October 16, 2017

Via Electronic Mail
Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1676-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Medicare Program: Cancellation of Advancing Care Coordination Through Episode Payment and Cardiac Rehabilitation Incentive Payment Models; Changes to Comprehensive Care for Joint Replacement Payment Model (CMS-5524-P)

Dear Administrator Verma:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am pleased to offer comments on the proposed rule that would cancel the Advancing Care Coordination Episode Payment Models and Cardiac Rehabilitation incentive payment model and make certain changes to the Comprehensive Care for Joint Replacement (CJR) model. Our comments are focused principally on changes to the CJR but we include some other more general comments as well.

Future Episode Model Testing on a Voluntary Basis

The proposed rule cancelling the Advancing Care Coordination Episode Payment and Cardiac Rehabilitation Incentive Payment Models indicates that CMS/CMMI will continue to offer opportunities for providers to participate in voluntary initiatives, including episode-based payment models. The rule notes that CMS/CMMI would not expect to implement voluntary models through rulemaking, but rather would use methods of soliciting applications and securing participants’ agreement to participate consistent with the process used for implementing voluntary models in the past.

AdvaMed recommends that, if CMS/CMMI does not use the proposed rulemaking process for future voluntary model initiatives, that it seek input from all of the broad range of stakeholders that would ensure the success of the models in achieving goals of improved efficiency and quality in care delivery. We believe that our medical technology and diagnostics companies should be consulted during the model development process for the critical role they play in reducing 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. Our companies are also increasingly positioned to offer services and solutions to providers through data analysis and telehealth technologies to help them achieve model goals (see immediately below for additional recommendations in this regard). We hope that we will be able to offer our expertise in voluntary model development going forward.

**Medical Technology Manufacturers as Collaborators in Episode Payment Models (EPMs)**

We have noted in previous comment letters to CMS that EPM participants may want to engage with organizations that are neither providers nor suppliers to assist with episode data analysis, local provider and supplier engagement, care redesign planning and implementation, beneficiary care coordination and management, and other related activities.

The agency, however, has not authorized manufacturers of medical devices and diagnostics to serve in the role as collaborator or convener. Many medical technology companies have in-depth knowledge of patient care protocols, best practices, and treatments that lead to improved patient outcomes. They are ideally suited to collaborate with EPM participants by integrating data analytics infrastructure and services to optimize care to achieve quality goals, by providing services that streamline the supply chain to reduce cost, or by sharing risk for the performance of innovative technologies used by EPMs to meet their savings and/or efficiencies goals in care delivery. AdvaMed urges that CMS allow medical technology manufacturers to serve as collaborators or conveners in EPMs and clarify the specific circumstances under which manufacturers can do so.

**Promoting Risk-Sharing Arrangements between Medical Technology Manufacturers and EPM Participants through Fraud and Abuse Law Waivers.**

We have also noted in previous letters to CMS that regulatory uncertainty concerning the application of the criminal Anti-Kickback Statute to EPM participants and medical technology companies chills innovative collaborations and value-based arrangements. While there are ways to construct some limited engagements currently, they do not offer the fluidity that would be possible with new value-based AKS safe harbors (see AdvaMed safe harbor proposals for value-based arrangements at [http://www.advamed.org/resource-center/advamed-aks-safe-harbor-proposals-value-based-arrangements](http://www.advamed.org/resource-center/advamed-aks-safe-harbor-proposals-value-based-arrangements)).

Current safe harbor protection is afforded only to those arrangements that meet all of the conditions set forth in the safe harbor regulations. Unfortunately, the safe harbor constructs are narrowly fashioned around fee-for-service payment models and this serves to inhibit using delivery reform models that have the potential for improving both quality and efficiency of care delivery. For example, the provision of items and services that are not reimbursed under the same payment methodology may not qualify for protection under the Discount Safe Harbor. This safe harbor includes the limitation that the bundled good or service be reimbursed by the Federal health care program using the same methodology and be earned based on purchases of that same good or service within a single fiscal year. The “same methodology” limitation can materially restrict the range of possible devices and services that may be integrated to deliver the best value because of the uncertainty around what items or services would be considered to fall
under the “same methodology.” Furthermore, one episode of care may span two fiscal years, which would also disqualify an arrangement from protection.

Additionally, the warranty safe harbor does not expressly allow a seller to provide anything as part of a warranty in excess of the cost of the item itself. As such, the warranty safe harbor was intended to address defective products, rather than a warranted outcome not being achieved. This precludes medical technology companies from having the option to more fully back up their products/solutions/services in a way that would hold greater appeal for providers and their patients. Until new value-based safe harbors are issued, we believe that it would be beneficial for CMMI to use its fraud and abuse law waiver authority to promote greater investments in value-based solutions.

Integral to developing and executing value-based arrangements between delivery reform participants and medical technology company collaborators is the need for manufacturers to be able to communicate with providers, payers and other stakeholders about clinical goals, efficiency measures, and economic performance terms and collaborative with one another on meaningful value-based arrangements. Starting points for these goals, measures, and terms may originate from economic and clinical data (with varying levels of support) that may not be specified in the approved or cleared label of the device. However, this scientific and health care economic information will be needed to both establish and optimize the clinical and economic goals of the value-based collaboration.

In light of the challenges noted above and until new value-based safe harbors are issued, AdvaMed believes that it would be beneficial for CMMI to use its waiver authority in the context of ACO and episode payment models being tested by the agency to:

- Create a waiver that will maintain protections for patients and Federal health care programs while allowing for greater involvement and investment in EPMs, by allowing:
  - **Value-Based Pricing Arrangements (VBPA)** – that accommodate Value-Based Price Adjustments dependent on the achievement of a measurable clinical and/or cost outcome and for the bundling of Value-Based Services (analysis, software, equipment, information and/or services provided to providers / patients—at no charge for the purposes of (1) determining the terms of the VBPA; (2) measuring collecting, calculating and reporting the metrics upon which the VBPA is based or the resulting adjustment that is payable; (3) optimizing the effectiveness and clinical utility of the reimbursable items and services; and (4) otherwise achieving clinical/cost outcomes.
  
  - Value-Based Price Adjustments would include a payment made by a seller to a buyer, or by a buyer to a seller, as a reduction to or increase in such buyer’s price or net cost for one or more reimbursable items and/or services under a VBPA. The terms and conditions of the VB Price Adjustment must be fixed and disclosed in writing in advance (e.g., fixed if the formula or other objective mechanism for determining the amount of the adjustment is set forth in writing).
This would allow for **Risk-sharing between ACO and EPM participants and medical technology company collaborators** that incentivize and reward improvements in clinical outcomes and/or reductions in cost.

- **Value-Based Warranties** – that allow manufacturers of products to make certain clinical and/or cost outcome assurances, and provide an appropriate remedy where such outcomes are not achieved. Similar to VBPA, this would also allow for the bundling of Value-Based Services and require that the terms and conditions of the Value-Based Warranty remedy be fixed and disclosed in writing in advance.

- **Outcome warranties** that specifically address warranting an outcome instead of a product failure and protect payments for bundled products and services provided when an outcome is not met. For example, this would provide a targeted approach to addressing scenarios where a medical device company agrees to reimburse a hospital not only its aggregate purchase price for the implant device acquisition costs, but also unreimbursed products and services if a patient is readmitted to the hospital within 90 days following the surgical procedure because the surgical site is infected or a revision surgery is needed.

- **Communications on efficiency** (e.g., performance/throughput claims), population outcomes/cost, and economics that are not specifically part of the product labelling to develop and operationalize value-based arrangements in ACOs and EPMs. We recommend that guidance be issued that clarifies that these communications are necessary and permissible and that varying levels of supportive data are acceptable (e.g., case study, big-data analytics).

### Establishing Meaningful, Longer-Term Quality Metrics for the CJR

AdvaMed has supported CJR incentives promoting 90-day episode savings and quality of care. However, we strongly encourage CMS/CMMI to develop long-term quality and value metrics that would apply to patient care outcomes as measured during periods beyond the currently defined episode of 90 days. Specifically, CMS/CMMI should use Medicare claims data to capture historical interim and longer-term revision rates for joint replacement, share that data with hospitals and physicians, and establish a mechanism to reward hospitals and physicians for lower long-term revision rates during the measurement period. This can include shared savings programs for providers with reduced revision rates relative to the average. We believe that CMS should measure revision rates in the near term, perhaps beginning with the 1-year period following the end of the episode and then extending the measurement period to 3 years and 5 years, and also including patient reported outcomes that will help define differences in outcomes related to implant selection. Lower revision rates as captured by claims data could also be used as a quality measure for CJR in place of the HCAHPS measure, to counter incentives within internal cost savings arrangements to use implants of lower quality not matched to patient lifestyle and functioning.
Developing an Adequate Risk Adjustment Mechanism for the CJR

A recent study published in *Health Affairs*, “Medicare’s New Bundled Payment for Joint Replacement May Penalize Hospitals That Treat Medically Complex Patients,” by Ellimoottil, et al, makes the case that adequate risk adjustment mechanisms are urgently needed if Medicare beneficiaries, especially those with high risk scores, are to have adequate access to high quality care. The authors of this study found that reconciliation payments for Michigan hospitals participating in CJR were reduced by $827 per episode for each standard-deviation increase in a hospital’s patient complexity. The article also argues that CMS should consider using the CMS Hierarchical Condition Category (CMS-HCC) for risk adjustment for hospitals participating in CJR during an interim period until a more adequate risk adjustment mechanism is developed.

AdvaMed recommends that CMS/CMMI reconsider its position on using the CMS-HCC, as it moves forward with the development of other risk adjustment methods. Proper risk adjustment is essential to the successful implementation of the CJR model and all other bundled payment programs.

With the likely removal of TKA and possible removal of THA from Medicare’s inpatient only list to allow these procedures to be done in hospital outpatient settings, the need for an appropriate risk adjustment mechanism to be incorporated in the CJR becomes even more critical in that mandatory program to ensure that providers and patient care will not be adversely impacted by the changes.

Removing Total Knee Arthroplasty (TKA), Total Hip Arthroplasty (THA), and Partial Hip Arthroplasty from the Inpatient Only (IPO) List

The proposed rule does not include discussion or proposals for addressing the impact removing TKA, THA, and partial hip replacement from the IPO List will have on target price calculations used in the CJR. As we have noted in our comment letters on the proposed CY 2017 and 2018 Hospital Outpatient Department Prospective Payment and Ambulatory Surgical Center Payment Systems Rules, if these procedures are moved to an outpatient setting, hospitals participating in the CJR may be left with a more acutely ill patient population having the procedures. This in turn would affect their ability to reduce spending below their benchmark or target price, since many of their healthier patients would be treated outside of the episode where the anchor is the inpatient stay. For similar reasons, we are concerned that movement of TKA to an outpatient setting could remove incentives for hospitals to participate in the Bundled Payments for Care Improvement (BPCI) program. Given CMS’ apparent plan to begin a BPCI Advanced program starting in calendar year 2018, hospitals and physician groups may not see any financial incentive to volunteer to participate in BPCI if they are already transitioning healthy patients to an outpatient setting and with benchmarks based on prior years’ data that reflect a mix of medically complex patients and less complex patients who would now be treated in the outpatient setting.
As we offered in our comment letter for the CY 2018 HOPD/ASC proposed rule, one possible solution to this problem would be to expand the definition of the Episode Initiator (EI) to include episodes initiated in the outpatient setting and permitting both the inpatient and outpatient claims to be represented in the payment model. Expanding the definition of the EI would not only allow CMS to study model performance across sites of care, it would also avoid the need for a potentially complicated methodological approach to risk adjustment and stratification. Including both inpatient and outpatient claims will also assure that providers participating in the CJR or BPCI episode payment models will make determinations of surgical site selections based on clinical conditions and patient preferences, and not on reimbursement. AdvaMed urges that CMS issue a proposed rule, with opportunity for comment, on how the CJR should be amended to account for TKA, THA, or partial hip procedures being allowed to be performed in outpatient settings.

Moving Forward with a New Surgical Hip/Femur Fracture Treatment (SHFFT) Episode Model

SHFFT as a focus for episode payment model development is a natural area for CMMI testing, given the substantial spending that Medicare patients needing treatment for these conditions incur for hospital readmissions and their extensive use of post-acute care following discharge from an inpatient stay.

AdvaMed encourages CMS/CMMI to move forward rapidly with a revised SHFFT model that would include, among other things, better segmentation of patients needing this care, e.g. separating older frail patients from those who are younger and healthier. In developing a revised model, CMS/CMMI should also consider how to encourage more providers to participate in the demonstration than the small number of hospitals currently participating in the model under the Bundled Payments for Care Improvement (BPCI) initiative. We understand that CMS/CMMI wishes to avoid mandatory models, but voluntary models should then be strongly encouraged, with expanded opportunities for hospitals and physicians to achieve shared savings tied to patient quality improvements and episode of care spending deductions.

Consistent with our recommendation that CMS allow medical device manufacturers to serve as CJR collaborators and conveners, we urge CMS/CMMI to allow these relationships in any future SHFFT model, whether tied to CJR or operating independent of CJR.

Proposed Adjustment to the Pricing Calculation for the CJR Telehealth HCPCS Codes to Include the Facility PE Values

The proposed rule notes that the final CJR rule established 9 HCPCS G-codes to report home telehealth evaluation and management visits furnished under the CJR telehealth waiver. Pricing for these 9 codes has been updated each calendar year to reflect the work and malpractice relative value units for the comparable office and other outpatient E/M visit codes on the Medicare Physician Fee Schedule. CMS, however, did not include the practice expense RVUs in the payment rate for these CJR model services, based on its belief that practice expenses incurred to furnish these services are marginal or are paid for through other fee schedule services. With
input from various stakeholders, CMS now believes that there are costs related to the delivery of telehealth services under the CJR model and proposes to use the facility practice expense RVUs for the analogous in-person services. CMS recognizes that this methodology does not provide a perfect reflection of practice resource costs actually incurred for remote telehealth services under the CJR model, but believes that it is a better proxy than assigning zero costs to such services. AdvaMed supports this CMS proposal and believes that it is one additional step in encouraging CJR hospitals and physicians to use telehealth technologies for improving the efficiency and quality of care delivery for patients undergoing joint replacement procedures. However, it is only one step. We believe that CMS and CMMI are missing an opportunity, through their existing waiver authorities, to use delivery reform models for creatively testing situations where additional flexibility in the provision of telehealth services would increase overall care efficiency and improve care quality.

AdvaMed has recommended that CMS and CMMI undertake demonstrations, through its delivery reform models, to determine whether and under what circumstances expanded coverage of telehealth can be cost effective and improve quality of care for Medicare beneficiaries. Both CBO and MedPAC have also called for such demonstrations to get to the bottom of issue as to whether such services can be cost effective. We also note that, at MedPAC’s October 2017 public meeting during sessions on Medicare’s coverage of telehealth services, several MedPAC Commissioners suggested that expanded services should be tested under CMMI models for this same purpose.

AdvaMed believes that demonstrations whose principal purpose is to test when expanded services can be cost effective will lead to creative new ways for incorporating telehealth technologies into care delivery. Waivers that have been approved thus for expanded telehealth services do not go far enough in testing the efficiencies and quality of care improvement potential of telehealth technologies. For example, waivers allow coverage only of those telehealth services on Medicare’s approved list of covered telehealth services. In addition, only services meeting the requirement of being furnished via an interactive telecommunications system would be covered. A broad range of other digital technologies, such as store and forward technologies, remote monitoring systems, and point-of-care testing, have been developed for providing services remotely and should be tested in demonstrations. In addition, no additional payment can be made to cover set-up costs, technology purchases, training and education, or related costs.

One possible scenario for testing expanded telehealth services coverage and payment would be to focus on specific patient population groups, such as those with specific chronic conditions or specific medical needs, e.g., those needing rehabilitation services or those who might be having a stroke. The demonstrations could also test alternative methods for paying for telehealth beyond fee-for-service, and include, for instance, capitation that would pay a delivery reform model participant a specified amount per month for telehealth services. If necessary, the demonstrations could be limited to models with two-sided risk.

CMS/CMMI’s delivery reform models offer the ideal scenario for testing and defining how these services can be cost-effective. To our knowledge, expanded telehealth services being provided
in CMMI models through waivers are not being evaluated for their cost effectiveness and AdvaMed urges CMS to define specific model testing for such purposes.

Sincerely,

Donald May  
Executive Vice President  
Payment and Health Care Delivery Policy