Ms. Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attn: CMS-1701-P  
Mail Stop C4-26-05  
7500 Social Security Blvd.  
Baltimore, MD 21244-1850

Re: Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations (ACOs)—Pathways to Success

Dear Administrator Verma:

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to provide comments on the Medicare Shared Savings Program proposed rule released August 9, 2018. AdvaMed member companies produce the medical devices and technologies that play an important role in allowing Medicare beneficiaries to lead healthy, productive, and independent lives, and in the process, serve the twin purposes and objectives of the Medicare Shared Savings Program (MSSP)—to reduce the rate of growth in Medicare spending and to improve the quality of care Medicare beneficiaries receive.

Ensuring Patient Access to Appropriate Care

Since their inception in the Affordable Care Act, AdvaMed has supported the Medicare Shared Saving Program and other delivery reform models implemented by CMS and the Center for Medicare & Medicaid Innovation. We have done so because we believe that our companies’ technologies can and do play a central role in improving quality and creating efficiencies in care delivery.

As we have written on several occasions, we are concerned, however, that the financial incentives in MSSP and other delivery reform models can have the inadvertent effect of discouraging providers from (1) considering the full array of treatment options, especially if they may increase costs above “benchmark” 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 than the standard of care in the short run. A broad range of medical technologies can be impacted by the incentives in these programs,
including new and less invasive technologies for treating heart disease, innovative joint implants that lead to shorter recovery periods and extend durability of the implant for many years, new molecular diagnostic tests that identify more effective treatment therapies for disease, and robotic-assisted surgical technologies that result in better outcomes for patients. The potential negative impact of the financial incentives of these models is magnified by the short payment windows used in the programs 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.

We have argued in past letters and continue to believe that adjustments for certain new technologies are necessary to ensure Medicare beneficiaries access to the full range of treatment options and new technologies considered by their providers as appropriate for their medical conditions—to the extent these are more expensive than a current standard of care. In the past, we have pointed to data analysis by one of our member companies that looked at utilization rates for several interventional treatment options for arterial procedures and utilization rates of these options for Medicare beneficiaries served by ACOs. The 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 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.

We have also written about some of our orthopedic companies finding that certain providers participating in bundled payment programs dramatically changing the types of hip and knee implants they order—ordering almost exclusively less expensive, lower utility hip and knee implants that may not corresponded to the lifestyle needs of patients, based on their life expectancy, level of activity, and medical conditions. The longer-term impact of using almost exclusively lower utility devices, when they are not 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--at greater expense to the Medicare program. 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 is appropriately demand matched to their unique needs to ensure the best possible outcomes and longevity, without cost entering the equation of the decision about which implant to use. These changes our orthopedic companies have witnessed seem to suggest a purely economic response to the financial incentives of the payment reform models, rather than a considered assessment based on medical criteria.
AdvaMed also notes that CMS has acknowledged the impact a higher cost innovative technology can have on providers’ ability or interest in using that technology in patient care when they participate in delivery reform models, specifically BPCI and the Comprehensive Care for Joint Replacement (CJR) bundled payment model. The Innovation Center has approved carve outs of 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 for providers participating in these programs. In proposing the carve out of NTAP amounts for the CJR model, CMS noted that it would not be appropriate for the 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 actual expenditures. AdvaMed recommends that this policy be extended to ACOs, both the MSSP program and Innovation Center ACOs, and that CMS apply a similar process to other technologies as recommended above and in our previous letters.

In addition, we have recommended that CMS and CMMI evaluate excessive device standardization for beneficiaries served in these models, and also compare care on several other dimensions (referrals to specialists, utilization guideline recommended care, outcomes for beneficiaries with multiple chronic conditions) for those served under these alternative payment models with those not receiving care from providers participating in the models.

For these reasons, we are concerned that the proposed rule, with its new and shorter transition to shared losses, could lead to even greater pressure on providers to respond to the program’s financial incentives to reduce spending on services. These pressures in turn may lead to greater risk that patient access to innovative treatments and technologies will be compromised, especially when these are more expensive than the standard of care embedded in benchmarks. **AdvaMed recommends that CMS extend the length of the agreement period for ACOs to seven years with a more gradual phase-in of shared losses.**

**Quality Measures Used in MSSP**

As CMS has observed on multiple occasions, quality measures are a critical element of value-based payment models, including the MSSP. AdvaMed has commissioned Discern Health to produce a study that assesses quality measure gaps, especially as they exist in value-based payment models. The study, *Medical Technology in the Value-Based Environment: An Assessment of Quality Measure Gaps*, observes that because value-based payment models include cost containment incentives, quality measures are essential to ensure that providers do not sacrifice quality of care to achieve financial benefits or avoid financial penalties.
The study defines quality measure gaps as both gaps in available measures and gaps in existing value-based measure sets where measures are available but are not being used. Specifically, the study assesses quality measure gaps across eight diverse clinical areas and example medical technologies that are indicated for the care of those conditions. We recommend this study to CMS for application to the MSSP and other value-based payment models, especially as the agency evaluates existing quality measures and seeks to establish new quality measure sets for these programs. The study may be found at: https://www.advamed.org/resource-center/medical-technology-value-based-environment-assessment-quality-measure-gaps.

Among its several recommendations related to quality measure gaps as they affect the use of medical technologies in value-based models, the study asks that CMS work with stakeholders to prioritize cross-cutting measure development that reduces provider burden and reflects patient-centered priorities and outcomes resulting from appropriate treatment, including access to medical technologies. Meaningful outcome measures, including patient-reported outcomes related to shared decision-making for the use of 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, including measure concepts identified in our study, would help ensure that new payment model financial incentives are balanced with incentives to improve quality, including the appropriate use of medical technology. We recommend that CMS and CMMI prioritize development funding for these purposes.

The study also recommends that alternative payment models incorporate a parsimonious set of short-term indicators to monitor issues potentially stemming from financial incentives. These indicators could 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 could be designed to enable CMS to monitor program-related concerns, 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, could be used by third-party evaluators to assess the broader impact of VBP models.

Finally, to improve the evaluation of value-based payment models into the future, we encourage that CMS and 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 from a 30-day period, with associated cost implications for the health care system. We encourage CMMI to
review the measure concepts and available measures identified in the Discern Health report, and partner with our members and professional societies to prioritize key quality measures for development and use in demonstration models.

We would be pleased to arrange a briefing with Discern Health for CMS and CMMI officials on these issues.

We appreciate the opportunity to comment on the MSSP proposed rule. If you have any questions about our comments, please contact Richard Price at rprice@advamed.org.

Sincerely,

Donald May
Executive Vice President
Payment and Health Care Delivery