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**AdvaMed**  
Advanced Medical Technology Association

March 1, 2016

**Via Electronic Mail to [episodegroups@cms.hhs.gov](mailto:episodegroups@cms.hhs.gov)**

Andrew M. Slavitt  
Acting Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, M.D. 21244

**Re: CMS Episode Groups**

Dear Acting Administrator Slavitt:

AdvaMed appreciates the opportunity to respond to the request for comments by the Centers for Medicare & Medicaid Services' (CMS) regarding the summary document "CMS Episode Groups" as posted on the CMS website.<sup>1</sup> Our comments touch on a number of topics in the Summary Document including considerations on constructing episode groups, evaluating episodes, developing patient condition groups and developing patient relationship categories.

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. Our members range from the largest to the smallest medical technology innovators and companies.

CMS indicates that it is developing the episode groups and requesting public input in accordance with section 101(f) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). This section requires CMS to establish care episode groups and patient condition groups, and related classification codes, to measure resource use for purpose of MACRA's Merit-Based Incentive Payment System (MIPS) and alternative payment models (APMs).

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<sup>1</sup> <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html>

CMS seeks comments in response to specific and general questions concerning care episode groups, patient condition groups, and patient relationship codes. As the process of developing appropriate components of episode groups is extremely complex and ongoing, we are providing feedback on a number of high level issues that are essential in the development of these measures.

## **I. Considerations on Constructing Episode Groups**

### **A. CMS Should Ensure that there will be Multiple Opportunities for Obtaining Stakeholder Input in the Development of Episode Groups.**

As noted in the summary document, CMS is required to seek stakeholder input throughout the development of care episode and patient condition groups and codes, patient relationship categories and codes, and resource use methodology through solicitation of comment and other appropriate mechanisms, such as town hall meetings, open door forums, or web-based forums. The timelines for these stakeholder input opportunities have been summarized in Appendix A of the summary document. We have previously advocated for these forums in the context of developing episode groups/groupers through which stakeholders can learn more about the status and features of the Medicare-specific episode grouper, and CMS's initial views about episode-related methodological issues. These also would provide a forum for all interested parties to provide valuable — and early — feedback to CMS regarding these matters. These opportunities are important but should not replace CMS seeking stakeholder input and decision making through the formal notice and comment rulemaking process.

**We recommend that CMS schedule, as soon as possible, a variety of educational and feedback forums via multiple modalities, including town halls, webinars, open-door forums on all components of episode groups/grouper in order to receive adequate feedback for proper construction and implementation of this initiative.** Additionally, 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.**

We believe from our discussions with other stakeholders during the course of developing these comments, that there is a general lack of familiarity about this initiative and the specific episodes being developed. **Therefore, we urge CMS to be open to requests to provide input into its process on an ongoing basis as it develops and refines various aspects of episode group construction.** This is especially important as CMS develops its draft list of codes to be announced later this year. While the sets of codes provided along with the summary document provides useful insight into the beginning stages of developing clinical episodes based on claims data, the questions that have been raised by CMS in the summary document demonstrate the inherent challenges involved to develop meaningful clinical episodes. Providing these code lists on an ongoing basis and raising specific questions with informed stakeholders would be a good preliminary step in the process, advance pertinent dialogue and be useful for all parties. In this way, CMS would benefit from more robust clinical input, and stakeholders would also benefit from participating in shaping the clinical episodes that will be applicable in their area. **At a minimum,**

**on an annual basis, CMS should also continue to post specific information about care episodes and patient condition groups and codes and solicit formal comments about annual updates.**

### **B. Episodes Dealing with Chronic Care Should Reflect the Complex Nature of Care Needed to Treat this Heterogeneous Population**

The CMS summary document poses a question concerning the appropriate duration of patient condition groups for chronic conditions. 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. However, 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. Unfortunately, this approach may ultimately fail to identify longer-term value and might unintentionally result in discouraging the adoption and use of innovative medical therapies that may result in longer-term cost savings.

We believe that, in constructing episodes for chronically ill and patients with complex illnesses, it would be helpful to understand and identify the desired state and some of the most common complications for each chronic episode group — as well as the steps that can be taken to maximize or minimize the likely occurrence of either the desired state or the common complications. This question also highlights the need for CMS to work collaboratively with external stakeholders to develop valid and reliable episodes, especially for chronic conditions.

## **II. Considerations on Evaluating Episodes**

### **A. CMS Should Provide Analysis Showing Episode Variation in Resource Use.**

Although it is useful that CMS has provided the code sets related to the list of episodes in the supplementary materials in order to help commenters understand the opening, grouping and closing construction of the episodes, more detail is needed for external stakeholders to fully understand and assess the validity and reliability of the proposed episodes.

**We recommend that CMS provide analysis showing the variation in resource use within and across episodes to more fully understand and assess whether it is possible to reliably predict, within any particular episode, the average cost, median and range of the episode at a per member/patient level. We also recommend that CMS provide analysis showing the longitudinal distribution of clinical events identified in the claims in order to provide meaningful comments about the appropriate period at which to close the episode. The claims data should assess both homogeneous and heterogeneous patient populations to best address the generalizability of the data and impact of significant co-morbidities.**

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 intuitively 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 any particular episode definition.

**AdvaMed urges CMS to make available episode variability statistics as soon as possible in its ongoing process.**

### **B. Resource Use Must be Determined Over an Appropriate Episode of Care.**

Resource use needs to be determined over an appropriate episode of care which includes a sufficient period of time to assess the overall value of the services provided. One could easily draw erroneous conclusions about the relative value of care if an inappropriate time period is used. For example, a provider may have a choice between a lower-cost medical device which is expected to need replacement within a few years, necessitating another hospitalization, and a higher-cost device which will last many more years. If resource use, or costs, are measured based on an episode of care that only considers the hospitalization and perhaps a 90-day period post-discharge, the “total” cost of the episode may appear on its face to be a better value because the initial cost of the device was lower. These assessments would be inaccurate, as it would not consider the additional costs associated with a subsequent readmission, surgical costs and device replacement costs that could have been delayed or avoided if the higher-cost, longer lasting device was initially chosen. Assessments should consider global components that contribute to the total costs of care and include cost offsets, costs avoided and outcomes assessments. Readmission time lines may be best varied by the type and complexity of the episode and therapeutic intervention. Patient characteristics and demographics may further refine this analysis. We note, that even a one-year period might be insufficient to assess the value of many new technologies to patients and/or the health care system overall.

### **C. Episodes Should be Developed with Flexibility to Allow for Adoption of Medical innovations and Breakthrough Treatments.**

Although well-defined clinical episodes can be useful tools to improve the management of patient care delivery and to identify areas for improvement, it must be acknowledged, however, that medicine is a rapidly evolving field and any payment system will need to accommodate innovation. For example, new breakthrough treatments that change, or even eliminate, the long-term course of treatment may be more costly within a short-term episode than existing therapies.

Episodes that are defined on the basis of historical costs could discourage adoption of a breakthrough treatment. Therefore, some method to recognize meaningful innovation is needed.

**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 include**

**all relevant stakeholder input in this process to ensure that CMS has access to the most up-to-date information with regard to best practices for treating patients.**

### **III. Considerations for Developing Patient Condition Groups**

#### **A. CMS Must Ensure that Episode Groups are Appropriately Risk Adjusted.**

The purpose of risk or severity adjustment is to account for the patient-related clinical factors that exist prior to the patient's encounter with the provider being measured. This adjustment provides safeguards that providers are accurately being measured on outcomes or processes that they can reasonably influence, rather than underlying differences in patient severity. There are also 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.

Risk adjustment is a key element that must be valid, reproducible, sensitive and specific. Any flaws that may be present in the methodology to examine risk adjustment can potentially lead to flawed conclusions and therefore compromise the validity of the resultant conclusions. Thus it is important to consider as many relevant variables as possible in developing episode groups. For example, absent many times from the discussion on determination of risk stratification factors concerning hip/knee implants are individual patient measures in the orthopedic context such as functional/range of motion status, presence or absence of specific orthopedic pre-operative deformities, and other indicators and/or disorders involving variability of bone quality, including diseases/disorders affecting bone growth/functions and medications affecting mineral absorption and bone quality. AdvaMed believes that these patient-specific factors should be included in the risk stratification for episodes, as they vary from patient-to-patient and can play a very significant role in the post-surgical complication rate. CMS might consider the significance and development of ICD-10 codes in the future that could capture these types of patient-specific variations in all clinical fields, beyond orthopedics, and which could be included in the risk adjustment model. In addition, AdvaMed recommends that CMS work closely with stakeholders to address the existing shortcomings of the CMS Hierarchical Condition Category model as they consider risk adjustment methodologies for the MIPS and other APMs.

### **IV. Considerations for Developing Patient Relationship Categories**

#### **A. Attribution Considerations**

Attribution has become increasingly important in an ever-changing environment of public reporting, pay – for – performance, and performance penalties, where improvements in outcomes may not be ascribed directly to a single provider. There is general agreement among interested stakeholders that guidance is needed concerning the assignment of attribution of patients and care episodes, as lack of clarity in attribution approaches continues to be major limitation in the use of outcome and cost measures. To this end, the National Quality Forum (NQF) is currently

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conducting an environmental scan using a multi-stakeholder Standing Committee, to examine the strengths and weaknesses of the attribution models identified in the environmental scan. The environmental scan will be used as a foundation for establishing a set of principles and recommendations for applying the models within a complex healthcare delivery system. **AdvaMed recommends that CMS closely track the findings and recommendations of the “NQF Attribution Principles and Approaches Project.”**

Thank you for the opportunity to comment on the CMS Episode Groups summary document. Please feel free to contact me or Steve Brotman at [sbrotman@advamed.org](mailto:sbrotman@advamed.org) or 202-434-7207 with any questions.

Sincerely,

/s/

Donald May  
Executive Vice President  
Payment and Health Care Delivery Policy