September 8, 2015

Via Electronic Mail

Andrew Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-5516-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1813

Re: Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement

Dear Acting Administrator Slavitt:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am pleased to offer comments on a proposed rule published in the Federal Register July 14, 2015, to establish a new bundled payment model for Comprehensive Care for Joint Replacement (CCJR) that would be mandated for certain acute care hospitals in the country (CMS-5516-P). AdvaMed has been a strong supporter of delivery reform models, such as bundled payments since their inception in the Affordable Care Act. We recognize the importance of the goals of bundled payment programs and other delivery reform systems as they seek to improve both the efficiency and quality of health care in this country and we applaud both CMS and the Center for Medicare & Medicaid Innovation (CMMI) for their continued commitment to finding new ways to deliver care that will enhance care coordination, encourage more provider investment in infrastructure and redesigned care processes for higher quality care, and creating incentives to provide higher value care across the acute and post-acute care continuum of services covered by Medicare.

We believe that our members’ technologies can play a critical role in assisting providers to achieve each of these goals. Our member companies do so through advances in medical technologies, diagnostics, and other advanced medical technologies that enable the provision of health care services remotely to patients. These products and services improve patient care quality and outcomes and many improve efficiency by reducing the lengths of stay of patients in health care facilities, enhancing perioperative productivity and reducing costs, allowing procedures to be performed in less intensive and less costly settings, providing early detection of disease and infections, and improving the ability of providers to monitor care, among other benefits.

Total joint replacement is one of the major success stories of American medicine. Total joint replacement procedures have been shown to restore mobility, relieve pain, and help patients with

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osteoporosis return to normal lives and functioning. Medicare patients receiving total hip and knee replacement show nearly half the risk of death after seven years compared to osteoarthritis patients not receiving total joint replacement.\(^1\) In addition, total knee replacement has been found to be cost saving. One study has found that total knee replacement surgery generates a net societal savings of approximately $19,000 per patient lifetime, due to reduced disability costs and improved productivity.\(^2\) This study found that in 2009 alone, savings in the U.S. were an estimated $12 billion.

CMS’s CCJR proposal offers a new and promising approach for paying for joint replacement and AdvaMed supports many of its key features for improving care delivery for Medicare beneficiaries undergoing total joint replacement procedures. We do, however, offer recommendations below to ensure that new payment models protect patients’ access both to appropriate and innovative medical technologies and provide lasting savings and quality of care improvements over the long term.

I. Gainsharing

A. Proposed Financial Arrangements [Comments related to Section III.C.10a.1—Financial Arrangements Permitted under the CCJR Model]

1. Protections Against Stinting on Care

Beneficiary access to the full range of treatment options appropriate for their medical conditions is critical to the health and well-being of Medicare beneficiaries. One of our overarching concerns with gainsharing arrangements is that their focus on short-term costs—those associated with a particular procedure or hospital admission for a period of 90 days used for the CCJR, for example—can lead to stinting on care. Stinting in this instance can take the form of selecting only lower utility and lower cost devices or not providing higher cost tests appropriate for a particular condition and intervention, or when patients’ medical conditions would require more intensive or costly resources/devices. It can also mean compromised patient access to innovative technologies when these are more expensive than a previous standard of care.

Many medical devices and technologies provide benefits over a period of time spanning multiple years; the financial incentives in delivery reform models with short episode windows, together with their promise of an additional stream of income for providers can be too compelling for providers, especially when the long-term value of expensive care or technologies is not factored in. As a result, savings on short-term costs could be outpaced due to suboptimal outcomes and/or an increase in revision rates which typically are not measurable for several years, if an appropriate treatment option is not used and/or quality of care is reduced through higher revision rates outside the 90-day episode of care and over the longer term. We also note the challenges in sustaining savings that funds gainsharing rewards year after year and how the pressure to do so


can challenge a provider’s decision process in particular when the realization of these risks could take several years before they are expressed in a way that requires further utilization. We discuss this last point in greater detail below.

We offer two real world examples of how financial incentives in delivery reform models can lead to what may be compromised patient access to appropriate medical technologies.

Some of our orthopedic company members have learned that certain providers participating in the Innovation Center’s Bundled Payments for Care Improvement (BPCI) initiative have radically changed the type of hip and knee implants that they buy and implant in patients.

In the past, these hospitals had purchased a range of device implants—including some implant that are more basic, without newer features and with varying levels of performance characteristics that improve range of motion or impact durability (e.g., lower utility implants). Providers made implant selection decisions that corresponded to the particular lifestyle needs of patients, including life expectancy, level of activity, and medical conditions. This process is called demand matching and is an effective method in managing utilization without limiting access to technologies that best meet individual patient needs. With participation in BPCI, these providers now purchase almost exclusively lower utility implants without respect to patient needs. Matching the utility of a device to a particular patient’s need is critical to ensuring a positive outcome for the patient and long-term effectiveness of the procedure. For example, an active, tennis-playing 65-year old requires a hip or knee of higher utility and performance characteristics than one that is appropriate for a sedentary 85-year old.

While it is possible that the patient mix of Medicare beneficiaries treated by the providers has changed since participation in BPCI began, it should be pointed out that lower utility devices are also initially less expensive than the higher utility devices, leading to potentially higher internal savings that can be shared in the short term. The longer term impact of using almost exclusively lower utility devices, when they may not be appropriate for the lifestyle and medical needs of individual patients, may not be known for several years, when active beneficiaries may require earlier than expected revision procedures or experience other negative outcomes. If the choice of a hip or knee device were made solely on the basis of patients’ relative health, lifestyle and life expectancy, patients would be provided a device that appropriately demand matched to their unique needs with cost not being a leading driver of this decision so as to ensure the best possible outcomes and longevity.

In AdvaMed’s comment letter to CMS on the proposed rule for the 2016-2018 MSSP program, we described data analysis by one of our member companies focused on utilization rates for several interventional treatment options for arterial procedures and utilization rates of these options for Medicare beneficiaries served by ACOs. The analysis is as relevant for bundled payment providers as it is for ACOs, since the financial incentives for both programs are very similar. This particular analysis showed an increase in utilization of a lower cost procedure option and a decrease in utilization of a higher cost alternative procedure for patients served by ACOs. The increase in utilization of the lower cost option when not as appropriate for the patient could mean more frequent re-interventions for patients in the future, with the result that
higher savings for ACOs in the short-term could also mean higher long-term spending for the Medicare program in the subsequent years.

In order to protect beneficiaries from these potential consequences of the financial incentives inherent to certain delivery reform models and to ensure that decisions about a patient’s care are made solely on medical grounds, AdvaMed first recommends that participating hospitals be required to make available to the public on Hospital Compare or via other reporting:

(1) whether or not the providers have participated in gainsharing, and the amount of gainsharing rewards that physicians and other providers receive from internal savings initiatives of the hospital, and
(2) savings they earn from reconciliation payments made for a performance year.

This is especially critical given the proposed rule’s requirement that all hospitals in specified MSAs participate in the model, leaving beneficiaries with practically no choice but to use a facility operating under the model’s financial incentives. AdvaMed strongly urges CMS to add these requirements for public reporting to proposed new § 510.500(d). With this information, Medicare beneficiaries will be armed with useful information to ask questions about how rewards and savings will affect their care and health care outcomes and also for making decisions with their providers about the most appropriate device for their particular health and lifestyle.

Furthermore, we strongly oppose any gainsharing programs that reward providers for using products simply because they are less expensive and not appropriate for patients’ needs. Internal gainsharing programs that focus on medical device savings simply drive providers to use devices because they are less expensive, even if it means higher Medicare spending in the long-run due to more frequent revision procedures in the future. AdvaMed urges CMS to put controls in place that protect patients against wholesale changes in device offerings of providers participating in the CCJR model and to consider prohibiting gainsharing altogether when tied to the use of less expensive and lower-utility devices. We further recommend that care in participating hospitals be carefully monitored for the appropriateness of device choice for individual patients and surgeons. Reconciliation payments that providers can earn from savings relative to the target price should be maintained as described in the proposed rule. These potential savings will encourage providers to work together to ensure discharge planning that will lead to appropriate post-acute care placement, fewer complications, and lower readmissions.

II. Transparency of Delivery Reform Model Performance and Monitoring Patient Care Outcomes [Comments related to Section III.F.3 and 4—Monitoring for Access to Care and Quality of Care]

The proposed CCJR bundled payment model has a structure and framework very similar to BPCI’s. Like BPCI, the CCJR model links internal cost savings and reconciliation payments to care redesign, with a specific requirement that the methodology for sharing savings be based on the care redesign elements associated with specific collaborators (§ 510.500(b)(1)(i)). In the
In the case of BPCI, we are not aware of any publicly available information about the specific methodologies BPCI participants use for sharing savings, how the methodologies are actually linked to care redesign objectives, or how CMS/CMMI monitors participants for achieving their care redesign goals, and whether shared savings with physicians and other providers are actually based on achieving the goals. While we agree with the proposed rule’s observation that professionalism and clinical standards can be effective in preventing beneficiaries from being denied medically necessary care, we do not agree that “the potential for denial of medically necessary care within the CCJR model will not be greater than that which currently exists under IPPS.”

AdvaMed’s specific concern is that the financial incentives and waivers provided for these bundled payment programs could potentially lead providers to generate savings primarily through the selection of devices that are not appropriate for patients’ needs, as described above, rather than through the more challenging care redesign expectations described in their documentation for participation and/or care redesign that advances processes that consider long-term performance and survivorship. AdvaMed recommends that additional beneficiary protections be included among those already enumerated in the rule to ensure that beneficiaries will have access to the devices most medically appropriate for their individual needs.

AdvaMed specifically recommends that CMS directly monitor participating hospitals for providing beneficiaries access to appropriate devices, including their access to new technologies or improved versions of older technologies. Claims data analysis will not provide this level of information. Instead CMS will have to do medical record audits to capture these data and we are pleased to read in the proposed rule that CMS is prepared to exercise its authority and responsibility to audit medical records in monitoring beneficiary access to care. We recommend that the final rule include an explicit commitment to analyze of beneficiary access to appropriate devices, including access to innovative technologies for joint replacement.

AdvaMed also recommends that CMS monitor hospitals’ performance on their commitments to care redesign, analyzing this information by specific types or categories of care redesign, and the extent to which they link care redesign to shared savings among providers and collaborators. In order to facilitate this monitoring, AdvaMed recommends that CMS require providers to submit annual reports that detail original care redesign objectives they agreed to implement, the progress they made in achieving those objectives and how achieving those objectives has been linked to gainsharing rewards.

All of this information and analysis should be made available to the public, and together with information about specific levels of gainsharing rewards received by individual providers, will greatly enhance beneficiaries’ ability to participate effectively with their providers in decision-making about their individual procedures.
III. Quality Measures [Comments related to Section III.D]

A. Proposal to Use 3 Quality Outcome Measures

AdvaMed supports the use of the three quality measures proposed by CMS for use in the CCJR bundled payment program for hospitals to qualify for reconciliation payments: (1) the hospital-level risk-standardized complication rate following elective primary total hip and knee arthroplasty, (2) the hospital-level 30-day, all cause risk-standardized readmission rate following elective primary total hip and knee arthroplasty, and (3) the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS). These three measures have been endorsed by the National Quality Forum and have been recommended by the Measure Applications Partnership. In addition, the first two measures consider outcomes specific to joint replacement procedures. AdvaMed strongly recommends that in the case of the third measure on patient experience of care that this measure evolve quickly to include patient surveys of post-acute care, since it is these settings where care will be provided for the longest period of time during the episode.

We also note that the BPCI Year 1 Evaluation and Monitoring Annual Report issued February 2015 analyzed hospital performance on two other measures under Model 2 for orthopedic surgical procedures (excluding spine): (1) all-cause mortality, and (2) emergency department use without hospitalization. Given the financial incentives that underpin the CCJR program for reducing spending, AdvaMed recommends including these additional quality measures, specific to total hip and knee arthroplasty, among those measures that will allow a hospital to qualify for reconciliation payments.

B. Voluntary Data Collection for New Quality Measure on Patient Outcomes

AdvaMed strongly supports CMS moving forward with a voluntary data collection initiative for identifying a uniform set of provider- and patient-level data elements that will be accurate indicators of improvement in patients’ functional status, pain levels, mobility, and quality of life following total hip and knee replacement procedures. We also support rewarding hospitals for their participation in this data collection effort and suggest further reducing the discount percentage used to set the target price. The proposed rule would reduce the discount percentage from 2.0 to 1.7 percent of expected episode spending for hospitals that successfully submit voluntary data. AdvaMed recommends that the discount be reduced to 1.5 percent, or even lower, in order to encourage hospitals to report successfully data that will be used for the development of the patient-reported outcome measure.

For the development of a new outcomes measure for total hip and knee arthroplasty, CMS notes in the proposed rule that it would need access to a nationally representative sample of patient-reported outcome data on total hip and knee arthroplasty procedures that is also consistently collected at the hospital-level and contains risk variables identified by orthopedic surgeons. AdvaMed strongly recommends that CMS consider using the American Joint Replacement Registry (AJRR) for these purposes. The AJRR already has almost 550 hospitals participating in its data collection activities and 50 percent of these are located in the 75 MSAs that CMS would
use for the CCJR model. Using the AJRR would avoid duplication of data collection efforts and, given the AJRR’s trajectory for new hospital participation in the next two years, could lead to development of the patient outcomes measure(s) more rapidly than would be the case if a new effort were undertaken.

AdvaMed recommends that hospitals collect the same information on function that is required of post-acute care providers to comply with the requirements of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The IMPACT Act requires implementation of quality measures for post-acute care providers that are standardized and interoperable across post-acute setting using standardized patient assessment data. Collecting consistent information across hospitals and post-acute setting would allow comparisons of cost, quality of care, and patient outcomes.

We offer additional observations about the proposed data collection activities. While we agree with CMS’s strategy for phasing-in data collection by pre-operative and post-operative cases, we caution the agency about its expectations that hospitals will be able to capture sufficient data from several of the mentioned survey instruments, given their length and the time they require for patients to complete. We recommend that CMS consider using instead existing shorter versions of certain survey instruments. We note that HOOS, KOOS, and WOMAC have shorter versions of their patient-reported outcomes surveys. AdvaMed further recommends that CMS avoid duplication in survey instruments that will be used for the initiative. For example, Promis Global and VR-12 each collect data on general patient health, and we recommend that CMS use one or the other and not both.

We are also concerned about the challenges that hospitals will face in collecting post-operative data from patients during the timeframe specified in the proposal. AdvaMed recommends phasing in the 80% requirement of eligible patients time over a three-year period, beginning with a 50 percent threshold requirement for year 1 of the effort.

C. Quality Measure for Shared Decision-Making

AdvaMed strongly supports CMS’s proposal to explore the development of a quality measure that would require providers to participate in shared decision-making with beneficiaries about appropriate therapies and procedures for a patient’s condition as well as the appropriate device to be used for joint replacement surgery. As we noted above in our discussion on gainsharing, AdvaMed is concerned that some providers participating in BPCI may be shifting almost exclusively to using lower utility devices. A requirement that providers and beneficiaries share in decision-making about the particular device to be used for a procedure will help protect patients from financial incentives that may lead to less than optimal device choices.

We also note that shared decision-making will be most effective for Medicare beneficiaries if they have available to them the information that we discussed above, including specific levels of gainsharing rewards received from providers participating in the model and how hospitals have achieved care redesign objectives. This information, together with information about quality
measure scores, should be built into the structure of the measure that is proposed by CMS for use in the CCJR model.

IV. Risk-Adjusting Target Prices [Comments related to Section III.C.4.b]

The proposed rule notes that CMS considered proposing an adjustment for episode target prices based on patient-specific clinical indicators, but did not do so because it did not believe that a sufficiently reliable approach exists suitable for CCJR episodes beyond MS-DRG-specific pricing. As CMS has noted elsewhere, in the absence of risk adjustment, providers treating a large number of beneficiaries with multiple chronic conditions or where certain procedures included in a given MS-DRG might be more expensive than others could end up avoiding treating these patients, and compromising their access to needed care. AdvaMed urges CMS to evaluate the case-mix adjustment methodologies being used by three States (Tennessee, Ohio, and Arkansas) in multi-payer bundles for hip and knee replacement episodes and to decide whether any of these, or a modified version of one, can be used in the CCJR model.

V. Scope of CCJR Bundled Payment Proposed Rule

AdvaMed recommends that CMS reconsider the framework for its proposed rule by basing its scope on ICD-9/ICD-10 procedure codes rather than on MS-DRGs 469 and 470. In so doing, CMS would be following the precedent of the three States mentioned above that have used ICD-9/ICD-10 procedure codes for defining their multi-payer bundled payment system for hip and knee replacement.

By using MS-DRGs, the proposed rule captures primary total ankle replacement, which has very different length of stay, facility costs, and post-discharge protocols from the intended, targeted procedures of total hip and knee replacement in MS-DRGs 469 and 470. We note that MedPAR data show significantly different length of stay and facility costs for total ankle replacement, as compared to total hip and knee replacement. In addition, operative time is much longer for total ankle replacement than it is for total hip and knee replacement. Furthermore, typically only foot and ankle specialists perform total ankle replacement procedures due to the high degree of complexity of the procedure. We believe that total ankle replacement is completely dissimilar from total hip and knee replacement and should not be included in the proposed model.

VI. Using Three Years of Historical Data to Set Target Prices [Comments related to Section III.C.4.b]

CMS proposes to use three years of historical CCJR episode data for calculating target prices. For performance years 3 and 4, CMS would use two years of historical episodes that started prior to the CCJR model—January 1, 2014 through December 31, 2015—and one year of episode data based on data from January 1, 2016 through December 31, 2016, the first year of the demonstration. By performance year 5, historical data would be based on episodes reflecting
spending occurring exclusively during the demonstration—January 1, 2016 through December 31, 2018.

This methodology of setting targets based on years when hospitals and their participating providers must reduce spending will result in ever greater pressure on hospitals to achieve even higher levels of savings during the 5-year performance period. Our concern is that this methodology will reinforce incentives inherent to the model that already pose risk to patients in the form of stinting on care and compromised patient access to innovative technologies. In its final rule for the MSSP program published June 9, 2015, CMS recognized the problem ACOs face in a second agreement period of potentially being penalized for success in generating savings and improving quality of care during their first agreement period when a benchmark for a second agreement period is based only on historical spending. In that final rule, CMS modified its benchmark methodology by making an adjustment to reflect the average per capita amount of savings earned by the ACO in its first agreement period. AdvaMed recommends that a similar adjustment be incorporated into the calculation of targets for hospitals in the CCJR model. Alternatively, CMS should consider not updating as often the target prices used for calculating reconciliation payments and use the initial 3-base year, trended forward, for the entire 5-year period. Then, at the end of that period, if the model is continued, CMS could make an adjustment for the next performance period to reflect savings earned during that period, just as it will be doing for ACOs during their second agreement periods.

VII. Billing and Payment for Telehealth [Comments related to Section III.C.11.c.]

Telehealth (including but not limited to remote patient monitoring technologies and services) is generally recognized today as a fundamental tool for improving the efficiency and quality of health care. AdvaMed is pleased to learn that the Innovation Center has provided waivers to BPCI Models 2 and 3 providers to allow them to offer currently covered telehealth services without regard to geographic site requirements under Medicare statute. We are also pleased to see that CMS is proposing to waive not only the geographic site requirements for CCJR providers but also the originating site requirements to allow CCJR providers to use telehealth services in the home. We strongly support these waivers and concur with CMS’s observation in the proposed rule observation that these waivers are essential to maximize the opportunity to improve the quality and efficiency of care provided under the CCJR model.

With advances in telehealth and remote monitoring technologies and services and their rapid diffusion across many different settings of health care, it is imperative that the process for assigning and/or developing codes accommodate the full range of services being provided through these new technologies. We appreciate CMS taking a first step in this direction by considering a new coding framework and relative values for evaluation and management (E/M) services delivered through telehealth technologies in the home. The modifier approach proposed by CMS for use for E/M services would reduce the total number of codes required to accommodate changes in non-face-to-face services and the technologies that enable these services, while also allowing tracking of utilization, costs, and outcomes of the new services.
CMS’s approach also allows new codes to be reserved solely for *innovative* non-face-to-face services that have no face-to-face equivalent.

**VIII. Excluding New Technology Payments from CCJR Episodes** [*Comments related to Section III.B.2.b*]

While AdvaMed strongly supports delivery reforms that improve efficiency and quality of health care, we are concerned, as discussed above, that the financial incentives in delivery reform models, including the CCJR model, can have the inadvertent effect of discouraging providers from (1) considering the full array of treatment options, especially if they may increase costs above target thresholds, or (2) using innovative treatments, technologies, and diagnostics that may bring value to the health care system over the longer term, but are more costly in the short run. The potential negative impact of the financial incentives of these models is magnified by the relatively short 90-day payment window used in CCJR to compare actual spending against benchmarks in order to determine the level of savings that may be shared among providers. Many medical devices and technologies provide benefits over a long period of time spanning multiple years.

AdvaMed applauds CMS’s proposal to exclude IPPS new technology add-on payments (NTAPs) from both the actual historical episode expenditure data used to set target prices and from the hospital’s actual episode spending that is reconciled to the target price. In the proposed rule, CMS notes that it would not be appropriate for the CCJR model to potentially hamper beneficiaries’ access to new technologies that receive NTAPs or to burden hospitals who choose to use these new technologies with concern about these payments counting toward episode actual expenditures.

AdvaMed believes that additional innovative technologies, beyond NTAPs, should qualify for a similar adjustment as that being made for NTAP approvals, and that CMS should establish a review process for these technologies to determine whether their cost should be removed from actual spending totals for participating CCJR hospitals. In brief, this process would allow manufacturers or developers to identify higher cost breakthrough technologies/treatments that offer clinical improvements for all or certain types of patients or offer significant therapeutic advances for new populations or conditions.

AdvaMed recommends that the review process for these technologies/treatments would be similar to the one now used by CMS for NTAPs. Manufacturers and developers would provide CMS the estimated incremental increase in spending that would result from each use of an approved treatment. They would also provide CMS the data and methodology for such estimates as part of the application process to assist CMS in determining whether a treatment or technology warrants special accommodation and what adjustments would be made. If approved by CMS, the adjustments would apply to use of the technology across all CCJR providers, and other relevant delivery reform models. But we also recommend that CMS would allow individual CCJR hospitals to request an adjustment if they were to adopt breakthrough/ high cost
treatments in advance of other hospitals. In this case, the adjustment could be applied to the individual hospital or all hospitals using the technology/treatment.

**IX. Implementation Timeline**

Given CMS’s proposal to mandate participation in the CCJR bundle payment model for all hospitals located in the MSAs where the demonstration would take place, as well as the time required for CMS to move forward with the changes we recommend above, AdvaMed urges CMS to work closely with those stakeholders most immediately affected by the proposed implementation date and to carefully consider comments regarding implementation. AdvaMed urges CMS to incorporate the additional patient protections discussed above for ensuring beneficiary and provider access to devices that are appropriate for patients’ particular needs before finalizing the rule and implementing the model. Doing so will allow for the continued delivery of high-quality care across a 90-day episode.

**X. Evaluation of CCJR [Comments related to Section IV]**

We are pleased to learn that CMS intends to undertake a comprehensive evaluation of the CCJR model. AdvaMed supports rigorous, ongoing evaluation of the CCJR model, as well as the monitoring recommendations that we have argued above are required for thorough evaluation. We also support evaluation of the CCJR model on an annual basis during the 5-year performance period, and up to two years after the performance period ends. We note that CMS states in the proposed rule that a final analysis after the end of the 5-year performance period will be important for ultimately synthesizing and validating results. We expect that CMS will not expand the model until this analysis has been completed and the public has had opportunity to comment on its findings and request that the final rule clarify this matter.

We offer the following recommendations beyond the description of the scope of the evaluation outlined in the proposed rule. First and foremost, the evaluation should examine changes in types of devices being used in total joint replacement procedures, comparing device types used by specific providers before and after their participation in the CCJR model as well as comparing types of devices used by providers participating in CCJR during the performance period with providers not participating in the demonstration. We observed above that some of our companies have found that some providers participating in BPCI have changed the mix of their device offerings for patients having hip and knee replacement procedures to use of almost exclusively lower utility devices. We note that in the earliest phases of implementation of the Acute Care Episode (ACE) Demonstration spokespersons for institutions participating in the demonstration publicly asserted that device offerings were among the first places they turned for meeting savings targets. Similarly, some institutional providers who speak about BPCI cost-reduction strategies point to limiting implant selections as an initial strategy.

Patient care outcomes cannot be satisfactorily or adequately evaluated without looking at how these programs affect provider decisions about device offerings. ACE did not evaluate this
question and neither BPCI nor CCJR seem to be on track of doing so. Evaluation of device offerings and patient access to innovative technologies for joint replacement is an absolutely essential element for any evaluation of impact of these programs on patient care—especially because the financial incentives underlying the program might lead providers to make decisions about care options on grounds that are not purely medical.

In addition, rigorous evaluation of a program requires transparency on the front-end on how the program is implemented and what beneficiaries and the public need to know about implementation and monitoring in order to inform a more complete understanding of impact. It is one thing to determine, as promised for the proposed evaluation, whether the program has a negative or positive impact on quality of care and patient experiences of care, or both. It is another to be able to explain why the impact may be positive or negative. If information about the details of implementation of BPCI is the model for the CCJR, the public will be left with only an incomplete understanding of impact and reasons for specific findings about impact.

We thank you again for this opportunity to comment on the proposed rule for the MSSP program. If you have questions, please contact Richard Price at rprice@advamed.org or 202-434-7227.

Sincerely,

/S/

Donald May
Executive Vice President,
Payment and Health Care Delivery