March 1, 2016

Andy Slavitt  
Acting Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Administrator Slavitt:

On behalf of the American Osteopathic Association (AOA) and the more than 123,000 osteopathic physicians and osteopathic medical students we represent, thank you for the opportunity to respond to the Centers for Medicare and Medicaid Services (CMS) Care Episode Groups and Patient Condition Groups.

The osteopathic profession strongly supported passage of the Medicare Access and CHIP Reauthorization Act (MACRA), and remains optimistic as we move toward a system that aligns well with the osteopathic philosophy of care – treating the whole person with a strong focus on prevention, wellness, and quality. During the law’s development, the AOA was especially supportive of MACRA’s focus on the value of care provided over volume. As defined in MACRA statute, application of new care episode groups as appropriate and patient condition groups creates a novel framework for assigning value to care. CMS is strongly positioned to favorably shape the implementation of MACRA and we are pleased to provide the following comments to the CMS on the listed questions as it undertakes this effort:

1. **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 offer that conditions and procedures that account for the bulk of spending vary between specialties and the site of service (hospital outpatient, physician’s office, etc.) in which care is provided. Conditions or procedures appropriate for grouping also will vary by specialty. In order to identify appropriate conditions and procedures, we recommend using a percentage of charges by the specialty to determine conditions and procedures, with 10 to 20 percent or higher volume as compared with total volume for conditions and procedures billed by that specialty. This will ensure sufficient volume to build the episode group as well as limit the number of conditions and procedures initially considered, until experience with the development of episode groups and payment mechanisms can be tested.
2. **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?**

Patient classification should be based on multiple components:

1. Risk adjustment for clinical factors including age, gender, condition, etc. as well as for non-clinical factors such as socioeconomic status and access to care, which impact clinical outcomes; and
2. Presence of multiple chronic conditions or co-morbidities, which merits further differentiation based on patient compliance with treatment, and disease management and improvement status (example: well-controlled and improving).

Aggregating clinical care into an episode group should follow actual clinical practice. In addition, episode groups should include definable beginning and end points. These points are easier to identify for acute care without history of illness (such as a ruptured appendix that necessitates surgical intervention), and planned surgical care (such as a knee replacement). However, for chronic disease as an example, beginning and endpoints are not present, as it persists over time. As such, grouping care related to a chronic disease into an episode would be based on an artificially established timeframe, which reoccurs. We suggest quarterly episode frequency as appropriate. For example, a patient’s care for diabetes may be cited as an episode from January to March, and then again from April to June, and so on.

Episodes can be split into finer categories, if needed, to align patient care with resource use. For example, for a knee replacement surgery, follow-up care will be different for a patient without complications than one who does have complications. In the latter case, additional resources and care will be needed to ensure the patient receives appropriate treatment. As such, the care episode split into the finer category of “with complications” ensures additional relevant resources and services are included in the episode.

As patients may face multiple health conditions at once, it is important that simultaneous episode groups are acknowledged. For example, the diabetic patient in the quarterly care episode for diabetes may require knee replacement surgery, which represents distinct and unrelated care in the same timeframe. The osteopathic philosophy lends itself to this holistic approach to patient care.

3. **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?**

We recognize challenges in assigning patients with multiple chronic conditions to patient condition groups. From a clinical point of view, many chronic conditions impact each other and the patient’s health. As such, it is nearly impossible to attribute specific aspects of a patient’s health to a single condition for patients with multiple chronic conditions. Therefore, we offer the following approach to assigning these patients.
First, peer-reviewed literature should be consulted to determine conditions that co-occur more than 50 percent of the time. Next, these conditions should be included in a single episode group identified by the predominant condition. Should the predominant condition change, the episode group also would change. This change in episode groups could occur as frequently as quarterly. However, billing for care under the episode group could occur on a more frequent basis, such as monthly. An illustration of this approach can be done with a diabetic patient. A high percentage of Type 2 diabetic patients have hypertension, hyperlipidemia, obesity, renal disease, and cardiovascular disease. In fact, practice guidelines require that these conditions be monitored and addressed in the diabetic patient, so the ‘diabetic condition’ episode should be constructed to include monitoring and treating all these conditions. If the patient develops renal failure, for example, the dominant condition would change to renal failure and the episode group also will change to reflect that. This change can be made in the first reporting quarter after the renal failure diagnosis is made.

Another aspect that is important to note is that chronic conditions can impact patient health differently based on risk factors (age, gender, etc.) and disease management (controlled and stable, or uncontrolled and unstable). For risk factors, patients will need to be stratified according to a common measure and to which each patient is compared. We note that this may be an easier task for physicians in larger practices. For disease management, we offer that two tiers should be defined with appropriate resource needs and payment attached to them: 1) controlled and stable, and 2) uncontrolled and unstable.

A final consideration is the resource use differential between facility and non-facility care. In order to ensure the episode group appropriately covers costs, two tiers may be appropriate for some conditions and procedures. For example, some patients with pneumonia require time in a hospital, while others may be treated outside of a hospital setting. Though the condition is the same, the resources used to treat the patient are not. As such, a distinction should be made between episode groups that include a facility versus ones that do not.

4. 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?

We appreciate CMS’ recognition that multiple co-morbidities are interrelated. This has several practical implications. First, we reiterate our point that peer-reviewed literature and practice guidelines can inform which comorbidities are included in the same episode group. For each episode group, the procedures and services that relate to care for the comorbidities included in the episode group can be identified based on aggregated claims from previous years. This approach will ensure procedures and services most often associated with care for those conditions are included in the episode group.

Second, the site of care may differ as patients may seek care in a physician’s office or hospital for the same disease. From a claims perspective, this means that multiple claims in multiple sites of service may relate to one patient with multiple co-morbidities. We reiterate our suggestion that episode groups should account for the use of facility-based versus non-facility care. This will require some claims to have a facility or non-facility indicator.
Third, multiple physicians and other health care providers may be involved in the care of a patient with multiple co-morbidities. As such, claims may be generated for multiple providers for a single patient with multiple co-morbidities. We offer that a care coordination team can aid in managing patient care and is of particular value for patients with multiple co-morbidities. As most health care providers will determine basic information, such as blood pressure, about a patient in their care, these patient interactions provide opportunities to collaborate and coordinate care across providers. To facilitate this coordinated care, we support the primary care provider as the lead of the care team. Further, we offer that the patient-centered medical home (PCMH) model provides an appropriate context for this care coordination.

Finally, in identifying and assigning claims related to patient care for patients with multiple co-morbidities, it will be likely that some claims will be missed or misassigned. We appreciate that even with well-coordinated care, other gaps may impact the attribution of claims. We seek insight from CMS as to the processes that will be set forth for providers to appropriately appeal any errors in assigning claims to episode groups.

5. **What should be the duration of patient condition groups for chronic conditions (e.g., shorter or longer than a year)?**

Patient condition can change more rapidly than a one-year period. In fact, we understand that some private insurers require patient assessment two times per year. This period of time may be appropriate for patients who are absent of major medical issues. However, for patients with chronic disease, clinical profiles can change more rapidly. As such, for these patients, we recommend a quarterly patient assessment for the purposes of assigning the patient to a patient condition group.

6. **How can care coordination be addressed in measuring resource use?**

Care coordination represents an investment in patient care from which better health outcomes generally result. As such, it is important that resource use is measured in terms of downstream outcomes, which may or may not be evident in a short period of time. Care coordination includes time with the patient to engage and educate, time with other health care professionals or staff to collaborate and share information, and time without others present to deal with administrative issues, such as appropriate documentation, follow up, and planning. This investment of time and documentation can reduce duplication of provider services and tests. It also fortifies non-clinical collaboration including referrals to community services and follow-up to learn if they were actually utilized by the referred patient. Further, claims data can be used to identify duplication of tests and other services within the same reporting period. As coordinated care would limit or eliminate duplication of services, this approach would highlight resource efficiencies associated with this care model. In order to track the proactive communication between providers who coordinate care, a separate code should be established, reported, and paid for to incentivize and reward coordination.

7. **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?**
We appreciate this question and CMS’ interest in streamlining measures. Streamlined measures may ease burden on providers and enable reasonable comparisons that can inform future care patterns. However, we caution that such alignment must be selective and carefully considered as resource use is often inversely related to quality measure outcomes. For example, for patients with chronic disease or multiple co-morbidities, increased resource use is needed to ensure high quality outcomes. As such, care must be tailored to the patients and their needs, which vary based on their health. We support accountability for resource use within the context of patient condition and need. However, we strongly oppose incentives for physicians to minimize resources to patients in order to meet measure use criteria. This is a disservice to patients and providers. Instead, we offer that accountability outside of measure reporting may provide appropriate incentives for providers. For example, unnecessary testing can be avoided by timely communication between specialists and primary care providers. This approach not only contributes to smart use of resources, but also improves health care quality, care coordination, and ultimately, patient outcomes.

8. 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?

We appreciate the challenges CMS identifies with this question. As much of reporting is quantitative information and coding rather than qualitative insight, current reporting is insufficient to use for validating episodes. However, we also appreciate that reporting should be minimized in complexity and volume in order to maximize providers’ time caring for their patients. We agree that there may be some conditions, such as cancer, that better align with this additional level of detail. For example, as cancer includes staging, we offer that other diseases to which this additional reporting would apply should be identified by a similar, simple series of identifiers. These may align with the identifiers we suggest for patient condition groups in question #3 above: well-controlled and stable; uncontrolled and unstable; care in facility, care in a non-facility setting. This approach may dovetail with the development of new codes for reporting purposes to capture unique situations that would have an effect on the episode inputs. Like patient condition group assignment, we offer that this validation can be done on a quarterly basis.

9. How can complications, severity of illness, potentially avoidable occurrences and other consequences of care be addressed in measuring resource use?

We appreciate that there are many factors which impact the use of resources. Further, the need for some of these resources is impacted by factors outside of the physician’s control such as patient compliance with recommended medication. In order to track and measure resource use, terms and standards need to be clearly defined, and providers must be able to implement them in real world clinical practice. The development, definition, and consistent use of standards across payers will not only ease provider adoption of these measures due to streamlining, but it also will provide a basis of data comparison across providers, which would further population health goals.

In addition, we offer that complications can be addressed by looking at established, where present, complication rates and incorporating these ‘acceptable’ rates in the development of episode groups.
This approach would reframe the notion that every complication has a negative impact, which is not reflective of real world management of clinical conditions and procedures. For the purposes of tracking and measuring complications, claims data can be used. In addition, truly avoidable complications could be identified by using existing standards such as the ‘never’ list hospitals and other facilities use to guide appropriate patient care.

10. Reliability of resource use measures are impacted by sample size. How should low volume patient condition groups and care episodes be handled?

We agree that low volume patient condition groups and care episodes are impacted by sample size. In order to ensure fair evaluation of resource use, we offer that low volume groups are supported in the current fee-for-service reporting and payment methods. We caution against comparisons between low and high volume groups for the purposes of resource use measures. In addition, we support approaches to initiate new resource use measures with only high volume groups until the methodology and implementation of more robust groups can be demonstrated in groups that are currently at low volume.

11. 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)?

We caution against attempting to assign resource usage on a granular level because this is sufficiently different than real world clinical practice. Furthermore, the extremes mentioned in this question represent statistical outliers, which in aggregate, will offset each other. Truncated episodes as a result of death will be offset by other episodes being miscalculated because of increased resource needs. When and if there is an onset of another episode, the provider will bill for the new episode in the next billing period. Assuming reasonable frequency of billing periods, such as monthly, overlap of related episode groups will be minimal and would negate the need for a complicated reconciliation process.

12. 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. 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.

Resources can best be measured when care is appropriately tracked in a single system. The PCMH provides a model for achieving these benefits. In this model, the primary care provider (PCP)
oversees the patient’s care and collaborates with members of the care team to coordinate care. As the PCMH is the central node of the patient’s care team network, relevant information about the patient and their care, including care from multiple providers and sites, is funneled into the patient’s central record. These clinical data inform further care and appropriately direct resources to the patient. The PCMH can be supported with a monthly payment for the coordination of care. This payment would be offset in part by efficiencies in resource use, such as avoiding duplication of testing and other services.

Using the PCMH model, the PCP would evaluate the patient and determine which, if any, episode groups appropriately describe the patient’s diagnoses. The PCP would bill for and receive payment for these services. Should the same patient require care in a hospital setting, payment for that care should be paid to the provider involved, which may or may not be the PCP. If a second provider is involved in providing care in the same episode, he should seek the primary provider who billed that episode to claim his percentage of the payment from that episode.

Care coordination is vital for high quality health care. In order to facilitate understanding of leadership roles, we have two additional suggestions. First, each episode group should have a lead provider based on the majority of the services provided in that episode group. For example, with a diabetes episode group, the primary care provider is the lead provider. With a myocardial infarction episode group, the cardiologist is the lead provider. Second, within each site of care in which a patient seeks care, a single provider should be identified as the lead provider. Further it will be the responsibility of the lead provider to coordinate with other providers in that site of care, as well as pass the baton to the lead provider in other sites of care, if and when the patient’s care is transferred to a new site. This model will maximize coordination and patient centrality.

Please do not hesitate to call on the AOA for insight as you develop these groups. To do so, or for additional information, please contact Ray Quintero, Senior Vice President for Public Policy, at rquintero@osteopathic.org, or (202) 349-8753.

Sincerely,

John W. Becher, DO
President