR Overlap Issue	Program			
	BPCI LEJR Episode	BPCI Non-LEJR Episode	MSSP (Aligned Hospital)	MSSP (Non-Aligned Hospital)
Program Precedence	BPCI LEJR	No precedence	No precedence	No precedence
Attribution of Savings	N/A	Not specified	CCJR	CCJR
CCJR Discount Factor	N/A	Not specified	CMS recoups CCJR discount paid out as MSSP savings	No adjustment

Note: “No precedence” means that a patient can be in CCJR and one of the other programs simultaneously.

BPCI

CMS proposes that BPCI LEJR hospital participants would be excluded from CCJR for the remainder of their BPCI performance period, but be required to enter CCJR once the BPCI performance period concludes. AAMC is concerned by the prospect of requiring hospitals and beneficiaries to automatically transition from one program to the other. As currently proposed, some BPCI participants may be required to enter CCJR in performance year 4 under 100 percent regional pricing. **AAMC recommends that CMS give BPCI participants the option to extend their participation in BPCI for an additional three year period rather than transitioning to CCJR.** Because BPCI is a widespread program, and manages risk for a number of conditions beyond LEJR, **AAMC supports the proposal that BPCI LEJR episodes would take precedence over CCJR episodes. However, AAMC recommends that this precedence rule be extended to all BPCI episodes** to cover those occasions in which a patient could simultaneously be in a CCJR episode and a non-LEJR BPCI episode (such as CHF). There is no accurate way to fairly attribute savings between CCJR and BPCI in these scenarios.

Shared Savings Models

As depicted in the table above, CMS proposes that hospitals that are part of an MSSP ACO or other shared savings model would still be required to participate in CCJR, and that CCJR savings would be attributed to CCJR and counted as regular performance period payments for the MSSP and other shared savings models. In effect, an MSSP ACO would have little chance of scoring savings for any patient in a bundled payment episode, and as bundled payment programs grow, MSSP savings would diminish, putting the model at risk.

AAMC encourages CMS to pursue policies that enable the integration of these programs. This is essential for both providers and beneficiaries, and to limit duplicative administrative costs. AAMC agrees that when an overlap occurs, it is appropriate to attribute savings to a bundled program as it has a shorter duration and is initiated by a major procedure involving an inpatient hospitalization. **As such, in the event that a CCJR-participant hospital is aligned to a Medicare ACO, AAMC supports the proposal to attribute savings to CCJR.**

However, as previously stated, AAMC believes that providers that have already voluntarily devoted resources to a different risk-based model should be afforded some protection. This issue becomes more critical when an ACO’s attributed beneficiary triggers a CCJR episode at a non-aligned hospital. **In the event that overlap occurs between a Medicare ACO and a non-aligned CCJR hospital, AAMC proposes that the Medicare ACO would take episode precedence.** As discussed later in the letter, this policy should be paired with a minimum episode volume threshold for participation in CCJR.

AAMC Program Overlap Recommendations

CCJR Overlap Issue	Program			
	BPCI LEJR Episode	BPCI Non-LEJR Episode	MSSP (Aligned Hospital)	MSSP (Non-Aligned Hospital)
Program Precedence	BPCI LEJR	BPCI Non-LEJR Episode	No precedence	MSSP
Attribution of Savings	N/A	N/A	CCJR	MSSP
CCJR Discount Factor	N/A	N/A	CMS recoups CCJR discount paid out as MSSP savings	N/A

AAMC acknowledges that this additional precedence rule could create confusion for non-aligned hospitals in markets with Medicare ACOs. As such, AAMC recommends that CMS provide hospitals with lists of patients prospectively who are assigned to Medicare ACOs.

AAMC’s alternative proposals would better enable different models to create synergies in the same market, although the challenges created by the existence of multiple risk-based models will persist with the inevitable introduction of new alternative payment programs. **It is imperative that CMS pursue a longer-term strategy for dealing with the potential overlap of different programs.** The absence of a broader plan for integrating and transitioning between different risk-based models will force the continued adoption of patchwork solutions such as precedence models, which increase the complexity of the nation’s health care system. AAMC is committed to supporting such a strategic planning process.

Hospitals with a Low Volume of CCJR Episodes Should Not Be Required to Participate in the Program

More AAMC members will be engaged in CCJR than are currently in BPCI. The Association is deeply concerned about the challenges presented to both CCJR and BPCI participants due to the coexistence of these programs. AAMC believes that BPCI participants, who have already voluntarily dedicated significant resources to implementing bundled payments, should take precedence over CCJR episodes. Nonetheless, AAMC acknowledges that hospitals mandated to take on CCJR risk should be afforded some protection given that beneficiaries could be attributed to physician group practices (PGPs) or other hospitals. Under the proposed precedence rules, hospitals mandated to participate in CCJR could lose a significant number of episodes to BPCI participants and their volume could decline to unsustainable levels. The previously mentioned data analysis conducted by AAMC and DataGen demonstrated the increased volatility and risk brought on by low-volumes. When comparing hospital-specific average episode payments to the regional average, the analysis showed that while hospitals with over 100 Medicare fee-for-service (FFS) episodes per year experienced a tight variation between 29 percent higher than the regional average to 20 percent lower than the regional average, but hospitals with less than 99 episodes experienced a wide variation in average episode payments from 205 percent higher than the regional average to 39 percent lower than the regional average. Inclusion of hospitals with LEJR volumes of less than 100 episodes would introduce tremendous random and uncontrollable risk for them.

As a result, AAMC recommends that CMS employ a minimum CCJR episode volume threshold. If a hospital has less than 100 episodes in a reference year (the number needed to reduce volatility in price and risk in AMC BPCI experience), or if over 50 percent of the hospital's episodes are attributed to a PGP BPCI risk-bearing entity, the hospital should not be required to participate in CCJR.

EPISODE DEFINITIONS

AAMC supports the CMS proposal to use many of the same BPCI Model 2 episode parameters to define CCJR episodes.

90 Days is the Appropriate Episode Duration

AAMC believes that 90 days is the most clinically appropriate length for a bundled payment episode and enhances the commitment to caring for patients over time. This duration is sufficiently long so as to capture many complications and engage multiple providers in inpatient, outpatient, and post-acute care settings. This duration also moves providers closer to achieving long-term population health management.

Clinical Dimension

CCJR Should Use the BPCI Model 2 LEJR Exclusions List and Should Exclude Hospice Care

AAMC supports the CMS proposal to utilize the BPCI Model 2 LEJR exclusion list to define exclusions for CCJR episodes. AAMC also emphasizes the importance of ensuring that all chemotherapy administration ICD-9 codes (99.25) are excluded from CCJR episodes. AAMC noted that hospice is excluded from BPCI LEJR episodes, yet CMS proposes to include hospice in CCJR episodes. AAMC strongly recommends that hospice be excluded from CCJR for consistency with BPCI and in order to prevent unintended perverse incentives.

High Risk Cases Such as Hip Fracture Diagnoses Should Be Excluded from CCJR

While AAMC supports using DRGs to define episodes, in some instances, patients who fall under the same DRG may have very divergent care pathways and outcomes. This is especially pronounced in the case of hip fracture patients vs. non-fracture patients in the major joint replacement of the lower extremity episode (DRGs 469 and 470). AAMC has extensively analyzed this subpopulation (which appears in both DRGs 469 and 470), and shown that when compared to patients with elective procedures, hip fracture patients experience twice as high readmissions and PAC utilization rates, as well as higher morbidity and mortality. AAMC has noted that the number of hip fractures treated by individual hospitals can vary widely on an annual basis, and may increase over time due to random variation as well as practice or population changes. One Model 2 BPCI participant's fracture rate in the major joint episode increased by approximately 11 percentage points between the baseline period and 2014. This hospital now faces an increased challenge to generate savings despite providing excellent care for very high risk patients. **AAMC's prior recommendations to create new DRGs or assign hip fractures to only DRG 469 have not been adopted by CMS, despite extensive analyses and consensus from hip and knee surgeon associations. As a result, AAMC believes that patients with hip fracture diagnoses should be excluded from CCJR.**

The American Association of High and Knee Surgeons (AAHKS) notes a similar concern about ankle replacements in their CCJR comment letter. While ankle replacements only comprise a small portion of LEJR episodes, AAMC observes that ankle fracture cases exhibit similar characteristics as fracture cases, with total episode payments being dramatically higher. AAMC agrees that total ankle procedure patients should also be excluded from triggering a CCJR episode.

CMS SHOULD INCORPORATE ADDITIONAL FACTORS IN THE EXCLUSION METHODOLOGY FOR CERTAIN MSAs AND A MINIMUM THRESHOLD FOR CCJR PARTICIPATION

CMS proposes to exclude MSAs from participation in CCJR if they have a low volume of LEJRs or if a majority of LEJRs were performed by BPCI participants. Specifically, an MSA would be excluded for the following reasons:

- 1) Less than 400 LEJR episodes occurred from July 1, 2013 through June 30, 2014;
- 2) Less than 400 non-BPCI LEJR episodes in the reference year;

- 3) 50 percent or more of the LEJR episodes were initiated by a Model 1, 2 or 4 hospital awardee, or a Model 3 SNF or HHA awardee; or
- 4) 50 percent or more of LEJR episodes were not paid under IPPS.

This methodology was intended to ensure that MSAs included a sufficient LEJR volume to detect a change in episode expenditures and an adequate number of non-BPCI LEJR episodes that would prevent a scenario that would “impair the ability of participants in either the CCJR model or the BPCI models to succeed in the objectives of the initiative or impair the ability to set accurate and fair prices”. This rational goal is commendable, but as currently proposed the methodology will not reach this aim due to the omission of two factors from the exclusion criteria:

- 1) BPCI LEJR episodes that enter the risk phase on October 1, 2015; and
- 2) BPCI LEJR episodes triggered by PGP awardees.

The AAMC recommends that CMS re-run the exclusion methodology to incorporate these factors. AAMC realizes that this process would produce a different group of 75 MSAs, and believes that this fact lends further credence to delaying the CCJR start date.

As of the July 1, 2015 go-live period, PGPs represented approximately 32 percent of all LEJR BPCI episode initiators. Not incorporating LEJR episodes initiated by PGP BPCI participants into the exclusion criteria diminishes the capacity of certain hospitals to effectively implement CCJR by significantly reducing the hospital’s episode volume.

Tampa General Hospital’s (TGH) experience provides an example of the potential extreme impact of such a scenario. In 2014, TGH had an annual LEJR episode volume of nearly 400 cases and was considering moving LEJR to the risk phase of BPCI. However, a local PGP was also in Phase 1 of BPCI. This PGP performs approximately 99 percent of the Medicare joint replacements at TGH. Indeed, TGH’s target price files, which were provided by CMS in November 2014, revealed that if the PGP were live with LEJR in BPCI, TGH’s three-year baseline episode volume would drop from over 1200 episodes to approximately 20 episodes. TGH recognized that under BPCI precedence rules, these episodes would be attributed to the PGP and ultimately decided not to move LEJR to the risk phase. As currently proposed, CCJR would force TGH into the situation they deemed untenable in BPCI.

Revising the MSA exclusion methodology to include BPCI LEJRs initiated by PGPs and by all BPCI providers that entered the risk phase in October 1, 2015 may prevent this scenario from occurring for many hospitals, but not for all. As a result, **AAMC recommends that this change be combined with the use of a minimum CCJR episode volume threshold. If a hospital has less than 100 episodes in a reference year or if over 50 percent of the hospital’s episodes are attributed to a PGP BPCI risk-bearing entity, the hospital should not be required to participate in CCJR. Published literature has consistently shown the relationship between hospital and surgical volume and complications, readmissions, patient safety and mortality,**

as well as the special risk for minority populations who disproportionately use low volume hospitals.²

Health Equity Issue

Finally, AAMC notes that CMS's MSA selection may have an unintended negative impact on the Agency's commitment to ensure optimal care to all races, socioeconomic strata, and urban/rural areas. The Association notes that few sites were selected in Georgia or Mississippi, yet southern Florida is included. The AAMC is confident that this was not intentional and is due to volume and the other stated criteria, but the result is that in some areas lower income and minority Medicare beneficiaries may be left out of this care innovation. Based on the UCLA study noted above, Hispanic ethnicity, and black and Asian race, were statistically significant predictors of utilization of a low-volume hospitals. The study also found that low volume hospitals had more low income patients and slightly more comorbidities than those in higher volume hospitals. This supports the AAMC position to recalculate MSAs.

LIMITING HOSPITAL FINANCIAL RESPONSIBILITY

CMS proposes to cap hospital's financial liability in the program through the following proposals:

- Cap losses at 10 percent of the target amount in year 2; and
- Cap losses at 20 percent of the target amount in years 3 through 5.

AAMC supports these limits on hospitals' financial responsibility in CCJR.

FRAUD AND ABUSE WAIVERS TO ALLOW GAINSHARING SHOULD BE PROMULGATED EXPEDITIOUSLY; CHANGES NEEDED TO OTHER FRAUD AND ABUSE LAWS

CMS proposes to allow gainsharing of Medicare savings and internal costs between hospitals and various providers defined as a "CCJR collaborator". CMS further proposes to allow sharing of downside risk, through the contribution of alignment payments. AAMC supports these options, and notes that similar gainsharing rules have played a key role in BPCI.

CMS proposes that Gainsharing Payments can only go to CCJR collaborators who "directly furnish services to CCJR beneficiaries." CMS further clarifies that a Gainsharing Payment made to a CCJR collaborator that is a physician group "must be shared only with physician or non-physician practitioners that furnished a service to a CCJR beneficiary during an episode of care . . ." The AAMC opposes this proposal and asks that it be withdrawn. The physician group practice should have the freedom to determine the most appropriate way to distribute Gainsharing Payments given the multiple disciplines involved in patient care. The many requirements that CMS proposes, including that all payments must be auditable by HHS, provide assurance that the distribution will be documented and supported, thus avoiding the possibility of program abuse.

² Soohoo NF, Farnig E, Zingmond DS. Disparities in the utilization of high-volume hospitals for total hip replacement. *J Natl Med Assoc.* 2011;103(1):31-5.

Among the proposals for both Gainsharing and Alignment Payments is that they must “comply with all provisions in this proposed rule, **as well as all applicable laws, statutes, and rules**” (emphasis added, 80 *Fed Reg.* at 41264 and 412655). It is critical that CMS, the Office of Inspector General (OIG), and other associated agencies coordinate their efforts and rapidly promulgate and waivers to those fraud and abuse laws that are identified as impediments to the financial arrangements that support the coordinated care in this proposed rule and in other programs. The highly regulated nature of this program guards against the possibility that patients will be denied care or will be given poor quality care. Revising contracts to reflect these new financial arrangements can take months; not only do regular contract processes require time, but these new financial arrangements, such as those in BPCI, introduce an entirely new lexicon to providers and hospital legal counsel.

WAIVERS SHOULD APPLY BEGINNING IN YEAR 1; SOME REVISIONS TO THE WAIVERS ARE NEEDED

CMS proposes to waive the various Medicare program rules to enable hospitals participating in CCJR to provide more efficient and coordinated care to LEJR patients. AAMC supports policies that afford hospitals operating under alternative payment models the additional flexibility needed to implement such programs.

While the waivers are similar to those provided for BPCI, CMS proposes some key differences. For example, the three-day hospital stay for skilled nursing facility (SNF) payment waiver under CCJR would require that beneficiaries must be discharged to a SNF with a three star or higher rating under the Five-Star Quality Rating System for SNFs, whereas BPCI program rules only require that the majority of patients be discharged to a SNF that meets this criteria. Some members of AAMC’s BPCI convened group were unable to adopt the three-day SNF waiver due to the lack of adequately ranked SNFs in their region. While prior to 2015, 78 percent of nursing homes scored 4 or 5 stars, now only 45 percent achieve 4 or 5 stars, with about one-third of SNFs ranking only 1 or 2 stars.³ Requiring all SNFs to have a 3 star rating or higher would further limit the number of hospitals able to use the waiver as clinically appropriate.

In addition, there seems to be no reason why CMS would prevent hospitals from using the three-day SNF waiver until year 2 of CCJR. It is important that hospitals be able to implement clinically appropriate care interventions from the onset of the program, as in BPCI. All waivers should apply throughout the entirety of the CCJR program duration.

CMS also proposes that waivers would apply to CCJR beneficiaries even if a CCJR beneficiary’s episode is later cancelled. Based on AMCs’ experiences in BPCI, we support this proposal and believe that it is critical in preventing unintended consequences for patients. As is likely to occur during the CCJR program, under BPCI there are a number of reasons that cause an episode to be dropped. A patient discharged under DRG 470 to a SNF after less than a three-day hospital stay may later be readmitted to a hospital within 90 days for a medically indicated second joint

³ [Boccuti C, Casillas G, Neuman T. \[Internet\] Reading the Stars: Nursing Home Quality Star Ratings, Nationally and by State. <http://kff.org/report-section/reading-the-stars-nursing-home-quality-star-ratings-nationally-and-by-state-issue-brief/>. Published May 14 2015 Accessed August 19, 2015](http://kff.org/report-section/reading-the-stars-nursing-home-quality-star-ratings-nationally-and-by-state-issue-brief/)

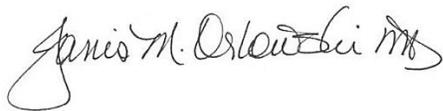
replacement. In this scenario, the second joint replacement would trigger an episode and the first episode would be dropped. Under BPCI, the SNF 3-day waiver for the initial discharge to SNF would no longer hold, and the patient would be financially responsible for the SNF stay. AAMC is pleased that as currently proposed, the CCJR rule would prevent beneficiaries from facing financial strife under this scenario; BPCI beneficiaries should have the same opportunity.

CMS proposes that when waivers are employed at a time when a beneficiary is not in a CCJR episode, the waiver would not hold and CMS would recoup payment from the beneficiary. The many rules for determining beneficiary eligibility, and the timing of when an episode is dropped, as well as which providers or programs have precedence, are complex. CMS should publish guidance that clearly delineates under which circumstances waivers would hold, and under which circumstances a beneficiary would be considered to have never been in a CCJR episode.

CONCLUSION

Thank you for the opportunity to present our views. We would be happy to work with CMS on any of the issues discussed above or other topics that involve the academic medical center community. If you have questions please feel free to contact Coleen Kivlahan, MD at 202-828-0053 or ckivlahan@aamc.org.

Sincerely,



Janis M. Orlowski, MD MACP
Chief Health Care Officer
Association of American Medical Colleges

APPENDIX

Figure 1: Percent of Hospitals Not Meeting CCJR Benchmarks on HCAHPS⁴

	Major Teaching	Minor Teaching	Non-Teaching	All Providers
Passing Providers	166	470	1402	2038
Failing Providers	137	219	480	836
Total Providers Analyzed	303	689	1882	2874
Percent not Meeting the 30th Percentile	45.2%	31.8%	25.5%	29.1%

Source: DataGen Analysis of Hospital Compare Data, released July 2015

Figure 2: Percent of Hospitals Not Meeting CCJR Benchmarks on All Measures⁵

	Major Teaching	Minor Teaching	Non-Teaching	All Providers
Passing Providers	86	291	920	1297
Failing Providers	217	398	962	1577
Total Providers Analyzed	303	689	1882	2874
Percent not Meeting the 30th Percentile	71.6%	57.8%	51.1%	54.9%

Source: DataGen Analysis of Hospital Compare Data, released July 2015

CCJR Measure Display Methodology:

⁴ HCAHPS percentiles were calculated using non-adjusted HCAHPS linear scores for the reporting period October 1, 2013 - September 30, 2014. “Never,” “sometimes,” “strongly disagree” and “disagree” responses were given a score of 0.

⁵ This data includes all IPPS hospitals reporting these three measures. Hospitals with insufficient data were assumed to be meeting the threshold. Data was pulled from Hospital Compare following the July 2015 update. The performance periods for the three measures used in this model are here:

- Hip/Knee Complications: Reporting Period April 1, 2011 - March 31, 2014
- Hip/Knee Readmissions: Reporting Period: July 1, 2011 - Jun 30, 2014
- HCAHPS: Reporting Period: October 1, 2013 - September 30, 2014

Figure 3: National Hip / Knee Readmission and Complication Measure Performance by Percentile based on July 2015 *Hospital Compare* Data

Percentile	Hip/Knee Complications	Hip/Knee Readmissions
10th	4.0 %	5.7 %
20th	3.6 %	5.4 %
30th	3.4 %	5.1 %
40th	3.2 %	5.0 %
50th	3.1 %	4.8 %
60th	3.0 %	4.7 %
70th	2.8 %	4.6 %
80th	2.7 %	4.4 %
90th	2.4 %	4.1 %
National Average	3.1 %	4.8 %