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Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services; Proposed Rule [CMS-5516-P]

Dear Acting Administrator Slavitt:

On behalf of the physician and medical student members of the American Medical Association (AMA), we appreciate the opportunity to offer comments to the Centers for Medicare & Medicaid Services (CMS) regarding the Proposed Rule on a payment model for Comprehensive Care for Joint Replacement (CCJR). The AMA strongly supports efforts by CMS to make appropriately structured alternative payment models (APMs) available to physicians and other providers, including bundled and episode payment models. We have concerns, however, that implementation of the specific payment model CMS has proposed for joint replacement could have serious unintended consequences for Medicare patients and physicians. We have developed detailed recommendations to improve the payment model design in order to address these concerns, which are described in subsequent sections of this letter.

Goals of the Program

Our recommendations are designed to achieve seven goals that are essential to the success of any new APMs and that CMS should support in developing a revised CCJR proposal and in developing other APMs:

1. Enable physician-identified improvements in care that cannot currently be implemented due to barriers created by current payment systems;
2. Provide adequate, predictable resources to support the delivery of high-value care to all patients;
3. Hold physicians and other providers accountable only for aspects of costs and quality that they can influence or control;

4. Allow voluntary participation by all interested physicians in all parts of the country;
5. Support physician leadership in redesigning care delivery;
6. Offer flexibility to support different organizational arrangements among providers; and
7. Design and implement the program in a collaborative approach between CMS and physicians.

Design of the Program

To allow the new CCJR program to fulfill these goals, the AMA recommends a number of changes be made to the proposal. The major changes are:

1. Instead of mandating participation by all physicians, hospitals, and post-acute care providers and their patients in randomly selected geographic regions, and instead of precluding participation by physicians and patients in other communities, participation in the CCJR program should be voluntary and it should be available to physicians in all localities, so that joint replacement patients all over the country can benefit from the reduced complications, shorter recovery times, increased coordination, patient engagement, and improved health outcomes that will be possible from redesigning care for joint replacements. This voluntary APM should be defined as an eligible APM under the Medicare Access and CHIP Reauthorization Act (MACRA).
2. Instead of trying to define a single bundled payment for the wide range of joint surgeries and causes of surgery that are currently included in hospital joint replacement Medicare severity diagnosis-related groups (MS-DRGs), the CCJR program should be specifically focused on elective total hip and knee replacements that are not the result of injuries or disease-related fractures.
3. Instead of CMS assigning providers to a CCJR episode after services are already delivered based on fee-for-service (FFS) claims that are received, the CCJR program should allow participating physicians to lead and assemble a “CCJR Team” that can provide all the services needed by hip and knee replacement patients from surgery through recovery. Prior to surgery, a participating physician and their patient should collaboratively decide which other physicians and providers the patient will use for the procedure and recovery services and they should agree on a treatment plan for the episode.
4. Instead of making hospitals responsible for managing payments and costs, each CCJR Team should designate or create a CCJR Management Organization to manage the costs and payments under a prospectively-determined budget for the bundled CCJR episode. The CCJR Management Organizations should be defined as Alternative Payment Entities under MACRA.
5. Instead of risk-adjusting payments based only on the characteristics that affect hospital costs, payments should also be risk-adjusted based on patients’ functional status and other characteristics that affect the types of post-acute care they need. Physicians should assess their patients’ functional status and other health problems and assign the patients to one of several acuity/risk levels. CCJR episode payment amounts should then be higher for patients in the higher-acuity/risk levels. In addition, instead of being ratcheted down each year depending on FFS trends, the CCJR episode payments should be regularly updated to reflect inflation in the

costs of inputs and periodically adjusted based on an analysis of the costs of delivering high-quality care during hip and knee replacement episodes.

6. Instead of imposing requirements for use of health information technology (HIT) that are not grounded in any evidence of patient benefit and tying CCJR payment allocation to FFS amounts, the CCJR program should give physicians and the other providers on CCJR Teams as much flexibility as possible to deliver services in different ways in order to improve patient outcomes, identify which services, communication technologies and information systems have the greatest benefits for patients at an affordable cost, and distribute CCJR payments based on the costs actually incurred by the providers on the team.

We describe our recommended goals for designing APMs and our recommended changes to the CCJR model in greater detail below. Additional details on the rationale for the specific changes and our comments on various elements of the proposed rule are contained in an attached Appendix.

Goals for the CCJR Program and Alternative Payment Models

Goal #1: Improving Care by Removing the Barriers in Current Payment Systems

At dozens of meetings the AMA has organized, physicians have described opportunities to improve care for patients in ways that will also lower the costs of care, but they indicate that they cannot pursue these opportunities due to barriers created by the way current Medicare payment systems are designed. Physicians have expressed strong interest in participating in APMs that would remove these barriers and give them the flexibility to redesign care in ways that will improve quality for their patients and reduce costs for Medicare and other payers.

These opportunities and barriers exist for joint replacement as well as many other conditions and procedures. For example: innovative orthopedic surgeons, physiatrists, and other physicians have been able to improve outcomes and/or reduce costs for joint replacement patients through initiatives such as pre-operative physical therapy and therapeutic exercise, shorter hospital stays, home-based post-discharge therapy, and shorter but more intensive inpatient rehabilitation. However, these alternative approaches are not paid for at all or are inadequately paid for under current Medicare payment systems.

It is essential to recognize that it is not the *payment model* that will improve care; it is the *physicians and other health professionals who will improve care*. Rather than CMS implementing a new payment model and “testing” it to see if the payment model improves care, greater benefits and fewer unintended consequences will occur if new payment models are specifically designed with physician input to ensure the model removes the existing barriers to better care and avoids creating new ones.

Implementation of a bundled payment program for joint replacement in Medicare should be designed to remove the current barriers to better care and give physicians and other providers adequate flexibility and sufficient resources to improve care and assume accountability for outcomes they can control. Unfortunately, the design of the CCJR payment model that CMS has proposed does not achieve these goals. The proposed model does not give physicians and other providers the necessary flexibility to significantly redesign care and it places providers at risk for costs they cannot control.

Goal #2: Adequacy and Predictability of Payment

A fundamental principle governing any new payment model is that it must provide adequate and predictable resources to enable sustainable delivery of high-quality care to patients. Achieving savings is only a desirable goal if it does not jeopardize access to care or quality of care. If savings are achieved by setting payment rates below achievable costs, physicians, hospitals, and other providers could be forced out of business and Medicare patients would face reduced access to care. Moreover, it is impossible for physicians and other providers to make investments in facilities and equipment or to recruit, train, and retain high quality personnel if they cannot predict how much they will be paid for their services or if significant changes in payment are made every year.

While the AMA supports CMS' goal of setting bundled payment rates at levels that will result in lower spending than would otherwise occur, we strongly oppose the proposed process of continuously adjusting the payment rates based on spending on FFS claims. One of the key reasons to implement a bundled payment model is to give physicians the flexibility to deliver different types of services in different ways than what is possible under current FFS payment and coverage rules. Continually reducing payment rates to match FFS payments discourages innovation and negates the benefit of creating the bundled payment.

The AMA recommends that once the initial payment rates are established for a new payment model, they be adjusted over time to keep them adequate to support the delivery of high-quality care. This is best done by making annual increases in payment amounts to compensate for inflation and conducting periodic studies to determine the costs of care delivery and the adequacy of payment amounts in relation to the costs of delivering care.

In addition, in order for a bundled episode payment system to provide adequate payments, there cannot be a single payment amount applicable to all patients, nor can payments be risk-adjusted solely based on the costs of one portion of an episode, such as the hospitalization. Payments must be appropriately risk-stratified based on the costs of care for the entire episode. Medicare patients receiving total joint replacements have very different needs for both acute and post-acute care; some need far more services and more expensive services than others. A single payment amount or a payment amount stratified only based on hospital MS-DRGs would inappropriately impose rewards and penalties based on patient differences unrelated to the quality and appropriateness of care. This could make it difficult for higher-need patients to obtain care and could force those who do care for higher-need patients out of business.

Goal #3: Accountability for Costs and Quality that Physicians Can Control

The AMA has discussed APMs with physicians from a wide variety of different specialties. In all of our discussions, physicians have indicated that they are willing to accept accountability for the aspects of quality and cost that they can control or influence, and moreover, as indicated earlier, that they can improve quality and reduce costs if barriers in the current payment system are removed. On the other hand, physicians indicate that they are very concerned about their ability to deliver high-value care under payment models that can penalize them for aspects of cost or quality that they cannot control or significantly influence.

Consistent with this view, a joint replacement payment model should hold physicians and other providers delivering services associated with joint replacement accountable only for the costs and outcomes specifically associated with joint replacement, not for costs or outcomes associated with other health problems. If those other health problems directly affect the costs or outcomes of joint replacement, then

their existence should be appropriately factored into the payments and outcome measures for joint replacement through risk adjustment. Accountability for the costs and outcomes of treatment for the other health problems should be assigned to the physicians and providers who are responsible for treating those other health problems.

Goal #4: Allowing Voluntary Participation in All Parts of the Country

Any Medicare payment change that could help improve patient care should be available in all parts of the country. Participation should be voluntary, not mandatory. If the CCJR payment model can benefit patients – and we believe it can, if it is properly designed – then those benefits should be made available to patients in all parts of the country, not just those living in randomly selected metropolitan statistical areas. If a team of physicians and other providers believe that they can use the flexibility and resources available in a bundled payment program to improve patient care, then they will have a strong incentive to voluntarily participate in a new payment model. If they do not believe they can improve care by participating in the model, and particularly if they believe that the CCJR payment model would compromise their ability to deliver high-quality care, CMS should not force them to participate.

The AMA does not believe there is any need for a mandate to encourage participation in a properly designed bundled payment system. On August 13, CMS announced that over 360 organizations have entered into agreements with CMS to participate in the Bundled Payments for Care Improvement (BPCI) initiative and an additional 1,755 providers have partnered with those organizations. Acting Principal Deputy Administrator and Chief Medical Officer Patrick Conway, MD said that CMS was “excited that thousands of providers...have joined us in changing the health care system to pay for quality over quantity – spending our dollars more wisely and improving care for Medicare beneficiaries.” In addition, 787 of these providers are specifically implementing one of the three BPCI models for total joint replacement, and they are located in 45 of the 50 states. Over 400 of these providers are participating in BPCI Model 2, which includes the full range of costs in an episode of care; one-third of these projects are being led by physician groups.

The large and diverse participation in the BPCI is clear evidence of the interest and willingness of physicians and other healthcare providers from across the U.S. to voluntarily implement new payment models. However, problems with the way the BPCI program has been designed, particularly the way it has been changed after it was first announced, have deterred many providers, particularly physician groups, from participating. The fact that many of those who applied and participated in the first phase of the BPCI did not continue to the risk-bearing phase of the program does not indicate an unwillingness to change, but rather that flaws in the program design are precluding broader participation.

Goal #5: Supporting Physician Leadership in Redesigning Care Delivery

Physician leadership is essential for successful implementation of any payment model intended to support a comprehensive approach to care for Medicare patients. Only physicians can make the determination as to what types of care could effectively address patients’ needs and in which settings those care services can be delivered safely and successfully. Patients rely on physicians to help them decide which choices to make when alternative types of care and alternative facilities are available, and patients rely on physicians to ensure that care is delivered safely and effectively.

The proposed CCJR payment model fails to recognize the central and essential role of physician leadership in care redesign. CMS has proposed to designate the hospital where the procedure was

performed as the accountable entity for all services the Medicare beneficiary receives, including services delivered by physicians and post-acute care providers, even though the patient will spend only a small portion of the entire episode of care in the hospital and the hospital may have little or no control over the care that is delivered before or after the patient's hospital stay. A bundled payment should instead be designed so that physicians are in charge of designing the care delivery process and ensuring that it achieves good patient outcomes without unnecessary costs. The physician and the hospital can then decide what role the hospital should play in the coordination and financing of care, rather than this being dictated by CMS in regulations.

Goal #6: Flexibility to Support Different Organizational Arrangements

While physician practices are the one essential component of the care that all joint replacement patients will receive (as well as care for other types of procedures and other health conditions for other patients), hospitals and a variety of post-acute providers will also be involved for most patients receiving joint replacements. The best way to involve these other providers in payment for the episode will depend heavily on the organizational structures, experience, and relationships in individual communities. In some cases, physicians, hospitals, and post-acute care providers will be able to easily organize themselves to accept a prospective bundled payment from Medicare and allocate it among the participating providers, whereas in other cases, it will be easier for providers to continue billing under current payment systems and then retrospectively reconcile those payments against a prospectively defined budget. The payment model under the CCJR program should have the flexibility to support both types of arrangements, i.e., it should enable providers to utilize a prospective payment without forcing them to do so.

One of the most important accomplishments CMS has made through the Center for Medicare and Medicaid Innovation is making multiple payment models available in the BPCI program for the same condition or procedure and making optional approaches available within those models for different providers. It would be an unfortunate step backward to define a single approach in the CCJR. Moreover, it would be a particularly unfortunate step backward to only use a retrospective payment model when many physicians and other providers would be willing to implement a simpler and more flexible prospective payment model if it were properly designed. The limited number of applicants for BPCI Model 4 is likely more a reflection of limitations and problems in the design of that model (such as failure to include post-acute care services and removal of outlier payments) than any fundamental unwillingness or inability of providers to manage prospective payment models.

Instead of offering only a totally retrospective model for the full episode of care or a totally prospective payment model that does not include the full episode of care, as CMS has done in the BPCI program, we recommend a hybrid approach, allowing a combination of prospective payment and retrospective reconciliation for the full episode of care, as described in more detail below.

Goal #7: Designing and Implementing Payment Models in a Collaborative Approach between Physicians and CMS with Provision of Timely Data

We believe that the greatest successes in improving the quality of care for Medicare patients, reducing and controlling spending for CMS, and maintaining the financial viability of physicians and other healthcare providers will be achieved by designing and implementing payment reforms through a collaborative approach between physicians and CMS. The significant barriers that are created by current payment systems make it impossible for CMS to know exactly how much money can be saved without harming patients. The bigger the barriers in the current payment system, the more significant the changes

in both payment and care delivery that are needed, but this also means that adequate time is needed to allow these changes to be implemented in ways that do not harm either patients or providers. This is certainly true for joint replacement. Although analyses of spending during joint replacement episodes have shown tremendous variation in total costs for patients receiving what is ostensibly the same basic procedure, it is unclear how much of this variation is avoidable and how much is necessary because of differences in patient needs. The BPCI demonstration projects will provide important insights into these issues, but most of those projects are still in the earliest phases of implementation.

Physicians and hospitals cannot estimate the potential savings associated with better care delivery without access to Medicare claims data on the full episode of care for patients. CMS has recognized the need for providers to have access to Medicare data, but only after the agency has already designed a payment model. CMS needs to establish a mechanism through which physicians who want to redesign care delivery can obtain the data they need to estimate the costs and savings of alternative care delivery approaches and the potential impacts of alternative payment models to support them.

We do not believe it is possible today to adequately define the details of an episode payment model for joint replacement that can be put in place for five years and then evaluated to determine its suitability for long-term implementation. In particular, as we describe in more detail below, we believe that payment rates in such a payment model must be stratified based on differences in patient need, but the information to do that can only be obtained by allowing providers to assess patient needs and implement new approaches to care delivery in a careful way without either excessive pressure to achieve savings or fears of financial risk. Physicians cannot develop an appropriate stratification structure without access to data on current utilization patterns for patients.

In addition to the data needed during the design process, physicians and other providers implementing an alternative payment model also need timely data during the implementation process so that they can (a) make refinements in the care delivery process, and (b) identify problems with the payment structure and determine how to correct those. Data *timeliness* is essential; for physicians to participate, they must have the assurance that they will receive data within a few months after services are delivered. It is inappropriate to place physicians at financial risk without giving them the information they need to successfully manage that risk.

Rather than attempting to mandate a payment model and then evaluate its impacts, a three-step process should be used. First, physicians who want to work with other providers to redesign care delivery should be given access to data and encouraged to design both changes in care delivery and an appropriate payment model to support those changes. Second, physicians should be encouraged to volunteer to implement a preliminary version of the new payment model and to work with CMS to refine the structure and parameters of the model over a several year period. Then, the refined model can be implemented more broadly.

AMA Recommendations for Changes to the Program Structure Proposed by CMS

We recommend that the following changes be made in the model defined in the Proposed Rule:

CMS Proposed Rule	Change Recommended by AMA
Providers would be required to participate in the CCJR program if they are located in randomly selected metropolitan areas and would be precluded from participating otherwise.	No provider would be forced to participate in the CCJR program, but those who choose to participate in the program could do so regardless of where they are located.
Medicare patients would choose which hospitals, physicians, and post-acute care providers to use throughout the episode.	Medicare patients would choose a CCJR Team of providers assembled by a physician and obtain all of the services needed during the episode of care from the members of the team.
Virtually all services that a patient receives during the 90 days following discharge from a hospital for joint replacement surgery would be covered by the episode payment.	Only services related to the joint replacement surgery would be included in the episode payment.
All providers would continue to be paid under current FFS payment systems. Payments for services assigned to an episode would then be retrospectively reconciled against an episode payment amount. Hospitals would be required to pay Medicare if total payments exceed the episode payment amount, and hospitals would receive all of the savings below the episode payment amount.	CCJR-participating physicians and other members of their Team would designate or create a jointly-governed CCJR Management Organization (CCJR-MO) that would be paid through new prospective episode payment codes. CCJR-participating physicians would be paid through the CCJR-MO rather than the Medicare Physician Fee Schedule (PFS) so they have the flexibility to deliver or arrange for a different mix of services than under current FFS payment systems. Hospitals and other providers would have the option of being paid through the CCJR-MO or through standard Medicare payment systems.
Hospitals would not be required to share any savings with physicians or other providers. CMS would restrict the ability of hospitals to share savings with physicians and other providers.	The CCJR-MO would have the flexibility to pay physicians and other providers on the CCJR Team for different services or pay different amounts for services than is possible under current Medicare payment systems.
The episode payment amount would be annually adjusted based on Medicare FFS spending during episodes. No adjustment would be made for the cost of services delivered that are not covered by current FFS payments.	The episode payment amount would be established initially based on historical Medicare FFS spending, then the payment amount would be increased annually based on inflation and adjusted periodically based on an analysis of the costs of services during episodes.
Payments would only be differentiated using the MS-DRG classification for the patient's inpatient stay. There would be no risk adjustment in payment based on patient functional status or other characteristics affecting the need for post-acute care services.	A family of new billing codes would be established that assign patients to clinical categories based on functional status and health conditions that will affect their need for post-acute care services.

How the AMA Recommends the CCJR Program Be Structured

More specifically, instead of the payment system defined in the Proposed Rule, we recommend that CMS use the following structure for payments to providers under the CCJR program:

Participating Providers

- Any physician who performs hip or knee replacement surgery should have the option of participating in the CCJR program regardless of the geographic area where they are located. Physicians who participate would agree that all elective joint replacement surgeries they perform that meet the criteria of the CCJR program would be paid through the CCJR program rather than through the standard Medicare PFS.
- A physician who participates in the CCJR program would form a physician-led team of providers – a Comprehensive Care for Joint Replacement Team (CCJR Team) – to coordinate delivery of all of the acute and post-acute care services needed by a Medicare beneficiary in order to receive and recover from elective hip or knee replacement surgery (i.e., the CCJR Episode). The hospitals, post-acute care providers, and other physicians who are part of the CCJR Team could differ from patient to patient based on the patient’s needs.
- Once the decision has been made that the patient is eligible for joint replacement surgery, the CCJR-participating physician and patient will develop and agree on a treatment plan that identifies the other physicians, the hospital, the post-acute care providers and other members of the CCJR Team that will deliver all of the services the patient needs during the episode of care that are related to the joint replacement surgery and recovery. Once the patient and physician have agreed to this plan, Medicare coverage for services delivered during the CCJR episode of care will be limited to the designated CCJR Team for all acute and post-acute care services included in the CCJR Episode. (Medicare coverage of physician services for other health conditions unrelated to the CCJR Episode would not be affected by these episode limits.)
- Hospitals and post-acute care providers could also organize CCJR Teams, but a CCJR Team would have to include at least one physician who performs hip or knee replacement surgery and who has agreed to be paid through the CCJR program rather than the Medicare PFS. The physician(s) would need to agree to work with the other providers who are part of the CCJR Teams if the Teams are assembled by other providers.

Eligible Patients and Services Included

- The focus of the CCJR program should be on patients receiving hip or knee replacements on an elective basis to address problems caused by osteoarthritis and similar conditions. Patients receiving surgery for problems caused by fractures due to injuries, cancer, or other conditions should be excluded. Surgery on joints other than hips or knees should also be excluded, at least at this time.

- The following services should be included in the CCJR Episode:
 - Professional services related to the hip or knee surgery, including services occurring between the time the decision to perform surgery is made and the surgery is actually performed;
 - Facility services for the patient's stay at a hospital or other facility where the procedure is performed;
 - Any other professional services performed during the patient's stay at the hospital or other facility where the procedure is performed;
 - All services delivered by Inpatient Rehabilitation Facilities (IRFs), Skilled Nursing Facilities (SNFs), Long-Term Care Hospitals (LTCHs), or Home Health Agencies (HHAs) if those services begin within 90 days after discharge from the hospital or other facility where the procedure is performed, even if the service extends beyond 90 days;
 - Any hospital admissions or outpatient services that occur between discharge from the facility where the procedure is performed and 90 days after discharge, including both facility charges and physician services, that are related to the initial joint replacement surgery or to a complication resulting from the surgery or the planned post-acute care; and
 - Any other physician service or services delivered within 90 days after discharge that is related to the joint replacement surgery, recovery from the surgery, or a complication of the surgery.

Payment Mechanism

- For each eligible Medicare beneficiary who selects a CCJR Team to perform hip or knee replacement surgery, the Medicare program would pay a single bundled payment amount (the CCJR Episode Payment) to cover the costs of all of the services included in the CCJR Episode. The amount of the CCJR Episode Payment for an individual patient would differ depending on two factors; (1) the specific type of surgery performed, and (2) a clinical category based on characteristics of the patient determined by a physician on the CCJR Team prior to performing the procedure. The physician would submit a claim form to CMS using a new billing code that indicates the clinical category for the patient and the type of procedure performed, and this billing code would determine the amount of the CCJR Episode Payment. CMS would designate the CCJR Episode Payment as an APM under the provisions of MACRA.
- The physician participating in the CCJR Program ("CCJR Physician") would designate an organizational entity – the CCJR Management Organization (CCJR-MO) – to receive the bundled payment amount from CMS for each eligible CCJR patient receiving a joint replacement from the participating physician. This entity would be designated as an Alternative Payment Entity under MACRA.
- Hospitals, post-acute care providers, and other physicians that agree to be part of CCJR Teams with a CCJR Physician would have the option of being paid for services they deliver to CCJR patients either through the CCJR-MO or through the standard Medicare payment systems. In order for a provider to be paid through the CCJR-MO, the provider would agree not to bill Medicare for any services that are part of a CCJR Episode for any patient managed by a CCJR Team that involves the participating physician. If a provider (a physician, hospital, or post-acute care provider) elects to continue being paid through the standard Medicare payment systems, the amount that Medicare pays that provider for a service to a CCJR patient that is included in a

CCJR Episode would be deducted from the Medicare payment to the CCJR-MO for that patient.

- In order for a hospital to be paid through the CCJR program for all eligible CCJR patients it admits, all of the physicians who perform joint replacement surgery on those patients would have to be participating in the CCJR program.

Payment Amounts

- During the initial year of the program, the CCJR payment amount to a CCJR-MO for each combination of procedure type and clinical category of patients would be based on the average Medicare spending for episodes of care to similar patients treated by the CCJR-participating physicians involved with the CCJR-MO during a baseline period (one year or longer) prior to the initial year of the CCJR program.
- During the second and subsequent years of the program, the CCJR payment amounts would be determined by taking the initial year's payment amounts and updating them for inflation based on CMS market basket measures. Smaller updates could be used for CCJR-MOs with above-average payment amounts during the initial year (because of above-average levels of spending in CCJR episodes during the baseline period); this would reduce the differences in payment rates across CCJR-MOs over time.
- The CCJR payment amount in each year would be adjusted up or down based on the performance of the physician and his or her CCJR Teams in achieving good outcomes for CCJR patients.
- In addition to the CCJR Episode Payment, a CCJR Outlier Payment would be paid to a CCJR-MO if an individual patient needed an unusually large number of services or unusually expensive services.
- In addition to Outlier Payments for individual patients, and in addition to annual updates and quality adjustments to payment amounts, the total payments to the CCJR-MO in each year would be adjusted using risk corridors to protect the physician and his or her CCJR Teams from excessive financial risks and to protect the Medicare program against paying too much for care. During the initial three years of the program, physicians and other providers who are paid through the CCJR-MO rather than standard Medicare payments would agree to continue collecting and submitting the same information that would be needed to determine standard Medicare payments for services delivered to CCJR patients, so that comparisons of CCJR payments and standard payments could be made for purposes of calculating the risk corridor adjustments.
- During the third year of the program, CMS would work with the CCJR-MOs and their CCJR Teams to refine the definitions of the clinical categories and to adjust the payment amounts for each combination of procedure and clinical category to ensure that CCJR payments accurately reflect the costs of care for different types of patients. These refinements and adjustments would be based on a study of the average total costs of all services delivered during CCJR Episodes by all CCJR Teams.

- Additional physicians would be eligible to form CCJR-MOs during 2018 and to be paid under the CCJR Program beginning in 2019 in order to qualify as participants in APMs.

Assuring Quality Care

- The complication rates, mortality rates, and readmission rates for the patients receiving surgery from a CCJR Physician would be calculated during the same baseline period that was used to calculate payment rates. Separate rates would be calculated for each type of procedure and clinical category of patients for which separate CCJR billing codes are defined. The CCJR Physician would be required to maintain or improve these rates in order to continue participation in the CCJR program. A statistically significant worsening in these quality measures would initially result in a reduction in CCJR payments and then, if improvements are not made, the CCJR-MO would be terminated from the program and all providers would revert to payment under standard Medicare payment systems. A CCJR Physician who achieves a large and statistically significant improvement in quality measures over the prior year would receive an increase in their CCJR payments.
- During the initial three years of the program, CCJR Teams would collect patient-reported outcome information measuring improvements in functionality and pain. Performance on these outcome measures would be used to establish performance benchmarks, and then the outcome measures would be incorporated into the quality measures for the program beginning in 2019.

Patient Cost-Sharing

- Each CCJR-MO would establish a flat copayment amount for each CCJR billing code that a Medicare beneficiary would be required to pay for all of the services delivered by CCJR Team members who are being paid through the CCJR. These copayments would be paid to the CCJR-MO. For services that beneficiaries receive from providers being paid through standard Medicare payment systems, the beneficiaries would pay the standard copayment/co-insurance amounts under those programs.
- Since the number and types of providers on the CCJR Team may vary from patient to patient, different copayment amounts would be established depending on whether only physicians, physicians and hospitals, etc. are being paid through the CCJR-MO. The copayment amounts could be no lower than the standard copayment/co-insurance amounts for the providers included based on the lowest payment they would have received under standard Medicare payment systems.
- A CCJR-MO could also establish a schedule of payments that it would make to CCJR patients based on the patient's adherence to specific steps in a treatment plan or achievement of specific treatment milestones. The CCJR-MO could also establish a schedule of payments it would make to CCJR patients if the CCJR Team failed to achieve specific quality standards that it defined in advance.

Waivers

- Current Medicare restrictions on the types of services that can be delivered and the conditions that must be met to deliver services would be removed with respect to services delivered within the CCJR Episode. In particular:
 - CCJR patients would not be required to have a 3-day stay in the hospital in order to be covered for post-acute care services during the episode.
 - CCJR patients would not be required to be homebound in order to receive home health services.
 - Providers on the CCJR Team could be paid by the CCJR-MO for any telehealth services or home based services delivered to CCJR patients that are related to the joint replacement.
- A CCJR-MO would be permitted to give CCJR patients in-kind services or to reimburse patients for costs related to activities or services associated with the CCJR episode.
- Current restrictions on gainsharing among providers would be eliminated to give the CCJR-MO the flexibility to allocate the CCJR payment among the members of CCJR Teams in new ways. There would continue to be a prohibition on having compensation to any provider designed to reward them for increases in the number of joint replacement procedures they perform. There would be no prohibitions on payments from the CCJR-MO to providers on the CCJR Team based on their success in controlling costs within the CCJR Episode.

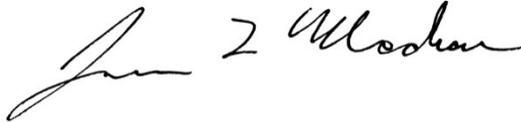
The rationale for our recommended changes is provided in the Appendix attached to this comment letter. The Appendix contains information on the following specific topics:

- Definition of the Episode Initiator
- Financial Responsibility for the Episode of Care
- Eligibility to Participate in the Payment Model
- Services Covered by the Episode Payment
- Methodology for Setting Episode Payment Amounts
- Ensuring Quality of Care
- Reconciliation of Payments
- Financial Arrangements Among Providers
- Beneficiary Contributions and Incentives
- Relationship to Other Payment Programs
- Waivers of Regulations
- Data Sharing
- Evaluating the Payment Model

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Thank you for the opportunity to comment on these important issues. The AMA looks forward to working with CMS on improving care delivery and payment models for joint replacement and for other types of patient health needs. If you have any questions or wish to discuss this issue further, please contact Sandy Marks, Assistant Director, Federal Affairs, at sandy.marks@ama-assn.org or 202-789-4585.

Sincerely,

A handwritten signature in black ink that reads "James L. Madara". The signature is written in a cursive style with a large, sweeping initial "J".

James L. Madara, MD

Attachment

APPENDIX:

Detailed AMA Suggestions & Rationale for Changes to Proposed CCJR Bundled Payment Model

Definition of the Episode Initiator

We strongly recommend that the “episode initiator” for CCJR episodes should be a physician, not a hospital. There are several reasons for this:

- A physician performs the procedure that triggers the CCJR episode and is responsible for ensuring that the procedure is done properly and for determining what kind of follow-up care is needed. Although hospitals and post-acute care providers deliver important services as part of the episode, the key clinical decisions about care within the episode are made by physicians. Similarly, the primary and most important decision for most Medicare patients is which physician will perform elective joint replacement surgery, with the choice of hospital generally a secondary concern.
- Although most joint replacement surgeries are performed during an inpatient hospital stay, the inpatient stays for patients have become shorter and shorter over time. A growing number of patients are now receiving joint replacement surgeries on an outpatient basis, although Medicare does not pay for them to be performed in an outpatient setting. National data indicate that in 2012, 8.3 percent of knee replacement surgeries and 2.2 percent of hip replacement surgeries were performed in an ambulatory setting.¹ The physician and patient should make the decision about when surgery can and cannot be performed safely in a particular setting. Since the facility where a physician performs outpatient surgery may or may not be part of the same facility where inpatient surgeries are performed, designating the physician as the episode initiator would ensure the CCJR program does not create a financial incentive to perform all surgeries on an inpatient basis even if they do not require an inpatient stay.
- Not every physician who performs joint replacement surgery at a hospital may want to participate in the CCJR payment system. Designating physicians who wish to participate as the episode initiators allows hospitals to participate without forcing all of their physicians to do so.
- Although there are clearly opportunities to improve quality and reduce costs for joint replacement surgery episodes, there are also opportunities to use non-surgical alternatives, and it is the physician and their patient who will make the decision as to whether surgery is appropriate as well as how to successfully deliver surgery when it is appropriate. In order to effectively connect payment for surgical care episodes to broader payment reforms for management of joint osteoarthritis, the central player will need to be the physician, not a hospital.

In most cases, individual patients would receive services from additional providers besides the physician, such as a hospital and post-acute care providers. The providers who deliver the services included in a CCJR Episode would be considered to be the CCJR Team for that patient. The CCJR Physician would be a member of each of these teams, but the CCJR Physician would have the ability to include different

¹ Wier LM, Steiner CA, Owens PL. Surgeries in Hospital-Owned Outpatient Facilities, 2012. Agency for Healthcare Research and Quality Healthcare Cost and Utilization Project, February 2015.

providers on CCJR teams for different patients, based on the patients' needs. For example, a physician may choose to perform routine surgeries on low-risk patients at a community hospital and perform more complex surgeries or surgeries on higher-risk patients at a hospital with more advanced capabilities. A patient without home supports might need to receive rehabilitation services in an inpatient setting, such as a SNF, while patients with home supports might be able to use home health services and outpatient therapy.

Financial Responsibility for the Episode of Care

Creation/Designation of an Organizational Entity to Accept Bundled Payment

We recommend that a physician who chooses to participate in the CCJR program (a CCJR Physician) designate an incorporated organization as the CCJR Management Organization (CCJR-MO) to accept overall financial responsibility for the costs and payment for joint replacement episodes under the CCJR program. The CCJR-MO could either be:

- an existing provider organization, if that provider organization will be part of some or all of the CCJR Teams including the CCJR Physician. This could be the CCJR Physician's practice, a hospital, or another provider organization.
- a newly formed organization. In order to qualify as a CCJR-MO, the CCJR Physician, or the CCJR Physician and other providers who will be involved in at least some CCJR Teams with that physician, should be required to hold a majority ownership stake in the CCJR-MO organization and to retain management control over the organization. The CCJR-MO could contract with other organizations to provide management services to the CCJR-MO, and it could allow those organizations or other investors to be co-owners of the CCJR-MO, as long as CCJR physicians and other providers maintained a majority ownership stake.

These options allow the flexibility to use existing provider organizations where appropriate and to create a new "neutral" entity where necessary, and the options ensure that healthcare providers remain in control of the delivery of care to patients.

CMS would designate the CCJR-MO as an organization eligible to receive Medicare payments under the CCJR program. The CCJR-MO would also be designated as an "Alternative Payment Entity" under the provisions of MACRA.

How Providers on the CCJR Team Would be Paid

A physician who chooses to participate in the CCJR program (a CCJR Physician) would need to agree that all procedures he or she performs on patients that meet the criteria for the CCJR program would be paid for through the CCJR-MO rather than directly from Medicare under the PFS. The physician would not bill Medicare under the PFS for services provided to CCJR patients that are included in the CCJR Episode. Instead, the physician would bill Medicare using one of a family of new CCJR codes. The AMA's Current Procedural Terminology® (CPT®) Editorial Panel and the AMA/Specialty Society Relative Value Scale Update Committee have established a joint workgroup that will explore potential creation of this new family of codes within the CPT system. Medicare would then make payments for these codes to the CCJR-MO that the CCJR Physician had designated, and the physician would then be paid by the CCJR-MO.

For patients who were not eligible for the CCJR program, the CCJR Physician would continue billing Medicare using standard CPT codes and be paid under the PFS. To avoid double payment for a CCJR

case (i.e., Medicare making a PFS payment to a CCJR physician for a service delivered to a CCJR patient as part of a CCJR Episode in addition to the CCJR payment for that patient), claims paid to the CCJR Physician would be periodically reviewed. Any duplicate billings that did occur would be deducted from future payments to the CCJR-MO, and the CCJR-MO would also be charged an administrative fee by CMS for any such payments.

Hospitals, post-acute care providers, and other physician practices that agree to be part of CCJR Teams with a CCJR Physician would have the option of being paid for services they deliver to CCJR patients either through the CCJR program or through the standard Medicare payment systems.

- If the provider elects to be paid through the CCJR Program, the provider would agree not to bill Medicare for any services that are part of a CCJR Episode for any patient managed by a CCJR Team that involves the participating physician. In order for a hospital or post-acute care provider to be paid through the CCJR program for all eligible CCJR patients that they care for, all of the physicians who performed joint replacement surgery on those patients would have to be participating in the CCJR program. Similar to the procedure described above for CCJR physicians, payments to the provider would be periodically reviewed to determine whether any claims had been filed for services to patients that are part of CCJR episodes, and if such payments were found, those payments would be deducted from future payments to the CCJR-MO and the CCJR-MO would also be charged an administrative fee by CMS for each such payment.
- If a provider (a physician, hospital, or post-acute care provider) elects to continue being paid through the standard Medicare payment systems, any payment for a service to a CCJR patient that is part of a CCJR Episode would be deducted from the payments made to the CCJR-MO along with an administrative fee.

These options encourage, but do not require, CCJR Team members other than the CCJR Physician to be paid for CCJR patients through the bundled CCJR Episode Payments, rather than through the existing Medicare payment systems for those providers. This flexibility is important for several reasons:

- Many Medicare beneficiaries who travel a long distance from their home to obtain surgery will want to return to their home community for some or all of their rehabilitation process, but the providers in their home community and the CCJR physicians may not have enough cases where they are both on the same CCJR Team to justify developing a different mechanism for paying those post-acute care providers through the CCJR-MO. Allowing those providers to continue billing Medicare makes it easier for CCJR Physicians to use those providers as part of CCJR Teams if they wish to do so. The administrative fee charged by Medicare reflects the additional work that will be involved in connecting those payments to the CCJR cases and encourages the CCJR Physician to recruit as many CCJR Team providers as possible to be paid through the CCJR-MO.
- If a CCJR Physician and another provider needed as part of a CCJR Team cannot negotiate an acceptable payment arrangement through the CCJR-MO, the physician can still participate in the CCJR program and rely on the standard Medicare payment system to pay that other provider.

These options also create an incentive for providers to develop the capabilities needed to accept prospective bundled payments and to transition to prospective payments on a schedule that makes sense for them.

If a physician delivers joint replacement surgery at multiple hospitals, the physician would need to agree to bill for all eligible CCJR patients through the CCJR-MO, even if some hospitals had agreed to be paid through the CCJR-MO and some had not. This would ensure that there is no effort to have lower-cost patients paid through the CCJR program and higher-cost patients paid through standard Medicare payment systems.

Choice of Providers for Patients

In order for an eligible Medicare patient to receive a CCJR procedure from a CCJR Physician, the patient and physician would need to agree in advance on a treatment plan for the entire episode that defines which hospitals, SNFs, IRFs, LTCHs, HHAs, physical therapy practices, and other providers will be part of the CCJR Team. It would be up to the CCJR physician to determine how many choices of hospitals and post-acute care providers to offer a patient, and this choice could vary based on the patient's characteristics. If the physician felt that the patient's needs could only be adequately met by one provider, the physician could require that the patient only use that one provider in order for the physician to be willing to deliver the CCJR procedure and manage the care for the patient during that episode.

Since CCJR would only apply to elective procedures, the patient would agree to the providers on the CCJR Team prior to receiving the procedure. If the patient wanted to use providers that the physician did not feel delivered high-enough quality at an acceptable cost, the patient would need to select a different CCJR Physician (or a physician that is not participating in the CCJR program, if there is one). This is not fundamentally different from what exists today during a hospitalization. A patient does not have the ability to independently choose the hospital, surgeon, anesthesiologist, and other physicians that will serve as their "team;" their choices are limited to the surgeons willing to perform the surgery, to the hospital(s) where each surgeon practices, and to the other physicians who practice at the selected hospital. Since the current "episode of care" under Medicare payment (i.e., the hospitalization) is being expanded to include the post-acute care period under CCJR, the patient should now make a choice of a team of providers that will collectively deliver all of the services during the full episode of care in a coordinated way.

Eligibility to Participate in the Payment Model

Eligible Providers

It is essential that the CCJR program is a voluntary option for physicians. The primary goal of the program should be to enable physicians and other healthcare providers to redesign the way care is delivered in ways that can lower costs while maintaining or improving the quality of care for patients, so it is essential that the initial participants in the program be physicians who want to actively engage in that type of redesign process. Moreover, because there are many details that still need to be resolved about the variables needed for risk-stratification of payments and the magnitude of the payments before a permanent program can be put in place, it is important to have willing participants who can work collaboratively with CMS to refine the payment model.

Hospitals and post-acute care providers who want to participate in the CCJR program should do so by encouraging participation by one or all of the physicians who perform joint surgeries on those providers' patients. We expect that physicians will be more likely to volunteer if they know that the providers who represent the majority of costs and the majority of avoidable costs in the episode are willing to participate.

Physician practices of virtually any size should be permitted to participate. In some communities, a single orthopedic surgeon may provide the majority of joint replacement surgeries, and an appropriately designed episode payment program can provide the flexibility that surgeon needs to design care more

appropriately for patients living in the local community. If the payment model is appropriately designed with provisions for risk adjustment, outlier payments, and risk corridors, it can enable small physician practices to participate and to generate savings for Medicare without requiring the physician practice to take on inappropriate levels of risk.

Physician practices and other providers should not be required to have specific types of information systems or other structural characteristics in order to participate in the program, nor should they be prohibited from using innovative approaches to delivering services. It is likely the case that CCJR Teams will benefit from using electronic health records (whether or not they are certified), health information exchanges, patient registries, and other HIT tools and communication technologies to coordinate and improve care, and the CCJR Episode Payment will give them a natural incentive to do that in a cost-effective way. Mandates from CMS to use particular information systems in particular ways are neither necessary nor desirable, and indeed, CMS mandates and performance measures based on HIT utilization can increase costs for providers and distract them from the primary goals of the program, i.e., improving care for their patients.

Physicians in all communities should be able to participate in the CCJR program. If the goal of the program is to improve care for Medicare patients, not just to save money for the Medicare program or to conduct research on the impacts of payment models, then Medicare patients in all communities should have the opportunity to benefit from better care in the CCJR program if they have providers in the community who are willing and able to redesign the delivery of care. Under the proposed regulations, a patient who wanted to take advantage of redesigned care in a CCJR Episode but who lived outside of any of the metropolitan statistical areas (MSAs) designated by CMS would have to travel to one of the designated MSAs to do so. It is inappropriate to force patients to travel to a different region to obtain better care at lower costs if there are provider teams in their own community who want to deliver improved care.

Conversely, under the proposed regulations, a Medicare patient who lived in one of the MSAs selected by CMS for the CCJR program would have to find a surgeon and hospital outside of the MSA if they were concerned about the incentives created by the CCJR program or if the providers in their home community stopped performing joint replacement surgery on patients like them due to the structure of the CCJR payment program. It is both inappropriate to mandate that providers participate in the CCJR program and inappropriate to force patients to travel for care because all providers in their own community are being forced to participate in a program they may not support.

Eligible Patients

The proposed regulations define much too broad a patient population for an episode payment. The hospital MS-DRGs for total joint replacement include patients receiving joint replacement surgery for a wide range of reasons and include patients receiving surgery for joints other than hips and knees. Although it may be appropriate to group these patients together in a diagnosis related group intended to measure differences in inpatient resources, analyses show that patients receiving surgery due to hip or knee fractures will need very different types and amounts of post-acute care from patients receiving elective surgery for osteoarthritis.

The appropriateness of excluding patients with fractures and excluding patients with other types of joint surgery has already been identified by the contractors CMS is using to develop quality and utilization measures for joint replacement. The 90-day episode of care spending measure developed for CMS by the Yale New Haven Health Services Corporation/Center for Outcomes Research & Evaluation specifically

excludes hip and knee procedures for patients with femur, hip, or pelvic fractures, presence of cancer in the pelvis, sacrum, coccyx, lower limbs, or bones, and other factors.²

We recommend that the focus of the CCJR program should be on patients receiving total hip or knee replacements on an elective basis to address problems caused by osteoarthritis and similar conditions. Patients receiving surgery for problems caused by fractures due to injuries, cancer, or other conditions should be excluded. Surgery on joints other than hips or knees should also be excluded, at least at this time.

Services Covered by the Episode Payment

The proposed regulations include much too broad a list of services in the definition of the episode for joint replacement. It is inappropriate to require physicians, hospitals, and post-acute care providers whose services are focused on delivering successful joint replacement surgery to take responsibility for also managing a patient's chronic diseases or to be accountable for virtually any health problem other than cancer or trauma that could result in the need for hospitalization or medical care for three months following surgery.

This type of broad definition is inconsistent with the definitions commercial payers have used for joint replacement episodes, and it is inconsistent with measures of episode spending CMS has been developing for joint replacement. The 90-day episode of care spending measure developed for CMS by the Yale New Haven Health Services Corporation/Center for Outcomes Research & Evaluation only includes claims that are related to hip replacement and knee replacement.

As noted in the letter, we recommend that the following services – and only these services – should be included in the CCJR Episode:

- Professional services related to the hip or knee surgery, including services occurring between the time the decision to perform surgery is made and the surgery is actually performed;
- Facility services for the patient's stay at a hospital or other facility where the procedure is performed;
- Any other professional services delivered during the patient's stay at the hospital or other facility where the procedure is performed;
- All services delivered by IRFs, SNFs, and HHAs if those services begin within 90 days after discharge from the hospital or other facility where the procedure is performed, even if the service extends beyond 90 days;
- Any hospital admissions or outpatient services that occur between discharge from the facility where the procedure is performed and 90 days after discharge, including both facility charges and physician services, that are related to the initial joint replacement surgery or to a complication resulting from the surgery or the planned post-acute care; and
- Any other physician service or services delivered within 90 days after discharge with a diagnosis code indicating that the service was related to the joint replacement surgery or a complication of the surgery.

We understand CMS' concern that the difficulty of determining the cause of health problems and the discretion providers have about coding could lead to excluding claims for some services from the joint

² Kim N et al. Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode of Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (Version 1.0), Prepared for Centers for Medicare and Medicaid Services, December 2014.

replacement episode that should have been included. However, this does not justify shifting the risk for services that are unrelated to joint replacement to providers who have no involvement in the care of their patients' other health problems and who have no opportunity to influence what services are used to treat those other health problems. During the initial years of the CCJR program, CMS has the ability to monitor claims and payments for other services delivered to joint replacement patients and through that monitoring, it can identify any situations in which a provider may be abusing its discretion and it can identify additional types of diagnoses or services that may be appropriate to include in the definition of the episode. Where there is evidence of abuse, CMS can take action against the individual providers responsible for that abuse without penalizing the majority of providers who are managing episode payments properly. Where it appears that a particular diagnosis, service, or combination of diagnoses and services should be added to the episode definition, CMS can propose to make that change after consulting with providers and the public. We oppose CMS' proposal to make such changes without formal rulemaking because of the potentially significant financial impacts these changes could have.

Methodology for Setting Episode Payment Amounts

Need for Risk Stratification

Analyses of spending during joint replacement episodes have shown tremendous variation in post-acute care costs for patients receiving what is ostensibly the same basic procedure. As in most areas of health care, some of this variation is likely avoidable, e.g., use of unnecessarily expensive settings for rehabilitation or use of rehabilitation services for unnecessarily long periods of time. Avoidable spending represents an opportunity for savings. However, some of this variation reflects legitimate differences in patient needs. Patients who have chronic illnesses and greater functional or cognitive limitations generally require rehabilitation for longer periods of time in more expensive settings than patients who are less impaired.

The CCJR program should be designed to enable teams of providers to redesign care in ways that reduce or eliminate the avoidable spending while ensuring that patients who need greater care are able to receive it. Moreover, the CCJR program must be designed so that it does not financially penalize providers who perform joint replacement surgeries on patients with greater needs and thereby either discourage providers from delivering procedures to such patients or encourage providers to stint on needed care.

This means that CCJR Episode Payment Amounts must be risk-adjusted or risk-stratified based on patient characteristics that would be expected to require significantly different types or amounts of services during the complete episode. One of the most important factors determining post-acute care spending is patient functional status, so differentiating patients and CCJR payments by functional status is essential.

Method for Risk Stratification

Defining two groups of joint replacement patients using MS-DRGs, as proposed by CMS, is not adequate for stratifying patients for an entire episode of care. The MS-DRG system is specifically designed to adjust for differences in inpatient hospital spending, not post-acute care spending. The team at 3M Information Systems that developed the DRG system has stated "MS-DRGs by themselves are inadequate for creating post-acute care payment bundles, and additional differentiations based on the patient's chronic illness burden must be added to the MS-DRGs."³ More recent research has shown that functional status can be as or more important than comorbidities in determining total amounts of Medicare spending

³ Vertrees JC et al. Bundling Post-Acute Care Services Into MS-DRG Payments. Medicare & Medicaid Research Review. 2013; Volume 3, Number 3.

as well as post-acute care needs after surgery. The two MS-DRGs used to differentiate hospital payments do not incorporate measures of functional status, and so they cannot be used to adjust for longer episodes.

The 90-day episode of care spending measure developed for CMS by the Yale New Haven Health Services Corporation/Center for Outcomes Research & Evaluation recognizes the need for risk adjustment beyond MS-DRGs in order to compare episode spending amounts across providers. However, the risk adjustment methodology it developed includes only measures of patient comorbidities, not functional status. The CMS payment systems for post-acute care services delivered by SNFs, IRFs, and HHAs all adjust payment amounts not only by patient health problems but based on functional measures, so it makes no sense to define an episode payment that includes post-acute care service but does not differentiate among patients based on their functional status.

The proposed regulation acknowledges the need for risk adjustment beyond MS-DRGs but concludes that because there is no standard for the best approach to risk adjustment, no risk adjustment will be done. This is the wrong resolution, particularly since the failure to incorporate any risk adjustment structure could make it difficult for Medicare patients with higher levels of need to obtain joint replacement surgery under an episode payment model.

CMS frequently establishes new payment codes and payment amounts with limited information and then adjusts them over time. We recommend that CMS view the initial years of the CCJR program as a transitional phase in which an appropriate risk adjustment system is phased in and adjusted over time. The initial risk stratification would be based on the types of functional status factors and comorbidities currently used in the IRF, SNF, and HHA prospective payment systems. However, these factors would now be assessed for all patients, not just those using an eligible IRF, SNF, or HHA service, and the assessment would be made by the patient's physician at the beginning of the episode, rather than after post-acute care begins.

Assigning Patients to Payment Categories

We recommend that the information needed to risk-stratify payments should be based on an assessment of patients by physicians at the beginning of the episode and that information should be used to assign patients to one of a series of discrete categories based on the patient's health conditions and functional status. These categories would be used to determine the payment for the episode. These clinical categories would be analogous to the clinical categorical systems used for hospital payment except that they would be determined at the beginning of the episode rather than after the end of the episode.

These clinical categories would be incorporated into a family of new CCJR billing codes. A physician would choose the appropriate billing code for an individual patient based on the specific procedure that would be performed and based on the clinical and functional characteristics of the patient prior to performing the procedure that would be expected to affect the patient's need for care during and following the procedure. The physician would bill CMS for the appropriate code based on the physician's assessment of the patient. For example, a patient receiving a total knee replacement with multiple comorbidities and limited functional status would be assigned a different code than a generally healthy, independent patient receiving the same procedure.

In a fashion similar to what is done for other CPT codes and for the clinical categories in the Inpatient Prospective Payment System and Medicare's other prospective payment systems, a set of weights would be assigned to these codes that reflect the relative level of total resources expected to be needed for all of the patient's care, i.e., since a relatively healthy patient who has home supports could be expected to have a shorter hospital stay and be more likely to use home-based rehabilitation, the weight for the code used for this kind of patient would be lower than for a patient with comorbidities and functional limitations

who would be expected to have a longer hospital stay and potentially require a stay at a SNF or IRF. CMS may be able to provide data from the BPCI demonstrations that would be helpful in setting these initial weights.

Establishing Initial Payment Amounts

As in other Medicare payment systems, a conversion factor would be established to convert the relative weight for each CCJR billing code into a dollar payment amount applicable to an individual CCJR-MO. The initial value of this conversion factor would be based on the prior average Medicare payments for each category of patients cared for by the physicians in the CCJR-MO. The look-back period would be one year or the number of months needed to gain a sufficient number of cases to generate reliable estimates. Actual payment amounts during this look-back period would be adjusted for differences in payment amounts in the years in which the care was delivered in order to make the spending totals comparable to the performance period. Because complete data on patient functional status will not be available from historical data, estimates of these characteristics will be required in order to set the initial conversion factors, and then the conversion factors can be adjusted after the CCJR program begins using actual data on patient characteristics determined by their physicians.

We recommend that CMS require only a modest discount from historical spending levels during the initial years of the CCJR program, e.g., one percent. There will be considerable work involved for providers to form CCJR Teams, redesign care delivery pathways, collect information on patient characteristics needed for risk adjustment, implement new billing codes and distribute bundled payments to other providers, measure patient outcomes, track performance on quality and utilization, and make adjustments to ensure high performance. Moreover, there is considerable uncertainty for providers about whether new episode payment amounts will be adequate if they experience changes in the types of patients they serve. The savings achieved through the CCJR program can serve as a natural mechanism for covering some or all of those costs, but not if those savings are retained by CMS through large discounts.

We believe that CMS will achieve significant savings in the CCJR program by creating appropriate payment levels for episodes of care and then increasing those payments over time based on inflation, since this will represent slower growth in spending than CMS has experienced to date. The aggregate savings for CMS will be greater if more providers participate in the CCJR program, and participation will be higher if CMS avoids making demands for immediate savings that are too high.

Payment Adjustments Based on Quality

The complication rates, mortality rates, and readmission rates for the patients receiving surgery from a CCJR Physician would be calculated during the baseline period used to calculate payment rates. Separate rates would be calculated for each type of procedure and clinical category of patients for which separate CCJR billing codes are defined. The CCJR Physician would be required to maintain or improve these rates in order to continue participation in the CCJR program. A statistically significant worsening in these quality measures would initially result in a reduction in CCJR payments and then, if improvements are not made, the CCJR-MO would be terminated from the program and all providers would revert to payment under standard Medicare payment systems. A CCJR Physician that achieves a large and statistically significant improvement in quality measures over the prior year would receive an increase in its CCJR payments.

During the initial three years of the program, CCJR Teams should collect patient-reported outcome information measuring improvements in functionality and pain. Performance levels on these outcome

measures would be used to establish benchmarks for performance, and then the outcome measures would be incorporated into the quality measures for the program beginning in 2019.

Outlier Payments

In addition to the CCJR Episode Payment, a CCJR Outlier Payment should be paid to a CCJR-MO if an individual patient needed an unusually large number of services or unusually expensive services. This could be done using a methodology similar to what is described in the proposed regulation; however, providers should be given options for the outlier threshold similar to the options that are available in Model 2 of the BPCI program.

Annual Updates to Payment Amounts

During the second and subsequent years of the program, the CCJR conversion factor for a CCJR-MO should be increased for inflation based on CMS market basket measures. Smaller updates could be used for CCJR-MOs with above-average payment amounts during the initial year (because of above-average levels of spending in CCJR episodes during the baseline period); this would reduce the differences in payment rates across CCJR-MOs over time.

We strongly oppose CMS' proposal to continuously adjust the episode payment amount in the CCJR program based on FFS claims for services delivered during episodes. What Medicare *pays* for services is not the same as what it *costs* providers to deliver those services. We expect that providers in the CCJR program will want to innovate by delivering services that are not currently paid for under standard Medicare payment systems or that are not compensated adequately under those payment systems. If CMS reduces episode payment amounts to match spending under fee-for-service claims, it will penalize those providers that have implemented these different approaches to services, and the greatest penalties will be imposed on the providers who have been the most innovative.

Once the initial payment rates are established based on historical episode spending, it will no longer be possible to measure the actual costs of services by looking at FFS claims. CMS will need to work with CCJR Teams to measure those actual costs and compare them to episode payment rates, similar to what is done now in every other Medicare payment system.

Adjustments to Weights and Conversion Factors

During the third year of the program, CMS would work with the CCJR-MOs and their CCJR Teams to refine the definitions of the clinical categories and to adjust the payment amounts for each combination of procedure and clinical category to ensure that CCJR payments accurately reflect the costs of care for different patients. These refinements and adjustments should be based on a study of the average total costs of all services delivered during CCJR Episodes by all CCJR Teams.

It will take time to adjust the definitions and weights for the payment categories in the CCJR program for two reasons:

- Information on all of the key variables necessary for adequate risk adjustment/stratification is not currently collected through Medicare claims forms, and so providers will need to collect and code this information after the CCJR program is underway.
- The amount of payment for a particular group of patients must be based on the costs of delivering an appropriate combination of services for those patients, and that can only be determined after

providers are given the flexibility to redesign care in ways that will deliver better outcomes at lower costs.

Risk Corridors

In addition to Outlier Payments for individual patients, the total payments to the CCJR-MO in each year should be adjusted using risk corridors to protect the physician and his or her CCJR Teams from excessive financial risks and to protect the Medicare program against paying too much for care. Physicians and other providers who are paid through the CCJR program rather than standard Medicare payments would agree to continue collecting and submitting the same information that would be needed to determine standard Medicare payments for services delivered to CCJR patients, so that comparisons of CCJR payments and standard payments could be made for purposes of calculating the risk corridor adjustments.

During the initial years of the program, CCJR-MOs should have the option of selecting narrow risk corridors because of the uncertainty about the adequacy of the risk adjustment structure and the accuracy of the payment weights. For example, in the initial year of the program, a CCJR-MO could choose to have no downside risk, similar to what CMS has proposed in the proposed rule, and also a limit on how much higher the payments to the CCJR-MO could be than FFS billings. Then the risk corridors could be increased over time, particularly after adjustments are made to the definitions and weights of the billing codes.

However, providers that have already developed or implemented revised approaches to care delivery should have the opportunity to select risk corridors in the initial year that give them the flexibility and resources they need to pay members of the CCJR Team in different ways that cover the costs of innovative services.

Ensuring Quality of Care

As noted above, providers participating in the CCJR program should be required to measure the quality of care and outcomes for their patients. Their payments should be reduced if the quality of care is diminished, and if quality remains low, the providers should be terminated from the program. We support CMS' proposal to use a limited and focused set of quality measures for CCJR episodes.

However, we do not support CMS' proposal to make only downward adjustments in payment based on quality. If CMS wants to improve care for Medicare patients, rather than merely achieve savings, then it should reward those providers who significantly improve the quality of care to patients. This can be done without increasing Medicare spending simply by reducing or eliminating the "discount" built into the payment conversion factor for a high-quality CCJR Team. This is authorized by Section 1115A of the Social Security Act (which CMS is using as the authority for the CCJR Program) which states that "the Secretary shall not require, as a condition for testing a model...that the design of such model ensure that such model is budget neutral initially with respect to expenditures under the applicable title."

Moreover, under the statute, the Secretary is permitted to continue a payment model if the Secretary determines that "the model is expected to improve the quality of care ... without increasing spending..." We also do not support basing quality rewards or penalties for one provider on the performance of other providers in the same year. Providers should know at the beginning of the year what performance goals they need to achieve, and they should be rewarded or penalized on that basis, not based on what other providers have done simultaneously.

Reconciliation of Payments

The CCJR episode payment should be triggered by the submission of a claim form by a physician participating in the CCJR program indicating that an eligible procedure was performed. The recommended CCJR code approach allows a more refined definition of the episode than an MS-DRG code, and it also allows the episode to be identified if the procedure is not performed during an inpatient hospital stay.

CCJR payments could be issued to CCJR-MOs in three parts:

- The first portion of the payment would be paid immediately when the physician files the CCJR Claim. This would help to support adequate cash flow for the providers who are being paid through the CCJR-MO rather than through the standard Medicare payment systems. This portion of the payment should be higher for CCJR Teams where the majority of providers have agreed to be paid through the CCJR-MO.
- The second portion of the payment would be paid at the end of the 90-day episode. This would allow adjustments to be made if a patient died or transferred to the Medicare Advantage program during the episode. This portion of the payment should also be higher for CCJR Teams where the majority of providers have agreed to be paid through the CCJR-MO.
- Finally, the remainder of the CCJR Episode Payment amount would be paid after all other claims are reviewed and a determination is made as to whether any chargebacks or adjustments are needed (e.g., adjustments for double billings). The proportion of the payment in this final category would be adjusted periodically for individual CCJR-MOs based on their experience in minimizing reconciliation amounts so that their payments are not being delayed any more than necessary.

We support CMS' proposal to exclude special payment provisions for hospitals and other providers that are not directly related to the services delivered for joint replacement from the payments assigned to the episode, e.g., payment adjustments under the Value-Based Purchasing Program, payments for Indirect Medical Education, etc. This will avoid penalizing or rewarding CCJR Teams based on differences in provider payments that are unrelated to care for joint episodes.

Financial Arrangements Among Providers

We believe that providers who agree to be paid through the CCJR-MO should be free to allocate those payments among themselves in whatever way they wish, without the kind of detailed rules and restrictions CMS has included in the proposed rule. Under the payment model we have proposed, these allocations are not "gain-sharing" payments, but in many cases the payments made by the CCJR-MO to other providers will represent the full compensation that these providers will receive for the services they deliver. Even if those other providers have elected to continue being paid through standard Medicare FFS payment systems for services that are eligible for payment through those payment systems, the CCJR Team may ask one or more of those providers to deliver additional or different services to a patient that are not eligible for payment under the current Medicare payment systems, and the CCJR-MO will need to pay those other providers for those services from the payment made to the CCJR-MO. One of the fundamental goals of the program is to remove the barriers to innovative care by not tying providers' payments to current FFS structures and restrictions.

We also recommend that the CCJR-MO have the flexibility to allocate a portion of its payments to providers who are still being paid through traditional Medicare payment systems if the CCJR-MO wishes

to do so. Again, CMS should not view these payments as “gain-sharing” payments, but rather mechanisms whereby providers can be compensated appropriately for costs they incur in delivering care that are not covered by standard Medicare payments or for losses in revenue they incur by reducing unnecessary services.

There could continue to be a prohibition on having compensation to any provider designed to reward them for increases in the number of joint replacement procedures they perform.

Patient Contributions and Incentives

Under the payment model we have proposed, some or all the services in a CCJR episode would be paid through the prospective payment to the CCJR-MO rather than through traditional Medicare FFS payment structures. We suggest that the patient’s cost-sharing for the portion of the services paid for through the CCJR-MO be established by each CCJR-MO as a flat copayment amount for each CCJR billing code. Since the providers on the CCJR Team may vary from patient to patient, different copayment amounts would be established depending on whether only physicians, physicians and hospitals, etc. are being paid through the CCJR-MO. CMS could require that the copayment amounts be no lower than the standard copayment/co-insurance amounts for the providers included based on the lowest payment they would have received under standard Medicare payment systems and no higher than the standard copayment/co-insurance amounts they would have received.

For services that patients receive from providers being paid through standard Medicare payment systems, they would pay the standard copayment/co-insurance amounts under those programs. We support allowing a CCJR-MO to give CCJR patients in-kind services related to their care as recommended by CMS in the proposed rule, but we also recommend allowing a CCJR-MO to reimburse patients for costs they incur related to activities or services associated with the CCJR episode, as long as the total out-of-pocket costs for a patient remains above the minimum cost-sharing amount established for the episode.

We also recommend allowing a CCJR-MO to establish a schedule of payments that it would make to CCJR patients based on the patient’s adherence to specific steps in a treatment plan or achievement of specific treatment milestones. This would be consistent with the types of value-based benefit designs now being used by many private payers.

Finally, we suggest allowing the CCJR-MO to establish a schedule of payments it would make to CCJR patients if the CCJR Team failed to achieve specific quality standards that it defined in advance.

Relationship to Other Payment Programs

As we stated at the beginning of this letter, we believe that a general principle that should guide APMs is that physicians and other providers should only be accountable for the aspects of costs and quality that they can control. Unfortunately, most of the APMs developed by CMS to date attempt to hold physicians accountable for all of the services received by their patients, regardless of whether the physicians have any control or influence over those services. One of the many problems this creates is that every new payment model will make more and more physicians and other providers accountable for the same services and costs, creating confusion for provider and patients and conflicts for CMS and providers in allocating savings and payments.

As we have suggested above, we strongly recommend that physicians and other providers participating in the CCJR program only be held accountable for the costs and quality of services directly related to joint replacement (including complications related to joint replacement). With this appropriately focused definition, we believe that the CCJR bundled payments can be used in place of FFS payments for services

included in CCJR episodes when tabulating total spending for ACOs and primary care practices that are participating in shared savings programs based on total spending. The providers participating in CCJR Teams can benefit from the savings generated during hip and knee replacement episodes, and the ACOs and PCPs can benefit from using CCJR providers to deliver episodes of care at lower costs and also from the savings resulting from any reductions they can achieve in the proportion of patients who need hip and knee surgeries, e.g., by providing better non-surgical management of hip and knee osteoarthritis.

If a physician that is participating in the BPCI program wants to participate in the CCJR program instead, we recommend that they be allowed to do so. If they do, we recommend that the CCJR program take precedence if a hospital or post-acute care provider who is part of a CCJR Team is participating in any other BPCI payment model.

Waivers of Regulations

In addition to the waivers of restrictions on gain-sharing and patient inducements described earlier, we recommend that all current Medicare restrictions on the types of services that can be delivered and the conditions that must be met to deliver services should be waived with respect to services delivered within the CCJR Episode. In particular:

- CCJR patients should not be required to have a 3-day stay in the hospital in order to be covered for post-acute care services during the episode.
- CCJR patients should not be required to be homebound in order to receive home health services.
- Providers should be able to be paid by the CCJR-MO for telehealth services and home-based services delivered to CCJR patients that are related to the joint replacement.

We strongly oppose CMS defining how services should be delivered to Medicare patients, as it attempts to do in the proposed regulations. For example, it is inappropriate for CMS to establish a maximum number of post-discharge home visits that a patient can receive following discharge from the hospital. If the patient's physician determines that more than nine home visits are needed in order to enable a patient to quickly and safely recover from surgery, and that this would achieve a better outcome for the patient at a lower cost than having the patient go to a SNF, then the physician should have the flexibility to deliver that service. It is the responsibility of physicians to define what kinds of care their patients do and do not need. If CMS is going to make a bundled payment for a joint replacement episode, then it should leave the decisions about how care will be delivered within that episode to the physicians receiving the payment. Quality should be assured by measuring outcomes, not by prescribing which services can and cannot be delivered to patients.

As discussed in the Goals section of the comment letter, a foundational element of this bundled payment program and all APMs should be flexibility for physicians and other providers to redesign care in ways that will improve quality while lowering costs. Although the proposed rule discusses certain policy changes which CMS views as waivers of existing restrictions, the proposal's continued reliance on the existing Medicare payment systems for the physicians and other providers involved in the episode leads CMS to propose narrowly-defined adjustments in those payment systems that may benefit some patients but may not provide the flexibility that is actually needed for other patients. For example, instead of simply waiving the homebound definition and the telehealth originating site requirements for joint replacement patients within the CCJR who need home health care and/or telehealth home visits during their recovery, CMS proposes new G-codes for home visits and telehealth home visits solely for use within a CCJR episode with restrictions on when and how they can be used. Instead of creating special codes that would only be used for a narrowly-defined set of services provided to joint replacement patients and creating detailed rules as to when new and existing codes can be used, we recommend

creating a set of codes for the overall episode that allow flexibility to determine what services are best for individual patients.

Data Sharing

We strongly support the proposal by CMS to distribute data to providers on a quarterly basis and to offer the option to providers of receiving either detailed claims records or summarized data. However, we believe that it is essential that CMS commit itself to deliver these data in a timely fashion. The regulations specify in great detail the standards of performance for providers and the penalties CMS will impose on providers for failing to comply with CMS requirements, but the regulations do not define the standard of performance that providers can expect from CMS or the penalties associated with failure to perform. We recommend that CMS establish a policy that if accurate data are not delivered to a CCJR-MO within 90 days after the end of a calendar quarter, payments to the CCJR-MO should be increased by five percent during the following quarter.

Evaluating the Payment Model

In order for providers to be willing not only to participate in the CCJR program, but to significantly change the way they deliver care to patients using the new payment model, they must be convinced that the program will not terminate within a few years. When CMS defines an initiative as a “test” that will last for a finite period of time with no indication as to when a decision will be made about continuation or the criteria that will be used in making that determination, providers are likely to perceive that there is a high risk in making significant changes in care delivery that they would be unable to sustain if the program is terminated. We believe that CMS should be more concerned about the risk that providers will not be willing or able to make the kinds of changes in care delivery that would improve outcomes and reduce costs than the risk that spending might increase.

We believe that CMS can and should provide greater certainty to providers about APMs than this. Rather than implying that the default outcome will be to terminate the program unless it meets an unspecified level of performance, we urge CMS to indicate that the default outcome will be to continue the program unless a determination is made that the program has increased spending or worsened the quality of care, and we further urge CMS to indicate that it will make every effort to modify the program to address any issues that could preclude its continuation. Section 1115A of the Social Security Act requires that the Secretary “terminate *or modify*” [emphasis added] a model unless the model is expected to improve quality without increasing spending or reduce spending without harming quality, and there is no timeframe defined for making the termination decision. We believe that more providers will volunteer to participate and that participants will be willing to make more significant changes in care delivery if CMS gives them greater assurance about the likelihood of continuation.