

March 1, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Request for Information Regarding Episode Groups

Dear Acting Administrator Slavitt:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to offer our comments to the Centers for Medicare & Medicaid Services (CMS) regarding the Request for Information (RFI) on Episode Groups, as required by Section 101(f) of the Medicare Access and CHIP Reauthorization Act (MACRA).

The AMA was deeply engaged in the legislative process that ultimately led to the enactment of MACRA. The new physician payment framework in MACRA must be implemented in a way that will facilitate and support significant improvements in the delivery of care for Medicare patients and more sustainable physician practices. We understand that the current RFI is the first of several opportunities for stakeholders to comment on the development of episode groups. The AMA welcomes feedback from the agency on steps that the physician community can take to assist in construction of episode groups and related provisions of MACRA. A participatory process will increase the likelihood that physicians will find them clinically relevant for their practices, administratively feasible, and helpful in achieving better care for patients with judicious use of resources while preserving and strengthening high-quality medical practices.

Proposed Episode Groups and Grouping Method in Appendix B

In general, the AMA sees the use of well-constructed episode groups as a potential means of making more accurate comparisons of physician resource use than is possible with the cost measures now used in the value-based payment modifier (VBM). Many of the episodes in Appendix B need significant modifications, however, and some of those designed to measure hospital resource use are not likely to ever be useful for measuring care of physicians who work primarily in ambulatory settings. MACRA gives CMS some latitude to apply new episodes as well as the current VBM measures “as appropriate.” In our view, therefore, CMS has the flexibility to define new and refine old episode measures prior to moving full speed ahead with their implementation. **Initial efforts should focus on validity of the measures, not the volume of costs that are covered. Priority should be placed on a small set of**

measures that were developed for use in physician offices, not hospitals, and that have the support of the specialties that provide the key services within the episodes.

The AMA notes that the Brandeis-led Episode Grouper for Medicare (EGM) project developed many of the episodes. Others were developed by Acumen, which also tested and evaluated 26 episodes and an additional 38 subtypes through Medicare's supplemental Quality and Resource Use Reports. Apparently, additional episodes are to be released next month. Neither the design report nor other documents make any reference to the process by which the contractors developed and/or validated the episodes. **The AMA urges CMS to provide transparency about episode development and evaluation.** Comments that we have received from medical specialties indicate that solicitation of clinical feedback from the appropriate specialties has been inconsistent and sometimes inadequate. In addition, even in the instances where input was sought, the clinicians who devoted significant hours of their time were not always kept apprised of the results of their efforts or asked to comment on the final product. Input from practicing physicians is critical to the creation of groups that are relevant and trusted by physicians, but it will be very difficult to engage them in these efforts if there is no follow-up and transparency in the process. Posting episodes developed by a contractor working with a handful of "experts" on a website will not be sufficient. We appreciate the work that CMS has done in testing episode measures through the Quality and Resource Use Reports (QRURs) and believe this effort should be expanded and that the process for consulting QRURs should be simplified to encourage greater physician awareness and understanding of the use of episode groups to measure resources of pay for bundles of care.

The AMA also encourages CMS to ensure far greater involvement of physicians and the professional societies that represent them in future efforts to design, evaluate, and implement episode groups. It will be critically important for CMS to provide adequate opportunity for the specialties that primarily provide the key services in the existing episodes to review and comment on the episodes and grouping methods covered in the RFI. Input from specialties that have taken a close look at these episodes suggests that at least some of the groups have technical flaws that must be corrected prior to widespread use in Medicare. CMS should work with the AMA and other entities to ensure notice of comment periods on episode groups is properly communicated, should ask respective professional societies to have clinicians provide specific guidance, and should look to clinicians for input on what professionals are leads for various episodes. We also believe that, given the timing and limited notice regarding this RFI, the agency should accept and consider comments that come in after the March 1st deadline.

The AMA further recommends that CMS look to specialty societies for assistance in assessing the impact on patient access of the proposed episode groups. The impact of an episode grouper on access will depend on how it is designed. Factors of design that will be critical to avoiding undesirable effects include incorporating appropriate exclusions, making certain that only relevant and controllable costs are attributed to a given physician, segregating different types of patients or stages of disease into different episodes where appropriate, ensuring that all relevant costs are accounted for in the episode, and ensuring that physicians are not held responsible for cost changes—such as for new drugs or devices—that they cannot control. Episodes that hold physicians responsible for total costs, including unrelated services from other providers, are counterproductive and generally unacceptable. While claims analysis and scholarly articles are essential tools for episode developers, only physicians who deliver the covered services can accurately predict specific changes in treatment patterns and patient selection that could be

triggered by a particular episode. As previously noted, specialty advice should therefore be an integral part of any episode development and relevant specialties should be consulted at every stage of their design and evaluation.

The AMA supports development of episodes that involve care of patients with chronic conditions. For those patients with multiple chronic conditions, we envision episodes that combine commonly co-occurring conditions but would continue to treat other less common chronic condition combinations separately. Involvement of the appropriate clinicians and specialty societies will be vital in determining which conditions could be combined and how that should occur.

Suggestions and Rationale for Additional Episode Groups

As it seeks to supplement, refine, or replace current measures, CMS should focus on episodes designed specifically for use in physician settings. As the AMA has repeatedly noted, repurposing hospital measures for use in smaller physician practices is generally inappropriate. Rather than expanding on this practice, CMS should replace current hospital-intended measures with episodes that were developed in cooperation with physicians' professional societies and designed for use in the setting where the particular services are most often delivered. **Potential sources for additional episodes include recommendations from the medical specialties, state Medicaid programs, Qualified Clinical Data Registries, and specialties' alternative payment model (APM) submissions to the Center for Medicare and Medicaid Innovation.** Private payer initiatives endorsed by relevant specialties could also be considered. CMS could hold meetings similar to those that were used to develop RBRVS PE units to hammer out elements of episodes.

A successful implementation of MACRA also will require coordination between various units of CMS, including those running the alternative payment programs created in the Affordable Care Act and those responsible for implementing both the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) sections of MACRA. A number of specialties have developed or are in the process of developing APMs that center on defined episodes of care. In designing these models, the relevant specialties typically will have already provided the clinical scrutiny and expertise needed to ensure that appropriate costs are included and inappropriate costs are not. In addition, the specialty will have focused on those conditions where there is agreement and opportunity to reduce costs. Information about potential designs for APMs that could apply to conditions and episodes managed by diverse specialties, as well as examples of models that several specialties are developing which illustrate the APM designs, is available in the report, "[A Guide to Physician-Focused Alternative Payment Models](#)," developed by the AMA and the Center for Healthcare Quality & Payment Reform, available at www.ama-assn.org/go/apm.

While episodes of care defined in APM proposals can serve as a starting point and should be consistent with episodes associated with the MIPS program, some variation between the two types of episodes may be needed. For example, for services such as care coordination, which are not fully covered by Medicare, an episode of care covered in an APM may include specific care coordination activities that are not payable in fee-for-service (FFS) medicine and would not therefore be part of an episode used to measure resource use in FFS Medicare. In addition, to allow for legitimate differences between episodes used in MIPS and APMs, CMS will need to exercise some flexibility in application of the measures, such as in cases where a physician involved in APMs did not meet the threshold to be exempt from MIPS. If

episodes are built on claims data and a lot of services physicians provide in an APM are not separately payable by FFS Medicare, they will be left out of the episode. For a stroke patient, for example, there may be claims from many different physicians and other professionals, but there will not be a claim for a team leader who is coordinating the overall care of the patient because Medicare does not pay for this service.

The definition of the trigger for the start of an episode is an important aspect of episode construction. For example, for a patient who comes to the emergency department, is kept under observation for a day, and later is admitted as an inpatient, would the episode start with the emergency visit, the observation visit, or the hospital admission? Similarly, tests may be ordered for purposes of establishing a diagnosis and for ruling out other diagnoses. It will be important for CMS to consider whether any of these tests trigger assignment to an episode or whether the episodes begin after a diagnosis has been established.

To minimize new administrative and reporting burdens for physicians, CMS should consider what information is already collected on claims that can be used to assign patients to episode groups. For example, site of service information is already collected on claims and can be used to identify patients who are in a hospital, nursing home, or other facility without requiring the physician to separately report it. Physicians should therefore not need to place a new patient condition code that merely identifies where they received services on the claim form.

CMS also must consider how to address attribution issues with a much greater degree of validity than used in its various pay-for-performance initiatives to date. If a reliable and valid set of patient relationship codes is developed, these could be of great assistance in the attribution process. The AMA has some questions/reservations regarding the particular relationship codes defined in MACRA, and would also like to ensure that the codes do not create yet another administrative burden for physicians. We also agree that accurate attribution requires the identification of physician relationships that are not considered in current CMS methodologies. For example, CMS will need to consider relationships that physicians cannot currently code due to Medicare payment policies, such as indicating that they are a consulting or referral physician providing a report back to another physician. As also mentioned above, there should be some mechanism, at least in the APM setting, for physicians to indicate that they are the leader of a multi-physician team, or are advising the patient's primary care physician, or are managing the patient's recovery following an acute episode.

Responses to Questions

It is the AMA's intention that the following comments will provide guidance to CMS on developing plans for implementation of episode groups, and we look forward to future opportunities to provide comment. The AMA also urges CMS to consider and incorporate the specific professional society comments on the individual episodes, which reflect the relevant services that tend to be provided by their members.

Care Episode and Patient Condition Groups

- *Within a specialty, a limited number of conditions and procedures account for the bulk of spending. Focusing on the top conditions and procedures for a specialty, what care episode groups and patient condition groups would you suggest?*

- We do not accept the premise that every condition that has high associated Medicare spending should automatically be considered a good candidate for episode-based payment. Nor do we believe that all 44 measures in the set presented in the RFI should be employed by Medicare. There are many conditions in Medicare that generate high spending, not because they are overused or overpriced, but because they are prevalent in the Medicare population. There are other conditions where what constitutes the “best” treatment is not well-established or where variation in patients makes definition of an episode extremely difficult. It would be wasteful, counter-productive, and risky to create episodes for these conditions. Instead, CMS should work with specialties and consult previously-mentioned sources such as qualified clinical data registries and Medicaid to design episodes that address conditions where clinicians can identify excess costs that they can reasonably be expected to reduce.
- To identify and make recommendations on what care episode groups and patient condition groups for the top conditions and procedures for a specialty will require a comprehensive review of the proposed care episode groups and patient condition groups and their outcomes. A full evaluation would require access to the EGM software. CMS needs to follow-up, provide transparency, and to develop a process that involves all specialties that provide the service.
- **The initial weight (10 percent) assigned to the resource category as well as the section requiring CMS to develop new tools for measuring resource use are evidence that Congress did not regard the measures in the VBM as an adequate way to make fair and accurate comparisons of physician resource use.** While the AMA believes that more work is needed prior to implementation of the 44 episodes linked to this RFI, we agree that the measures used in the VBM are seriously flawed. CMS needs to devote significant data analysis and resources to this effort in order *to replace, not expand*, the current VBM cost and resource use measures. Simply layering new episode-based measures on the current system is unacceptable. CMS should also not transfer the existing VBM cost and resource use measures to the quality category, as suggested in CMS’ Quality Measure Development Plan Request for Information.
- In addition to their other flaws, VBM measures today are irrelevant for many physicians—either because no patients get attributed to them, or because the services provided are only a small percentage of total costs, and hence the physician had little or no opportunity to influence these expenses. Shortcomings in the attribution and risk adjustment methodology can also exacerbate the problem. If properly selected and designed, clinical quality measures aligned with episodes of care could increase the relevance, validity, reliability, and value of resource use measures and make physician feedback reports more actionable. This would also offer an opportunity to adapt risk adjustment and attribution methodologies to the individual condition or service being measured. However, it is likely that episode groups will never cover all physicians. CMS will need to think carefully and consult with the physician community on how to ensure that these physicians are not disadvantaged in the scoring process.

- *What specific clinical criteria and patient characteristics should be used to classify patients into care episode groups and patient condition groups? What rules should be used to aggregate clinical care into an episode group? When should an episode be split into finer categories? Should multiple, simultaneous episodes be allowed?*
 - CMS should consider professional society proposals regarding clinical criteria and patient characteristics for patient classification while allowing for flexibility for variation in patient care models across the Medicare population.
 - When aggregating clinical care into an episode group, CMS should consider things physicians can control, patient conditions where there is widespread agreement on appropriate care, conditions where you can reasonably identify start and stop points in care, and patient care where exclusions and exceptions can be explicitly described.
 - CMS should consider whether episodes should always be tied to the condition or disease that a patient has, or whether patients who have the same disease but very different treatment plans should be in different kinds of episodes. For example, would all patients with a particular type of cancer be grouped together, or would they be grouped based on medical management vs. surgery. Similar questions arise with regard to patients with different severity levels or stages of disease, as well as those with different comorbidities. As noted above, CMS could consider use of existing place of service in lieu of new patient condition codes to identify hospitalizations or other facility-based care.
- *Medicare beneficiaries often have multiple co-morbidities. Recognizing the challenge of distinguishing the services furnished for any one condition in the care of patients with multiple chronic conditions, how should CMS approach development of patient condition groups for patients with multiple chronic care conditions?*
 - The AMA urges CMS to ensure that episode groups capture the variety of structures of patient care models that exist, including the care coordination relationship between providers. Specifically, CMS should consider starting with conditions that are less likely to have multiple co-morbidities, are well understood and predictable, and where the major professional specialties endorse the episode group definition.
- *Given that these co-morbidities are often inter-related, what approaches can be used to determine whether a service or claim should be included in an episode?*
 - It will be necessary for CMS to consult with practicing physicians to glean this information, and different approaches may be needed for different types of episodes. For example, patients with diabetes frequently have hypertension, eye problems, and other comorbid conditions or complications. Whether the same physician typically manages the underlying condition and the comorbidities may affect the choice of approach. In MIPS, there may be overlap between episodes for different chronic diseases because payment will still go to whoever delivered the service.

- *What should be the duration of patient condition groups for chronic conditions (e.g., shorter or longer than a year)?*
 - The AMA believes that the duration of a patient condition group should allow for variation across patient populations and conditions and should be determined by clinicians who provide the services.
- *How can care coordination be addressed in measuring resource use?*
 - Care coordination should be promoted between providers of services. For example, support for care coordination for chronically ill patients at high risk of hospitalization can be provided through provider networks that include care coordinators, a chronic disease registry, and home telehealth technology. In many cases, care coordination will be rewarded by higher payment because it will lead to lower resource use and generate payment bonuses. However, these bonuses are not likely to totally compensate physicians for infrastructure costs associated with the most robust care coordination programs. Accordingly, CMS should consider other means of reimbursing physicians for these costs.
 - There are many high-value services that physicians provide that are not payable by Medicare and will not show up in claims. Physicians who consult with other physicians about how to improve management of their patients with particular conditions or comorbidities, who manage multidisciplinary teams, who provide self-management training to their patients and monitor data provided to them via phone or email, or who invest in after-hours care coordination services to reduce emergency visits and better coordinate care with emergency departments when such visits occur cannot be compensated for these services. As noted above, delivery of these services is unlikely to be reflected in episode groups because it will not be recorded on claims, yet it may lead to lower costs for the episodes. CMS should consider paying for additional care coordination services and should consider how to address these types of services in episode group and patient relationship code development.
- *CMS has received public comment encouraging CMS to align resource use measures (which utilize episode grouping) with clinical quality measures. How can episodes be designed to achieve this goal?*
 - The AMA agrees that you cannot truly interpret cost and resource use measures without explicit consideration of quality. As such, episode groups must be aligned with corresponding quality measures to ensure that costs are not reduced at the expense of quality. For example, an episode associated with a specific condition should have corresponding quality measures for the conditions to gain a full picture of the quality and efficiency of care for that condition.
 - Professional societies have significant expertise in identifying shortcomings with measure calculations and data, and can provide valuable input into the development of appropriate episodes with relevant quality measures. CMS, working in conjunction with

specialty societies, should identify where there are good conditions or procedures that can be captured through an episode and then wrap a quality measure around this potential episode. The episode group must be built first and then the quality measure(s) that go into it. In some instances, the quality measure may be in existence; others may require the development of new quality measure(s) to appropriately correspond with the episode.

- Currently, we are unaware of any resource use measures and clinical quality measures that are jointly developed. Hence, there will be challenges in aligning current measures by patient eligibility criteria, measure or data collection period, and other criteria. The AMA would urge CMS, at a minimum, to follow the recommendations regarding patients with diagnosis or procedure proposed in [“Efficiency and Value in Healthcare: Linking Cost and Quality Measures,”](#) a National Quality Forum commissioned paper. “Whenever possible, it is preferable for the specifications of the cost and quality indicators to be harmonized. This includes measuring cost and quality for comparable populations of patients, for the same time intervals of measurement, and the methods used to risk-adjust....”
- Episode measures potentially could account for both costs and quality measurement. This would require the identification of specific outcomes related to the condition or service being measured, rather than some general measure such as All Cause Readmissions.
- Therefore, CMS must have the ability for episode groups in the MIPS resource use category to interact with the quality category, including if a physician is participating in a QCDR. CMS will need to work in concert with the AMA and specialty societies to make this determination. As previously noted, we also urge CMS to eliminate the current cost and resource use measures utilized within the VBM as it moves to the adoption of episode groups.
- The existing cost and resource use measures do not provide actionable information back to the physician and, as mentioned earlier in our comments, are seriously flawed. The existing measures also penalize physicians multiple times for the treatment of the same costly patient due to their multiple comorbidities and unique situation.
- *Information that is not in the claims data may be needed to create a more reliable episode. For example, the stage of a cancer and responsiveness history may be useful in defining cancer episodes. How can the validity of an episode be maximized without such clinical information?*
 - The episodes could be constructed to include clinical data available and reported to CMS from electronic health records, registries, or large group practices. Specialties could help CMS identify the best data sources for constructing episodes. CMS should take care not to create massive new administrative burdens for physicians in its desire to ensure that costs are accurately attributed and measured. Physicians will be more willing to report data that they regard as useful in evaluating and improving care if CMS also eliminates some of the reporting burdens associated with the current cost and quality measures.

- CMS should conduct evaluations on the reliability of the episodes and share these results with the specialties that provide the service. These clinicians could then provide expert advice on the validity of the measure and any concerns that they have with the reliability scores. It should be noted that reliability of some of the value modifier measures are lower than many experts would recommend.
- *How can complications, severity of illness, potentially avoidable occurrences and other consequences of care be addressed in measuring resource use?*
 - Severity of illness is not a consequence of care and should not be treated as such. Complications and other consequences of care may or may not have been avoidable and may or may not have been predictable in a given subset of patients. In some cases, a risk adjustment could be designed to take account of likely complications in certain types of patients. Given the variability of these factors across patient populations, however, this is yet another place where input from the related professional societies will be essential.
- *Reliability of resource use measures are impacted by sample size. How should low volume patient condition groups and care episodes be handled?*
 - When making decisions about resource use measures, CMS should continue to adhere to its current policy of selecting only those measures which prove to be valid, reliable, and accurate upon analysis; are deemed statistically comparable; meet a minimum sample size of patients; are not first-year measures; and have proven, through concept testing, to be of value to consumers. With regard to appropriate minimum thresholds, CMS should keep in mind that these thresholds may vary across measures and even across specialties. Because CMS initially plans to focus on conditions that account for significant spending in Medicare, it seems unlikely that the conditions themselves will be low volume. Rather, the question would be whether individual physicians have enough patients that fall into a particular type of episode to reliably measure their resource use. These cases should be addressed with application of flexibility for decisions on resource use measures.
 - CMS should consider forming virtual groups as a means to increase sample sizes. CMS does not currently select only valid, reliable, and accurate measures.

Patient Relationship Codes

- *Episode Groups have traditionally considered a patient's course of care as a unit; including in it all care relevant to the course regardless of the specific provider. Section 101(f) of MACRA requires CMS to distinguish the relationship and responsibility of physicians and practitioners during the course of caring for a patient and to allow the resources used in furnishing care to be attributed (in whole or in part) to physicians serving in a variety of care delivery roles. While CMS will seek additional public comment on patient relationship codes in the future, we seek stakeholder input on how to simultaneously measure resource use based upon patient relationship while promoting care coordination and patient centrality.*

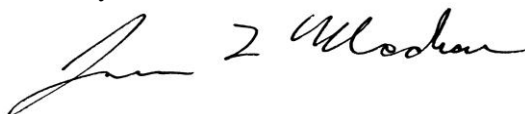
- The AMA supports robust engagement and consideration of feedback from professional societies to promote care coordination and patient centrality. CMS should allow for flexibility to aid in the implementation of measurement of resource use based on patient relationship. The AMA is seeking input from our members on the categories outlined in the law and will provide further input in the future.
- *Section 101(c) of MACRA requires CMS to give consideration to the circumstances of professional types (or subcategories of those types determined by practice characteristics) who typically furnish services that do not involve face-to-face interaction with a patient. Are there specific issues that should be considered when developing resource use measures which apply to these professionals?*
 - The AMA believes professional societies representing professionals who typically furnish services that do not involve face-to-face interaction with a patient should be engaged in development of resource use measures that apply to these professionals.

Additional Considerations

- *How should the resources be reported for an episode that is truncated (cut short, likely resulting in a resource usage reduction) by death or the onset of another related episode? Should imputed values be used to add resources to the truncated episode (for comparison purposes)?*
 - CMS should allow for a variety of approaches to report an episode that is truncated with an evaluation period for professionals to provide feedback, including potentially dropping these episodes. Imputed values should not be used to add resources or build out truncated or any other episodes.

Thank you for your careful consideration of the AMA's comments on the CMS RFI on Episode Groups. We appreciate the continued opportunities to offer recommendations to improve the implementation of MACRA. If you have any questions regarding this letter, please contact Sharon McIlrath, Assistant Director, Federal Affairs at Sharon.Mcilrath@ama-assn.org or 202-789-7417.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD