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December 19, 2016

Via Electronic Mail

Andrew Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-5517-FC
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models; Final Rule with Comment Period

Dear Acting Administrator Slavitt:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am pleased to offer comments on the final rule with comment period on the Medicare Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule (CMS-5517-FC) published in the *Federal Register* November 4, 2016. 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 MIPS and APMs for the physician fee schedule and a value-based approach in setting payments for physician services. AdvaMed acknowledges that this is a complex program and appreciates that CMS has provided a variety of pathways for eligible clinicians to successfully begin participation in this program. We believe that CMS should continue to provide gradual transitions within MIPS and between the MIPS and APM portions of the program.

Our comments are organized into several sections related to the following overarching categories:

- **MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS)**
 - MIPS: COST PERFORMANCE CATEGORY
 - MIPS: CLINICAL PRACTICE IMPROVEMENT ACTIVITIES (CPIA) PERFORMANCE CATEGORY

MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS)

MIPS: COST PERFORMANCE CATEGORY

1. Episode-based Measures for the MIPS Cost Performance Category

In the final rule, after consideration of comments, CMS modified its proposal and for the 2017 performance period it finalized only 10 of the 41 proposed episode-based measures: Mastectomy, Aortic/Mitral Valve Surgery, Coronary Artery Bypass Graft (CABG), Hip/Femur Fracture or Dislocation Treatment (Inpatient-Based), Cholecystectomy and Common Duct Exploration, Colonoscopy and Biopsy, Transurethral Resection of the Prostate (TURP) for Benign Prostatic Hyperplasia, Lens and Cataract Procedures, Hip Replacement or Repair, and Knee Arthroplasty (Replacement). CMS states it selected these measures because they have been included in 2 years of feedback information to clinicians in the sQRUR reports. As there are numerous issues that need to be considered for the appropriate development and implementation of episode cost measures, **AdvaMed recommends that for 2018, CMS should maintain only the 10 episode-based measures put forth in the final rule and not provide additional episode measures without first receiving feedback from clinicians on the performance of these measures. In addition, AdvaMed recommends that CMS continues to provide performance feedback to clinicians before implementing them in the cost measure.**

In addition to the consideration of having clinicians gain experience with episode-based measures before expanding this portion of the program, there are additional concerns that warrant gradual adoption of these types of measures, which we have noted in our previous comments to CMS including the following:

- **CMS Should Ensure that there will be Multiple Opportunities for Obtaining Stakeholder Input in the Development of Episode Groups.**
 - In order to facilitate consideration of additional or different episodes from those CMS has identified, **we recommend CMS work collaboratively with medical specialties and provider networks to gain feedback on understanding which episode groups would be most appropriate.**

- **Episodes Dealing with Chronic Care Should Reflect the Complex Nature of Care Needed to Treat this Heterogeneous Patient Population**
 - By definition, chronic conditions are ongoing and open-ended since they are life-long for the patient. As such, the longer the duration of the episode (especially for episodes longer than a year) the more difficult it becomes to attribute provider responsibility for the treatment that may occur throughout the episode. Conversely, too short a duration may lead to episodes that risk further distorting incentives for care coordination. These episodes of shorter duration may capture a sicker underlying patient population that requires continual care and will only account for short-term costs and benefits. **AdvaMed recommends that CMS, with input from stakeholders, take into consideration a range of potential risk-factors and health outcomes in developing episodes for patients with chronic health conditions.**

- **Episodes Should be Developed with Flexibility to Allow for Adoption of Medical innovations and Breakthrough Treatments.**
 - We recommend that CMS develop a process for updating the items and services that are included in an episode group to reflect changes in the standard of care, including the use of new medical technologies and breakthrough treatments. **We recommend that CMS allow stakeholder input into this process to ensure that CMS has access to the most up-to-date information regarding best practices for treating patients.**

- **CMS Must Ensure that Episode Groups are Appropriately Risk Adjusted.**
 - Risk adjustment ensures that providers are accurately measured on outcomes or processes that they can influence, rather than underlying differences in patient severity. There are some inherent limitations in the handling of risk in the development of episodes. Given that many episode groupers use administrative claims data, there may not be sufficient granularity in the data in many cases to capture clinical characteristics or severity for certain episode types. **AdvaMed recommends that CMS consult with providers and other stakeholders in developing appropriate mechanisms for risk adjusting episode groups.**

- **CMS Should Provide Analysis Showing Episode Variation in Resource Use.**
 - The analysis of resource use variability across clinical episodes may help CMS to identify those clinical areas requiring more understanding prior to implementing an episode approach. For example, careful consideration of episodes where there is above average variation may reveal the need for subgroup splits that may not be obvious. Because wide variation in resource use represents greater risk to

providers treating patients within the episode, this information is essential to any meaningful assessment of the validity of an episode definition. **AdvaMed urges CMS to make episode variability statistics available to stakeholders.**

MIPS: CLINICAL PRACTICE IMPROVEMENT ACTIVITY (CPIA) PERFORMANCE CATEGORY

1. Inclusion of Additional Telehealth Services in CPIA Inventory

AdvaMed applauds CMS for providing innovative and creative ways to advance patient care for eligible clinicians or groups to satisfy the CPIA reporting requirements in multiple subcategories. In the final rule, CMS discusses the CPIA performance recommendations related to telehealth and notes that they will take these into account for future rulemaking. AdvaMed appreciates that CMS is continuing to focus and consider how important aspects of telehealth and remote monitoring could be implemented into the MIPS/APM program.

In the final rule, the use of remote monitoring or telehealth is mentioned only in two subcategories of the “Finalized Improvement Activities Inventory” (TABLE H): the Expanded Practice Access subcategory and the Population Management subcategory. Telehealth and remote patient monitoring technologies are generally recognized as fundamental tools for improving the efficiency and quality of health care. As the use and adoption of telehealth and remote monitoring is rapidly becoming an essential component of improving patient access to proper medical care and improving patient outcomes, **we request that, in the future, CMS include telehealth technologies among the examples in each of the subcategory activities included in the CPIA performance category and inventory.**

AdvaMed appreciates the opportunity to submit these comments in response to the Final Rule on Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule. If you have any questions, please contact me or Steve Brotman at sbrotman@advamed.org.

Sincerely,



Donald May
Executive Vice President
Payment and Health Care Delivery Policy