



March 1, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS Care Episode and Patient Condition Groups

Dear Acting Administrator Slavitt:

The American College of Physicians (ACP) appreciates the opportunity to provide feedback to the Centers for Medicare & Medicaid Services (CMS) on care episode and patient condition groups. The ACP is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 143,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

Reducing excessive healthcare spending is an important goal to the College as it is to CMS. However, the College is concerned that as CMS begins to align physicians through episodes of care, the resource use measurement may hold physicians accountable for services and care provided to patients when that care is not fully under their control. The development of episodes of care must not take a one-size-fits-all approach, subjecting all physicians to the same practice, payment, and specialty measures. **As CMS moves forward with development of regulations related to the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the College recommends CMS clarify how the care episode and patient condition groups will be implemented as they relate to the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) pathways.**

An episode of care group responsible for setting prospective bundled payment rates in an APM may not support that of a retrospective feedback report meant to educate and drive performance improvement under MIPS. Systems based on prospective payments generally have highly complex formulas. These formulas make it very difficult for anyone but professionals to understand, including patients, which can lead to misunderstandings and the

misclassification of medical procedures within the formula. The formula may not be able to easily account for quality or safety because those factors simply cannot be accurately expressed in figures. Today CMS employs variable measures for Hospital Value-Based Purchasing, Medicare Shared Savings Program Accountable Care Organizations, and the physician Value-based Payment Modifier. The proposed episode of care methodology and measures should follow suit – embracing the differences in the approaches for success associated with each program.

Implementing Episode Groups

The College recognizes that effective episode groups must be valid and reliable from a clinical perspective, identify practice patterns appropriately, and have risk adjustment capabilities that can account for differences in disease severity and the presence of comorbidities. **ACP urges CMS to gradually roll out episode groups to allow physicians the time to learn how to effectively integrate this new form of resource use measurement into their practices.** This will ensure that physicians and non-physician clinicians have the time to better understand the methodology and for any issues to be resolved. **During the first year learning phase, the College recommends that CMS not hold physicians accountable for audits or be targeted for recoupments based on use of episode groups.**

Involvement of Physicians, Patients, and Family/Caregiver Representatives

The College strongly urges CMS to include more physician involvement and transparency in the development process for episode groups. There will be wide variability in the effect that episode groups have on physicians that is dependent on a number of factors including practice setting, primary care v. other specializations, and the complexity of patient populations. The care episode analysis may be the first time many physicians and other eligible clinicians receive an assessment of resource utilization by Medicare. Increased physician involvement will be needed to arrive at the new episodes of care measures that are reliable, valid and provide easy-to-understand and well-documented reports. In addition to including physician specialists throughout the process, it is critical that patients and family/caregiver representatives be involved to ensure that development and implementation of episode groups considers the impact on patient access to quality care and avoids any negative, unintended consequences on patients.

Risk Adjustment

The prevalence of chronic comorbidities often requires multiple specialties treating a single patient for different conditions. Because of this, a single patient may have multiple concurrent episodes of illness requiring treatment. This issue leads the College to make the following recommendations:

- **The College recommends that CMS build into episode groups appropriate risk adjustments for severity to ensure that the episode itself is clinically homogeneous.** The goal of an episode of care is to focus care and clinically homogeneous pathways around the patient.

- **The College recommends that CMS require the patients' socioeconomic status be considered in risk adjustment methodology systems to avoid creating a disincentive to take on more difficult, disadvantaged populations.** It is important that physicians whose patient mix may be more severely ill not be disadvantaged by their resource use measures. Creating a disadvantage to taking on the more severely ill, medically complicated patients through inadequate risk adjustment methodology will also have a direct negative impact on patients and their families/caregivers in terms of access to appropriate, timely, quality care that is best suited to their unique needs. While socioeconomic status has been clearly linked to morbidity and mortality, the mechanisms responsible for the association may not be as well understood. Only focusing on health behavior is potentially problematic, if this behavior is viewed simply as a lifestyle choice. Episode groups must also promote access to the resources needed to engage in health-promoting behavior.
- **The College recommends that any risk adjustment method limit its adjustment to the severity of the patient or other characteristics the patient may have and not rely too heavily on the types of services to adjust payments.** It would be counter intuitive for the risk adjustment to factor out the variation that episodes are created to capture and incorrectly distinguish between physicians with healthier patients and those who provide better care.

Resource Use Management

Improving care cannot be measured by simply reducing healthcare spending associated with an episode of care. This approach could incentivize clinicians to choose the least costly alternative in treatment that may not offer the best quality of care for the patient, putting beneficiaries at risk. Clinicians should not have to be concerned with being penalized for selecting the best quality of care option to meet the unique needs of their patient population. Appropriate quality measures paired with resource use measurement is a strategic way of assessing improvement. Relevant clinical quality measures directly related to alleviating poor outcomes should be paired with episodes of care within the patient population. The agency could utilize such measures as readmission, mortality, complications, and patient experience as well as measures of beneficiary access to care. **The College recommends CMS study how to best link resource measures with quality measures to assess value associated with episodes of care and not simply cost.**

Small Group Practice

ACP also recommends that important consideration should be given to solo physicians and small group practices who may handle a low volume of patients in given care episodes or patient condition groups. Because the sample size for resource use measures for these physicians may be too small to be reliable and valid, there could be potential for unintended negative effects when evaluating resource use. The approach to setting up groups must be evaluated to ensure that physicians in all practice settings and sizes are given appropriate considerations. Measures should be specialty-adjusted and be determined to be sufficiently

reliable and valid for a given number of cases before physicians can be held accountable for their results.

ACP Responses to Specific Questions Posed by CMS:

- 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 would you suggest? Are they already included in Table 1 or should be included? Should any be excluded and why?**

The use of an economic analysis by specialty to determine the diagnoses, procedures, and conditions that account for the bulk of spending would be very beneficial in preventing some physicians from being disproportionately affected than other physicians. For example, a physician may see a paucity of diagnoses that would affect allergists and rheumatologists. The list of diagnoses included in the methodology should account for an equivalent sampling (say 50 to 70 percent of total charges) across all specialties (infectious disease doctors and orthopedic surgeons alike).

The criteria for including conditions on the list seem unclear given that some of the more common conditions have not been included. Common conditions missing from the list are hypertension, diabetes mellitus, anemia, osteoarthritis, and depression. However, we caution CMS against creating episode groups for all common chronic conditions due to the difficulties that may arise for a variety of reasons including:

- Some of the most common chronic conditions frequently occur in patients having comorbidities, making it difficult to isolate a single diagnosis and the related costs into one episode group. CMS should carefully consider how to account for this scenario before moving forward with creating episode groups for these conditions.
- Many medications that were developed for the treatment of one condition can be prescribed for other unrelated conditions (e.g., antihypertensive and antidepressant medications). The Agency should consider how to account for the costs of medications and treatments that can be used in the treatment of multiple, unrelated conditions so that they are not inappropriately tied to an episode group for a patient with a condition for which they were not prescribed as a treatment.
- The costs of testing for some conditions account for much higher resource utilization than the costs of treatment, and some conditions have treatments that cannot be captured with claims data. For example, the costs of testing for anemia likely outweigh the costs of treatment for the condition, which may include over-the-counter treatments like iron supplements that would not be captured by claims data.

Diagnostic groups should not be too broad and contain diagnoses that pertain mostly to a Medicare population. ACP recommends that CMS consider the following examples in determining which conditions and procedures to focus on for certain specialties:

Gastrointestinal

- Gastrointestinal (GI) hemorrhage is a term that is too non-specific for the purposes of determining an episode group. The College recommends that CMS divide GI hemorrhage into upper and lower GI hemorrhages and consider the possible other procedures that may be needed (e.g., upper endoscopy v. colonoscopy, CT scan may be necessary for lower GI bleed but not for upper GI bleed) as well as frequency of needing surgery, different medications, intensive care unit (ICU) stays, etc., which are different when the condition is upper (e.g., esophagitis, varices, ulcer) versus lower (e.g., diverticular, ischemic bowel). The Agency should also clarify whether this episode group refers to an acute GI hemorrhage requiring admission to a hospital.

Vascular

- CMS should add peripheral extremity arterial ischemic disease (frequently seen in either bypass or angioplasty procedures).

Musculoskeletal

- Spinal fusion is one of many spinal procedures, and it differs from other like laminectomy/discectomy in terms of expected hospital stay, possible complications, needs for post-hospital care, etc. CMS should consider whether to create additional episode groups for other spinal procedures or lump all procedures into one episode of spinal stenosis management.
- CMS should exercise caution if the Agency is considering developing an episode group for osteoarthritis because of inconsistent coding of the diagnosis due to the multiple different causes and related treatments that may not be captured within the diagnosis codes.

Metabolic

- Including osteoporosis as an episode group may prove difficult given the lack of clarity in how the diagnosis of the disease is related to the cause in any specific patient. CMS should consider adding other metabolic conditions with frequent diagnoses such as hypothyroidism.
- Chronic renal insufficiency should be considered, with care given the difficulties that may occur in teasing out the high-utilization involved with end-stage renal disease patients on dialysis and the many patients who are slowly getting "renal insufficient" and have that diagnosis tagged to them.

Cardiovascular

- Many cardiovascular conditions often occur in the setting of other cardiovascular conditions. To account for this, CMS should consider the difficulty that arises in determining which tests and medications should be attributed to the triggering diagnosis for the episode group when other cardiovascular conditions are present. For example, chronic atrial fibrillation, heart failure, and chronic ischemic heart disease are conditions that often occur along with other cardiovascular conditions.

To account for this issue, CMS should consider developing episode groups that include multiple cardiovascular conditions that frequently occur as comorbidities.

Cerebrovascular

- For ischemic stroke, CMS should clarify whether this refers to an acute stroke or whether it includes anyone with a history of stroke.

Infectious Disease

- CMS should reconsider the usefulness of having an episode group for urinary tract infection (UTI), and if the Agency determines that it is necessary, it should distinguish between men and women for UTI episode groups.

Respiratory

- The usefulness of having a group for acute upper respiratory infection (URI) is questionable. Given that over-the-counter treatments for URI are not captured by claims data, it may be difficult to accurately capture the costs associated with the episode of care.

2. Medicare beneficiaries often have multiple comorbidities. 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?

An equitable severity adjustment methodology should be applied within each diagnosis group, since patients with more comorbidities will have higher costs than other patients with fewer comorbidities even though they may have equivalent outcomes.

The initial condition groups that CMS has developed currently lack a separation of services that are under the control of various specialists. In further development of episode groups, we encourage CMS to aggregate the diagnostic tests and treatment expenses that are under the control of the specialist and ensure that attribution of costs is tied to those tests and treatment expenses that are under the control of the specialist.

CMS should also consider creating episode groups for selected combinations of conditions that often occur together, such as: a) atrial fibrillation and heart failure; b) hypertension and ischemic heart disease; c) hypertension, diabetes mellitus, and hyperlipidemia.

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

The duration of patient condition groups for chronic conditions should be empirically derived from the claims data based on the nature and severity of different chronic conditions and should not be selected through a one-size-fits-all approach. For example, an episode of diabetic ketoacidosis (DKA), congestive heart failure (CHF), chronic

obstructive pulmonary disease (COPD), or knee replacement might best be described with a 30- or 90-day duration, while a malignancy or vasculitis might best be described by a longer 6- or 12-month duration. As an example of the metric, one could size the duration of the grouper based upon allocating 70 or 85 percent of the total costs to that diagnosis in the time period.

Another approach may be subdividing episodes for chronic conditions. An arbitrary duration could reasonably be selected for a stable patient with a chronic condition. However, for those patients with episodic exacerbations, an arbitrary duration may not prove to be accurate. A physician may risk having one or several high-utilizing outlier patients for a particular disorder, which can give a false impression of having worse outcomes than a “typical” patient with the disorder.

The College greatly appreciates the opportunity to submit our comments on episode groups in response to the questions raised by CMS. If you have any questions regarding this letter, please contact Stacey Harms at sharms@acponline.org or (202) 261-4556.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert McLean MD, FACP, FACR". The signature is fluid and cursive, with the letters "R", "M", and "J" being particularly prominent.

Robert McLean, MD, FACP, FACR
Chair, Medical Practice and Quality Committee