March 1, 2016

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

Submitted electronically: episodegroups@cms.hhs.gov

CMS Episode Groups Request for Information

Dear Acting Administrator Slavitt:

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide written comments on the CMS Episode Groups Request for Information (RFI). As required by section 101(f) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), CMS is soliciting comments on specific episode groups and on specific clinical criteria and patient characteristics to classify patients into care episode and patient condition groups. Additionally, CMS seeks suggestions and rationale for additional episode groups.

ASTRO members are medical professionals practicing at hospitals and cancer treatment centers in the United States and around the globe. They make up the radiation treatment teams that are critical in the fight against cancer. These teams include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists and social workers. They treat more than one million cancer patients each year. We believe this multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy and coding for radiation oncology services.

CMS Designated Episode Groups

ASTRO appreciates CMS' desire to use episode groups as a mechanism for resource use management as required by the Merit Based Incentive Payment System (MIPS). However, we urge CMS to work with stakeholders in a transparent and collaborative way in the development of these episodes to ensure that they adequately account for all of the services involved in the process of care. We remain concerned that the methodologies used to develop other bundled payments, such as those for APCs and C-APCs in the hospital outpatient setting as well as the broader bundle developed for the CMMI Oncology Care Model, remain flawed. This can only be addressed through the implementation of a collaborative and transparent process for developing payment methodologies.

Additionally, ASTRO urges CMS to consider the application of episode groupers from a broader perspective. We understand that not all alternative payment models (APMs) will qualify as Physician Focused Alternative Payment Models as prescribed under MACRA. This indicates that some physicians may be operating in APMs and need to comply with the MIPS program. As such, APMs should also serve as episode groups where appropriate.

The CMS designated episode groups include surgical care associated with mastectomy and prostatectomy. However, there are no episodes that involve cancer treatment associated with radiation oncology. We urge CMS to consider episodes crafted in collaboration with specialty groups, such as radiation oncology, that dovetail with existing CMS episodes. ASTRO has developed two APMs that address episodes of care for the palliative treatment of bone metastases and the treatment of early stage breast cancer. Both models include distinctive points at which the episode of care begins and when the episode ends. The models feature defined services covered by a single payment that allow physicians the flexibility to choose treatment modalities appropriate to their patient's needs, as well as quality measures that ensure improved patient outcomes. These models are defined episodes of care that can achieve our shared goals of improving quality of care and ensuring appropriate utilization of health care resources. We urge CMS to work with stakeholders on the implementation of specialty specific APMs that can meet the requirements of both the APM and MIPS initiatives.

While episodes of care defined in APMs 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. 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 number of the services physicians provide in an APM are not separately payable by FFS Medicare, they will be left out of the episode. For a cancer 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.

<u>Response to Episode Grouper RFI Questions:</u>

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?

In identifying the conditions and procedures which would be appropriate for episode groups or patient condition groups, CMS should consider those conditions and procedures for which there

are established processes of care. ASTRO used existing Evidence-based Guidelines, as well as *Choosing Wisely* recommendations, when developing its APMs. Choosing Wisely recommendations reflect strong consensus recommendations within the field regarding when tests and procedures may be appropriate.

ASTRO cautions CMS against focusing only on those conditions and procedures which consume the bulk of Medicare spending. While this is certainly important, many high cost procedures are particularly complex and costly for a variety of reasons. For the purposes of establishing initial episodes of care, it is more important to focus on procedures and conditions for which there are evidence-based guidelines. Additionally, CMS should take measures to prevent the potential for underutilization that are sometimes associated with episode groups. Guidelines can provide protection against underutilization and assurances that treatments are appropriately used.

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?

Flexibility should be given on the development of the appropriate clinical criteria and patient characteristics used to classify patients into care episodes. CMS should start with conditions and procedures for which there are clear evidence-based guidelines and then risk adjust the episode to account for variation in clinical conditions (i.e. stage I breast cancer patient with a BMI exceeding a certain threshold). In addition to risk adjusting for co-occurring clinical factors, CMS should establish a mechanism for excluding patients who present with too many concurrent conditions that may complicate treating the primary diagnosis. It will be key for CMS to engage medical specialty stakeholders to develop appropriate criteria.

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?

CMS should develop episode groups that clearly define and attribute responsibility for care to physicians that they can reasonably control. As previously stated, ASTRO urges CMS to include risk adjustments that address multiple chronic care conditions. The agency should also establish a stop loss policy that would prevent harming the physician financially for taking on complex cases with multiple chronic conditions.

As an example, the ASTRO palliative care for bone metastases model seeks to establish an episode that encompasses the treatment and follow up care needed to treat this particular patient group. The model contains a treatment guarantee for up to 28 day post treatment. Patients who continue to experience pain associated with bone metastasis are retreated within the episode of care during that post treatment period at no additional cost.

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?

Again, episodes of care must be clearly defined and they must include those outcomes that the physician can reasonably control and, to some extent, prevent.

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?

Episodes need to be clearly defined and recognize all of the activities involved in the process of care, and we agree that key clinical information such as cancer stage may be critical in defining a cancer episode. Another significant challenge for episodes based on claims data is that they will not recognize the services physicians currently provide that are not payable by FFS, such as care coordination. CMS must recognize this deficit in the claims data and work with specialty groups to identify and value those services that improve the quality of patient care but are currently not paid for under the FFS system.

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

As stated above, CMS must consider how to risk adjust resource use to recognize these issues. Additionally, ASTRO urges CMS to institute a stop loss policy to prevent physicians who care for more medically complex patients from being penalized.

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

ASTRO urges CMS to focus on episodes for which there are known evidence-based guidelines. By starting with episodes that are easily defined by existing processes of care, CMS is more likely to achieve its intended goal of instituting a value based payment system. CMS should avoid episodes that involve conditions that may not include standards of care. These cases, deserve more thought and consideration before resource use is measured, especially in situations where the resource use may vary significantly from patient to patient due to condition complexity.

Additional considerations

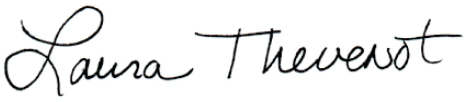
How should the resources be reported for an episode that is truncated (cut short, likely resulting in a resource usage reduction) by death or the onset of another related episode? Should imputed values be used to add resources to the truncated episode (for comparison purposes)?

We agree that episode groups must account for situations where patients may rapidly decline or die as a result of their condition or another condition. While it cannot always be known if a patient will be able to complete an episode of care at the onset of the episode, there should be a mechanism for addressing situations in which a patient does not complete the episode of care for

any reason. This is particularly important in cancer care. In order to better understand this phenomenon and its impact, CMS should consider running models with multiple approaches to the situation to better understand the impact and how to account for it.

ASTRO appreciates the opportunity to comment on the CMS Episode Groups RFI. If you have any questions or require additional information, please contact Anne Hubbard, Director of Health Policy at 703-839-7394 or anne.hubbard@astro.org.

Sincerely,



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