November 20, 2017

Via Electronic Mail
Ms. Amy Bassano
Acting Deputy Administrator, Innovation and Quality
Director, Center for Medicare & Medicaid Innovation
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1676-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Comments on the Request for Information Regarding Innovation Center New Directions

Dear Deputy Administrator Bassono:

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to respond to Request for Information published by CMMI for input from stakeholders on new directions CMMI might pursue in the future for testing and demonstrations. AdvaMed member companies play a critical role in helping providers meet the goals set out by CMMI for delivery reform programs it has implemented during the past 6-7 years. Our companies do so through medical technologies and diagnostics that improve both the quality and delivery of health care 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.

We have identified for your consideration the following areas that we believe have great potential for leading to continued improvements in the quality and efficiency of care delivery.

Promoting Value-Based Arrangements between Medical Technology Manufacturers and Demonstration Participants by Incorporating Certain Waivers and Guidance Into Current and Future Demonstration Models

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

Current AKS 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, providing a discount on a combined product and services offering may not qualify for protection under the discount safe harbor unless the product and services are both reimbursed by a federal health care program using the same methodology. Because the reimbursement rules are complicated and can vary significantly depending on the site of care (e.g. acute care hospital versus physician clinic or skilled nursing facility) this “same methodology” limitation can materially restrict the range of possible innovative devices and services that may be integrated to deliver the best value because of the uncertainty around what products or services would be considered to fall under the “same methodology.”

The other significant safe harbor limitation is that for customers who provide cost reports to CMS (e.g. acute care hospitals) discounts must be both (1) earned on the purchased item or service within the same year the item or service is purchased and (2) claimed on the purchased item or service in the same fiscal year in which the discount is earned or the following year. We understand that the purpose of the fiscal year restriction is to ensure that discounts and rebates are being timely reported to CMS for any potential impact on CMS’ annual rate-setting activities. With new CMS reimbursement demonstration (and other payment for value models), however, the need to submit cost reports in order to impact annual rate-setting activities is largely not needed. In addition, it is impractical to impose the fiscal year requirement since one patient episode of care may span two fiscal years of the hospital, which could disqualify a discount arrangement from protection. For these reasons, the current Discount Safe Harbor not only fails to enable, but is in fact a strong deterrent for, manufacturers, hospitals, and other participants to collaborate toward meaningful innovation of health care delivery.

Additionally, the AKS 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 or stand behind the performance of their products/ solutions/ services in a way that would hold the company more accountable for both expected clinical outcomes and associated cost savings, as well as unexpected adverse events and associated cost increases in connection with the use of the company’s product/solution/service. For example, if a product did not meet an intended clinical outcome (not due to a product defect) and the expected cost savings was not achieved, the safe harbor would not permit the company to share any financial exposure with the purchaser of the product. Furthermore, if a product did not achieve an expected clinical outcome (either because it was defective or simply did not meet an agreed upon clinical target) and in turn increased the hospital’s overall cost of care and potentially increased cost to the federal health care program, the current safe harbor would not permit the medical technology company to share the financial
risk for that negative economic impact to the health care system through a contractual indemnification, or otherwise. 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. Starting points for these goals, measures, and terms may originate from economic and clinical data 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 current and future demonstrations to capitalize on and demonstrate the benefits of medical technology manufacturers sharing in the risk to deliver on clinical and cost outcomes.

AdvaMed proposes instituting the following waivers and guidance across existing and future demonstrations, which include protections for patients and Federal health care programs, while allowing for greater involvement and investment in demonstrations:

- **Value-Based Pricing Arrangement (VBPA) AKS Waiver**—This waiver would allow for
  1. Value-Based Price Adjustments that are dependent on the achievement of a measurable clinical and/or cost outcome and
  2. the bundling of Value-Based Services (analysis, software, equipment, information and/or services provided to providers / patients—at no charge for the purposes of: (a) determining the terms of the VBPA; (b) measuring collecting, calculating and reporting the metrics upon which the VBPA is based or the resulting adjustment that is payable; (c) optimizing the effectiveness and clinical utility of the reimbursable items and services; and (d) otherwise achieving clinical/cost outcomes.

  - Value-Based Price Adjustments would include payments made between Participants and medical technology manufacturers that reduce or increase the net cost for one or more reimbursable items and/or services based on whether or not a clinical and/or cost outcome was achieved.

  - The terms and conditions of the Value-Based 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 incentivizes and rewards improvements in clinical outcomes and/or reductions in cost.
• Value-Based Warranties AKS Waiver—This waiver would allow manufacturers of medical products to make certain clinical and/or cost outcome assurances, and provide an appropriate remedy where such outcomes are not achieved. Similar to VBPA's, 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.

  o This would allow for Outcome Warranties that specifically address warranting an agreed upon clinical and/or economic outcome instead of against only 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 Guidance—This guidance would affirmatively state that communications on efficiency (e.g., performance/throughput claims), population outcomes/cost, and economics that are not specifically part of the product labelling are permissible to develop and operationalize value-based arrangements in demonstrations and that varying levels of supportive data are acceptable (e.g., case study, big-data analytics).

• Uniformity of Benefits Requirement Waiver—This waiver would increase flexibility to target value-based interventions to the “right patients” at the “right time”. While no treatment or procedure is right for all patients, value-based arrangements may require additional treatment criteria or use cases to identify patient populations most likely to benefit from the intervention. As the uniformity of benefits requirement generally requires that a plan's benefits and cost sharing be the same for all plan enrollees, a waiver would promote the integration of interventions for appropriate patients within a value-based arrangement. This waiver may also prove to be of value in the context of Guiding Principle 6 on Small Scale Testing.

The proposed waivers and guidance are a means to furthering Guiding Principle 1 (Choice and competition in the market) by creating a platform where manufacturers of all sizes can compete on the basis of outcomes (both clinical and cost). With regard to Focus Area 8, Program Integrity, AdvaMed proposes that the above waivers and guidance be incorporated as a layer on top of existing and future models to encourage the voluntary participation of medical device manufacturers in value-based arrangements. Aligning the interests of all participants in the delivery of care has to potential to drive further outcome improvements and cost reductions.
In response to question 6, AdvaMed believes that the above waivers and guidance should be considered necessary to help providers innovate care delivery. Medical technology manufacturers are uniquely positioned to drive value-based care solutions and advance providers' efforts to optimize patient care. First, manufacturers are experts in how their technologies may affect clinical outcomes. This expertise gives them the specialized knowledge to design solutions that can reduce adverse events and the associated costs of treating those events. Second, value-based health care is largely driven by data. Many medical devices either generate data on their own or work in an ecosystem to contribute to data collection and aggregation. This natural data hub capacity should be harnessed to operationalize value-based arrangements and support clinical decision making.

**Medicare’s Coverage of Telehealth Services**

The GAO findings in the report cited above and its call for a forward-looking process for providing Medicare beneficiaries access to innovative technologies leads us to recommend that CMMI test specifically the integration of telehealth, remote patient monitoring, and a broad range of other digital technologies into health care delivery to provide beneficiaries access to the benefits offered by these technologies. This is a rapidly evolving area of medical technology development that demands new thinking and testing on how to incorporate them into health care delivery—especially given that very few episode initiators have used telehealth waivers available under Models 2 and 3 of the Bundled Payments for Care Improvement initiative—less than 5 percent in the case of Model 2 and 1 percent in the coast of Model 3.

Medicare’s current benefit category for telehealth narrowly defines the types of technologies and services that can be covered and the location where beneficiaries may receive these services. The CMMI does have authority to cover a broader range of telehealth, remote patient monitoring, and digital technology services beyond what is allowed by current law, but has chosen to do so in only a limited way, without, it appears, a plan to determine just how expanded telehealth services achieve CMMI goals for reducing spending and achieving the same or higher quality of care. GAO observes that the consequences of not having a forward-looking process for accommodating significant changes in health care are that CMS, and other insurers that follow Medicare payment policy, may not recognize advances in technology that may provide potential cost-savings and better health outcomes and value in terms of coordination. Most important, beneficiaries are not provided access to technologies and related services that may improve their health and well-being. AdvaMed recommends that CMS develop a detailed plan for testing broader Medicare coverage for telehealth, remote patient monitoring, and other digital technology services. The plan should also explore payment methodologies different from fee-for-service, and should suggest specific pathways for expanding coverage of these services. We suggest reviewing S. 787 as a model to serve as a starting point for expanding covered services. This bill proposes to cover expanded coverage for using a wide variety of different technologies to manage certain chronic conditions for beneficiaries being served in ACOs and bundled payment programs.
Quality Measurement and Evaluation

AdvaMed recommends that CMS work with stakeholders to prioritize cross-cutting measure development that reduces provider burden, but also reflects patient-centered priorities and outcomes resulting from appropriate treatment options, including medical technologies used in those treatments. Meaningful outcome measures, including patient-reported outcomes related to shared decision-making for the use of a specific technology, and outcomes focused on issues impacted by medical technologies, such as surgical interventions, can be used in place of burdensome process measures. Effective use of measures together with measure concepts would help ensure that new CMMI payment model financial incentives are balanced with incentives to improve quality, including improvements accompanying the appropriate use of medical technology.

AdvaMed further recommends that CMMI prioritize development funding for outcome measures that are impacted by the use of medical technology and cross-cutting measures that assess incorporation of patient-centered decision-making in the use of medical technology. This includes patient-reported outcome measures of functional or health status, outcomes tied to utilization of care such as length of stay or unplanned re-operations, and longer-term surgical outcome measures.

In addition, AdvaMed recommends that CMMI demonstration models incorporate a small set of short-term indicators to monitor issues potentially stemming from financial incentives. These indicators should include claims-based measures of utilization such as emergency room visits, hospital admissions and adverse events, as well as measures of provider and patient experience. These indicators should be designed to enable CMMI to monitor program-related concerns urgently, without burdening providers with unnecessary reporting. Longer term measures of trends in provider spending, change in patient-reported outcomes, and multi-year outcomes, such as unplanned re-operations, should be used by third party evaluators to assess the broader impact of value-based payment models.

We also recommend that CMMI consider evaluating models on a multi-year basis, as quality considerations tied to use of medical technology may extend beyond a single performance year. For example, a patient-centered measure such as functional outcomes following implant surgery may be different over a 2-year period than a 30-day period, with accompanying cost implications for the health care system. We encourage CMMI to review the measure concepts and available measures identified in our report, and partner with our members and professional societies to prioritize key quality measures for development and use in demonstration models.

For purposes of transparent model design and evaluation, we recommend that CMMI partner with independent, third-party entities to assess and evaluate the impact of value-based payment models on affected markets. All third-party evaluations should incorporate input from stakeholders affected by the models, including patients, medical professional societies, and drug and medical technology manufacturers. These reports should incorporate shorter-term indicators—assessments of problem areas conducted within a performance year—and longer-term evaluations—studies conducted over a multi-performance year period. Short-term indicators should allow CMS to identify problems in care delivery, such as inappropriate
utilization, spending, or patient experience, and address them as quickly as possible. Longer term evaluations should include multiple data streams, including data provided by CMS to evaluators who study the impact of VBP over time. Importantly, evaluators should study trends in spending and utilization tied to high-cost and innovative treatments that may otherwise be disincentivized under cost containment models.

**Establishing Meaningful and Longer-Term Quality Metrics and Shared Savings for the Comprehensive Care for Joint Replacement (CJR) Episode Payment Model**

As a subset of our recommendations above on quality measurement, AdvaMed strongly encourages CMS/CMMI to develop quality and value incentives that would encourage improved patient outcomes 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 shared savings mechanism to reward hospitals and physicians for lower long-term revision rates during the measurement period. We believe that CMS should also include patient reported outcomes in determining quality, as that will help define differences in outcomes related to implant selection. Lower revision rates at one, two, or here years as captured by claims data could also substitute as a much more meaningful quality measure for the existing HCAHPS measure, which counts for 50 percent of a hospital’s Composite Quality Score in the CJR. This would counter incentives within internal cost savings arrangements to use implants of lower quality not matched to patient lifestyle and functioning, and promote higher quality of care for beneficiaries.

**Improving the Quality of Wound Care for Medicare Beneficiaries**

AdvaMed’s Wound Healing and Tissue Regeneration Sector has embarked on a project to develop a conceptual framework for an alternative payment model focused improving the quality and efficiency of wound care for Medicare beneficiaries. Studies have shown that a large percentage of Medicare beneficiaries are treated for various types of wounds that account for a significant amount of spending during a year when a wound is the underlying cause of treatment. AdvaMed’s Wound Sector has begun data analysis, focusing on diabetic foot and venous ulcers, and spending related to those wounds and provided in the outpatient hospital setting or physician’s office. Our preliminary analysis shows significant spending for beneficiaries where these types of wounds are the principal diagnosis. In addition, our preliminary analysis indicates fragmented care, lack of specialist leadership in the provision of care, and variation in the treatment modalities used in caring for these patients. We hope to expand our data analysis to compare patterns of care in outpatient hospital- based departments versus physician offices. While we are not presently able to propose a specific approach for a wound care model, we include mention of this in our comment letter to indicate our intent to discuss a model in the future.

AdvaMed recommends that CMS prioritize patient engagement and the use of patient preference information (PPI) to inform CMS coverage models and decision-making. Over the last few years, FDA has increased its efforts and commitment to engage with patients to ensure that their preferences and priorities are considered during regulatory review of new medical technologies. FDA’s efforts include establishment of the Patient Engagement Advisory Committee (PEAC), dissemination of guidance regarding the use of PPI in benefit-risk determinations, and hosting of public workshops to facilitate discussion around PPI study methods, FDA expectations, and pathways for inclusion of PPI in regulatory submissions. These efforts are yielding important data about patients’ risk tolerance given probable benefits, and leading to shifting paradigms around the conduct of clinical trials and medical technology development. Further, FDA, patients, and medical technology companies anticipate that continued engagement and pursuit of rigorous and meaningful PPI will facilitate the commercialization of life-changing medical technology.

AdvaMed recommends that CMMI use its demonstration authority to develop policies and procedures to promote engagement with patients similar to FDA’s. This engagement could take place in at least two ways. First, CMS could include patients in its decision-making process for coverage decisions about innovative technologies and treatments. In addition, CMMI could include patients in an advisory capacity for deciding which demonstrations to undertake in the future. AdvaMed believes a coordinated effort by CMS and FDA around patient engagement will have a significant, beneficial impact on healthcare costs and patient outcomes.

Medicare Advantage (MA) Innovation Models

As a general matter, AdvaMed supports CMS/CMMI’s desire to work with MA plans to drive innovation, better quality and outcomes, and lower costs, including through incentives for MA to compete for beneficiaries in fee-for-service. We note, however, whether through the traditional Medicare fee-for-service program or an MA plan or delivery reform model, a beneficiary’s access to the full range of treatment options appropriate for a given medical condition is critical for positive health care outcomes to be achieved. While AdvaMed supports CMMI initiatives whose goals are improvements in the quality and efficiency of care delivery, we are concerned that the financial incentives in these programs, as well as MA plans, have the potential to compromise patient access to the full range of appropriate treatment options for a given medical condition, especially those that are more expensive than others, including innovative treatments that are more expensive than the current standard of care, even when they produce better outcomes for patients. We, therefore, believe that these initiatives must be accompanied by beneficiary protections that will guard against stinting on care. These will include claims data analysis of patterns of care for persons served by MA plans or delivery reform models compared to persons in fee-for-service, and more granular analysis of a sample of patient medical records to determine whether the services actually received by beneficiaries in MA plans correspond to existing standards of care and whether they also include innovative treatments and procedures appropriate for a beneficiary’s medical condition. It is only at this more granular level of analysis that CMS will be able to see whether patients are receiving the care they require.
Again, we thank you for the opportunity to respond to the RFI. 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 Policy