August 21, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-5522-P: Medicare Program; CY 2018 Updates to the Quality Payment Program (QPP)

Dear Administrator Verma:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am pleased to offer comments on the proposed rule on the CY 2018 Updates to the Quality Payment Program (QPP), published in the Federal Register June 30, 2017 (CMS-5522-P). AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

We commend CMS for the extensive effort required to implement the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) provisions establishing the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) for the physician fee schedule and a value-based approach in setting payments for physician services. AdvaMed understands that the Quality Payment Program is very complex and supports CMS’ efforts to implement this program slowly over time with full transparency. Our specific comments on the QPP Proposed Rule follow.

MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS)

1. Cost Performance Category: Weight of the Cost Performance Measure / Feedback on Cost Performance Category

In the 2017 QPP final rule, CMS finalized a weight of zero percent for the 2019 MIPS payment year and ten percent for the 2020 MIPS payment year. Starting with the 2021 MIPS payment year, the cost performance category will be weighted at thirty percent. For the 2018 MIPS
performance period, CMS proposes to keep the weight of the cost performance category at zero percent of the final score for the 2020 MIPS payment year. CMS indicates this will allow more time to improve clinician understanding of the measures and continue development of episode-based measures.

AdvaMed supports CMS’ proposal that the cost performance for the 2020 MIPS payment year remain at zero percent to enable physicians to acclimate to the changing measure environment. This is especially important since CMS is still in the planning stages in the development of numerous clinical episode-based measures to be used in this performance category and the number of issues related to developing these measures will need significant time for formal stakeholder feedback and vetting.

In addition, in the proposed QPP Update Rule, CMS is soliciting feedback on whether it would be helpful to provide more frequent feedback on the cost performance category using rolling 12-month periods or quarterly snapshots of the most recent 12-month period. Related to our comments above, AdvaMed believes that feedback should be provided more frequently than a 12-month period and recommends quarterly snapshots provided in a fully transparent manner to the clinicians and groups. It will be important for CMS to include also include performance information about episode-based measures before these measures are implemented.

2. Cost Performance Category: Episode Groups

For the 2018 MIPS performance period, CMS is proposing not to use the 10 episode-based measures that were adopted for the 2017 MIPS performance period. Although data on the episode-based measures have been made available to clinicians in the past, CMS notes that they are in the process of developing new episode-based measures with significant clinician input. AdvaMed agrees with CMS in this approach as it is critical to develop measures that incorporate ICD-10 coding and public input from all interested stakeholders.

As CMS continues to develop these new episode-based measures, AdvaMed would like to reiterate several points which we described in detail in our March 1, 2016 comment letter to the Agency. Specifically:

- CMS should ensure that there will be multiple opportunities for obtaining stakeholder input in the development of episode groups;
- Episodes dealing with chronic care should reflect the complex nature of care needed to treat this heterogeneous population;
- CMS should provide analysis showing episode variation in resource use;
- Resource use must be determined over an appropriate episode of care;
- Episodes, including benchmarks, should be developed with flexibility to allow for adoption of medical innovations and breakthrough treatments; and
- CMS must ensure that episode groups are appropriately risk adjusted.
These issues are especially relevant given the publication in the Federal Register of CMS’ proposed rule (CMS-5524-P) cancelling the Episode Payment Models – models for acute myocardial infarction (AMI), coronary artery bypass graft (CABG), and surgical hip/femur fracture treatment (SHFFT) – and the Cardiac Rehabilitation incentive payment model, which were scheduled to begin on January 1, 2018. Although these were mandatory models, as noted in the proposed rule many stakeholders had additional concerns such as provider burden and challenges related to the many concerns, including model design, quality measures, and episode length. AdvaMed has concerns with these same issues. These are similar concerns that have been noted with the prior episode-based measures that were developed. Therefore, CMS should work to ensure that future episodes are appropriately configured before implementation. As CMS moves to configure new episode-based measures with significant clinician input, we support any efforts to keep this process open and transparent. In this regard, we also recommend that CMS consider changing from the current sub-regulatory process to notice and comment rulemaking for more complete transparency.

3. Proposed Improvement Activities with Changes for the Quality Payment Program Year 2 and Future Years

AdvaMed supports the proposed changes noted in Table G (“Proposed Improvement Activities with Changes for the Quality Payment Program Year 2 and Future Years”) to IA_AHE_3, Leveraging a QCDR to Promote Use of PRO Tools (see below). In particular, we support the title change to Promote Use of Patient Reported Outcome Tools, including the examples of patient-reported Wound Outcome and patient-reported Nutritional Screening and elevating the weighting to “high”.

Wound deterioration and malnutrition are principal causes for re-hospitalizing patients each year. Continuity of nutritional care for malnourished and at-risk individuals is essential, especially for older adults. Increasing the risk of malnutrition is the presence of high-impact and costly chronic conditions, including conditions such as cardiovascular disease, stroke, diabetes, cancer, chronic obstructive pulmonary disease (COPD), renal disease, depression, and dementia. For nutritional screening we recommend use of tools such as the Malnutrition Screening Tool (MST) and the DETERMINE Checklist to collect community-dwelling older adults’ self-reported nutrition risk.

These changes will help in awareness of this activity and expanding the application of this improvement activity to include employing the PRO tools and corresponding collection of PRO data. Also, providing the additional examples of activities that may be appropriate for this improvement activity will add clarity for those seeking to use this activity.

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3 Watson et al., J Nurs Care 2014, 4:1; http://dx.doi.org/10.4172/2167-1168.1000224.
ALTERNATIVE PAYMENT MODELS (APMs)

1. Medical technology manufacturers as collaborators in Advanced Alternative Payment Models (AAPMs).

CMS has recognized that episode payment model participants may want to engage with organizations that are neither providers nor suppliers to assist with matters such as 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. 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 AAPM 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 AAPMs to meet their savings and/or efficiencies goals in care delivery.

AdvaMed urges CMS to allow medical technology companies to be official collaborators in AAPMs. Short of actually allowing medical technology manufacturers to serve as collaborators with Advanced Alternative Payment Models, CMS should request that CMMI, with its broad waiver authority, undertake demonstrations for defining circumstances when collaborative relationships between manufacturers and already permitted AAPM collaborators can take place for purposes of improving patient care outcomes.
2. Promoting risk-sharing arrangements between medical technology manufacturers and episode payment model (EPM) participants through Fraud and Abuse law waivers.

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. Further, the current Anti-Kickback Statute (AKS) safe harbors are narrowly constructed. 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).

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 Discount 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. 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 more fulsome 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.

**Recommendation:** In light of the challenges noted above and until new value-based safe harbors are issued, we believe 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.

- This would allow for 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.

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).
AdvaMed appreciates the opportunity to submit these comments in response to the Proposed Rule on the CY 2018 Updates to the Quality Payment Program (QPP). If you have any questions, please contact me or Richard Price at rprice@advamed.org or Steve Brotman at sbrotman@advamed.org.

Sincerely,

Donald May  
Executive Vice President,  
Payment and Health Care Delivery