April 19, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-5519-IFC
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Medicare Program: Advancing Care Coordination through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR); Delay of Effective Date

Dear Administrator Verma:

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to respond to the interim final rule asking for comments on the appropriateness of further delay of the final rule, Advancing Care Coordination through Episode Payment Models (ACC-EPM) and Changes to the Comprehensive Care for Joint Replacement Model (CJR).

AdvaMed member companies can play a critical role in helping providers meet the goals set out for delivery reform programs. They do so through improvements in medical technologies, diagnostics, and other advanced medical technologies, which, among other things, allow health care services to be provided 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.

AdvaMed has been a strong supporter of delivery reform models, including bundled or episode payment programs like the CJR. We recognize the importance of the goals of these programs as they seek to improve both the efficiency and quality of health care in this country and we believe they hold great promise for achieving these goals. However, at the present time, we believe that
additional delay of the ACC-EPM rule is in order, especially for those sections of the rule dealing with the cardiac bundles and surgical hip/femur fracture. The longer delay will provide time to CMS to reconsider positions incorporated in our original letter on the proposed rule (attached) and to reevaluate some of the positions advocated by our company members in their individual responses to the proposed rule.

Below we highlight a few issues from our own comment letter as well as our members’ letters that we believe merit reconsideration. We also cite below recently published literature that came to our attention after the submission of our original letter that suggests to us a need to reevaluate original positions.

EPM Collaborators and Safe Harbors for Bona Fide Value-Based Arrangements between EPM Participants and Medical Technology Collaborators

In its recently issued FY 2018 IPPS proposed rule, CMS included a Request for Information that the agency is using to signal its intention to initiate a national conversation about improvements that can be made to the health care delivery system to reduce unnecessary burdens for clinicians, other providers, and patients and their families. With this RFI, CMS is asking for ideas for regulatory, subregulatory, policy, practice, and procedural changes to achieve these goals. The proposed rule states that ideas could include payment system redesign, elimination or streamlining of reporting, monitoring and documentation requirements, aligning Medicare requirements and processes with those from Medicaid and other payers, operational flexibility, feedback mechanisms and data sharing that would enhance patient care, support of the physician-patient relationship in care delivery, and facilitation of individual preferences.

Our attached comment letter from last October argued for an expanded list of collaborators, beyond ACOs, hospitals, and CAHs, to include manufacturers of medical devices and diagnostics. We also argued for waivers that would provide protections for bona fide value-based arrangements between EPM participants and medical technology company collaborators. We specifically recommended waivers for:

- **Risk-sharing between EPM participants and medical technology company collaborators** that incentivize and reward improvements in clinical outcomes and/or reductions in cost. This waiver should allow for sharing value-based rewards and the shifting of risk over the course of an arrangement so long as such risks and rewards are set in advance.
- **Bundling medical technologies with services to collect and monitor data, analytics, monitoring equipment, and IT infrastructure.**
- **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. Currently when this occurs, there is arguably protection under the safe harbor warranty for only the device cost when the device fails.

In light of the RFI from last week and CMS’s stated interest in new ideas for payment system redesign, we believe that that our proposals from late last year merit new consideration.

Risk Adjustment

Our comment letters on the original ACC-EPM proposed rule as well as the CJR proposed rule urged CMS to move forward with the development of an adequate risk adjustment mechanism for bundled payment programs. A recent study published in *Health Affairs*, entitled “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 the 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 the CJR during an interim period until a more adequate risk adjustment mechanism is developed. *Advamed recommends that CMS reconsider its position on using the CMS-HCC, especially in light of the mandatory nature of participation in the CJR and ACC-EPM models, as it moves forward with the development of other risk adjustment methods. Proper risk adjustment is essential to the successful implementation of all bundled payment programs.*

Cardiac Bundles Configuration

Some of our member companies recommended in letters on the ACC-EPM models that CMS consider splitting the AMI bundle into two separate bundles (AMI medical management and AMI PCI), similar to the structure under the Bundled Payment for Care Improvement Initiative. We believe that this action would simplify the AMI bundle and allow the agency to do more longitudinal analyses of bundled payments based on the experience under both BPCI and the ACC-EPM cardiac bundles under the ACC-EPM program.

In addition, we believe that CABG and other episode bundles where the majority of 90-day spending is accounted for in the index hospitalization are not necessarily good targets for bundled payment programs. For episodes such as these, the opportunities to change delivery of care across the episode to realize savings are fairly limited. It is, therefore, critical that a bundle for CABG be appropriately structured and that CMS apply a low volume threshold to the bundle, similar to what agency uses for the AMI bundle.
Expanded Telehealth Services under Bundled Payment Programs

AdvaMed has been a strong supporter of CMS’s decisions to provide waivers to bundled payment programs to allow in-home telehealth visits and to permit telehealth services to be covered in all rural and urban areas included in the ACC-EPM and CJR models. We have also recommended that CMS and its Innovation Center 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 and we believe that such demonstrations will lead to creative new ways to incorporate these technologies into care delivery. We recommend that these demonstrations go beyond a framework based on fee-for-service payments for expanded telehealth and instead explore the feasibility of capitated payments for telehealth or, alternatively, incentives for investment in telehealth/digital technologies that are not necessarily accompanied by new streams of fee-for-service revenue but instead improve care delivery efficiency through adjustments to benchmarks or actual spending total for ACOs or bundled payment programs. We offer this recommendation in the context of the IPPS rule’s RFI for new ideas payment system redesign and support of the physician-patient relationship in care delivery.

Improving Quality of Care in the CJR

As noted above, AdvaMed supports the successful implementation of CJR but remains concerned about the potential of stinting in care delivery. In a recent Journal of the American Medical Association article by Dummit, et al., entitled “Association Between Hospital Participation in a Medicare Bundled Payment Initiative and Payments and Quality Outcomes for Lower Extremity Joint Replacement Episodes,” the authors conclude, after comparing cost data of hospitals participating in BPCI lower extremity joint replacement episodes, that additional studies are needed to assess longer-term follow-up as well as patterns for other types of clinical care needed and received by patients. AdvaMed is concerned that the financial incentives in delivery reform models can lead to stinting on care received by patients. Stinting in the case of the CJR 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.

Many medical devices and technologies, including hips and knees, 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 of inappropriate treatment options that might include the suboptimal selection of a lower utility hip or knee for a higher functioning more expensive device, short-term savings could be outpaced due to suboptimal outcomes and/or an increase in revision rates which typically are not measurable for several years. To address these concerns and to respond to the Dummit article’s call for longer-term follow-up of patients treated under joint replacement bundled payment models, AdvaMed recommends that CMS consider developing a metric of long-term revision rates for joint replacement procedures to ensure that high quality care continues to be available to Medicare beneficiaries. This metric would establish an incentive for providers to use high-quality products that are demand-matched to an
individual patient’s life-style and need and not use products that will work in short-term but will need to be revised a few years later.

We thank you for this opportunity to provide comments on the interim final rule. If you have any questions, please contact Richard Price at rprice@advamed.org or 202-434-7227.

Sincerely,

Donald May
Executive Vice President,
Payment and Health Care Delivery