



ACUMEN

**Episode-Based Cost Measure Development for
the Quality Payment Program**

Public Comment Summary Report:
Verbatim Comments

October 2017

1. OVERVIEW

This document contains the verbatim comments received in response to the Centers for Medicare & Medicaid Services (CMS) posting for public comment in December 2016. The comments are summarized, with responses to comments, in the accompanying document titled “Episode-Based Cost Measure Development for the Quality Payment Program: Public Comment Summary Report.”

CMS’s request for feedback consisted of two documents:

- A draft list of episode groups and trigger codes for public comment, as required by Section 101(f) of Medicare Access and Children’s Health Insurance Program (CHIP) Reauthorization Act of 2015 (MACRA)¹
- A document outlining episode-based cost measure development for the Quality Payment Program which included specific questions for stakeholders².

The public comment period for these two documents (“December 2016 posting”) was open from December 23, 2016 to April 24, 2017. During this period, Acumen, LLC, the measure development contractor, received 69 comments from stakeholders as listed in Table 1, below.

Table 1. Index of Commenters

#	Submission Date	Name	Professional Title	Organizational Affiliation
1	1/2/2017	Matt Hawkins	Director, Pediatric Interventional Radiology	Children’s Healthcare of Atlanta at Egleston
2	2/3/2017	Rachel Groman*	Vice President, Clinical Affairs and Quality Improvement	Hart Health Strategies
3	3/27/2017	Cheryl L. Nimmo	President	American Association of Nurse Anesthetists
4	3/29/2017	Terrence L. Cascino	President	American Academy of Neurology
5	4/5/2017	Susan Kay	Quality Manager	Teton Valley Health Care
6	4/9/2017	Harold D. Miller	President and CEO	Center for Healthcare Quality and Payment Reform
7	4/13/2017	Amanda Cassidy*	Health Policy Advisor	Arnold & Porter Kaye Scholer, LLP
8	4/19/2017	Mark A. Levine	--	--
9	4/19/2017	James S. Kennedy	President	CDIMD – Physician Champions
10	4/20/2017	David Slotwiner	Chair, HRS Health Policy Committee	Heart Rhythm Society
11	4/21/2017	Sharon L. Dunn	President	American Physical Therapy Association
12	4/24/2017	Laura I. Thevenot	Chief Executive Officer	American Society for Radiation Oncology

¹ Draft List of MACRA Episode Groups and Trigger Codes, *CMS MACRA Feedback page*, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/draft-list-of-care-episode-and-patient-condition-groups-and-codes.zip>

² Episode-Based Cost Measure Development for the Quality Payment Program, *CMS MACRA Feedback page*, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Episode-Based-Cost-Measure-Development-for-the-Quality-Payment-Program.pdf>

#	Submission Date	Name	Professional Title	Organizational Affiliation
13	4/21/2017	Samir Fakhry	Chair	Trauma Center Association of America
14	4/24/2017	Kerry D. Solomon	President	American Society of Cataract and Refractive Surgery
15	4/24/2017	Peter D. Stetson	Chief Health Informatics Officer, Deputy Physician-in-Chief	Memorial Hospital for Cancer and Allied Diseases
16	4/24/2017	Wanda D. Filer	Board Chair	American Academy of Family Physicians
17	4/24/2017	Caroll Koscheski	Member, ACG Board of Trustees	American College of Gastroenterology
18	4/24/2017	Sharad Lakhanpal	President	American College of Rheumatology
19	4/24/2017	Dale N. Schumacher	President	Rockburn Institute
20	4/24/2017	James L. Madara	Chief Executive Officer & Executive Vice President	American Medical Association
21	4/24/2017	Gail J. Richard	President	American Speech-Language-Hearing Association
22	4/24/2017	Jeffrey Plagenhoef	President	American Society of Anesthesiologists
23	4/24/2017	Henry W. Lim	President	American Academy of Dermatology Association
24	4/24/2017	Amanda Cassidy*	Health Policy Advisor	VisionCare, Inc
25	4/24/2017	James C. Denny III	Executive Vice President and CEO	American Academy of Otolaryngology - Head and Neck Surgery
26	4/24/2017	Andrés Rodríguez	VP, Clinical Affairs	Infectious Diseases Society of America
27	4/24/2017	Jacqueline W. Fincher	Chair, Medical Practice and Quality Committee	American College of Physicians
28	4/24/2017	Christine M. Jackson	Sr. Director, Global Health Policy, Reimbursement, and Health Economics	Medtronic
29	4/24/2017	William J. Maloney	President	American Association of Orthopaedic Surgeons
30	4/24/2017	Raymond Russell	President	American Society of Nuclear Cardiology
31	4/24/2017	Josanne K. Pagel	President and Chair of the Board	American Academy of Physician Assistants
32	4/24/2017	Michael X. Repka	Medical Director for Government Affairs	American Academy of Ophthalmology
33	4/24/2017	Annie Purcell	Chair, Reimbursement and Policy Review Committee	American Academy of Physical Medicine and Rehabilitation
34	4/24/2017	James Gardner	Medical Science Officer, Vice President Reimbursement	Cook Medical
35	4/24/2017	Kenneth C. Anderson	President	American Society of Hematology
36	4/24/2017	Anders Gilberg	Senior Vice President, Government Affairs	Medical Group Management Association
37	4/24/2017	Lisa Miller Jones	Regulation, Policy Manager	American Urological Association
38	4/24/2017	Thomas A. Buchholz	Executive Vice President and Physician-in-Chief	The University of Texas MD Anderson Cancer Center
39	4/24/2017	Krishna Komanduri	President	American Society for Blood and Marrow Transplantation
40	4/24/2017	Ronald Fairman	President	Society for Vascular Surgery
41	4/24/2017	Ellen Flaherty	President	American Geriatrics Society
42	4/24/2017	Karen Bird	Executive Director	Alliance of Dedicated Cancer Centers
43	4/24/2017	Sharmila Sandhu	Counsel and Director of Regulatory Affairs	The American Occupational Therapy Association
44	4/24/2017	Debra Johnson	President	American Society of Plastic Surgeons
45	4/24/2017	David B. Hoyt	Executive Director	American College of Surgeons
46	4/24/2017	Boyd R. Buser	President	American Osteopathic Association

#	Submission Date	Name	Professional Title	Organizational Affiliation
47	4/24/2017	Gregory B. Seymann	Chair, Performance Measurement and Reporting Committee	Society of Hospital Medicine
48	4/24/2017	Tod Ibrahim	Executive Vice President	American Society of Nephrology
49	4/24/2017	Bob Hussey	--	Wolters Kluwer Health
50	4/24/2017	Howard Rogers	Physician	Advanced Dermatology
51	4/24/2017	Steve Phillips	Senior Director, Global Health Policy	Johnson & Johnson
52	4/24/2017	Carolyn C. Ha	Director, Policy & Research	Pharmaceutical Research and Manufacturers of America
53	4/24/2017	Ira H. Kraus	President	American Podiatric Medical Association
54	4/24/2017	Stephen A. Tilles	President	American College of Allergy, Asthma, and Immunology
55	4/24/2017	Robert Coughlin	Reimbursement Manager	Moffitt Cancer Center
56	4/24/2017	Cynthia R. Moran	Executive Vice President	American College of Radiology
57	4/24/2017	Donald May	Executive Vice President, Payment and Health Care Delivery Policy	AdvaMed
58	4/24/2017	Thomas Stasko	President	American College of Mohs Surgery
59	4/24/2017	Joseph A. Hill	Chair, Advocacy	Heart Failure Society of America
60	4/24/2017	David B. Peden	President	American Academy of Allergy, Asthma & Immunology
61	4/24/2017	Michael Camilleri	Chair	American Gastroenterological Association
62	4/24/2017	Daniel F. Hayes	President	American Society of Clinical Oncology
63	4/24/2017	Michael Stevens	President	Coalition of State Rheumatology Organizations
64	4/24/2017	James L. Gajewski	--	--
65	4/24/2017	Kenneth R. McQuaid	President	American Society for Gastrointestinal Endoscopy
66	4/24/2017	Carolyn Magill	CEO	Remedy Partners, Inc.
67	4/24/2017	Gary H. Swartz	Senior Advisor for Public Policy	American Academy of Home Care Medicine
68	4/25/2017	Mary Norine Walsh ⁺	President	American College of Cardiology
69	5/5/2017	Andrea P. Thau ⁺	President	American Optometric Association

* While these stakeholders did not directly comment on the December 2016 posting, their feedback was related to the measure development process and previous episode groups postings, so have been included in this report for completeness.

⁺ These commenters submitted a comment after the close of the public comment period on April 24, 2017. Their comments have been included in this report for completeness.

2. VERBATIM COMMENTS

This section contains the verbatim comments received in relation to the December 2016 posting. The comments are organized by the comment numbers in Table 1, above, and include the submission date of the comment, and the commenter's name, professional title, and organizational affiliation. Attachments have been noted but not included in this report.

COMMENT 1 OF 69

Date: 1/2/2017

Commenter Name, Professional Title, and Organizational Affiliation: Matt Hawkins, Director, Pediatric Interventional Radiology, Children's Healthcare of Atlanta at Egleston

Text of Comment:

Thank you for the opportunity to provide feedback as it relates to the process of cost measure development. I will try to limit my comments to the development process at this point, rather than on the specific episode/procedure groups. Two major issues regarding the process require mention at this point.

1) Re: Responsibility Attribution

Two specialties are in a particularly challenging situation as it relates to cost attribution. Those are radiology and pathology. In many/most instances, these physicians have little to no control over what studies are ordered by other physicians. However, once ordered, their expertise is required to interpret images/pathology specimens. Certainly, there are instances where radiologists are the CAUSE of additional imaging, either b/c of a recommendation, or b/c the wrong test was performed in the first place. This conundrum re-emphasizes the importance of clinical-decision support software, that can hopefully curb unnecessary utilization of medical imaging. However, these specialties may require difference consideration/weighting for this MIPS component (cost) unless stronger mandates regarding CDS software are implemented.

2) Re: Risk adjustment

Additional risk adjustment is required than the CMS-HCC Risk Adjustment Model. Although this model is well-tested – it does not take into account the most up-to-date patient health status. Both one-year prior and concurrent risk adjustment is necessary. This is particularly important for the acute episode groups and procedure groups. This of course seems obvious, but needs to be accounted for. It may be most appropriate if some of the procedural episode groups that deal with very hyperacute diseases (ie. AAA repair, thoracic aortic aneurysm repair, coronary thrombectomy, stroke/arterial thrombectomy) be eliminated – as the severity of illness in these settings can vary tremendously, be very different from what data is available prospectively, and be un-measurable using claims data.

Lastly – a few notes regarding procedural episode groups: 1) Vertebroplasty should include kyphoplasty as well; 2) Upper and lower diagnostic endoscopy should be included. (Screening colonoscopy is the only enteric endoscopy included now)

COMMENT 2 OF 69

Date: 2/3/2017

Commenter Name, Professional Title, and Organizational Affiliation: Rachel Groman, Vice President, Clinical Affairs and Quality Improvement, Hart Health Strategies

Text of Comment:³

I am a consultant for 10+ professional societies who are interested in commenting on the draft MACRA episode groups and trigger codes. However, we are confused about this latest posting, which only seems to include the names of the episode groups and the trigger codes, but no other relevant information about the episode parameters/relevant codes. Should we assume that the Episode Workbooks posted late last year and available for download at the very bottom of this website are still valid and should be matched up to the newest list of episode groups and trigger codes? If not, when can we expect to see more details about each episode beyond the trigger codes?

Date: 3/14/2017

Text of Comment:

As a follow-up to my earlier inquiry below, I was wondering if you could clarify whether the 10 episode-based cost measures that were finalized for the 2017 MIPS are still evolving under the process outlined below or if we can assume that CMS will maintain them in their current form going forward (when the cost category is potentially no longer zeroed out). We are giving a presentation on episodes that impact gastroenterologists and they would like to know more about what the future of cost measurement under MIPS looks like. Since colonoscopy was included on the list of 10 approved for MIPS this year, we would appreciate some insight on what we they can expect in the future in terms of this particular cost measure. Thanks so much for your ongoing assistance.

COMMENT 3 OF 69

Date: 3/27/2017

Commenter Name, Professional Title, and Organizational Affiliation: Cheryl L. Nimmo, President, American Association of Nurse Anesthetists

Text of Comment:

The American Association of Nurse Anesthetists (AANA) welcomes the opportunity to comment on the Centers for Medicare & Medicaid (CMS) posting entitled “Episode-Based Cost Measure Development for the Quality Payment Program.” The AANA makes the following comments and requests of CMS:

³ While this comment did not directly respond to the December 2016 posting, the feedback was related to the measure development process and previous episode groups postings, so has been included in this report for completeness.

- Ensure equal treatment of CRNAs and anesthesiologists.
- All episode group cost measures attributed to anesthesia providers should be based on the care that is influenced or directly managed by them.
- If an attribution methodology cannot adequately account for the anesthesia services CRNAs and other anesthesia professionals furnish, CMS should develop anesthesia care episode groups with corresponding anesthesia group measures.

Background of the AANA and CRNAs

The AANA is the professional association for Certified Registered Nurse Anesthetists (CRNAs) and student nurse anesthetists, and AANA membership includes more than 50,000 CRNAs and student nurse anesthetists representing over 90 percent of the nurse anesthetists in the United States. CRNAs are advanced practice registered nurses (APRNs) who personally administer more than 43 million anesthetics to patients each year in the United States. Nurse anesthetists have provided anesthesia in the United States for 150 years, and high-quality, cost-effective CRNA services continue to be in high demand. CRNAs are Medicare Part B providers and since 1989, have billed Medicare directly for 100 percent of the physician fee schedule amount for services.

CRNAs provide every aspect of the delivery of anesthesia services including pre-anesthesia patient assessment, obtaining informed consent for anesthesia administration, developing a plan for anesthesia administration, administering the anesthetic, monitoring and interpreting the patient's vital signs, and managing the patient throughout the surgery. CRNAs also provide acute and chronic pain management services. CRNAs provide anesthesia for a wide variety of surgical cases and in some states are the sole anesthesia providers in nearly 100 percent of rural hospitals, affording these medical facilities obstetrical, surgical, trauma stabilization, and pain management capabilities. According to a May/June 2010 study published in the journal of Nursing Economic\$, CRNAs acting as the sole anesthesia provider are the most cost-effective model for anesthesia delivery, and there is no measurable difference in the quality of care between CRNAs and other anesthesia providers or by anesthesia delivery model.¹ Furthermore, an August 2010 study published in Health Affairs shows no differences in patient outcomes when anesthesia services are provided by CRNAs, physicians, or CRNAs supervised by physicians.² Researchers studying anesthesia safety found no differences in care between nurse anesthetists and physician anesthesiologists based on an exhaustive analysis of research literature published in the United States and around the world, according to a scientific literature review prepared by the Cochrane Collaboration.³ Most recently, a study published in Medical Care June 2016 found no measurable impact in anesthesia complications from nurse anesthetist scope of practice or practice restrictions.⁴

CRNAs play an essential role in assuring that rural America has access to critical anesthesia services, often serving as the sole anesthesia provider in rural hospitals, affording these facilities the capability to provide many necessary procedures. The importance of CRNA services in rural areas was highlighted in a recent study which examined the relationship between socioeconomic factors related to geography and insurance type and the distribution of anesthesia provider type.⁵ The study correlated CRNAs with lower-income populations and correlated anesthesiologist

services with higher-income populations. Of particular importance to the implementation of public benefit programs in the U.S., the study also showed that compared with anesthesiologists, CRNAs are more likely to work in areas with lower median incomes and larger populations of citizens who are unemployed, uninsured, and/or Medicaid beneficiaries.⁶

AANA Request: Ensure Equal Treatment of CRNAs and Anesthesiologists

Anesthesia providers should be attributed episode groups based on the CPT/HCPCS codes they bill, which accurately represents the anesthesia care services they provide and not their professional title. Distinguishing between CRNAs and anesthesiologists based solely on their titles fosters professional discrimination between providers that furnish the same anesthesia care to all patients. We ask that CMS should ensure equal treatment for CRNAs, as listed as 43 under the Healthcare Provider Taxonomy Code Set, and anesthesiologists, as listed as 05 under the Healthcare Provider Taxonomy Code Set. Both CRNAs (43) and anesthesiologists (05) should be recognized equally as eligible clinicians under the specialty of anesthesiology as providers that render anesthesia services.

AANA Request: All Episode Group Cost Measures Attributed to Anesthesia Providers Should be Based on the Care that is Influenced or Directly Managed By Them

Merit-Based Incentive Payment System (MIPS) eligible clinicians, such as CRNAs, will be attributed procedural treatment measures and acute care measures and Medicare beneficiaries under the Cost performance category. The attribution of measures and beneficiaries is significant to CRNAs since resource use is a key factor in assessing a clinician's performance based on cost. We urge CMS to ensure that all episode group cost measures attributed to anesthesia providers must be based on care that is influenced or directly managed by a CRNA or an anesthesiologist. CRNAs may be at financial risk under the Cost category if the total cost for all services in the episode is determined to be "high cost." This designation may have an unjustified negative impact on a CRNA's overall composite performance score. The episode group measures should accurately account for the true cost of providing anesthesia care services and should accurately attribute anesthesia care services to the proper clinician. Anesthesia professionals cannot afford to absorb costs that were caused by and the responsibility of other clinicians. We also recommend that CMS develop an anesthesia care services measure to ensure that anesthesia services are appropriately attributed to the provider that furnished the service.

AANA Request: If an Attribution Methodology Cannot Adequately Account for the Anesthesia Services CRNAs and Other Anesthesia Providers Furnish, CMS Should Develop Anesthesia Care Episode Groups with Corresponding Anesthesia Group Measures

If an attribution methodology cannot adequately account for the anesthesia services CRNAs and other anesthesia providers furnish, we propose that CMS develop an episode measure that is specific to anesthesia care services with corresponding anesthesia group measures. Anesthesia care services necessitates its own distinct episode group that is currently not reflected in the episode-based measures. The AANA recommends that CMS work collaboratively with the AANA for guidance on how specialty services like anesthesia should be grouped to ensure that anesthesia care services are properly attributed to the specific anesthesia provider who furnished the service. The AANA stands ready to work with the agency.

We thank you for the opportunity to comment on the CMS Episode-Based Cost Measure Development for the Quality Payment Program.

1 Paul F. Hogan et. al, “Cost Effectiveness Analysis of Anesthesia Providers.” Nursing Economic\$. 2010; 28:159-169.

2 B. Dulisse and J. Cromwell, “No Harm Found When Nurse Anesthetists Work Without Physician Supervision.” Health Affairs. 2010; 29: 1469-1475.

3 Lewis SR, Nicholson A, Smith AF, Alderson P. Physician anaesthetists versus non-physician providers of anaesthesia for surgical patients. Cochrane Database of Systematic Reviews 2014, Issue 7. Art. No.: CD010357. DOI:10.1002/14651858.CD010357.pub2.

4 Negusa B et al. Scope of practice laws and anesthesia complications: No measurable impact of certified registered nurse anesthetist expanded scope of practice on anesthesia-related complications. Medical Care June 2016, http://journals.lww.com/lwwmedicalcare/Abstract/publishahead/Scope_of_Practice_Laws_and_Anesthesia.98905.aspx

5 Liao CJ, Quraishi JA, Jordan, LM. Geographical Imbalance of Anesthesia Providers and its Impact on the Uninsured and Vulnerable Populations. Nurs Econ. 2015;33(5):263-270.

<http://www.aana.com/resources2/research/Pages/NursingEconomics2015.aspx>

6 Liao, op cit.

COMMENT 4 OF 69

Date: 3/29/2017

Commenter Name, Professional Title, and Organizational Affiliation: Terrence L. Cascino, President, American Academy of Neurology

Text of Comment:

The American Academy of Neurology (AAN) is the premier national medical specialty society representing more than 32,000 neurologists and clinical neuroscience professionals and is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system such as Alzheimer’s disease, stroke, epilepsy, Parkinson’s disease, migraine, multiple sclerosis, and brain injury.

The AAN thanks Acumen and the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide feedback on the episode groups recommended for cost and quality attribution in the MIPS Quality Payment Program (QPP).

CMS proposes to define Episode Groups (EGs) to measure physician quality and cost. The AAN recommends that CMS adopt a long-term plan to make Alternative Payment Models (APMs) fill two roles. First, APMs should be the vehicle for physicians to bill CMS. Second, the AAN recommends that APMs, rather than EGs, act as the method for CMS to determine physician cost and quality.

The AAN recommends that CMS develop APMs to assess physician costs and quality under the QPP, rather than using EGs. APMs with homogeneous patient populations and services are likely to be more useful than EGs.

- It appears that EGs are being developed first by defining a list of episodes and procedures, and then by extracting relevant services from among many concurrent services provided to a patient during a specific time interval. On the other hand,

APMs specifically define the patient population, the treatment period, and the services provided to those patients. The patient acuity, time period and services rendered can be prospectively and retrospectively verified both by CMS and by the provider.

- EGs are useful only if patients and services are correctly attributed to physicians. Attribution methods are not now mature, as CMS is defining patient relationship categories. Costs are assigned to providers using arbitrary standards; for example, the provider with most visits, or higher charges within an episode, may be held as the responsible provider for an entire EG. When physician ratings are based on services they cannot control, the high-ranking physicians have little incentive to improve, while the low-ranking physicians have no real means to improve. On the other hand, APMs are services specifically billed by the providers performing the services, over which they have some degree of control. Apparent low-ranking providers should know exactly which service quality and cost improvements are within reach.
- After the EG services are extracted from the total care package using proprietary algorithms, cost and quality adjustments must be made to account for factors including patient complexity. Although current HCC risk adjustment algorithms are effective to predict costs for large patient populations, they are not validated to be accurate to predict costs for specific specialties, subspecialties, or for each individual disease entity. CMS proposes a large number of EGs for diabetes, depression, and other chronic disorders, attempting to define more homogeneous patient groups. CMS proposes only one EG for Parkinson's disease, though the diagnosis encompasses patients with very different needs. On the other hand, APMs can be defined to include patients with relatively uniform diagnosis and concomitant risk factors, and APMs define the services provided, or specifically excluded, for each patient group.
- Assuming that Medicare uses EGs to extract specific services, and then aggregates multiple EGs within a year to rate physician quality and cost, providers cannot use the resulting data to improve their performance. The services included in each EG may be different from patient to patient and from one disease entity to another; the provider cannot replicate the grouping methods based on clinical data, and the provider cannot identify areas for potential practice improvement. Physicians cannot control many of the EG costs, including hospital services. On the other hand, physicians know exactly what services are included in each APM. If we are compared to our peers based on APMs, we will know exactly what services we have used, and for which patients; we will have the opportunity to negotiate lower costs outpatient services, and to use higher quality–lower cost hospitals.
- The proposed EGs are defined to include a high percentage of all services billed to CMS. There are very few relevant to neurologists. There are none relevant to neurologic subspecialists in epilepsy, multiple sclerosis, neuromuscular disease, and other areas. On the other hand, APMs can be developed relatively rapidly by the AAN or other groups, now that PTAC has specified its initial APM criteria. Specialty societies cannot develop EGs to extract services from the CMS database of all services, because the methods are proprietary and are opaque to the societies. The AAN believes that neurologists are more likely than primary care specialists to

develop consensus standards to improve quality and cost for neurologic disorders, and the AAN can build APMs from best-practice standards of care. Using APMs for QPP will allow the AAN and other specialty societies to bring many more physicians into the QPP, more quickly.

- EGs are to be extracted retrospectively from the pool of services provided to a patient over a time period. On the other hand, the services within an APM can be reported to CMS through a qualified clinical data registry (QCDR). QCDRs should be able to help providers to verify and understand their MIPS scores, develop specialty-specific analysis to enhance QPP ratings, and help specialists to adopt best practices based on APM, QPP, and other data.

AAN Comments on Proposed Episode Groups.

1. There are very few Acute Inpatient Medical Condition Episode Groups that are relevant for neurologists and our patients. The AAN is concerned that neurologist MIPS scores will be based on a very low number of episodes, too few to provide statistically reliable ranking.
2. Acute Ischemic Stroke with Use of Thrombolytic Agent: This group is likely to capture the neurologist as the treating physician for many patients. Its practical usefulness will be limited by CMS ability to segregate services related to stroke, patient attribution, risk adjustment, and other factors. We are concerned that those stroke patients referred for neurologist care may be higher risk than those managed by primary care providers, and that risk adjustment methods may not capture this difference.
3. Seizures and Transient Ischemia: For each of these disorders, there are few patients who require hospitalization. As with acute ischemic stroke, we are concerned that patients requiring an inpatient stay under a neurologist's care may be higher risk than those managed by primary care providers, and that risk adjustment methods may not capture this difference.
4. Poisoning & Toxic Effects of Drugs, Psychoses, Syncope & Collapse: These groups will rarely capture the neurologist as the treating physician.
5. Procedural Episode Groups: No proposed procedural EGs are frequently performed by neurologists.
6. Chronic Condition Episode Groups include 65 categories of migraine and 1 category for Parkinson's disease. The AAN expresses concern about the Migraine category:
 - If there are to be 65 EGs for migraine, then each category is likely to yield few EGs for each neurologist in MIPS, and the overall physician assessment may be flawed.
 - If CMS plans to consolidate these categories, we recommend three:
 - Migraine, not complicated or intractable

- Migraine, intractable but not complicated. Patients with intractable migraine likely have higher costs, including IV meds, ED or hospital visits, and medication adverse effects.
- Migraine, complicated. This category would include hemiplegic, ophthalmoplegic, persistent aura, or migraine with cerebral infarction. Clinical presentations for these disorders require evaluations similar to stroke, TIA, and epilepsy. In addition, there is significant variation in presentation and risk within each group.

To repeat another concern: Neurologists who do not treat migraine or Parkinson’s disease will not be assessed within QPP.

AAN Comments on Proposed Episode Group Methods

The AAN is concerned that the current list of EGs is too small, and that many neurologists may be excluded from meaningful participation in QPP. Neurologists specializing in dementia, multiple sclerosis and epilepsy, among others, can help to minimize expensive patient admissions, but their work would not be reflected in their MIPS rankings under the proposed APMs.

We are concerned that there is little evidence base to guide CMS as it defines the triggering clinical events, termination points, and patient populations for each EG; rather, expert opinion will guide that development. We are concerned that expert opinion will not be adequate to define EGs, and that negative rankings and serious financial penalties may accrue incorrectly to providers who actually have high quality patient care and modest resource use.

Because of these and other concerns, we recommend that CMS minimize the impact of quality and cost rankings until the underlying assumptions are well validated, and until the methods can be reproduced and verified by each affected provider from our own patient data. The AAN strongly recommends CMS continue the “Pick Your Pace” process into 2018 as physicians learn more about the new quality programs.

Conclusion

The AAN appreciates that the list of proposed Episode Groups is a first step in a long process. We will better judge their potential utility for QPP only when their full definitions include triggering events and clinical endpoints, and when they can be used as accurate benchmarks for quality and cost. We are concerned EGs cannot be productive tools until there is extensive testing and validation of the underlying risk adjustment and episode grouping technology. Even when that work is complete, the episode group technology will always be opaque to physicians. Our members will not be able to audit or correct errors in patient attribution or in costs assigned to us, and we will never be sure that our rankings are reflect our performance. The AAN feels that EGs could never approach the accuracy, transparency, and utility of APMs to compare physicians under the QPP and to help physicians to make meaningful practice improvements based on those comparisons.

At present providers bill CMS using CPT codes. CMS and HHS can audit our performance and cost by matching CPT services with diagnostic codes, as modified by risk adjustment methods.

We recommend that CPT use APMs in a similar role for the future. We recommend that CMS aid specialty societies to develop APMs that included relatively homogeneous patient populations and defined services, so that all specialist physicians will be able to participate in QPP with confidence that the benchmarks are accurate.

We greatly appreciate this opportunity to share the views of the AAN in response to the questions raised by CMS.

COMMENT 5 OF 69

Date: 4/5/2017

Commenter Name, Professional Title, and Organizational Affiliation: Susan Kay, Quality Manager, Teton Valley Health Care

Text of Comment:

As a CAH, we have not been able to obtain specific cost detail that has been attributed to our facility because we had less than 20 eligible pts (from SQRUR). If our reimbursement is affected by our cost then we need to be able to get this information in order to make any improvements! Hoping with MIPS we will be able to get this information for any number of eligible pts.

Also, it seems in the past we have been assigned the cost of the whole patient episode even for services that we don't even offer for patients that may have started in our facility and we transferred to pt to a larger facility with specialized care. This needs to be addressed when discussing differing rules for CAH's.

COMMENT 6 OF 69

Date: 4/9/2017

Commenter Name, Professional Title, and Organizational Affiliation: Harold D. Miller, President and CEO, Center for Healthcare Quality and Payment Reform

Text of Comment:⁴

I am writing to express serious concerns regarding the proposed Patient Condition Groups and Care Episode Groups that were posted on the CMS website on December 23, 2016, to provide suggestions for improvements, and also to provide comments and respond to the questions in the document titled "Episode-Based Cost Measure Development for the Quality Payment Program" that was posted at the same time.

The Urgent Need for Better Claims Data to Support Value-Based Payment

As you know, all of the current value-based payment methodologies used by Medicare and other payers are based primarily on information derived from healthcare claims data. However, the information contained in claims data was not designed for this purpose. The limited information

⁴ This commenter attached a copy of an earlier letter to CMS dated February 15, 2016.

available in current claims data creates weaknesses in the payment models that are based on the data, which in turn creates serious problems for the healthcare providers paid under these models and for the patients who need care from those providers.

In developing the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Congress recognized that current healthcare claims data would not be adequate for either resource use measurement under the Merit-Based Incentive Payment System (MIPS) or for the development and implementation of Alternative Payment Models (APMs). To address this, Section 101(f) in Title I of MACRA added Section 1848(r) to the Social Security Act (42 U.S.C. 1395w-4(r)), which requires development of three new sets of information – Care Episode Groups, Patient Condition Groups, and Patient Relationship Categories – and corresponding codes to record this information on claims forms. Congress also recognized that obtaining better claims data was an urgent need, and so Section 1848(r) mandates a very detailed process and specific deadlines in order to ensure that better data can be recorded on claims forms beginning on January 1, 2018.

The CMS Proposal Doesn't Address the Needs for Better Coding

In light of the importance and urgency of this issue, we were extremely disappointed with the material that CMS posted for comment in December. **The proposed Care Episode Groups and Patient Condition Groups fall far short of what could or should have been developed in response to Congress's mandate.** Specifically:

Care Episode Groups should be more than relabeled procedure and diagnosis codes.

The Care Episode Groups and codes that MACRA requires in Section 1848(r) are needed in order to provide a better approach to defining and measuring episodes of care than the “episode grouper” approaches CMS and other payers have been using. Episode groupers are complex and highly error-prone because they try to determine the relationship between the services a patient receives long after those services have been delivered, using information on claims forms that was designed for billing purposes, not for defining clinical episodes. Although resource use measures calculated using these imperfect grouper methodologies may provide helpful information in some cases, they will never be sufficiently accurate or reliable to use for defining Alternative Payment Models or for holding physicians accountable for resource use under the Merit-Based Incentive Payment System (MIPS).

By requiring the creation of Care Episode Groups and codes, Congress clearly signaled a desire to assure that episode definitions and measures would no longer be constrained by the limits of current procedural and diagnostic coding on claims forms. It also clearly wanted to enable physicians to indicate the nature of the care episode that was underway at the time care is delivered, rather than having CMS try to determine that retroactively.

Yet the “episode groups” posted for comment in December are nothing more than retitled ICD-10 codes for chronic conditions, HCPCS codes for procedures, and DRG codes for acute inpatient medical conditions. Using the exact same codes that already appear on claims forms, as CMS has proposed, does nothing to provide the greater breadth and depth of information needed for both MIPS and APMs. **Recommendations for a better approach are provided later in this letter.**

Patient Condition Groups shouldn't simply be another name for diagnosis codes.

The resources required to care for an individual patient during a particular episode of care and the outcomes that can be achieved for that patient will depend heavily on the specific needs and characteristics of the patient and the physicians' and patient's ability to access and use different treatment options. Unless measures of resource use during episodes of care are appropriately adjusted for differences in these factors, one physician could be penalized for being "high cost" relative to other physicians when in reality, that physician's patients had greater needs than the patients treated by other physicians.

Unfortunately, the risk adjustment systems currently being used by CMS and other payers do not identify or adjust for many of the most important differences in patient needs. Many of the characteristics that cause patients to legitimately require more services and resources or to have worse outcomes aren't captured in current diagnosis codes, such as stage of cancer, severity of heart failure, functional status, etc.

But rather than creating a mechanism through which physicians could identify the patients who have these characteristics, CMS has apparently decided to interpret the "patient condition groups" required in MACRA as a synonym for "chronic condition episodes" and to simply use existing ICD-10 codes to define them. Here again, CMS's proposal to use the exact same codes that already appear on claims forms does nothing to improve the accuracy or reliability of risk adjustment systems either for MIPS or APMs. **Recommendations for a better approach are provided later in this letter.**

Failure to Consider the Needs of Alternative Payment Models

We were also extremely disappointed that the document released with the proposed codes discusses episode groups and codes only in the context of the Resource Use measures required as part of MIPS, and there is no discussion in the document of the important role these codes can and should play in Alternative Payment Models. In the very first paragraph of Section 1848(r), Congress stated that the purpose of developing Care Episode Groups and Patient Condition Groups was "for purposes of the Merit-based Incentive Payment System...and alternative payment models..." [emphasis added]. Yet in the document "Episode-Based Cost Measure Development for the Quality Payment Program" that CMS released in December, alternative payment models are only mentioned briefly in the descriptions of MACRA at the beginning of the Executive Summary and in the Introduction section of the document, and nowhere else.

We urge that CMS explicitly seek input from providers, medical specialty societies, and other stakeholders who are developing or implementing Alternative Payment Models in order to determine how Care Episode Groups and Patient Condition Groups can best support Alternative Payment Models.

Lack of Collaboration and Transparency in Response to MACRA's Mandates

Congress clearly wanted CMS to work collaboratively and interactively with stakeholders in developing the Care Episode Groups and Patient Condition Groups and associated codes. Indeed, Section 1848(r) is titled "Collaborating with the Physician, Practitioner, and Other Stakeholder

Communities to Improve Resource Use Measurement.” Two separate rounds of input regarding the care episode and patient condition groups and codes are mandated by MACRA.

To date, CMS has also not released any information on the comments and input that it has received nor has it explained whether and how it has used that input. Although notice and comment rulemaking clearly does not support the kind of collaborative approach Congress wanted to see, one advantage of notice and comment rulemaking is that all comments submitted are publicly available and CMS responds specifically to each comment submitted. In contrast, the public comments submitted to date on the care episode groups and patient condition groups do not appear to be accessible anywhere. The document posted in December states that CMS received comments, but the document does not describe what those comments were and it does not indicate whether and how the proposal responds to those comments.

For example, CHQPR submitted detailed recommendations to CMS on how to define Care Episode Groups and Patient Condition Groups 14 months ago (a copy of our February 15, 2016 letter is attached). There is no indication in the material posted in December that CMS gave any consideration to these recommendations.

The CMS website indicates that Acumen “convened a Clinical Committee comprised of more than 70 clinical experts from over 50 professional societies... from August – September 2016. This Committee provided input on identifying a candidate list of episode groups for development and in determining the billing codes that trigger each episode group. The clinical review and recommendations obtained from the Clinical Committee were used to inform the draft list of episode groups and trigger codes posted by CMS in December 2016 for public comment.” However, no information has been made publicly available on what was recommended by the committees created by Acumen.

We urge CMS to (1) publicly post all of the comments it has received, all materials that its contractor has developed, and summaries of the meetings that the contractor has held; and (2) explicitly respond to the comments it receives.

Failure to Meet the Deadlines in MACRA

Finally, we are very disappointed that **CMS has failed to meet the statutory deadlines established in MACRA.** Section 1848(r)(2)(E) required that a “draft list of the care episode and patient condition codes ... (and the criteria and characteristics assigned to such code)” be posted no later than 270 days after the end of the previous comment period. The previous comment period ended on February 15, 2016; 270 days after that was November 11, 2016. However, the draft codes were not posted until six weeks later, on December 23, 2016.

It is clear in reading Section 1848(r) that the specific deadlines Congress mandated for each step in the input process were designed to ensure that the new codes would be finalized and available for use on claims forms beginning on January 1, 2018. Under MACRA, there are four steps CMS is required to take in developing Care Episode Groups and Patient Condition Groups, and the times allowed for those steps are, respectively, 180 days, 120 days, 270 days, 120 days, and 270 days following the completion of the previous step, starting with the enactment of MACRA on April 16, 2015 and ending with CMS posting an “operational list of care episode and patient condition codes (and the criteria and characteristics assigned to such code).” The cumulative

effect of those deadlines is that the operational list of codes would be posted before the end of 2017.

However, due to the delay in posting the draft codes, the current comment deadline of April 24, 2017 is only 220 days before the end of 2017. If CMS takes the 270 days currently allowed under statute to finalize the codes, the codes would not be ready until February of 2018, after the codes are supposed to already be in use on claims forms.

Of even greater concern, however, is that what was posted in December did not include “the criteria and characteristics assigned to such code” as required in MACRA. In fact, in the spreadsheet that contains the proposed groups and codes, CMS explicitly states “the draft list does not currently include specifications for episode sub-groups.” The spreadsheet states that “future development of acute inpatient medical condition episodes will entail an evaluation ... of whether patients who share a given DRG are sufficiently similar to patients assigned other DRGs to warrant lumping into a single episode group, or sufficiently different from one another to warrant splitting into two or more sub-groups,” and it states that “CMS is considering development of episode sub-groups” “for surgical and percutaneous approaches,” “by indication,” “for mastectomy with or without breast reconstruction,” “by location (i.e., cervical, thoracic, lumbar),” and “by etiology of fracture as well as number of levels treated.” (These statements suggest that to date, CMS has primarily focused attention on inpatient and surgical procedure episodes rather than chronic conditions or acute medical conditions that do not require surgery.)

Due to the superficial and incomplete nature of the current version of the proposed codes, it is clear that significant revisions will be needed before the groups and codes can be operationalized. **It will be essential for stakeholders to have another opportunity to review and comment on a revised and more detailed version of the codes before they are finalized. We urge that CMS make a commitment to: (1) release a revised set of Care Episode Groups/codes and Patient Condition Groups/codes, with full definitions, no later than June 30, 2017; (2) allow stakeholders at least 60 days to comment on the revised groups/codes; and (3) incorporate the input received into the definitions and codes and release final versions no later than November 30, 2017. This will allow the new codes to be used on claims forms beginning on January 1, as Congress intended, and provide stakeholders with full information on the codes at least one month in advance.** CMS commendably released a revised set of Patient Relationship Categories and codes for additional comment in advance of the statutory deadlines, and it should also release a revised set of Care Episode Groups, Patient Condition Groups, and associated codes as soon as possible this year to allow additional stakeholder input.

How to Create Better Care Episode Groups and Patient Condition Groups

A number of medical specialty societies are developing Alternative Payment Models (APMs) to support high-quality care for patients who have the acute and chronic conditions that physicians in those specialties treat. In many cases, these APMs include specific definitions and codes for two or more phases or “episodes” of care experienced by patients with those conditions, and the APMs also define categories of patients and associated codes based on patient characteristics that affect resource use and outcomes in a particular phase or episode of care.

Since Section 1848(r)(1) explicitly states that the purpose of developing Care Episode Groups and Patient Condition Groups is to support alternative payment models as well as MIPS, it would be very unfortunate if CMS tries to develop Care Episode Groups and Patient Condition Groups and associated codes for MIPS in ways that conflict with the efforts of the specialty societies and others who have been working to develop APMs. Consequently, **we urge that CMS contact medical specialty societies that are developing APMs and make every effort to either adopt or adapt the episode groupings and patient categories those societies have developed into the overall framework for care episode and patient condition groups that CMS develops in response to MACRA.**

Fortunately, despite being independently designed to support care for very different types of health conditions, the APMs that have been developed to date by several specialty societies have many common elements to their structures. These commonalities suggest a default structure for Care Episode Groups and Patient Condition Groups that CMS can use for most health conditions and combinations of conditions until specific Alternative Payment Models have been developed for those conditions or combinations of conditions.

Defining Episodes in Terms of Phases of Care

One common element in many of the APMs currently being developed is that separate payment amounts and quality measures are being defined for two or more phases of care that correspond to clinically distinct sets of services and outcomes for patients. For example, APMs being developed for several different types of chronic diseases have identified the following distinct phases of care:

- (1) the diagnostic phase, when a physician makes a determination as to whether a patient with symptoms has a particular disease or not;
- (2) the treatment planning phase, when treatment options are identified and discussed with a patient diagnosed with a disease;
- (3) initial treatment for a chronic disease, when the patient begins to receive the chosen treatment along with appropriate education and support, and when effectiveness and side effects are monitored in order to adjust treatment; and
- (4) maintenance of treatment for a chronic disease, when a patient continues to receive a treatment that is achieving its expected effect.

A patient may cycle back and forth through one or more of these phases, e.g., because their condition worsens, because they develop other acute or chronic health problems that require adjustments in treatment, because new, more effective treatments become available, or because the patient's poor response to treatment calls into question the accuracy of the diagnosis.

Since different types and amounts of services, different types of outcomes, and in many cases different physicians will be associated with each of these phases of care, it makes sense to define each of them as a separate "episode of care." Resource measures and payment models based on these four separate episodes will be far more clinically meaningful than lumping all patients who have been diagnosed with the chronic disease regardless of the phase of care into a single never-ending "episode" the way that most episode groupers do.

For acute conditions, there is also a diagnostic phase and a treatment planning phase, but instead of an initial treatment phase and maintenance phase, one can define a different phase:

(5) (time-limited) treatment for an acute condition, when the patient receives a treatment (e.g., medication) or a procedure (e.g., surgery) for the condition and also any follow-up care needed for recovery. This same category can be used for a procedure performed for diagnostic or screening purposes (e.g., a colonoscopy).

A separate phase of care should also be defined for complications:

(6) treatment of a complication, if a new acute condition has resulted from previous treatments for other conditions. This category could also be used for treatment of an acute exacerbation of a chronic condition.

Finally, there is a different phase of care for patients who do not have an acute or chronic health problem that requires active treatment, but who need help in preventing problems from developing:

(0) a preventive care phase, when patients without a health problem are monitored to ensure they receive evidence-based preventive services. (When a preventive service is actually delivered, the procedure would be treated as part of category 5.)

Defining Groups of Patients with Similar Needs and Expected Outcomes

Another key commonality among many APMs currently being developed is that 3-4 categories of patients are being defined within each phase of care. The patients in each category are similar to each other in terms of their needs for services and expected outcomes, but they differ from the patients in other categories based on objective characteristics that affect the amount of resources needed to treat the patients, the outcomes that can be achieved for the patients, or both. Different payment amounts can then be established for each category of patient in the same episode of care, reflecting the fact that the patients will need different types and amounts of services, and quality or outcome measures can be calculated separately for each category of patients to reflect the differences in expected outcomes.

Instead of assuming that there is a linear relationship between patient characteristics and resource needs or outcomes that can be determined through a regression formula, as the CMS HCC system and many other risk adjustment systems do, categorical stratifications allow for non-linear relationships without requiring a complex coding system. Using 3-4 different severity/risk categories for each type of condition rather than continuous risk adjustment is very similar to the structure used in the MS-DRG system for hospitals and it is similar to a structure that CMS is using to stratify the Care Management Fees in its Comprehensive Primary Care Plus demonstration.

The patient characteristics that have the biggest effect on resource use and outcomes during an episode of care will differ depending on the specific type of condition that is being treated during the episode. For example, if a patient is being treated for cancer, the stage of cancer has a very large impact on the cost of treatment and the likelihood of survival, far more than whether the patient has a comorbidity such as knee osteoarthritis. On the other hand, for a cancer-free patient who is being treated for knee osteoarthritis, stage of cancer is meaningless, but the severity of

their arthritis is very important to understand in determining what will be needed to treat their knee problem and the ability of alternative treatments to improve their mobility. There are no ICD-10 codes for either stage of cancer or severity of knee arthritis, so this information cannot be obtained from claims forms today. The only way to obtain the information is to ask physicians to record it for the patients for whom it is relevant.

In addition to the stage and severity of disease, the following patient characteristics that are not adequately reflected in ICD-10 codes will likely affect resource use for many types of patients:

- **Patient Functional Limitations.** A patient's functional limitations (e.g., inability to walk) can have an equal or greater effect on costs and outcomes as do their medical conditions. Patients who are unable to walk or drive or are unable to carry out activities of daily living will have greater difficulty caring for themselves and greater difficulty obtaining traditional office-based ambulatory care services, which can lead to increased use of more expensive healthcare services. For example, one analysis found that there were hospital admissions for 34% of Medicare beneficiaries who had functional limitations as well as chronic diseases, but there were admissions for only 20% of the Medicare beneficiaries who had 3 or more chronic conditions but no functional limitations. The researchers also found that the majority of the beneficiaries on whom Medicare spent the most had both chronic conditions and functional limitations.
- **Barriers in Accessing Healthcare Services.** Having health insurance does not automatically assure that a patient can access the care they need. High deductibles or high cost-sharing levels may discourage individuals from seeking needed care or taking prescribed medications, which can result in avoidable complications and higher overall expenses that are outside the control of their physicians and other healthcare providers. Living in rural areas where long distances are required to travel to provider locations and where there is a lack of public transportation can also make it difficult for patients to obtain needed care regardless of the benefit design in their health insurance plan.

Suggested Care Episode Groups, Patient Condition Groups, and Codes

In order to define Care Episode Groups and Patient Condition Groups consistent with the above concepts, we recommend that CMS establish the following new HCPCS codes to indicate the following phases of care and categories of patients:

G9900: Preventive care

G991x: Diagnosis of a new symptom

G9911: Level 1 – Low Need Patients

G9912: Level 2 – Moderate Need Patient

G9913: Level 3 – High Need Patients

G9914: Level 4 – Very High Need Patients

G992x: Treatment planning for a new diagnosis

G9921: Level 1 – Low Need Patients

G9922: Level 2 – Moderate Need Patient

G9923: Level 3 – High Need Patients

G9924: Level 4 – Very High Need Patients

G993x: Initial new or revised treatment for a newly diagnosed or significantly worsened chronic condition

G9931: Level 1 – Low Need Patients

G9932: Level 2 – Moderate Need Patient

G9933: Level 3 – High Need Patients

G9934: Level 4 – Very High Need Patients

G994x: Continued treatment for a chronic condition

G9941: Level 1 – Low Need Patients

G9942: Level 2 – Moderate Need Patient

G9943: Level 3 – High Need Patients

G9944: Level 4 – Very High Need Patients

G995x: Treatment for an acute condition, treatment for an exacerbation of a chronic condition, or delivery of a diagnostic procedure

G9951: Level 1 – Low Need Patients

G9952: Level 2 – Moderate Need Patient

G9953: Level 3 – High Need Patients

G9954: Level 4 – Very High Need Patients

G996x: Treatment for a complication resulting from a treatment or procedure

G9961: Level 1 – Low Need Patients

G9962: Level 2 – Moderate Need Patient

G9963: Level 3 – High Need Patients

G9964: Level 4 – Very High Need Patients

These generic episode codes would be converted to a specific condition-based episode using the relevant ICD-10 code that the provider reports along with the episode code. For example, if a provider submitted the G9942 Care Episode Code along with an ICD-10 code for heart failure, it would indicate that a patient was receiving continued treatment for their heart failure and that the patient had other characteristics (such as moderate severity of their heart failure and some

difficulty accessing outpatient services) that indicated they needed a moderate level of services. (All of the Care Episodes should be tied to the underlying condition being treated, not to a procedure, so that there is no financial incentive to deliver one procedure over another in achieving the best outcomes for the patient.)

The generic Care Episode codes described above would only be used for a particular health condition until more specific codes were developed for that condition by the relevant medical specialty society. As condition-specific Care Episode Groups and Patient Condition Categories are developed by specialty societies, either for MIPS or APMs, these codes could be reviewed and approved by the CPT Editorial Panel just as procedural service codes are today. This would ensure consistency of definitions. (There would likely need to be a new category of CPT codes established for Care Episode Groups since they do not represent discrete services as existing Category I and III CPT codes do.)

Associating Individual Services with Episodes

For each combination of Care Episode code and ICD-10 code, the services that would be included or excluded from the episode would need to be identified in order to measure resource use within that episode and to avoid double payment under an APM. **Rather than having CMS use episode grouper software to guess at how to assign services to episodes, providers should be given a way to explicitly indicate the type of episode to which a service should be assigned. To accomplish this, 7 modifiers (Y0, Y1, Y2, Y3, Y4, Y5, Y6) should be created for use with existing CPT/HCPCS codes to enable the provider of a discrete service to indicate which type of episode that service was associated with.** For example, if an office visit for an established patient was part of the initial treatment for a newly diagnosed chronic disease, the provider could report 99213-Y4, indicating that a Level 3 office visit was provided in conjunction with initial treatment of the chronic disease.

Definitions of which services should be assigned to particular episodes will still be needed, but these can be used by physicians and other providers to ensure accurate coding of episodes (just as they currently use CPT definitions to ensure accurate coding). CMS should defer to the definitions medical specialty societies are developing as part of APMs wherever possible rather than creating conflicting definitions for MIPS.

Patient Characteristics Used to Define Levels of Need

New Patient Condition Codes should be defined to supplement existing ICD-10 codes in order to objectively assign patients to the different need levels in the HCPCS codes above based on important characteristics that are not captured in ICD-10. The criteria for assigning these to patients would differ depending on what the relevant condition or episode is. For example, the same severity of condition codes could be used for both COPD and heart failure but the criteria for assigning “high severity” to a patient with COPD would differ from the criteria for assigning that same category to a patient with heart failure. In cases where stage or severity levels are captured by ICD-10 codes, those codes would be used instead of the generic Patient Condition Codes.

ZZ1.xx Stage/Severity of condition

ZZ1.1 Early Stage/Mild Severity

ZZ1.2 Intermediate Stage/Moderate Severity

ZZ1.3 Advanced Stage/High Severity

ZZ2.xx Patient Functional Status

ZZ2.1 High Functional Status

ZZ2.2 Moderate Functional Status

ZZ2.3 Low Functional Status

ZZ2.4 Very Low Functional Status

ZZ3.xx Access to Healthcare Services Needed for Treatment

ZZ3.1 Little Difficulty Accessing Necessary Healthcare Services

ZZ3.2 Moderate Difficulty Accessing Necessary Healthcare Services

ZZ3.3 Significant Difficulty Accessing Necessary Healthcare Services

Use of Patient Relationship Categories and Codes

The Patient Relationship Categories that MACRA requires could be identified by attaching modifiers to both the Care Episode codes and the CPT HCPCS codes for the discrete services. As was described in our January 6 letter commenting on CMS's revised proposal for patient relationship categories and codes (a copy of which is attached), we recommend modifiers be created for the following six Patient Relationship categories.

Z1. Continuing Comprehensive Care and Coordination. A clinician who is taking responsibility for coordination of all or most of the patient's care, with no planned endpoint. The clinician may deliver all, some, or none of the actual treatment or preventive care services that the patient receives for their health problems or risk factors, but the clinician does accept responsibility for assuring the appropriateness and quality of care the patient receives from other clinicians.

Z2. Continuing Condition-Focused Care and Coordination. A clinician who is taking responsibility for coordination of all or most of the patient's care for one or more specific conditions, with no planned endpoint. The clinician may deliver all, some, or none of the actual treatment services that the patient receives for these conditions, but the clinician does accept responsibility for assuring the appropriateness and quality of care delivered by other clinicians for the condition(s) on which the clinician is focused.

Z3. Time Limited Comprehensive Care or Coordination. A clinician who is taking responsibility for coordination of all or most of the patient's care for one or more specific conditions during a time-limited period, including any services needed from other clinicians for those conditions.

Z4. Time-Limited Focused Services. A clinician who orders or delivers one or more specific services to a patient for a specific health condition or other issue, but who does not take responsibility for coordinating services delivered by any other clinicians.

Z5. Delivery of Specific Services Ordered by Other Clinicians. A clinician who delivers one or more specific services to a patient in response to an order from another physician.

Z6. Diagnosis of Symptoms. A clinician whose role is limited to determining a diagnosis for a patient's symptoms, for verifying the accuracy of an existing diagnosis, or for ruling out a diagnosis for those symptoms.

For example, if a physician reported a G9942-Z2 Care Episode Code and Patient Relationship Modifier along with an ICD-10 code for heart failure, it would indicate that the physician was taking responsibility for continuing care and coordination for the patient's heart failure. If a provider reported G9942-Z5, it would indicate that the provider was delivering a specific service ordered by another clinician as part of the ongoing management and treatment of the patient's heart failure.

The Advantages of Coded Categories for Payment and Performance Measurement

Using new CPT/HCPCS codes for the Care Episode Groups and Patient Condition Groups enables the codes to be used both for MIPS and different types of APMs, as Congress intended:

- If the provider is participating in an APM in which payment will be made prospectively for an entire episode, then the provider could bill and be paid for the Care Episode code for that episode, and no separate payment would be made for services delivered as part of that episode of care.
- If the provider is participating in an APM in which payments are made for individual services but total spending is reconciled against an episode budget, then the provider would continue to bill and be paid for individual services described by CPT/HCPCS codes, but the provider would also submit the Care Episode Group code to indicate that the patient was part of a particular type of episode for which a payment budget had been defined.
- If the provider is participating in MIPS, the provider would continue to bill and be paid for individual services described by CPT/HCPCS codes, but the provider could also submit one or more Care Episode Group codes to indicate the context in which the services were being delivered so that resource use and quality measures could be calculated and compared to other similar patients.
- Moreover, creating HCPCS codes that define episodes and patient need categories enables an Alternative Payment Model to be implemented by both providers and payers using their existing billing and claims payment systems, rather than forcing providers to wait to find out what they will be paid until after payers have made risk adjustment calculations and forcing payers to create a new step in the process of determining the provider's payment.

Implementing the Codes on the CMS 1500 Form

The codes and modifiers described above could be used with the current CMS 1500 Billing Form through the following process:

- Reporting of all of the codes should be voluntary. Physicians and other providers who do not want to participate in an APM or to better control how resource use is measured for the care they deliver can continue to code and bill exactly as they do today.
- The ICD-10 codes and any Patient Condition Codes for additional patient characteristics relevant to an episode of care should be reported on line 21 of the CMS 1500 form, the same line where all ICD-10 codes are already being reported. The new Patient Condition Codes described above would only be reported on a CMS 1500 form when the form is being used to report a G99xxx Care Episode Code.
- The ICD-10 code for the primary condition associated with the episode should be reported in field 21-A, which is already used for the primary diagnosis associated with individual procedures.
- The G99xxx Care Episode Code(s) should be reported on line 24, the same line where all HCPCS codes are already being reported. The Diagnosis Pointer in field 24-E should refer to the diagnosis code that defines the episode.
- In field 24-E, the provider reporting the episode should include a modifier indicating the appropriate Patient Relationship Category defining the provider's role in the episode.
- Any discrete service associated with a particular episode should be reported using the appropriate CPT/HCPCS code along with (1) a modifier indicating the type of Care Episode Group and (2) a modifier indicating the provider's Patient Relationship Category.

This process is intended to allow the new codes to be used on the existing CMS 1500 Billing Form in a way that will limit the need for changes in current billing and claims payment systems. However, no matter what process is used, **it will be difficult to implement Alternative Payment Models successfully using a billing form that was designed for the traditional fee-for-service payment system. We urge that CMS begin immediately to develop a new billing form that is specifically designed to report Care Episode Groups, Patient Condition Groups, and Patient Relationship Categories as well as discrete services and diagnoses.**

Comments and Responses to Questions on the Document Posted in December

In addition to the above recommendations, we offer the following comments on the information and questions in the document "Episode-Based Cost Measure Development for the Quality Payment Program."

- The document purports to describe issues associated with "cost measures," but the issues discussed all relate to measures of *CMS spending*, not actual *provider costs*. For example, on page 7, the document states "a cost measure represents the Medicare payments... for the items and services furnished to a patient during an episode of care..." The amount that CMS pays for a service may have little or no relationship to the actual costs of

delivering that service, and there are many high-value services that healthcare providers deliver for which there is no payment at all. Under Alternative Payment Models, the “cost” to CMS (i.e., its payments) for a patient’s services and the actual costs providers incur to deliver those services may differ in new ways. Consequently, the proposed measures should not be referred to as “cost measures” unless CMS intends to actually try to measure providers’ costs for delivering services. MACRA uses the term “resource use” measures, and CMS should use that statutory term for measures of spending, while reserving the term “cost measures” for measures designed to truly measure the actual cost providers incur in delivering care.

- On page 8, the document states that “episode groups focus on clinical conditions requiring treatment.” This is an inappropriately narrow definition. There are patients with clinical conditions that require active monitoring but not necessarily “treatment,” and many patients at end-of-life require palliative care or other types of support but not “treatment.”
- On page 8, the document states that a chronic condition episode should be “triggered using codes for evaluation & management combined with ICD-10 diagnostic information on claims.” If this were desirable, there would have been no need for Congress to include a section in MACRA requiring the development of care episode groups and codes. A patient with a chronic disease could receive the assistance they need through services that are not currently described by evaluation & management codes, so trying to define episodes solely with E/M codes is inappropriate.
- On page 9, the document states that the goal of dividing episodes into sub-groups is to “offer a meaningful clinical comparison,” but then says this must be balanced “against the need to have an adequate number of cases that can be attributed to a given clinician.” If a clinician only treats a small number of cases of a particular type, that may be a reality of the care delivery process (e.g., reflecting the fact that there are relatively few patients with the condition being treated in any particular community) and statistical manipulations cannot overcome this. Combining dissimilar patients into a single group for measurement purposes may increase the number of cases but also increase the uncontrollable variance and thereby reduce the reliability of the measure.
- On page 10, the document states that “Acumen, LLC is soliciting expert clinical input ... regarding how to use information from claims to inform the attribution of services to clinicians.” The purpose of the Patient Relationship Categories and codes required by MACRA is to avoid the need for retrospective attribution systems. CMS has already released two versions of the Patient Relationship Categories and is required to finalize the categories and codes this month (April 2017). These should be used as the mechanism for attributing episodes and services to clinicians.
- On page 13, the document states that episodes are initiated by a “trigger event” which is “identified by certain procedure or diagnosis codes,” and then “the grouping algorithms identify and aggregate the related services.” As noted above, MACRA requires the creation of Care Episode Groups and codes in order to provide a way for clinicians to indicate whether an episode has been initiated and what services are associated with it, reducing or eliminating the need for grouping algorithms that rely solely on procedure and diagnosis codes.

- On page 14, the document indicates that episode groups may only be developed for conditions where there are “opportunities for improvement.” Although it is likely that there are opportunities for improvement in all aspects of healthcare, it is inappropriate to ignore patient conditions and procedures where quality is currently high and spending is low, since healthcare payment systems need to support continuation of good care, not just improvement where there are currently problems.
- On page 17, the document indicates that CMS is considering defining acute episodes in a way that does not distinguish the place of service or the performance of a procedure. We support this approach. The generic episode groups that we recommended earlier are all based on the patient’s underlying conditions and needs, not on the specific procedures or treatments delivered or the locations where the services were delivered.
- On page 18, the document indicates that CMS is considering a “single episode group for outpatient chronic care with adjustment for comorbidities and demographics.” Patients with different types of chronic diseases need very different kinds of services, and patients who have a particular chronic disease need different kinds of services at different stages of their care. Consequently, it would be completely inappropriate to try and group them all into a “single episode group.”
- On page 18, the document asks for comments on how to obtain information on disease severity and staging. As we recommended earlier, new Patient Characteristic codes should be created for important patient characteristics that are not currently captured in ICD-10 codes, and these should be used to assign patients to different Patient Condition Groups (need levels) within individual Care Episode Groups.
- On page 19, the document again discusses “attributing” services to clinicians and suggests that this might be done using “percentages of the resources for an episode that could be attributed to physicians serving in different roles.” As noted several times above, the purpose of the Patient Relationship Categories and codes required by MACRA is to avoid the need for retrospective attribution systems. Moreover, in addition to Care Episode Groups, Patient Condition Groups, and Patient Relationship Categories, a fourth piece of information is essential to effective resource use measurement – identifying the physician who *ordered* a service, not just the physician who *delivered* the service. The current measures of resource use that are used by CMS are seriously flawed because they may assign accountability for a service to a physician who delivered the service even if the physician did not order it, and the resource use measures may fail to assign accountability for a service to the physician who ordered the service if it was delivered by a different physician or provider. Congress recognized the importance of solving this problem, and so in addition to the requirements in Section 1848(r)(4)(A) that claims forms include codes for Care Episode Groups, Patient Condition Groups, and Patient Relationship Categories, Section 1848(r)(4)(B) requires that the National Provider Identifier of the ordering physician or practitioner be included on the claims form if the service was ordered by a different physician or practitioner than the individual who delivered the service. Although Medicare regulations already require this information, the statutory requirement in MACRA will ensure that this information is consistently available. **We recommend that measures of resource use within Care Episode Groups utilize information on whether a provider ordered a service or made a**

referral for services in addition to the information provided by the codes for Care Episode Groups, Patient Condition Groups, and Patient Relationship Categories. (Detailed suggestions on how to do this were contained in our February 15, 2016 letter, a copy of which is attached.)

- On page 20, CMS asks how to incorporate Part D spending into episode group development. Medications are a major mechanism of treatment and prevention. In some cases, use of medications is a more cost-effective way to treat or prevent a condition and in other cases, other types of care are more cost-effective. Failing to include spending on medications in measures of resource use or in alternative payment models creates an inappropriate financial incentive to use medications instead of other types of treatment or care. Since the majority of medications received by Medicare beneficiaries are paid for through Part D, it is clearly essential that Part D spending be included in episode spending measures. Moreover, including spending on Part B medications but excluding spending on Part D medications would create an inappropriate incentive for physicians to prescribe Part D medications even when Part B medications would be more cost-effective. It is certainly possible that a shift in treatment from Part D medications to Part B medications or other services paid for under Part A or Part B would increase *Medicare* spending even though *total* spending would decrease (because the Part D plans would receive the savings), but this is an artifact of the way Medicare pays for services. Providers should not be penalized for delivering the most cost-effective care to patients simply because of differences in the categories under which Medicare pays for particular services.

By enacting Section 1848(r) as part of MACRA, Congress created a unique opportunity to address long-standing weaknesses in the information collected on claims forms and to solve serious problems with the design of current pay-for-performance systems and alternative payment models that derive from those weaknesses. Rapidly implementing these provisions of MACRA in the most effective and innovative way possible needs to be a high priority for CMS. We would be happy to provide any assistance that would be helpful to you in this process.

COMMENT 7 OF 69

Date: 4/13/2017

Commenter Name, Professional Title, and Organizational Affiliation: Amanda Cassidy, Health Policy Advisor, Arnold & Porter Kaye Scholer, LLP

Text of Comment:⁵

Hi - I was looking at the procedures that are identified as triggers for the Cataract Surgery IOL episode group and noticed that the list includes the procedure code 0308T Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis and the device code C1840 Lens, intraocular (telescopic). This procedure and device code describe

⁵ While this comment did not directly respond to the December 2016 posting, the feedback was related to the measure development process and previous episode groups postings, so have been included in this report for completeness.

insertion of the Implantable Miniature Telescope (IMT). The IMT is not intended to treat cataracts but instead is a treatment for patients with end-stage age-related macular degeneration (AMD). Patients receiving the IMT have no other treatment options available for AMD. Those patients are wholly different from the typical cataract population and receive substantially different treatment.

Therefore we do not think it is appropriate that these codes are included in the Cataract IOL episode group and that their inclusion is a technical error. I brought this to the attention of Ted Long at CMS who suggested that I contact you as the measure steward.

I wanted to see if there was a process for correcting technical errors in the episode groups and/or providing further comments on the groups finalized for 2017. We'd be happy to provide written comments or discuss as needed.

Please let me know what is needed to correct this situation.

COMMENT 8 OF 69

Date: 4/19/2017

Commenter Name, Professional Title, and Organizational Affiliation: Mark A. Levine, Individual

Text of Comment:

This document is submitted in response to the request for comment on CMS's December 23, 2016 posting, Episode-Based Cost Measure Development for the Quality Payment Program. The comments below represent my personal perspective as an individual, though informed by my experience with cost measure development when I was previously a member of the CMS team working on this project.

The comments are organized to respond specifically to each question or consideration that is posed in the December document, with the specific question or consideration cited in dark font and my comment or response in red.

Page 9: CMS seeks comment on where sub-groups could be created in the draft list of episode groups referenced in this posting. This should be iterative, starting in the clinical subcommittees and informed by data analysis of proposed subgrouping to consider the tradeoff of clinical specificity/actionability/validity with statistical reliability. It is impossible to provide meaningful comment at this early stage of development and absent data analysis.

Page 9: seek input from stakeholders, including specialty societies, clinicians, and other interested parties, regarding the development of episode groups that align with the work and responsibilities of clinicians and on their future use in the development of cost measures. To align with the work and responsibilities of physicians, attribution must focus on each clinician's billed services, as these completely align with the clinician's work. Aligning with responsibility requires the perspective of the patient relationship. If broad and continuous, the clinician's billing are their direct costs for the total care of those patients; thus we need episode groups that align with total cost per beneficiary (applicable only to those clinicians attributed continuous,

broad patient responsibility). If the relationship is focused (either continuous or episodic), it is important to identify the clinical focus, the episode for which then becomes the unit of analysis to compare clinicians. If the relationship is episodic, it is essential to identify the limitations and boundaries of the episodic relationship. For example, the episodic relationship might be site-related (i.e., a hospitalization or a post-acute stay) or condition or procedure-specific. In sum, the alignment of cost measures with clinician's work and responsibility requires correlation with the clinician's relationship to the patient and the clinician's clinical focus. A given clinician may have multiple responsibilities, perhaps a continuous/broad relationship with some patients, continuous/focused with others and episodic/broad with yet others. In this scenario, the clinician's cost 'score' would be the sum of the clinician's work as measured by consideration of each of these individual patient relationships.

Page 10: soliciting expert clinical input from clinical committees regarding how to use information from claims to inform the attribution of services to clinicians, in addition to further public comment. Per the above comment, the patient relationship codes are essential information, though in order to become informative, they must become much more precise than the 4 rough categories that have been proposed. The clinical focus must be identified, either through correlation with billed diagnoses or through specific additional coding.

Page 10: We are also considering additional information that could be used to clarify the relationship between the patient and the clinician. As above.

Page 10: consider stakeholder perspectives throughout the development of the attribution method (in the context of patient responsibility categories and codes). As above.

Page 11: CMS seeks comment on appropriate methods for risk adjustment, as noted in the Questions for Public Comment section of this posting. HCC risk adjustment is appropriate for episodes that encompass patients' total costs of care for all conditions and all procedures, such as recommended episodes for the continuous-broad patient relationship. However, focused condition-specific, procedure-specific or site-specific episodes require categorical risk adjustment to consider primarily those risks shown to pertain to the limited focus, as HCC adjustment is intended for broad clinical circumstance.

Page 12: CMS seeks public comment on strategies for aligning cost measures with quality. In the long run we need a strategy to align cost measures with objective patient outcomes. Until that occurs, best use should be made of indicators of quality identifiable in claims, such as hospitalizations, unplanned care, and indicators of overuse, underuse and misuse. The alignment of cost and quality is needed to avoid rewarding clinicians simply because their care is cheaper.

Page 12: We have solicited public comment on the elements of an episode of care in these past postings. We value continued comment to ensure that we develop episode groups with robust stakeholder input. [in the context of the 5 components of cost measure development: 1) define episode group, 2) cost assignment, 3) attribution, 4) risk adjustment, and 5) align with quality] Chronic episode groups are not yet defined, and their evolution may require re-evaluation of these 5 components. A potential 6th component is scoring. CMS must avoid unintended consequences such as encouraging clinicians to treat less complex patients, rewarding failure to provide necessary services or penalizing clinicians who care for disadvantaged populations. Benchmarking the costs of care will require thoughtful consideration of multiple factors to yield

meaningful judgments and avoid perverse incentives. Until this can be done reliably, scoring needs to be broad and forgiving (non-punitive) until and unless there is meaningful correlation of costs with quality patient outcomes.

Page 14: We seek comment on the length of time for analysis of chronic conditions. At least 1 year (and longer than 1 year would be difficult due to changing clinician-patient relationships and other factors).

Page 14: We welcome public comment on how to include Part D expenditures in future development. Recommend deferring until there is good grasp of the current challenges.

Page 15-16: CMS welcomes comment on the episode groups and trigger codes that accompany this posting, as well as the process to be used to develop cost measures from the episode groups, as described in this document. See comment for the 1st question (page 9).

QUESTIONS FOR PUBLIC COMMENT (pages 17-26)

- seeks input on the accompanying episode groups recommended for development and their associated episode triggers
- also request comment regarding the approach to developing cost measures that are based on episode groups.
- CMS welcomes a wide range of public comments. These specific questions are included to highlight some of the pertinent issues and are not designed to restrict or limit commentary.

Episode Group Selection

- In selecting the episode groups to be considered for development, CMS used criteria including an episode's share of Medicare expenditures, clinician coverage, and the opportunity for improvement in acute, chronic, and procedural care settings. We welcome comment on these episode groups and potential additional episode groups that should be considered for development. Opportunity for improvement is difficult to understand. How is this determined? If it is judged by variation in spending per episode, that is not necessarily opportunity for improvement, as it depends on elements that determine specificity, such as trigger rules, subcategorization, attribution and risk adjustment (and probably additional factors). Recommend that Opportunity for Improvement not be considered a criterion unless/until it is defined in greater detail and appropriate benchmarking of performance is understood and accepted.

Episode Group Definition

- The episode groups that accompany this posting are defined by the listed trigger events and codes (CPT/HCPCS for procedural episode triggers, evaluation & management codes combined with ICD-10 diagnostic information for chronic episode triggers, etc.). CMS solicits comment on the inclusion or exclusion of specific service codes used to identify each episode group. This is work that starts with input of the clinical sub-committees. See comment to the 1st question above.

Acute Inpatient Medical Condition Episode Groups

- The acute inpatient medical condition episode groups that accompany this posting include only inpatient events. CMS seeks comment on outpatient events that could be considered candidates for development as acute condition episode groups, which could include chronic condition exacerbations that require acute care but not inpatient hospitalization. Cost measures need to develop in the context of total patient care, accounting for patient preference, clinical complexity and available treatment options and resources. The focus should not be on the performance of specific procedures, rather on the care delivered to accomplish a clinical outcome. An example (admittedly a clinically complex one) is the treatment of patients with community-acquired pneumonia, which does not always require hospitalization.
- Acute episodes of care might occur on either an inpatient or outpatient basis and may or may not include surgery. CMS is considering a single Acute Episode Group type that does not distinguish the place of service or the performance of as procedure and welcomes comment on this approach. This approach is commendable. Clinical decisions to hospitalize, perform procedures or use resources must account for all options to meet the needs and preferences of whole patients, not merely the performance of specific procedures.

Chronic Condition Episode Groups

CMS is aware of many challenges in constructing episode groups for chronic conditions. These include coding habits that may obscure some chronic conditions and overemphasize others. In addition, it may be difficult to assign a given treatment to a single condition for patients with multiple comorbidities. For example, are the resources for treatment to reduce cholesterol for a patient with diabetes, hypertension, and coronary artery disease to be assigned to only one of those diagnoses, to all of them in proportion, or should we develop a chronic condition episode specific to the management of patients with diabetes, hypertension and coronary artery disease, i.e., a patient condition group to better compare cost to treat like patients? An extension of this approach might be a single episode group for outpatient chronic care with adjustment for comorbidities and demographics of the population served by the clinician. We welcome comment on these and any other options for constructing episode groups for chronic conditions. The measure “Total per capita Medicare Part A and B costs/year”, as currently reported by CMS, is the best initial metric for assessing the cost-effectiveness of primary care physicians, including patients with multiple chronic diseases (the continuous/broad patient relationship). An episode would be defined as the sum of Medicare A and B costs for the total care of the cohort of patients attributed to the clinician in a year. Steps will need to be taken to assure that patients are attributed to a single primary physician.

This approach offers multiple advantages:

- It is consistent with the “whole” patient orientation of primary care
- It is a measure that, if adequately risk-adjusted, reflects the influence of the physician’s effectiveness, both clinically and as steward of taxpayer dollars. It encourages more effective chronic care, care coordination, and prudent use of costly downstream resources.

- It covers virtually the entirety of a physician’s practice and generates the largest available sample size, reducing the small numbers problem.
- It avoids entirely difficult issues of attribution of costs to individual disease-specific episode groups in patients with multiple chronic diseases.
- It permits the application of the HCC risk adjustment system, which has proven and meaningful risk adjustment utility in Medicare Advantage and other CMS population-based payment environments.
- Similar measures of primary care influence on cost have been used extensively by physician groups participating in Medicare Advantage, and enjoy widespread acceptance by physicians as meaningful measures of performance.

Certain specific conditions, such as cancer, present other challenges. The costs of caring for patients at different stages of disease are likely to vary. For instance, a single episode for a type of cancer is likely to differ in a predictable manner depending on the stage of the cancer. Information on disease staging is not easily or predictably available from claims. CMS welcomes comment on methods to incorporate disease severity or staging information to improve meaningful comparison of cost and quality of care furnished to patients, both generally and for specific clinical conditions. For example, how could a disease staging code be reported on claims to facilitate comparison of episodes for patients at like stages of cancer? We look forward to the time when clinical data, such as that populated in clinical registries, will be linked to claims and provide the clinical information that is needed to inform on patient preference, disease staging and other important clinical perspectives that are not currently available yet are essential for understanding clinical decision-making.

Procedural Episode Groups

- We solicit comment on the procedural episode groups that accompany this posting, including the service and diagnosis codes used to identify the existence of the procedural episode groups. We also welcome comment on additional procedural episode groups to consider for future development. This seems the work of the clinical sub-committees and is difficult to conceptualize absent meaningful collegial interaction. See initial comment above.

Cost Measure Development

- Cost measures are being considered for development from episode groups after adding additional context, such as expenditure assignment, attribution, risk adjustment, and consideration of quality. We welcome comment on each of these elements and whether there are additional elements to consider in developing cost measures from episode groups. See above comments regarding attribution, patient relationship, clinical registries and scoring.
- As described above, the degree of responsibility of attributed services might be considered separately. Those services furnished by the attributed clinician for the clinical purpose of the episode group might be differentiated from the services provided by others for the same clinical purpose. The services furnished by the attributed clinician might be considered directly attributable services. These could be correlated with the services delivered by others for the same clinical purpose, which might be considered indirectly attributed services. The consideration of both directly and indirectly attributed services

might be weighed in reporting both the provision and the coordination of care within the episode group relative to each clinician contributing to the care. An alternative approach would be to obtain recommendations from multi-specialty panels about percentages of the resources for an episode that could be attributed to physicians serving in different roles. We welcome comment on these concepts of differential attribution or alternative methods to align attribution with the clinical activities of clinicians. Recommend using as the primary unit of analysis the total costs expended for the pertinent clinical care of the cohort of patients cared for by the clinician whose cost performance is being measured. The pertinent care should be defined relative to the patient relationship and the clinician's responsibility. In the context of a broad, continuous relationship the clinician should be responsible for the total costs of the cohort of patients with that relationship. For relationships that are focused, the clinician should be responsible for the total costs of the patients for the focused responsibility during the period of responsibility. For instance, if the focus of responsibility is restricted to a given site of service, the unit of analysis/comparison should be the total costs while the patient is in the site of service (plus pertinent consequences). If the focus of care is a specific clinical condition, the unit of analysis/comparison should be the total costs for the clinical condition (plus pertinent consequences) of the cohort of patients cared for by the clinician.

- The Medicare Advantage program uses the CMS-HCC Risk Adjustment Model to determine rates. We seek comment on the use of this model or an alternative for risk adjusting episode groups in the construction of cost measures. In addition, should concurrent or prospective risk adjustment be used, and should a full year of data or more targeted data from before the episode be used to adjust? HCC risk adjustment is appropriate for long-term (1 year or longer) broad patient relationships, such as primary care. Limited or focused relationships require categorical risk adjustment that is specific to the focused area being considered.
- The draft list does not currently include specifications for episode sub-groups (a subgroup is intended to achieve greater clinical comparability and is a subdivision of an episode group that further refines the specifications of episode trigger codes and grouping rules to yield more clinically homogenous cohorts of patients with similar expected cost). An example is an episode group for spine surgery with sub-grouping for number of levels and anatomic location. CMS solicits public comment on these draft episode groups and potential sub-groups. This should be considered in an iterative manner, starting in the clinical subcommittees and informed by data analysis of proposed subgrouping to consider the tradeoff of clinical specificity/actionability/validity with statistical reliability.
- CMS is especially interested in comments regarding methods to align quality of care with cost measures and welcomes recommendations and suggestions. Considerations for aligning episode groups with quality measurement are described in this document, but are not intended to be an exhaustive list of options. We welcome comment on these methods, as well as any other strategies that could be used to align quality of care considerations with cost measures. See above comments regarding clinical registries.
- CMS wishes to avoid any unintended consequences of using cost measures in MIPS, and seeks comment on issues of concern in this regard, such as taking steps to avoid disadvantaging clinicians who assume the care of complex patients such as by applying

episodes for comparison of complex patients (i.e., comparison of like-patients of different clinicians). CMS must obtain

- and utilize data in addition to those in claims to reach these important goals. Until such additional data is available, CMS should avoid making arbitrary decisions regarding the worth of resource use. There are many reasons to avoid the assumption that cheaper is better at this early stage of cost measure development.
- CMS acknowledges that prescription drug costs are a large driver of the cost of medical care for Medicare beneficiaries. What would be the best way to incorporate Part D costs into the episode group development? Recommend deferring this issue until the more pressing issues above are addressed.

Thank you for the opportunity to respond to these important considerations. I look forward to the successful completion of this important project.

COMMENT 9 OF 69

Date: 4/19/2017

Commenter Name, Professional Title, and Organizational Affiliation: James S. Kennedy, President, CDIMD – Physician Champions

Text of Comment:

My understanding is that CMS plans to risk-adjust the episode-based costs using ICD-10-CM codes.

This will cause considerable difficulty unless CMS uses its influence as a member of the ICD-10-CM/PCS Cooperating Parties to bring more sanity to the system. Options include:

- Allowing inpatient physicians to report uncertain diagnoses on their 99238 or 99239 codes. At this time, inpatient hospitals can report uncertain diagnoses documented at the time of discharge but inpatient physicians cannot. It would make sense that the diagnosis codes on the physician’s final bill match those of the hospital.
- Allowing physicians and hospitals to use old records to update a patient’s diagnosis list for chronic conditions. At this time, if a patient has HIV disease (B20) but the doctor only documents +HIV (Z21), the ICD10-CM Cooperating Parties do not allow a coder to obtain the necessary specificity from an old record. The physician must redocument this again.
- Allowing codes to be based on CMS definitions for conditions rather than just on provider documentation. For example, CMS can endorse a certain definition for conditions that impact risk adjustment, such as functional quadriplegia, sepsis (sepsis-2 or sepsis-3?) chemical dependency, presence of a cancer versus “history of”, malnutrition, and the like that can be clinically abstracted as to be coded rather than having the physician use the magic words that must be in the record as to assign the code. If you don’t do this, physicians who “play the game” of using the magic words will have a better risk adjustment and tempt the physician or biller into “upcoding”. Google the term “outpatient CDI” to learn that these activities are already in place.

I am fearful of using the CMS-HCC methodology in that it is also prone to “playing the game”. HCCs were meant to fund the Medicare Advantage program for a calendar year; however they are now being used for multiple reasons. Physicians will now have to deal with Risk-Adjustment Data Validators and the OIG, something that they are not accustomed to.

Challenges with HCCs include that bacterial pneumonia are not a HCC; however, a specified bacterial pneumonia is. End-stage renal disease has the same risk-adjustment as chronic kidney disease, stage 4, even though ESRD requires chronic dialysis and stage 4 does not.

If you do use HCCs, then you should allow for any chronic condition reported during the encounter or within the previous 12 months (not just in the last calendar year) to count in the risk-adjustment and any acute condition within the previous 6 months to factor into these. Physicians should be given a list of ICD-10-CM codes that impact these risk adjustments which should be released when the annual proposed physician rule is released, just like when CMS releases the IPPS rule for hospitals. Same goes for any other methodology you may embrace (e.g. AHRQ CCS; Optum’s Episodic Treatment Groups).

There should be a easy resource for physicians to access that describes these codes and encourages physicians to adhere to the ICD-10-CM Official Guidelines. What physician looks in the Index and then the Table? Almost no one; most physicians pick a code from a list in their EHR. Since Coding Clinic for ICD-10-CM/PCS is not in the public domain, this publication must be made available to physicians in a cost efficient manner. A current electronic subscription is over \$1000. Go to <https://codingclinicadvisor.com/> to see for yourself.

COMMENT 10 OF 69

Date: 4/20/2017

Commenter Name, Professional Title, and Organizational Affiliation: David Slotwiner, Chair, HRS Health Policy Committee, Heart Rhythm Society

Text of Comment:

The Heart Rhythm Society (HRS) appreciates the opportunity to respond to CMS’ latest solicitation for feedback on its ongoing work related to episode-based cost measure development for the Quality Payment Program (QPP). Founded in 1979, HRS represents more than 5,100 specialists in cardiac pacing and electrophysiology, consisting of physicians, scientists and their support personnel. Electrophysiology is a distinct specialty of cardiology, and electrophysiologists are board certified in clinical cardiac electrophysiology through the American Board of Internal Medicine, as well as in cardiology. HRS’s members perform electrophysiology studies and curative catheter ablations to diagnose, treat and prevent cardiac arrhythmias. Electrophysiologists also implant pacemakers, implantable cardioverter defibrillators (ICDs) and cardiac resynchronization devices in patients who are indicated for these life-saving devices.

In general, HRS is supportive of efforts to improve the manner in which CMS measures and attributes costs among clinicians. While quality measurement has evolved substantially over the last five years, cost measurement has been more vexing and many gaps remain. As such, HRS

appreciates CMS' commitment to developing more specific episode-based cost measures and its ongoing effort to engage in outreach to promote awareness of this work and to ensure that relevant stakeholders have the opportunity to contribute to this work.

The Society highly recommends that the Agency take all possible steps to avoid overlap or duplications of efforts as the episode groups are identified and defined. For example, HRS has nominated three physicians to serve on a Clinical Subcommittee specifically with Acumen in answering questions related to episode group and episode measure development. Below we offer more specific feedback on topics of interest to CMS.

Episode Group Selection

In selecting the episode groups to be considered for development, CMS used criteria including an episode's share of Medicare expenditures, clinician coverage, and the opportunity for improvement in acute, chronic, and procedural care settings. CMS welcomes comment on these episode groups and potential additional episode groups that should be considered for development.

In general, HRS believes that the proposed episode groups relevant to our specialty are reasonable targets for this exercise. We appreciate CMS' ongoing engagement of specialty societies in the selection of conditions and procedures and its commitment to developing clinically meaningful episode groups to inform cost measurement.

Episode Group Definition

The episode groups currently open for feedback are defined by proposed trigger events and codes (CPT/HCPCS for procedural episode triggers, evaluation and management codes combined with ICD-10 diagnostic information for chronic episode triggers, etc.). CMS solicits comment on the inclusion or exclusion of specific service codes used to identify each episode group.

In general, HRS does not have any major concerns about the trigger events and codes listed. However, the Society does find it challenging to provide meaningful feedback on the list of trigger codes without any other contextual information. In the absence of other critical details about the episode-- such as the episode window, the rules governing which services will be assigned to the episode, and risk adjusters—it is difficult to determine the appropriateness of the trigger codes.

As mentioned above, the Clinical Subcommittees should have a role in determining episode group definitions. Atrial Fibrillation (AF) is an excellent example of the need for clinical discussion. Defining AFib as an episode will involve a variety of healthcare providers. AF can be broken down into sub-categories based on the type of AF. AF also can be addressed as an episode based on medication management, or procedural management such as transcatheter ablation. The Cardiovascular Clinical Subcommittee's discussions should be driving factors in how AFib is addressed.

Our only episode specific concern at this time has to do with one of the proposed trigger codes for the procedural episode "Implantable Cardiac Defibrillator (ICD) Implantation." HRS is not

clear what the following trigger code refers to: “0294T: Insertion of Left Upper Heart Monitor and Pacing Defibrillator Pulse Generator, with Radiological Supervision and Interpretation”.

Overall, HRS encourages CMS to continue to adhere to a transparent and clinically informed process when defining episode groups. It is equally important that CMS rely on episode grouping methodologies that can be expressed via a simple list of rules and that are easily understood by clinicians, rather than methods that impose complicated hierarchies in what is often inaccessible back-end software. Additionally, the episode trigger claims should be constructed in a way so that clinicians know whether an episode will be attributed to them at the time of service.

Cost Measure Development

Cost measures are being considered for development based on episode groups after adding additional context, such as expenditure assignment, attribution, risk adjustment, and consideration of quality. CMS welcomes comment on each of these elements and whether there are additional elements to consider in developing cost measures from episode groups. Specifically, CMS welcomes comment on the concepts of differential attribution or alternative methods to align attribution with the clinical activities of clinicians. For example, the consideration of both directly and indirectly attributed services might be weighed in reporting both the provision and the coordination of care within the episode group relative to each clinician contributing to the care. An alternative approach would be to obtain recommendations from multi-specialty panels about percentages of the resources for an episode that could be attributed to physicians serving in different roles.

In general, it is important that clinicians understand and trust that the cost measure accurately reflects their performance and their unique role in treating the patient. We are supportive of CMS’ efforts to develop patient relationship categories and codes, which has the potential to better capture the varied roles of a physician in a specific episode of care and to result in more accurate attribution of resource use. However, we also believe that much work remains on this front.

HRS reminds CMS of the challenges of assigning cost performance to an individual clinician. We request that CMS carefully consider whether individual accountability for cost measurement is even appropriate and urge the agency to alternatively consider ways of accounting for more team-based care and measuring cost at a more aggregate level.

If CMS decides to move ahead with individual-level accountability, HRS supports it adopting an approach to episode-based cost measure construction, at least initially, which only assigns costs that are *directly* influenced by the care of the attributed clinician. Cost measurement, particularly at the individual-level, is complex and must be approached in a gradual manner. Attempting to evaluate indirectly attributed services or to assign percentage-based levels of attribution based on the varying roles of a physician is too complicated of a task to take on when first rolling out these measures. CMS should start with the least complicated targets by focusing only on those services/procedures for which costs can be clearly and directly attributable to a “lead” physician to whom it is appropriate to assign the total costs of the episode. This will not only ensure more equitable accountability, but that feedback produced by the measure is understood by the clinician (and patient) and actionable. If the episode creates any ambiguity related to attribution

or is influenced substantially by indirect care decisions, then it should not be targeted for cost measurement at this early stage.

Risk Adjustment

The Medicare Advantage program uses the CMS-HCC Risk Adjustment Model to determine rates. CMS seeks comment on the use of this model or an alternative for risk adjusting episode groups in the construction of cost measures. In addition, should concurrent or prospective risk adjustment be used, and should a full year of data or more targeted data from before the episode be used to adjust?

HRS appreciates that CMS aims to avoid any unintended consequences of using cost measures in MIPS. HRS strongly supports that CMS should take steps to avoid disadvantaging clinicians who assume the care of complex patients. While risk adjustment helps to mitigate some of these issues and is critical, the Society also asserts that performance benchmarks should only compare similar types of patients in similar settings.

Aligning Quality and Cost

CMS is especially interested in comments regarding methods to align quality of care with cost measures and welcomes suggestions on this topic.

If cost measurement occurs in isolation it can create incentives for clinicians to skimp on appropriate care. As such, it is critical that CMS focus only on episode-based cost measures that can be paired with quality measures that share similar characteristics. By doing so, patients and clinicians can interpret patient outcomes, such as functional status and mortality, side-by-side with cost. CMS also must develop tools that help patients and clinicians understand what cost means relative to quality, how to interpret incremental shifts between the two, and more holistic and accurate ways to value health gains.

Pairing cost with quality also will ensure that measurement is driven by value and not simply an effort to cut costs. This is especially critical when it comes to preserving incentives for innovation. CMS must not lose sight of the fact that while innovation and technology might drive health care spending, it also drives health improvement. By properly tying cost to quality and tracking data over the long-term, CMS will help to ensure that innovation is not stymied.

COMMENT 11 OF 69

Date: 4/21/2017

Commenter Name, Professional Title, and Organizational Affiliation: Sharon L. Dunn, President, American Physical Therapy Association

Text of Comment:

On behalf of our 95,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) is pleased to submit comments on the MACRA episode-based cost measures. APTA's goal is to foster advancements in physical therapist practice, research, and education. The mission of APTA is to further the

profession's role in the prevention, diagnosis, and treatment of movement dysfunctions and the enhancement of the physical health and functional abilities of members of the public.

Our hope is that our comments will influence implementation of the resource-use measures in the Merit-Based Incentive Payment System (MIPS), as these will impact outpatient physical therapists in private practice, as well as outpatient physical therapy services furnished by hospitals, outpatient rehabilitation facilities, public health agencies, clinics, skilled nursing facilities, home health agencies, and comprehensive outpatient rehabilitation facilities. In other words, implementation of MIPS will affect eligible professionals across the entire spectrum of the physical therapy delivery system.

Comments on Episode-Based Cost Measures

Episode Group Selection

As mentioned above, physical therapists practice across the continuum of care in a variety of settings, and our patient population is a diverse representation of many conditions and diagnoses. APTA believes that the identified high-impact conditions are a good beginning for our professionals, as physical therapists are part of the care team for a number of conditions included. Many of these initial groups include orthopedic conditions such as knee and hip replacements, hip fractures and dislocations, knee joint repairs, and spine procedures and fusion. Additionally, physical therapy codes are included in several cardiac condition groups, the rheumatoid arthritis group, and neurologic groups such as Parkinson disease and ischemic cerebral vascular accidents.

Acute Inpatient Medical Condition Episode Groups

APTA has concerns about creating only 1 acute episode group type, which would not distinguish the place of service or the performance of a procedure. We believe that creation of a single acute episode group for these patients, who may represent a wide diversity of conditions, will make the measure difficult to interpret and impact. Instead, we encourage CMS to consider creating several acute measures that are directed at more defined patient populations such as patients with cardiac conditions, chest pain, shortness of breath, and other related symptoms.

Chronic Condition Episode Groups

A significant number of Medicare beneficiaries suffer from chronic conditions, creating a need for episode groups for these patient populations. Defining episodes for chronic conditions poses several challenges. Many patients with chronic conditions have multiple comorbidities or multiple chronic conditions that are often interrelated. APTA recommends that CMS test a chronic condition episode group that represents several conditions that typically occur concurrently (CMS's example includes diabetes, hypertension, and coronary artery disease) versus a single chronic condition episode that has been adjusted for multiple comorbidities, to compare the benefits of each type of methodology. APTA believes that CMS should select the methodology that best accounts for resource use and makes the best clinical sense for providers who will need to identify and manage these patients. Additionally, APTA encourages CMS to look at other electronic data sources such as patient registries.

APTA believes that staging for conditions may be beneficial in comparing like episodes of care. Additionally, accounting for the severity of the condition is also important in the comparison of resource use across episodes, and APTA encourages the inclusion of such variables in the resource-use methodologies.

Cost-Measure Development

As discussed above, APTA believes that the cost measures should include risk adjustment that could account for comorbidities, severity of condition, and staging of condition when relevant. It will be important to account for patient characteristics within the cost measures to ensure that providers are being compared fairly and accurately on cost. Additionally, APTA believes that CPT billing codes in combination with diagnosis codes (ICD-10) should be used to determine services for a care episode. Because Medicare beneficiaries may seek physical therapy services for multiple conditions at one time, use of both billing and diagnostic codes will increase the likelihood of capturing the physical therapy charges related to the defined-episode group while excluding physical therapy services for unrelated conditions or diagnoses. We encourage CMS to continue to work with key stakeholders to ensure that all relevant CPT and ICD-10 codes are included in the episodes.

APTA believes that expenditure assignment is important in the development of cost measures. We believe there is value in providers seeing expenditures that are directly attributable as well as the services delivered by others for the same clinical purpose, which might be considered indirectly attributed services. We support the consideration of both directly and indirectly attributed services and the concept of weighting the direct and indirect services in reporting. We support this concept over a panel assigning percentages of the resources for an episode to specific providers. We believe that assigning fixed percentages within episodes will not account for changes in the care delivery system as episodic and bundled models evolve over time.

APTA believes that in the future CMS should align resource-use measures with clinical-quality measures. One possible approach to this would be a measure set that includes cost measures, key outcomes, patient engagement, and process of care measures for a specified condition or diagnosis. APTA believes these sets could be created within MIPS using measures from several of the categories to more precisely determine the value of services for specified patient populations. APTA also encourages CMS to incorporate measures from these sets into alternative payment models, where appropriate, to further encourage alignment of quality measures across programs and payment models.

APTA supports concurrent risk adjustment for the episode-based cost measures. We believe that concurrent risk adjustment will allow for more accurate comparison of costs within the episode of care. APTA also supports episode sub-groups. We believe that the creation of episode sub-groups will allow for greater clinical comparability of more clinically homogenous cohorts of patients with similar expected costs.

APTA believes these episode-based cost measures will require pilot testing with key stakeholder feedback prior to full implementation in MIPS. We encourage CMS to provide this data with any benchmarking data to all providers (MIPS and non-MIPS participants such as physical therapists) in 2018 with the continued neutral weighting in the cost category. This will allow all

clinicians to provide feedback to CMS on these measures as well as give clinicians the opportunity to understand the new methodology for the measures. Up to this point, many of the cost measures have been attributed to providers using rules around the plurality of services and are primarily directed toward physicians and other primary care providers. Our providers, and other nonphysician providers, have little to no exposure with episode-cost data. For these reasons, APTA believes CMS should continue to work with nonphysician professionals such as physical therapists on these episode groups to ensure that they make sense for nonphysician professionals, who typically are not primarily responsible for the ongoing care of these patients.

Conclusion

Once again, we thank CMS and Acumen for the opportunity to comment on the MACRA episode-based cost measures, and we look forward to working with CMS as the methodologies continue to evolve.

COMMENT 12 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Laura I. Thevenot, Chief Executive Officer, American Society for Radiation Oncology

Text of Comment:

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide written comments on the CMS Episode-Based Cost Measure Development for the Quality Payment Program document issued on December 23, 2016. Care episode groups take into account the patient's clinical indications at the time medical services are furnished during an episode of care and are used to define episode groups for procedures and acute inpatient medical conditions.

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). We applaud the implementation of a Clinical Committee to assist CMS with the development of episode groups. This transparent and collaborative approach is a positive step towards ensuring that the identified episodes adequately account for all of the services involved in the process of care. We urge CMS to continue this approach with the establishment of the Clinical Sub-Committees which are expected to include episodes of care that involve the treatment of cancer.

Below are ASTRO's responses to several of the questions posed for public comment:

Episode Group Selection

In selecting the episode groups to be considered for development, CMS used criteria including an episode's share of Medicare expenditures, clinician coverage, and the opportunity for improvement in acute, chronic, and procedural care settings. We welcome comment on these episode groups and potential additional episode groups that should be considered for development.

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. As previously mentioned, ASTRO is pleased that CMS is interested in establishing Clinical Subcommittees to assist with the development of episode sub-groups, which in the future may include radiation therapy.

In identifying the conditions and procedures which would be appropriate for episode groups or patient condition groups, CMS should consider those conditions or procedures for which there are established processes of care. ASTRO is currently working on a Radiation Oncology Alternative Payment Model (RO-APM) that features guideline adherence for episodes of care for seven disease sites. Existing ASTRO Clinical Practice Guidelines and Choosing Wisely recommendations are the basis for the ASTRO RO-APM. A similar approach should be taken in the development of episode groups for the MIPS episode-based cost measure.

We urge CMS to work with stakeholders on the identification of episodes of care that can meet the requirements of both the APM and MIPS initiatives. This will be particularly important for physicians who start out in the MIPS program or in a MIPS APM, who seek the opportunity to transition into an Advanced APM.

Episode Group Definition

The episode groups that accompany this posting are defined by the listed trigger events and codes (CPT/HCPCS for procedural episode triggers, evaluation & management codes combined with ICD-10 diagnostic information for chronic episode triggers, etc.). CMS solicits comment on the inclusion or exclusion of specific service codes used to identify each episode group.

ASTRO agrees with the concept of establishing appropriate trigger events and codes that define an episode group. In fact, the ASTRO RO-APM features a two-prong trigger that indicates the commencement of a radiation oncology episode of care. There are three radiation therapy treatment planning codes (77261, 77262, 77263). A treatment planning code is assigned to every patient receiving radiation therapy. Additionally, an ICD-10 diagnosis code is the second prong that triggers an episode of care for a particular disease site within the APM. We believe that the use of these code sets would also be appropriate for the identification of episode groups.

Acute episodes of care might occur on either an inpatient or outpatient basis and may or may not include surgery. CMS is considering a single Acute Episode Group type that does not distinguish the place of service or the performance of a procedure and welcomes

comment on this approach. If the Agency is to pursue a site neutral Acute Episode Group type, ASTRO recommends that CMS consider the various distinctions between sites of service, particularly the operational and fixed costs. The Agency must take great care to ensure that transition to a site neutral approach does not disadvantage one setting over another, potentially making the operation of sites financially unviable, resulting in an access to care issue.

Chronic Condition Episode Groups

CMS is aware of many challenges in constructing episode groups for chronic conditions. These include coding habits that may obscure some chronic conditions and over-emphasize others. In addition, it may be difficult to assign a given treatment to a single condition for patients with multiple comorbidities. For example, are the resources for treatment to reduce cholesterol for a patient with diabetes, hypertension, and coronary artery disease to be assigned to only one of those diagnoses, to all of them in proportion, or should we develop a chronic condition episode specific to the management of patients with diabetes, hypertension and coronary artery disease, i.e., a patient condition group to better compare cost to treat like patients? An extension of this approach might be a single episode group for outpatient chronic care with adjustment for comorbidities and demographics of the population served by the clinician. We welcome comment on these and any other options for constructing episode groups for chronic conditions.

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 patient characteristics. 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. 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 previously mentioned, it will be key for CMS to engage medical specialty stakeholders to develop appropriate criteria.

Certain specific conditions, such as cancer, present other challenges. The costs of caring for patients at different stages of disease are likely to vary. For instance, a single episode for a type of cancer is likely to differ in a predictable manner depending on the stage of the cancer. Information on disease staging is not easily or predictably available from claims. CMS welcomes comment on methods to incorporate disease severity or staging information to improve meaningful comparison of cost and quality of care furnished to patients, both generally and for specific clinical conditions. For example, how could a disease staging code be reported on claims to facilitate comparison of episodes for patients at like stages of cancer?

Episodes need to be clearly defined and recognize all the activities involved in the process of care. ASTRO agrees that key clinical information such as cancer stage may be critical in defining a cancer episode. However, cancer is a complex disease and the difficulties associated with a cancer diagnosis cannot be adequately attributed just to staging. Patient co-morbidities, age and other characteristics also play a role in determining treatment scenarios such as combined modality treatment which impact the potential cost of cancer care. While a disease stage code

may assist in identifying specific cancer stages, it will not recognize the remaining complexities associated with treating cancer.

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.

Procedural Episode

We solicit comment on the procedural episode groups that accompany this posting, including the service and diagnosis codes used to identify the existence of the procedural episode groups. We also welcome comment on additional procedural episode groups to consider for future development.

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. At this time, ASTRO defers to other specialty groups on the content of the currently defined episode groups. We look forward to opportunities to engage with the Agency on the development of episodes specific to cancer care.

Cost Measure Development

Cost measures are being considered for development from episode groups after adding additional context, such as expenditure assignment, attribution, risk adjustment, and consideration of quality. We welcome comment on each of these elements and whether there are additional elements to consider in developing cost measures from episode groups.

As previously stated, 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.

As described above, the degree of responsibility of attributed services might be considered separately. Those services furnished by the attributed clinician for the clinical purpose of the episode group might be differentiated from the services provided by others for the same clinical purpose. The services furnished by the attributed clinician might be considered directly attributable services. These could be correlated with the services delivered by others for the same clinical purpose, which might be considered indirectly attributed services. The consideration of both directly and indirectly attributed services might be weighed in reporting both the provision and the coordination of care within the episode group relative to each clinician contributing to the care. An alternative approach would be to obtain recommendations from multi-specialty panels about percentages of the resources for an episode that could be attributed to physicians serving in different roles. We welcome

comment on these concepts of differential attribution or alternative methods to align attribution with the clinical activities of clinicians.

ASTRO would support efforts that allow multi-specialty panels, with representatives from all relevant specialties, the opportunity to determine appropriate attribution. CMS should develop episode groups that clearly define and attribute responsibility for care to physicians that they can reasonably control. CMS should focus on those services for which there are well defined processes of care and clinical treatment guidelines that have been vetted and agreed upon. There are numerous services that fit into this category and they should be given immediate consideration.

Those services that are more complex should be given further consideration and study. ASTRO supports the concept of engaging multi-specialty panels to determine appropriate attribution for medical services that involve multi-disciplinary care.

The Medicare Advantage program uses the CMS-HCC Risk Adjustment Model to determine rates. We seek comment on the use of this model or an alternative for risk adjusting episode groups in the construction of cost measures. In addition, should concurrent or prospective risk adjustment be used, and should a full year of data or more targeted data from before the episode be used to adjust?

ASTRO is concerned that CMS is still at the beginning stages of developing risk adjustment and attribution methodologies for the episode-based cost measures. We urge CMS to use concurrent rather than prospective risk adjustment. Without including current comorbidities and diagnoses, CMS cannot properly risk adjust patients.

In addition, ASTRO urges CMS to consider risk adjustment beyond clinical adjustment. While it is obvious that factors such as patient's functional status should be risk adjusted, it may be reasonable to include socioeconomic and demographic factors in any final risk adjustment methodology. For example, barriers to accessing healthcare services (such as living in a rural area) may appropriately be included in a risk adjustment calculation.

ASTRO understands the complexity around developing appropriate and accurate risk adjustment and attribution methodologies. The agency will need detailed clinical input from across medical specialties to improve risk adjustment and attribution going forward, and we urge CMS to utilize its clinical committees to develop these methodologies. CMS will also need to consider a strategy that is not overly burdensome and dependent upon physicians collecting and documenting a significant amount of information and data.

The draft list does not currently include specifications for episode sub-groups (a sub-group is intended to achieve greater clinical comparability and is a subdivision of an episode group that further refines the specifications of episode trigger codes and grouping rules to yield more clinically homogenous cohorts of patients with similar expected cost). An example is an episode group for spine surgery with sub-grouping for number of levels and anatomic location. CMS solicits public comment on these draft episode groups and potential sub-groups.

ASTRO has noted that CMS intends to explore “Oncologic Disease Management – Medical and Surgical” as a future Clinical Subcommittee. The appropriate use of radiation is an essential component (along with surgery and systemic drug therapy) in the management of oncologic disease. It is appropriate that the proposed Clinical Subcommittee on Oncologic Disease Management include Medical, Surgical and Radiation Oncology in the charge and that physicians from each specialty be called upon to participate.

The American Cancer Society estimates that there were 1.7 million new cancer cases in 2016¹. Of those cancer patients, 250,000 were diagnosed with breast cancer; 225,000 were diagnosed with lung cancer; 181,000 were diagnosed with prostate cancer; 95,000 were diagnosed with colorectal cancer; and 72,100 were diagnosed with head and neck cancer. Medicare SEER data analysis indicates that, of the Medicare patients receiving radiation therapy, 83 percent had one of five primary disease sites, which accounts for 93 percent of the total Medicare spend on radiation therapy services between 2007 and 2011².

ASTRO looks forward to engaging with the agency on the development of episodes, particularly for the primary disease sites listed above, as we believe these sites cover the largest portion of the Medicare patient population fighting cancer.

CMS is especially interested in comments regarding methods to align quality of care with cost measures and welcomes recommendations and suggestions. Considerations for aligning episode groups with quality measurement are described in this document, but are not intended to be an exhaustive list of options. We welcome comment on these methods, as well as any other strategies that could be used to align quality of care considerations with cost measures.

ASTRO has given serious consideration to the intersection of cost and quality, specifically how adherence with clinical guidelines can improve quality of care and reduce unnecessary costs. ASTRO’s RO-APM is built around guidelines adherence as a proven methodology for improving care and reducing the cost of care. We believe a similar approach can be used in the development of episode groups. Quality measures can be derived from evidence-based guidelines that ensure that appropriate care is delivered and costs savings are achieved. By starting with episodes that are easily defined by existing processes of care and clinical guidelines, CMS is more likely to achieve its intended goal of instituting a value based payment system.

CMS wishes to avoid any unintended consequences of using cost measures in MIPS, and seeks comment on issues of concern in this regard, such as taking steps to avoid disadvantaging clinicians who assume the care of complex patients such as by applying episodes for comparison of complex patients (i.e., comparison of like-patients of different clinicians).

As previously mentioned, CMS should develop episode groups that clearly define and attribute responsibility for care to physicians that they can reasonably control. ASTRO also urges CMS to include risk adjustments that address multiple chronic 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. Lastly, it is critical that any future Oncologic Disease Management Clinical Subcommittee include radiation oncology.

1 Cancer Facts & Figures 2016, American Cancer Society,
<https://old.cancer.org/acs/groups/content/@research/documents/document/acspc-047079.pdf>

2 Chen MD MPP, Aileen, et al., Medicare Spending in Cancer: A SEER-Medicare Analysis, Dana-Farber Cancer Institute, Boston, MA, 2016

COMMENT 13 OF 69

Date: 4/21/2017

Commenter Name, Professional Title, and Organizational Affiliation: Samir Fakhry, Chair, Trauma Center Association of America

Text of Comment:

The Trauma Center Association of America (TCAA) is a non-profit, 501(c)(6) association representing trauma centers and systems across the country. TCAA is committed to ensuring access to life-saving trauma services, and it is out of that commitment that we submit these comments for your consideration.

TCAA in collaboration with the American Trauma Society (ATS) and the Eastern Association for the Surgery of Trauma (EAST) appreciates CMS' engagement of the stakeholder community in its development and refinement of Merit-based Incentive Payment System (MIPS) cost measures. We agree with stakeholder feedback to-date that has emphasized the importance of having patient outcomes at the center of these cost measures. We also agree that it is critical to apply a clear and transparent attribution methodology to ensure the appropriate assignment of episode groups to clinicians. Finally, we support the development of cost measures that both account for patient complexity and appropriately address traumatic injury.

Below we provide our specific feedback to several of the questions outlined on pages 17-20 of CMS' posting titled, "Episode-Based Cost Measure Development for the Quality Payment Program." We hope our feedback will facilitate the further refinement of these cost measure development process.

Risk-Adjusting Episode Groups

The TCAA agrees that it is critical for CMS to adjust for factors that can influence expenditures but are outside a clinician's control. For example, patients differ in their severity of illness, function, age, type and number of comorbidities and chronic conditions, etc. must be taken into consideration in any risk adjustment methodology that is used. Additionally, accounting for patient complexity and health status, including traumatic injuries and chronic conditions, is critical to ensure that clinicians who treat particularly unhealthy or complex patients, such as trauma patients, are not penalized.

At a minimum, once a patient suffers a traumatic injury, we believe these patients be excluded from the cost measure. Traumatic injuries should be defined by any institutional claim with admission type "5" for trauma and/or any primary ICD-10 diagnosis codes:

S00-S99 with 7th character modifiers of A, B, or C ONLY. (Injuries to specific body parts – initial encounter) T07 (unspecified multiple injuries) T14 (injury of unspecified body region) T20-T28 with 7th character modifier of A ONLY (burns by specific body parts – initial

encounter) T30-T32 (burn by TBSA percentages) T79.A1-T79.A9 with 7th character modifier of A ONLY (Traumatic Compartment Syndrome – initial encounter).

Excluding the following isolated injuries which may be a primary diagnosis:

S00 (Superficial injuries of the head)

S10 (Superficial injuries of the neck)

S20 (Superficial injuries of the thorax)

S30 (Superficial injuries of the abdomen, pelvis, lower back and external genitals)

S40 (Superficial injuries of shoulder and upper arm)

S50 (Superficial injuries of elbow and forearm) S60 (Superficial injuries of wrist, hand and fingers) S70 (Superficial injuries of hip and thigh)

S80 (Superficial injuries of knee and lower leg)

S90 (Superficial injuries of ankle, foot and toes)

Late effect codes, which are represented using the same range of injury diagnosis codes but with the 7th digit modifier code of D through S, are also excluded.

The TCAA believes that trauma patients should be excluded altogether because trauma care itself and the patients are ill suited to the objective of episodes, attribution and cost control. Trauma care is team-based care that includes numerous specialties, both within the same group practice and across group practices. Patient out-come is a function of team-based care and difficult to attribute to any single clinician. Trauma patients do not lend themselves to benchmarking or care pathways because few trauma patients are similar in the mechanism of injury and the number and types of injuries. For these significant reasons, we believe trauma patients should be excluded from cost-based episodes entirely.

Should CMS proceed with inclusion of trauma patients, the TCAA asks whether CMS has conducted any studies on the ability of HCCs to account for the expense of patients suffering a traumatic injury. The retrospective or prospective nature of HCCs as they are currently deployed will not explain current year expenditures for an unexpected traumatic injury. The TCAA strongly believes any risk adjustment for trauma patients should be concurrent.

Furthermore, because HCC risk adjustment scores impact Part C payment for a third of Medicare beneficiaries, it is important for all clinicians and providers to know the risk adjustment score for each patient. For improved transparency with the provider community, the TCAA recommends that the HCC score assigned to each patient be included as a data element in the Common Working File and released with each eligibility response (i.e., 271 transaction) to providers. This will enable providers to begin to understand HCCs. CMS should consider an appeal process provider believes the HCC risk score is significantly different from what it should be based on more current data, including recent traumatic injuries.

Attribution and Episode Definitions

The TCAA understands that MACRA requires new patient relationship categories and codes to be reported on claims as of January 1, 2018. We further understand that CMS expects to release an operational list of these categories and codes for review in April 2017. Since the information has not yet been released, the TCAA is unable to provide meaningful feedback to CMS on how the codes should best be incorporated into its attribution model, particularly for trauma patients. We ask CMS to provide another comment period after the patient relationship codes are released to provide meaningful input on use of the relationship codes and attribution methodologies.

We also believe CMS needs to be very thoughtful in attribution of trauma patients because as noted above attribution to any one clinician is nigh to impossible. We note that hospital claims only have fields to report one attending physician and one primary surgeon. The lack of specific physicians on hospital claims makes attribution very difficult. For acute episodes how will the trigger event be attributed to a clinician? What if the trigger event, such as a nephrectomy is due to a trauma. Will the attribution be based on the hospital claim data or the professional claim data or will they be matched? What happens if the claims do not match.

As previously mentioned, trauma patients often have numerous specialty physicians involved in their care as well as several physicians within the same group practice due to the extended time of trauma episodes. Will every hospital claim for a trauma be attributed to every physician involved in the patient's care? What happens to a patient with a chronic episode and then a trauma claim occurs? How are ambulance costs attributed? Including these claims is likely to create an outlier situation for the clinician to whom the hospitalization and ambulance is attributed.

Because the trauma is outside the control of the clinician who is managing chronic or other acute conditions, we believe it is inappropriate to attribute any trauma claims to clinicians and believe they should be excluded.

We request CMS disclose how it plans to treat outliers. How will outliers be defined? Will outliers be excluded from the cost calculation or not? Will patients who die be included in episodes or excluded? We request CMS define inclusion and exclusion criteria and outlier provisions that will help shape episodes that reflect clinician management of patient care rather than serendipitous events that may also occur and significantly impact beneficiary cost of care.

Implementation Timing

Given the number and nature of the questions associated with the development and refinement of the MIPS cost measures, the TCAA recommends that CMS delay implementation. We suggest that the cost category not be factored into the final MIPS score until payment year 2021 or 2022 at the earliest. In other words, we encourage CMS to keep the cost category weighted at zero percent (0%) of the MIPS final score until it has better data to use and the risk adjustments and episode definitions have been fully defined with stakeholder input. This would also give clinicians more time to understand the relationship codes, cost measures and attribution methodologies.

Should CMS wish to continue to include trauma patients, the TCAA along with other trauma stakeholder groups and professional associations would like to be included in future discussions with CMS to determine whether cost episodes for trauma patients can be fairly defined and attributed to clinicians.

The TCAA, ATS and EAST sincerely appreciate the opportunity to provide input into the development of MIPS cost measures. If you have any questions, please do not hesitate to contact us.

COMMENT 14 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Kerry D. Solomon, President, American Society of Cataract and Refractive Surgery

Text of Comment:

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing nearly 9,000 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care.

Thank you for the opportunity to provide comments on the Episode-Based Cost Measure Development for Quality Payment Program (QPP). We have provided comments on two previous requests for information related to episode-based measures and our members have participated in technical expert panels convened by CMS on this topic.

We are pleased that many of the recommendations ASCRS has made are considered and reflected in this most recent document. CMS now seems to recognize that major changes are needed to the attribution and risk adjustment of the models to ensure they are reliable, credible, well understood by physicians, and do not pose any threats of adverse selection on patient care.

Due to this identified need to test and improve these measures, our chief recommendation is that CMS significantly narrow the scope of the effort to develop new measures and limit an initial test phase to just a few conditions or procedures before expanding to the development of measures for all procedures and conditions identified in the most recent posting. There is significant work to be done to address the attribution and risk adjustment, and CMS still has not proposed how these measures will be factored into a physician's cost score. Furthermore, we encourage CMS to consider how the administrative efforts and the time spent to update clinical processes to adapt to these measures may contribute to practices' already heavy regulatory burdens. Physicians and practices should not be required to make these adjustments until they are confident the cost measures are refined and will accurately measure the cost of care they provide. Until these issues can be addressed, CMS should only proceed with a limited test group of measures.

Care and deliberation must be taken to ensure that the episode groups reflect the following:

- The attribution methodology appropriately holds physicians responsible for the cost of care they themselves provide and control.
- Episode-based measures must be adequately risk-adjusted to ensure the sickest patients do not lose access to care.

- There must be an identified need to improve clinical practice and reduce disparities in the quality and cost of care to create an episode measure. For example, when controlling for major ocular co-morbidities there is very little cost variation in cataract surgery, other than the site of service.
- The methodology for determining cost should be flexible to allow for choice of a treatment option that is best for the patient and will lead to a potentially better outcome, rather than determine a resource use score solely based on the cost of that care. In some cases, such as when treating glaucoma, a relatively higher one-time cost of selective laser trabeculoplasty (SLT), may result in better outcomes for the patient and ultimately save more to Part D for discontinuing the use of eye drops.
- Recognize that existing co-morbidities, socioeconomic factors, health condition, patient compliance, and health disparities—all outside the physician’s control—contribute to the type and cost of treatment patients receive, as well as their outcomes.
- The measures must reflect the site of service for a procedure, since facility payments for cataract surgery performed in HOPDs are more than 40% higher than for those done in ASCs. In most instances, where the surgery is performed is out of the physician’s control.
- The measures must exclude the cost of Part B drugs administered in the office, since physicians cannot control the cost of the drugs.
- CMS must demonstrate how or if these measures will be applied in conjunction with existing measures, such as Medicare Spending per Beneficiary and Total Cost per Capita.
- Please find, below, general comments on the development of the episode groups and direct comments on each of the ophthalmology related proposals.

ASCRS CONCERNS WITH TIMELINE, SCOPE, AND IMPACT OF EPISODE GROUPS

As we noted above, we appreciate that this new proposal begins to take many of our previous comments into consideration and attempts to include in the methodology elements to improve attribution, episode construction, and risk adjustment. Even though CMS has recognized the breadth and diversity of the care Medicare beneficiaries receive, it seems like the work done on addressing these issues is superficial and not yet ready for implementation. This is particularly disturbing now that the list of episodes covers nearly every condition, procedure, and specialty numbers into the hundreds. **We warn CMS that without proper testing before implementation, Medicare beneficiaries’ access to care could be put at severe risk.**

We also advise CMS not to disregard our concerns about adverse selection and the possible unintended consequences of a model that is too punitive and could limit access to care for the most complicated and sickest patients. If the resource measures are not properly risk-adjusted, physicians will be disincentivized from providing costlier and riskier care to patients—which, in ophthalmology, may include efforts to keep a patient from going completely blind—because they know they will be penalized. Physicians must not be forced to choose between upholding their ethical duty to provide care for their patients and the need to keep their practices financially sound.

We propose that CMS and its contractors re-focus this project on a limited number of procedures or conditions—perhaps just one or two episodes from each category (inpatient, procedural, chronic)—and ensure they are adequately tested and risk adjusted to demonstrate to the medical community that the measures are credible, will not result in loss of access to care, and can be scaled up to include a wider range of conditions and

procedures. In addition, CMS must demonstrate how these measures will be benchmarked and eventually tie into a physician's MIPS score.

Additional Development of Attribution and Risk Adjustment Models Necessary

- **As noted above, ASCRS appreciates that CMS has taken our concerns about risk adjustment, patient attribution, and possible adverse selection into consideration and included them in the request for information.** In addition, we appreciate CMS' efforts to make the process to develop these measures more transparent with the ongoing opportunities to provide input through technical expert panels and listening sessions. In earlier comments on episode proposals, we expressed concern that the medical community—and, in particular, the medical specialty community—was not adequately involved in the development. By including us in the process and responding to our feedback, this most recent request for information **begins** to incorporate how these issues will be addressed in the episodes. **However, this proposal includes very few details for how CMS and its contractor will work to overcome these impediments to fair and accurate measurement.**
- **The request for comments notes that CMS is interested in receiving feedback on methods to attribute episodes to individual physicians and risk adjust the episodes.** In our past comments, ASCRS has given many examples of how to fairly attribute costs—so as not to hold physicians accountable for care they did not provide or could not influence—and noted that excluding patients with major ocular co-morbidities in a manner similar to existing quality measures would be a good starting point to ensure the sickest patients do not lose access to care. However, none of those suggestions are fleshed out in this request for information, and it is unclear how CMS plans to operationalize creating these methodologies. **Simply acknowledging that a better attribution process and risk-adjustment method are needed is not sufficient for ASCRS or others to provide relevant feedback to ensure CMS and its contractor are on the right path.**
- **We continue to urge that CMS re-focus its efforts on a much shorter list of episodes to ensure sufficient time and effort are devoted to addressing issues with attribution and risk adjustment.** We recommend that CMS create a pilot program for these episodes using historical data from claims and clinical data registries to demonstrate clearly how episodes will be attributed to physicians, how high-risk patients with costlier treatments will be measured or excluded, and how the data will be used to score the physician before proceeding with developing episodes for all the conditions and procedures listed in the most recent document.
- **Given the extensive work yet to be done on these episodes, we also urge CMS to extend the current 0% weight of the Cost category of MIPS at least through the 2018 performance period/2020 payment year.** Under the MACRA statute, CMS may re-weight the four categories of MIPS. Following our recommendations in comments on the MIPS and Advanced Alternative Payment Model (APM) proposed rule, CMS re-weighted the Cost category for the first year to zero, since the proposed measures relied on a flawed attribution methodology and episode-based measures were un-tested. The statute also gives CMS ability to consider the second year of the program a “transitional” year. Extending the 0% weight for the Cost category would give additional time to develop and test the new episode measures.
- **We urge CMS not to lose sight of ensuring the measures are valid, tested, and understood before continuing with the current implementation timeline. It is more**

important to ensure the measures are correct than implemented quickly. CMS has yet to propose how the measures will be scored, and until physicians have time to understand how the measures will impact their scores, they should not be included in the final MIPS score calculations.

Education for Physicians and Practices

- **Not only do we believe the episode groups need extensive testing, far more outreach to—and education for—physicians and practices on these groups is necessary.** We realize that CMS has made supplemental quality and resource use reports (QRURs) available to physicians with a demonstration of how their practice would be attributed costs under the Method B cataract episode. However, the existence of the reports was not well publicized, and it is extremely difficult for practices to find online, as well as difficult for the average physician not familiar with this effort to interpret. We encourage CMS to calculate what percentage of physicians have downloaded these reports to determine to what extent physicians may be familiar with existing cost measures. Further, even our physician members who volunteer their time for ASCRS and medical community public policy efforts—including the development of episode measures—and who have a greater knowledge of current health policy issues find these reports to be beyond their understanding. **ASCRS recommends that CMS conduct extensive testing and training to ensure resource use reports are understandable, user friendly, and actionable before implementing these episode groups to ensure physicians understand how they will be used to measure resource use.**

ATTRIBUTION AND EPISODE CONSTRUCTION

ASCRS has long opposed CMS' existing policies for attribution—first as part of the Value-Based Payment Modifier (VBPM) and then continued in the MIPS program—because the measures are primary care-based and potentially hold certain physicians, particularly specialists such as ophthalmologists, responsible for care they did not provide. **We continue to believe episode-based measures hold the promise of more fairly attributing the cost of specialty care, but maintain that only costs that are within the physician's control should be evaluated.**

- **The episodes must be formulated to account for the total cost of care attributed to that condition for the patient and recognize that, particularly in specialized care such as ophthalmology, the type, length, and outcome of the treatments can vary widely.** Some treatments may be more expensive than others, but they may be the correct treatment for that patient and lead to a better outcome. For example, a patient whose visual loss is no longer progressing will be able to live a happier and more independent life, with fewer costs to society. However, it is difficult to measure the satisfaction and savings of the individualized treatment plan for that patient in relation to a treatment for a different patient with different needs. Alternatively, the sickest patients with the most severe disease states often require the costliest treatments, and due to the severity of the disease, may have a higher likelihood of poorer visual outcomes. **Physicians who are using their clinical judgement to provide a specialized course of treatment for a particular patient—such as an ophthalmologist striving to prevent a patient from going totally blind—should not be penalized for working to find the right treatment for their patients. We are concerned that the current proposals would do just that.**

- CMS must clearly define how costs will be attributed to specific physicians based on these episode groups, and how they will be used to measure resource use.** Ophthalmology is one of the few specialties that provide both ongoing medical care as well as episodic surgery, and as such, ophthalmologists have a variety of treatments to treat both chronic disease and acute episodes. Due to this range in the type of diseases and treatments offered, ophthalmologists might have a disincentive to offer only the least expensive form of treatment. For glaucoma patients, for example, some patients may be well managed using drops but would benefit from surgery. However, if cost is only measured in discreet time periods within the episode window, this creates an incentive to keep the patient on drops and not perform the surgery. While the surgery may increase the cost of the treatment in the immediate term, maintaining the patient’s regimen of drops for the chronic disease would be far costlier to Medicare in the long term. For example, a 2012 study found that the savings of performing laser trabeculoplasty (LTP) as opposed to continuing a course of generic topical prostaglandin analogs (PGAs) are realized in 13.1 months.¹ Another 2012 study estimated that LTP provided a cost saving of \$2,645 per quality adjusted life year compared to PGAs.² **The savings, not only to Medicare, but for the potential improved quality of life for the patient, are significant. However, if resource use measures are only based on the cost of one-time episodes, such as a surgical intervention, and do not take a holistic view, especially when considering the ongoing costs of caring for chronic disease over time, physicians could ultimately be penalized for providing care that may cost more in the immediate term, but have lasting savings over the long term.**
- We encourage CMS to incorporate the patient relationship modifiers into the development of the episodes to provide prospective attribution.** The patient relationship modifiers ensure physicians know which patients’ cost of care they are responsible for, and can therefore develop courses of treatment and monitor patients in an appropriate way to impact cost scores. **In the request for comments, CMS mentions that efforts to develop the patient relationship modifiers are underway and may be used in attribution for the episodes in the future. We urge CMS to combine efforts to develop the patient relationship codes and episodes at the same time, so that the modifiers can be incorporated into the attribution process for the episodes at the beginning, rather than having to further refine the episode measures later.**
- The site of service—which is not always in the physician’s control—should be accounted for in the attribution methodology. Physicians practicing in one type of facility should only be compared to other physicians practicing in the same type of facility.** Ophthalmic surgery can be performed in either hospital outpatient departments (HOPDs) or ambulatory surgery centers (ASCs). The facility reimbursements for ASCs are well below HOPDs. Cataract surgery, for example, is reimbursed 45% less in the ASC than in the HOPD. While some ophthalmologists have the option of building and owning their own ASC, state certificate of public need laws prevent some physicians from opening new ASCs, so they may be forced to operate in HOPDs. In addition, some physicians, especially sole practitioners, may not have the resources to construct and manage their own ASC, and must operate in whatever facility, either ASC or HOPD, is available. In feedback provided as part of the clinical TEP process, we and other ophthalmic groups recommended that separate episodes be created for each site of service, so that cost comparisons are equitable; however, we do not see that recommendation reflected in the current request for information. Despite these limitations and given the choice, ophthalmic surgeons would likely prefer to operate in the lower

cost ASC. ASCs are not subject to the same requirements as HOPDs, such as extensive pre-operative testing, that are not relevant to treating ophthalmic disease. In addition, patients may prefer to undergo surgery in ASCs, since they are easier to navigate. Ophthalmic surgeons want to make the cost-effective choice, but cannot always do so. **Given that, the episodes must take site of service into account by only comparing the cost of episodes that were performed in the same type of facility, since the site of service is not always in the control of the physician.**

- **ASCRS recommends that CMS exclude the cost of Part B drugs from episode measures. The price of certain drugs administered in the office is rarely in the physician’s control, and other options—especially compounded or repackaged drugs—may not be available.** Ophthalmologists, both in general practice and retina subspecialties, frequently use intravitreal injections to treat diabetic retinopathy and age-related macular degeneration (AMD). On-label use of bevacizumab packaged for ophthalmic use to treat AMD costs in the tens of thousands of dollars over the course of the treatment, and means high out-of-pocket costs for patients. Off-label use of repackaged bevacizumab is much less expensive. While recently updated draft guidance from the FDA would make the repackaging of bevacizumab more feasible, it is concerning that physicians could potentially be penalized for prescribing on-label drugs, and that CMS is thereby indirectly requiring the use of off-label drugs. **Episode measures should not include Part B drugs to ensure patients receive the drugs they need, and so that physicians are not forced to use off-label drugs.**
- **Throughout the request for comments, CMS notes its goal of developing measures that provide “actionable” information to physicians.** ASCRS strongly supports the goal of actionable information. The current resource use measures may include the cost of care that the individual physician did not provide to the patient, and information related to a physician’s cost calculation—provided in obtuse and not easily accessed reports—is not available until almost a year after the performance period ends, which all proves to be nearly useless to physicians and practices seeking to improve clinical care and administrative efficiencies. **We are encouraged that CMS is seeking to make these measures more meaningful and actionable; however, if factors such as site of service and the cost of Part B drugs are included in the calculations, cost measure data will not be useful or actionable.**
- **The framework for determining resource use should also account for the severity of the patient’s disease, which impacts the type and cost of care a physician may provide.** As mentioned above, the sickest patients often need the most expensive treatments and—despite the concentrated effort of the physician—may not have positive outcomes. **If the resource use methodology penalizes physicians for providing costlier and riskier care, this may pose a threat to access to care for the sickest patients, since physicians would be disincentivized to provide the most specialized care.**
- **Physicians should not be attributed the costs of care that they, or other physicians, are required to provide due to such issues as patient compliance or socioeconomic factors, which are beyond their control.** For instance, patients with diabetic retinopathy can be treated with injections or laser treatments, but if the patient does not seek to control the progression of the underlying disease of diabetes, the diabetic retinopathy will continue to worsen. If the patient lives in an area without access to grocery stores with fresh fruits and vegetables, or cannot or will not exercise, his or her disease will continue

to progress. Patient compliance can have an impact on the progression of the disease, and ultimately the cost of care. Similarly, patients suffering from other chronic eye disease, such as glaucoma, may have difficulty attending regular doctors' appointments for pressure checks and may not always be able to follow the prescribed treatment of eye drops. The ophthalmologist treating this type of patient should not be penalized for providing the more expensive care when the patient could not comply with the original course of treatment.

- There are also a variety of socioeconomic factors that impact overall care for certain patients. For example, lower income patients or patients in rural areas may have difficulty making regularly scheduled appointments if they do not have access to reliable transportation or must travel longer distances. In addition, older patients have mobility issues and rely on other caregivers to bring them to the physician's office. In general, ophthalmologists tend to treat older Medicare patients, who may not have the manual dexterity required to administer their medicated eye drops. Poor adherence to the course of treatment can lead to poor visual outcomes. **All of these factors can impact their ability to receive regular care, as well as the ultimate cost of care, and should not be attributed to the physician.**
- **Physicians also should not be attributed the extra costs for treatments required due to other care the patient is receiving from other physicians.** For instance, if a cataract patient is prescribed Tamsulosin by a primary care physician, that patient will likely require the use of iris retractors during cataract surgery, leading to the use of the complex cataract surgery code 66982, reimbursed at a higher value than cataract surgery, 66984. It is not currently possible to determine how those costs would be attributed from the proposed episode groups.
- **The attribution model must account for co-management of post-surgical care by multiple physicians.** Frequently in ophthalmology, an ophthalmologist may perform the surgery, but post-surgical care is provided by another ophthalmologist or an optometrist. This arrangement is at the request and consent of the patient, and is generally done so patients can maintain a relationship with an existing provider or because they may need to travel some distance for the surgery and may prefer not to travel for follow-up care. Billing for co-managed post-surgical care is done using the 54/55 modifiers and under current episode measures finalized in the MIPS rule, all costs are attributed to the surgeon. **Episode-based measures must also attribute costs appropriately to all physicians providing care throughout the episode.**

RISK ADJUSTMENT

ASCRS has significant concerns regarding risk adjustment and the method CMS will use for these episode groups. Throughout quality reporting and resource use programs, CMS has not determined how to adequately adjust for patients with certain co-morbidities and risk factors. In this most recent request for comments, CMS devotes only two paragraphs to discussing risk adjustment and seeks comments on developing a methodology. **ASCRS and others in the ophthalmic community have always maintained, and we will reiterate below, that the methodology should be based on the exclusionary criteria from ophthalmic quality measures, which remove patients with relevant ocular co-morbidities from calculation. While these exclusions are necessary, additional work must be done to ensure that vulnerable patient populations, with factors outside the physician's control, do not lose access to care because of these measures. The lack of work done by CMS and its contractors in developing such a methodology is yet another reason why the entire episode**

measure project should be more narrowly focused at first, so that these issues can be addressed.

- **Without an accurate risk-adjustment methodology, CMS risks creating a system that encourages the care of less severe and uncomplicated patients and discourages the care of the sickest, most complex patients. This prioritization goes against our members' ethics as physicians and must be prevented.**
- **The patient's ability to comply with the prescribed treatment, and socioeconomic factors, also affect the cost of care. We are not aware of any models that adequately adjust for risk factors outside of the physician's control. Episode measures must incorporate appropriate risk adjustment so physicians are not penalized for factors they do not control.** As we have discussed above, patient compliance, health disparities, and socioeconomic factors may all have a significant impact on the cost of the care and the outcome. To ensure that the cost of care due to these factors beyond the control of the physician are not attributed when determining resource use, CMS must develop a transparent and robust risk adjustment model.
- **Without an appropriate risk adjustment model, the sickest patients, who may require more advanced courses of treatment, may have limited access to the care they require.** Occasionally with cataract surgery, if a surgeon sees a patient whose case has a high likelihood of complication, the surgeon may send the patient to another cataract surgeon with more expertise in high-risk cases, or a cataract surgeon who also has a retinal surgeon in his or her office in case of complications. **If risk adjustment is not done correctly, the providers accepting the high-risk cases will get penalized for consistently seeing more complicated cataract cases.**
- **Ophthalmologists treat diverse patient populations nationwide. One physician's patient base in one area may be on average younger and more able to access care and comply with treatments, while another ophthalmologist in another area may have relatively older, less mobile patients who have difficulty attending regular appointments or lack manual dexterity to apply eye drops. Without acknowledgement of diverse patient populations, the sickest and most vulnerable patients, whose care is often the most complex and expensive, are at risk of losing access to care.** Some cataract surgeons do enough procedures to avoid the problem of adverse risk selection, while others do not and may choose to see lower-risk cataract patients to avoid being penalized for the extra resources needed to treat high-risk cataract patients. Choosing a course of treatment for a patient so as not to adversely impact a resource use score becomes a difficult ethical dilemma for a physician who wants to uphold his or her sworn duties. However, if a physician does not keep these considerations in mind, it may impact the overall viability of his or her practice, and thereby the ability to care for other patients. Not only would this situation place physicians in an ethical quandary, the day-to-day task of monitoring the cost of care for each patient will add considerably to the already heavy regulatory burdens physicians face. **If cost measures are not developed with appropriate risk adjustment, the physicians who care for the most complicated and sickest patients, who are most likely to have a poorer outcome, will be more likely to be penalized. If physicians know that treating certain high-risk patients may negatively impact their resource use scores, they may choose not to treat those patients. Further, all patients are at risk of limited care if, prior to treatment, a physician is forced to make individual cost calculations to estimate how the patient may affect his or her cost score.**

Include Quality Measure Exclusions

- **One way CMS should begin developing risk adjustment models is to account for comorbidities identified as exclusionary criteria in the quality measures already in use in the QPP.** For example, Measure 191, Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery, notes that patients with documentation of more than 50 different significant ocular conditions, reflected in hundreds of possible ICD-10 diagnosis codes, are excluded from the measure calculation. The exclusions include conditions such as diabetic retinopathy, macular degeneration, and glaucoma.
- These types of ocular conditions can complicate cataract surgery and may require the use of more resources to treat adequately. For example, patients taking Tamsulosin or similar medications often have complications requiring further surgery, such as vitrectomy. Furthermore, those patients very frequently require the use of iris retractors, leading to the use of code 66982 instead of the usual 66984. **Therefore, patients with these significant ocular conditions should be excluded from episode groups used to measure resource use. It would not be fair to compare cases with these significant ocular conditions to less complicated cataract surgeries.**

COST CATEGORY SCORE

Not only has CMS not provided adequate details to evaluate the attribution and risk adjustment for these measures, there still has been no complete proposal to demonstrate how the cost data will be factored into a measure, and then calculated to determine the physician's score. Without a specific proposal, and credible results from pilot testing, it is impossible to evaluate the ultimate impact and fairness of these measures. We understand that CMS plans a phased approach to building procedural and conditions-based episodes, however the development of new episodes will begin before other episodes are complete and tested. We urge CMS to listen to our recommendation to narrow the scope of this project considerably and complete and test a small number of episodes before moving forward on such an extensive list of episodes.

Relation to Current Cost Measures

- **As noted above, ASCRS has long opposed the current cost measures in MIPS— Medicare Spending per Beneficiary and Total Cost per Capita—that were retained from the VBPM.** The attribution methodology of these measures potentially holds physicians accountable for the cost of care they did not provide. There has been no clarification of whether these measures will still be used as part of physicians' cost scores if they have one or more types of episode measures attributed to them, or if they will be used when no episodes are attributed. **We continue to oppose the inclusion of these measures and urge that they not be used even if no other episode measures are attributed to the physician.**

Overlapping Episodes

- **The measure developers have noted that a key factor in accurately attributing the cost of care for a patient who may be suffering from several chronic conditions and/or has received several procedural treatments is to open several different overlapping episodes.** While we support the effort to attribute the cost of, for example, an orthopedic procedure to an orthopedic surgeon during an unrelated open ophthalmic episode, it is unclear how these overlapping episodes will be weighted to determine cost.

If an ophthalmologist is both treating a patient for diabetic retinopathy and performs cataract surgery, how will the existence of the two ophthalmic episodes factor into the ophthalmologist's cost score? **CMS must provide a comprehensive proposal for calculating and scoring costs, and allow for input from relevant stakeholders before moving forward with this effort.**

Ongoing Maintenance and Updates of Episode Measures

- **We urge CMS to develop a process that incorporates input from specialty societies to update and maintain episode measures to keep pace with new treatments, drugs, and devices.** We urge CMS to recognize that new treatments and medical products have the potential to improve patient outcomes. However, if episode measures are not updated, or are too punitive, it could deter physicians from innovating and exploring new treatment options. Frequently, innovative procedures or medical products are more expensive than existing options, but they may offer better outcomes. If physicians know that the cost of the new treatment may adversely affect their cost scores, they will be less likely to seek out and use new techniques or products. Similarly, drug and device manufacturers will be less willing to seek approval for new products if they know physicians will be penalized for using them. **Cost measures must be regularly updated with input from relevant specialists to reflect the cost of new treatment options and ensure they do not put a chilling effect on medical innovations.**

We reiterate our recommendation that the cost category of MIPS be weighted at 0% again for the 2018 performance period and 2020 payment year to give time to develop a more thorough proposal and allow for testing and medical community feedback.

ROUTINE CATARACT REMOVAL WITH IOL IMPLANTATION EPISODE GROUP

No Identified Gap in Cost or Quality of Cataract Surgery

ASCRS continues to caution CMS that complications after cataract surgery are extremely rare. There is very little differentiation among cataract surgeons both for cost and in outcomes. Cataract surgery is reimbursed under Medicare Part B with a 90-day global period physician fee and a facility payment to either an ASC or HOPD. When complications, but also variations in outcome occur, it is often due to patient co-morbidities, such as diabetes, glaucoma, macular degeneration or retinal disorders, or other significant pre-existing health issues. There have not been demonstrated gaps in the quality, cost, or access to care. In the last 50 years, since the advent of phacoemulsification, ophthalmologists have made tremendous strides in improving cataract surgery so that complications are relatively rare. While still an intensive procedure requiring the special skill of ophthalmologists, the medical innovation of the last half-century means that patients will have a reliable assurance that the outcome of their surgery will contribute positively to their overall well-being. **We contend that when episodes are properly risk-adjusted and patients with ocular co-morbidities are excluded, there will be very little variation in cost and quality to measure, and thereby evaluate, a physician's resource use.**

CMS lays out several criteria for selecting episode groups in the request for comments, including share of Medicare expenditures, opportunity for improvement, clinician coverage, and alignment with quality measures. As the number one Medicare-reimbursed procedure, cataract surgery represents a significant share of Medicare expenditures. The high incidence of cataracts in older adults has allowed ophthalmologists to hone surgical techniques and clinical processes to the extent that the procedure has a very low complication rate and very

little cost differential. As mentioned above, complications are generally due to ocular co-morbidities, and site of service is generally the determining factor in the cost of cataract surgery. The facility fee for a hospital outpatient is significantly higher than for an ambulatory surgery center. Depending on the location, an ophthalmologist may not be able to choose where to perform the surgery. **It is likely that when proper risk adjustment is applied, and different measures are used to compare surgeries performed in the two different facilities, there will not be a significant cost or quality differential. CMS must resolve these issues and develop a proposal for measuring cost that would meaningfully measure the cost of care.**

Trigger Codes Included in Cataract Surgery Episode Group

- We support the use of CPT code 66984 as the only relevant code that should be used as a trigger for a cataract episode group. Including other codes, such as complex cataract surgery, 66982, will not yield comparable enough data to measure a physician's resource use accurately.
- **We reiterate our recommendation that CMS create two cataract episode groups—one for procedures performed in ASCs and the other in HOPDs—so that surgeons are only compared to others practicing in the same type of facility.**

Episode Window and Grouping of Services Unrelated to Cataract Surgery

- ASCRS believes that the episode window should be aligned to the current global period of one day prior to surgery to 90 days post-op. We caution CMS that a longer episode window might include services unrelated to cataract surgery.
- The ophthalmic community recommends that most preoperative testing, such as electrocardiograms or blood glucose tests, is only needed if there are signs indicating a need for it. However, many hospitals or surgical centers still require this preoperative testing. The additional testing costs should not be attributed to the cataract surgeon, since those are often requirements of the hospital or surgical center. **Separate episode groups for HOPDs and ASCs would help resolve this issue so that physicians who have no choice but to practice in the HOPD would not be unfairly compared to surgeons practicing in ASCs, who may not require these tests.**
- In addition, CMS should ensure that laterality is considered. Cataract surgery is unique in that patients often require cataract surgery in both eyes within a short period. The second surgery is often performed within 30 days of the first, but since it is a separate surgery, performed on essentially a different organ, the costs for each individual surgery must be recognized. CMS should ensure that both eyes are accounted for as it moves forward with a cataract episode group.

Costs Related to Cataract Surgery

- There are some costs related to cataract surgery that would need to be accounted for in the episode groups. CMS should carefully determine whether each of these costs should be attributable to the cataract surgeon. These could include the preoperative testing addressed above, anesthesia charges, drug charges, and facility charges. Surgeons may choose to use different types or levels of anesthesia, or may be required to use a specific method due to the requirements of a facility where they operate. In addition, the cost of the intraocular lens is part of the facility fee and should not be included separately. **Developing separate episodes for each type of facility where cataract surgery is performed will assist in assuring that physicians are not penalized for costs that are beyond their control.**

Related Quality Measures

- **As noted above, the episodes should align with the current quality measures related to cataract surgery. The exclusionary criteria in the measures is a first step in building a risk-adjustment methodology that will prevent physicians from being penalized for factors outside their control, such as co-morbidities.**
- We urge CMS to align the cost measures with the following cataract quality measures:
 - Measure 191: Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery
 - Measure 192: Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures
 - Measure 303: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery
 - Measure 304: Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery
 - Measure 388: Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vitrectomy)
 - Measure 389: Cataract Surgery: Difference Between Planned and Final Refraction

DIABETIC RETINOPATHY EPISODE GROUP

ASCRS and other ophthalmic organizations who participated in the Fall 2016 Clinical TEP are disappointed that we were not given the opportunity to review this episode group, under the Diabetes episode group, as part of the TEP process. We were not given access to other specialties' episodes and are concerned that this episode did not receive proper consideration from ophthalmic experts. **We oppose the inclusion of this episode group until ophthalmologists are given the chance to review the trigger codes as part of a clinical TEP, and CMS completes the test phase on a limited number of episodes as we recommended previously.**

- **We reiterate our recommendation to remove the cost of Part B drugs administered in office from cost scores.** Current treatments for diabetic retinopathy rely heavily on intravitreal injections, specifically bevacizumab. We reiterate our concerns that without excluding Part B drugs, CMS is incentivizing the use of the cheaper, off-label repackaged preparation of the drug. Further, since physicians do not control the price of any Part B drug, they should not be included at all. **If physicians are penalized for the cost of Part B drugs, it could lead to Medicare beneficiaries' reduced access to these sight-saving drugs.**

CONCLUSION

We appreciate the opportunity to provide comments on this request for information on episode groups. We believe that the input CMS receives from the medical community will ensure that the models accurately and fairly measure cost. **While this request for information begins to identify the myriad issues related to attribution, risk adjustment, possible unintended consequences, and scoring, we still are not confident that CMS recognizes the enormity of the task ahead to deal with all these issues for such a broad and diverse set of procedures and conditions. We urge CMS to step back and refocus this effort to building and testing a limited number of episodes, with additional emphasis on addressing attribution and risk**

adjustment and developing a comprehensive proposal for how the measures will be scored before proceeding.

1 Seider MI, Keenan JD, Han Y. Cost of Selective Laser Trabeculoplasty vs Topical Medications for Glaucoma. Arch Ophthalmol. 2012;130(4):529-530. doi:10.1001/archophthalmol.2012.355.

2 Stein JD, Kim DD, Peck WW, et al. Cost-effectiveness of medications compared with laser trabeculoplasty in patients with newly diagnosed open-angle glaucoma. Arch Ophthalmol. 2012; 130:497-505.

COMMENT 15 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Peter D. Stetson, Chief Health Informatics Officer, Deputy Physician-in-Chief, Memorial Hospital for Cancer and Allied Diseases

Text of Comment:

Memorial Hospital for Cancer and Allied Diseases (Memorial) appreciates the opportunity to offer feedback on the proposals outlined in *Episode-Based Cost Measure Development for the Quality Payment Program*, which will further implement the physician payment reforms authorized by the Medicare and CHIP Reauthorization Act (MACRA) of 2015. Memorial is the oldest hospital in the nation devoted solely to the research and treatment of cancer. Today, Memorial employs nearly 1,000 attending physicians, as well as many more non-physician practitioners. These providers include a high concentration of specialists – general medicine, medical oncologists, anesthesiologists, pathologists, radiologists, nuclear medicine specialists, etc. – who exclusively treat patients with cancer, giving Memorial a unique perspective on the implementation of the Quality Payment Program.

As acknowledged by the Centers for Medicare and Medicaid Services (CMS) in its proposal, stakeholder feedback to date has identified some key areas for continuing focus. Among these issues are several that are of considerable importance to Memorial, including feedback that:

- Cost measures should account for patient complexity and the challenge of addressing overlapping conditions, i.e., accurate risk adjustment is necessary.
- Attribution of episode groups to clinicians should be clear and credible.
- Patient outcomes should be at the center of cost measures.

Our comments on the following pages will focus on these themes, with a particular emphasis on risk adjustment, both as it applies in the context of developing episodebased cost measures and in the Quality Payment Program more generally. Adequately addressing these issues holds immense importance for ensuring that the Quality Payment Program is designed to fairly and accurately assess resource use and outcomes, particularly for practitioners who exclusively treat patients with cancer.

Accounting for patient complexity and overlapping conditions, i.e. risk-adjustment:

In *Episode-Based Cost Measure Development for the Quality Payment Program*, CMS requests stakeholder feedback on the methodology that should be employed for risk adjustment. Specifically, the proposal seeks feedback on whether the CMS-HCC risk adjustment

methodology or an alternative methodology should be used to risk adjust episode-based cost measures, as well as whether prospective or concurrent risk adjustment should be used.

Memorial is pleased that CMS is actively reviewing the appropriateness of the CMS-HCC risk adjustment methodology and has proposed the possibility of pursuing alternative approaches. As Memorial and others have commented previously, the CMS-HCC Risk Adjustment model is inadequate for accurately capturing and adjusting for differences in patient acuity and complexity, particularly when applied in the context of assessing the resource use of practitioners who are based at a tertiary cancer center with a highly complex patient population. CMS could significantly improve its risk adjustment methodology – both for the episode-based cost measures under development and for the Quality Payment Program resource use measures more generally – by:

- Using concurrent, rather than prospective, risk adjustment.
- Exploring the use of alternative risk-adjustment methodologies.
- Capturing additional relevant data, such as cancer stage, and incorporating this data into the assignment of a risk score.
- Considering methods to ensure the comparison of like patients to like patients, including by creating episode subgroups.
- Removing outliers from the episode-based and other cost measures.

First, CMS should use concurrent risk adjustment with a full year of data. As we have noted in earlier comments, prospective risk adjustment as employed by the CMS-HCC methodology is highly ineffective in assessing resource use by practitioners treating a high concentration of complex patients. Of particular concern is the failure of a prospective model to capture or adjust for the resource use of patients who are newly diagnosed with cancer during the performance period. Patients with newly diagnosed cancer are all but guaranteed to significantly exceed the predicted costs assigned by prospective HCC risk adjustment, and Memorial and other tertiary cancer centers see a higher than average concentration of such patients. In 2015, approximately one-quarter of the patients seen by the Memorial Medical Consultation group were newly diagnosed, and more than half of these patients had had non-localized disease, including regional and distant metastases. Internal analyses of the 2015 data for all Medicare beneficiaries attributed to Memorial under the Value Modifier program (which employs prospective adjustment using the CMS-HCC methodology) demonstrate that the CMS-HCC model has very poor predictive value when applied to our patient population. In fact, the CMS-HCC methodology resulted in agreement between the quartiles for payment and the HCC risk score only 37 percent of the time. Perhaps more alarmingly, the more complex a patient's diagnoses, the worse the CMS-HCC methodology performed. Among attributed beneficiaries at MSK with a stage IV cancer diagnosis recorded in the tumor registry, the CMS-HCC score predicted just one percent of the variation in payments. By contrast, for attributed beneficiaries with in situ cancer, it predicted 26 percent of the variation.

Using concurrent, rather than prospective, data would improve the predictive value of the CMS-HCC methodology. As a proxy for using a concurrent rather than prospective risk adjustment model, Memorial performed an analysis of our attributed beneficiary data for only those patients who were seen in 2014 (and thus would have a cancer diagnosis reflected in their risk score),

which improved the agreement between the payment and CMS-HCC risk score quartiles to 49 percent. While this is a significant marginal improvement, the CMS-HCC risk adjustment leaves a great deal of the variation in payment unexplained.

Given the poor ability of CMS-HCCs to explain variation in the total cost of care for our complex patient population, Memorial urges CMS to assess whether alternative risk adjustment methodologies – such as the 3M Clinical Risk Group (CRG) or HHS-HCC models – would present a more accurate and reliable solution.

Both the CRG and HSHCC models offer greater specificity, i.e., more diagnoses and risk categories, than the CMS-HCC model, which may allow for a more accurate comparison of like patients with like patients. Regardless of which methodology is employed, the use of concurrent data will ensure the best possible level of accuracy.

Capturing additional relevant data, such as cancer stage, and incorporating this data into the assignment of a risk score would also improve the predictive value of the chosen risk-adjustment methodology.

As CMS notes in the proposal, “the costs of caring for patients at different stages of disease are likely to vary. For instance, a single episode for a type of cancer is likely to vary in a predictable manner depending on the stage of cancer.” In fact, treating advanced stage cancers has been demonstrated to be associated with significant incremental cost increases compared with treatment of early stage cancers.^{1,2,3} For example, an analysis of breast cancer treatment costs by stage found that Stage I/II cancers averaged a per patient cost of \$82,121 in the initial 12 months postdiagnosis, while stage III cancers averaged \$129,387 per patient. Unfortunately, the CMSHCC model is only able to differentiate between metastatic and non-metastatic cancers, leaving important differences in cancer stage unaccounted for by its methodology. In response to CMS’s request for information on how cancer staging information could be reported on claims in order to facilitate episode comparisons, the Alliance of Dedicated Cancer Centers (ADCC), of which Memorial is a member, is in the process of developing a proposal to allow for standardized reporting of cancer stage on the UB-04 (institutional) and 1500 (professional) claims. In brief, the ADCC believes that cancer stage or “CS” could be reporting using a code of CS-0 to CS-4, representing in-situ to stage IV cancer, in the form locator fields 39-41 on the UB-04 and in item number 19 representing “additional claim information” on the 1500. A more detailed proposal from the ADCC is under development and will be forthcoming.

CMS should consider methods to ensure the comparison of like patients to like patients, including by creating episode-based cost measure subgroups.

As acknowledged in the CMS proposal on episode-based cost measure development, “specific conditions may confer higher or lower risk for certain episode groups.” Particularly given the inadequacies of the CMS-HCC risk-adjustment methodology (as described above), Memorial is deeply concerned by the prospect of our providers being assessed by an episode-based cost measure for a procedure that may or may not be performed as a result of a known or suspected cancer diagnosis. For example, a patient might undergo a thyroidectomy or colon resection for a variety of reasons, which might or might not include an underlying cancer diagnosis. However, costs for the thyroidectomy or colon resection episode are highly likely to vary accordingly.

Similarly, significant cost variations can be expected between diagnostic and preventative endoscopies. Therefore, Memorial strongly recommends that CMS consult with clinical experts to systematically identify episode-based cost measures for which cancer and non-cancer subgroups should be developed.

Finally, Memorial urges CMS to consider removing outliers from the episode-based and other cost measure calculations. While CMS uses the HCC methodology to risk adjust payments made to Medicare Advantage and Exchange plans, it also administers supplemental programs designed to account for outliers, i.e., patients with extremely high-cost cases that are not well predicted by the HCC risk adjustment methodology, in order to protect plans from catastrophic costs. Memorial urges CMS to consider taking a similar approach in assessing resource use or cost under the Quality Payment Program by removing outliers from the calculations in the cost performance category.

Attribution of episode groups to clinicians:

If the assessment of cost or resource use by clinicians is to have its intended impact and effectively drive reductions in future resource use, physicians and non-physician practitioners should be reasonably able to predict which patients will be attributed to them under the Quality Payment Program. To date, the patient attribution criteria employed by CMS to assess physician resource use have not adequately met that bar. For example, under the patient attribution criteria used by the Value Modifier program for the Total Per Capita Costs measure, Memorial physician groups were attributed some patients whose encounter data make their attribution surprising, if not necessarily incorrect. For example:

Twenty-two beneficiaries assigned to Memorial physician groups had standardized payments of less than \$500 from Memorial evaluation and management (E&M) claims while having over \$5,000 from E&M claims billed by “other physicians.” In the most extreme example, the Memorial physician group E&M payment was only \$51 when other E&M payments totaled \$15,736. It is difficult to imagine how this beneficiary was attributed to the Memorial physician group given these numbers.

At present, it is unclear how the new patient relationship categories and codes that are expected to be released sometime this month will be operationalized. These codes may offer some improvement in the ability to reasonably predict patient attribution. However, given our concerns with the transparency of the existing attribution mechanisms and the lack of clarity around the upcoming patient relationship categories and codes, Memorial requests the opportunity to provide additional input once those categories and codes have been made available.

In addition, as noted by the ADCC, we understand that CMS is likely to use new HCPCs modifiers to establish the patient-provider relationship. While the use of modifiers offers a familiar and relatively simple mechanism for providers to record this information, the list of required modifiers has been growing rapidly and it is unclear whether all reported modifiers are read. CMS should verify that *all* reported modifiers will be read by its pricer/editor systems, regardless of the number of modifiers and the order in which they are appended.

Patient Outcomes Should Central to the Development of Cost Measures: At its core, the Quality Payment Program is designed to incentivize both efficient and high-quality health care

delivery. However, not every health care episode, particularly those defined as a “chronic condition episode group,” will necessarily lend itself to an accurate evaluation of resource use or of quality/patient outcome on a one-year (or shorter) timeframe.

The difficulty of assessing cost and quality for chronic care episodes on a one-year time frame is exemplified by data on Memorial’s patient outcomes and resource use. For example, a 2015 study in *JAMA Oncology* showed that patients treated at Memorial and other PPS-exempt cancer have better survival outcomes during the first year of treatment, and this survival advantage persisted over a five years. At the same time, our own analyses of Medicare claims for continuously enrolled beneficiaries newly treated for cancer at PPS-exempt cancer centers shows that our costs are somewhat higher in the first 24 months of treatment. Importantly, however, **our costs are lower by the end of year three**. Presently, however, survival rates are not assessed by the Quality Payment Program, and resource use is evaluated on a one-year or shorter basis. As such, Memorial could well offer a survival advantage at a marginally higher cost on a one-year timeframe – all while offering more efficient care over the entire episode of treatment – and still incur a penalty under the Quality Payment Program.

CMS should explore avenues to address these flaws. For example, CMS might consider the addition of bonus points for measure that are especially important for assessing patient outcomes, i.e., survival rates for cancer and other life-threatening conditions.

¹ Blumen, H., Fitch, K., & Polkus, V. (2016). Comparison of Treatment Costs for Breast Cancer, by Tumor Stage and Type of Service. *American Health & Drug Benefits*, 9(1), 23–32.

² Mittmann, N., Porter, J. M., Rangrej, J., Seung, S. J., Liu, N., Saskin, R., Earle, C. C. (2014). Health system costs for stage-specific breast cancer: a population-based approach. *Current Oncology*, 21(6), 281–293.

³ Luo, Z., Bradley, C. J., Dahman, B. A., & Gardiner, J. C. (2009). Colon Cancer Treatment Costs for Medicare and Dually Eligible Beneficiaries. *Health Care Financing Review*, 31(1), 35–50. Luo, Z., Bradley, C. J., Dahman, B.A., & Gardiner, J. C. (2009). Colon Cancer Treatment Costs for Medicare and Dually Eligible Beneficiaries. *Health Care Financing Review*, 31(1), 35–50.

COMMENT 16 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Wanda D. Filer, Board Chair, American Academy of Family Physicians

Text of Comment:

On behalf of the American Academy of Family Physicians (AAFP), which represents 124,900 family physicians and medical students across the country, I write in response to the request for comments on the Episode-Based Cost Measure Development for the Quality Payment Program as published by the Centers for Medicare & Medicaid Services (CMS) on December 23, 2016.

The AAFP appreciates the opportunity to work with CMS and its contractors to develop cost measures that are based on episode groups and we also appreciate that the agency seeks public input on the development of cost measures. We offer the following responses to the italicized questions asked in the request for comments.

Episode Group Selection

In selecting the episode groups to be considered for development, CMS used criteria including an episode's share of Medicare expenditures, clinician coverage, and the opportunity for improvement in acute, chronic, and procedural care settings. We welcome comment on these episode groups and potential additional episode groups that should be considered for development.

The AAFP encourages CMS to initially develop episodes that encapsulate high-cost centers such as hospitals and surgical centers. In doing so, CMS would maximize their potential to acquire large cost savings and could use those episodes to learn the best methodology in which to apply episodes to physicians, and any unintended consequences that might occur. We also encourage CMS to focus on the implementation of the existing cost category episode groups called for in the 2017 MACRA final rule before any new episode groups are introduced.

Even though services provided by family physicians are not high-cost when compared to sub-specialty services, family physicians have nevertheless been held responsible for total cost of care. CMS has the opportunity to rectify this imbalance as episode measures are selected that hold those truly responsible for high-cost care more accountable.

We urge CMS to refine their attribution methodologies to determine whether or not patient relationship codes are useful. We also urge CMS to review and adhere to our April 12, 2016 and December 21, 2016 letters regarding patient relationship category and codes.

Episode Group Definition

The episode groups that accompany this posting are defined by the listed trigger events and codes (CPT/HCPCS for procedural episode triggers, evaluation & management codes combined with ICD-10 diagnostic information for chronic episode triggers, etc.). CMS solicits comment on the inclusion or exclusion of specific service codes used to identify each episode group.

The AAFP reviewed the listed trigger events and codes. We are concerned that the trigger(s) for the acute inpatient medical condition episode groups appear to be DRG-related, whereas AAFP and our members are more familiar with CPT-related terminology and codes. Since our members may still be the primary physician responsible for the episode, instead of DRG-related terminology and codes, we ask CMS to use inpatient evaluation & management diagnostic codes to trigger inpatient medical condition episodes.

Acute Inpatient Medical Condition Episode Groups

The acute inpatient medical condition episode groups that accompany this posting include only inpatient events. CMS seeks comment on outpatient events that could be considered candidates for development as acute condition episode groups, which could include chronic condition exacerbations that require acute care but not inpatient hospitalization.

Per our response to the episode group selection question, the AAFP urges CMS to start with inpatient episodes, given they are a high-cost place of service. We discourage CMS from prematurely examining outpatient episodes without first learning from inpatient episodes, since that is where the biggest cost savings will be.

Acute episodes of care might occur on either an inpatient or outpatient basis and may or may not include surgery. CMS is considering a single Acute Episode Group type that does not distinguish the place of service or the performance of a procedure and welcomes comment on this approach.

The AAFP believes acute episode groups could be an appropriate approach, as long as the site of service is initially an inpatient setting or an ambulatory surgical center per our earlier comments. Generally, acute episodes could include ambulatory surgery procedures.

Chronic Condition Episode Groups

CMS is aware of many challenges in constructing episode groups for chronic conditions. These include coding habits that may obscure some chronic conditions and overemphasize others. In addition, it may be difficult to assign a given treatment to a single condition for patients with multiple comorbidities. For example, are the resources for treatment to reduce cholesterol for a patient with diabetes, hypertension, and coronary artery disease to be assigned to only one of those diagnoses, to all of them in proportion, or should we develop a chronic condition episode specific to the management of patients with diabetes, hypertension and coronary artery disease, i.e., a patient condition group to better compare cost to treat like patients? An extension of this approach might be a single episode group for outpatient chronic care with adjustment for comorbidities and demographics of the population served by the clinician. We welcome comment on these and any other options for constructing episode groups for chronic conditions.

By definition, a chronic condition is not an episodic illness. It is a continuous health problem that is identified at diagnosis and often lasts for the patient's lifetime. Arbitrarily dividing that continuum into "episodes" is problematic and will likely misrepresent the cost of caring for those patients, especially for primary care physicians who provide ongoing care of those conditions.

In addition to the complexity of trying to develop an episode using multiple chronic conditions, there is a challenge to develop an episode that encompasses multiple chronic condition specialists. Often, patients see multiple providers to manage different parts of their chronic disease. However, in family medicine, we treat most, if not all, of these conditions. How can an episode group be constructed fairly to assign cost to one physician caring for three to four chronic conditions vs. three to four physicians caring for the same type of patient? Family physicians should be rewarded for managing these patients, not held to a higher standard than colleagues who refer every patient to a specialist, thus over utilizing care and overburdening the system.

Additionally, the AAFP recommends CMS factor in socioeconomic and social determinants of health into chronic condition episode groups since they can add significant cost variables that are difficult to quantify but clearly impact care.

Finally, chronic condition episode groups may be too complicated to develop currently since CMS doesn't yet have data on how effective the ten episodes called for in the 2017 MACRA final rule were. We urge CMS to pause and make adjustments based on research in order to determine the most effective approach.

Certain specific conditions, such as cancer, present other challenges. The costs of caring for patients at different stages of disease are likely to vary. For instance, a single episode for a type

of cancer is likely to differ in a predictable manner depending on the stage of the cancer. Information on disease staging is not easily or predictably available from claims. CMS welcomes comment on methods to incorporate disease severity or staging information to improve meaningful comparison of cost and quality of care furnished to patients, both generally and for specific clinical conditions. For example, how could a disease staging code be reported on claims to facilitate comparison of episodes for patients at like stages of cancer?

The AAFP disagrees strongly with the assertion made in the question. Cancer is not predictable and how it differs between patients in various stages is unique. We remind CMS that the Oncology Care Model is testing the effect of bundled payments around administration of chemotherapy and we therefore recommend that CMS assess the outcome of these bundles before developing other cancer-specific bundles.

Procedural Episode Groups

We solicit comment on the procedural episode groups that accompany this posting, including the service and diagnosis codes used to identify the existence of the procedural episode groups. We also welcome comment on additional procedural episode groups to consider for future development.

The AAFP reviewed the 62 procedural episode groups with a total of 955 trigger codes, and none of them will be primarily claimed by family physicians. The AAFP strongly urges CMS to attribute the costs of the episode primarily (if not exclusively) to the physician who provided the trigger procedure.

Cost Measure Development

Cost measures are being considered for development from episode groups after adding additional context, such as expenditure assignment, attribution, risk adjustment, and consideration of quality.

We welcome comment on each of these elements and whether there are additional elements to consider in developing cost measures from episode groups.

The AAFP insists that cost attribution for patients within care episode groups should be to the physician with the highest Part B allowable charges, based on paid claims, rather than by which provider sees the patient the most. When a patient has multiple providers assigned to an episode, it is important to consider which provider is responsible for the cost. For example, a hospitalized patient might be seen more often by a primary care physician, but most of the cost may be accumulated by a specialist assigned to the case who performed a procedure (which may or may not lead to a complication). It is important to not attribute an episode strictly based on who sees the patient the most because the cost of each interaction can vary so widely. Ideally, episode groupers should be able to apportion costs of an episode among the providers (based on TIN, NPI, or both) involved. To the extent episodes support cost measures, expenditure assignment and attribution should be based on contributions to the cost of the episode (i.e. who billed the most expensive overall charges or got paid the most) rather than who saw the patient the most number of times. As stated previously, the AAFP strongly urges CMS to attribute the costs of

procedural episodes primarily (if not exclusively) to the physician who requests payment for the most expensive trigger procedure.

The AAFP supports risk adjustment in quality and cost measures. We applaud CMS for seeking input from clinical committees, which include expertise and input from practicing family physicians, on the proper methodology for risk adjusting. We urge CMS to continue soliciting, and more importantly, incorporating, such public and clinical input and to develop a robust education campaign for medical practices.

As described above, the degree of responsibility of attributed services might be considered separately. Those services furnished by the attributed clinician for the clinical purpose of the episode group might be differentiated from the services provided by others for the same clinical purpose. The services furnished by the attributed clinician might be considered directly attributable services. These could be correlated with the services delivered by others for the same clinical purpose, which might be considered indirectly attributed services. The consideration of both directly and indirectly attributed services might be weighed in reporting both the provision and the coordination of care within the episode group relative to each clinician contributing to the care. An alternative approach would be to obtain recommendations from multi-specialty panels about percentages of the resources for an episode that could be attributed to physicians serving in different roles. We welcome comment on these concepts of differential attribution or alternative methods to align attribution with the clinical activities of clinicians.

As described in previous answers, the AAFP strongly encourages CMS to monitor for unintended consequences as episodes are assigned. For example, if an episode is assigned based on percentages of total cost of care, CMS must determine if doing so led to withholding needed care or involving more specialists than needed in order to offset episode responsibility.

The AAFP encourages CMS, if this alternative approach is utilized, to work with Congress to create a new *Federal Advisory Committee Act* (FACA) committee that includes stakeholder input from physicians, payers, economists, patient representatives, and other stakeholders for this purpose.

The Medicare Advantage program uses the CMS-HCC Risk Adjustment Model to determine rates. We seek comment on the use of this model or an alternative for risk adjusting episode groups in the construction of cost measures.

Adequate risk adjustment is essential to protect against cherry picking patients, inappropriate underutilization of services, and undue risk on practices. The AAFP supports using the CMS-HCC Risk Adjustment Model but we encourage the agency to transition to using the Minnesota Complexity Assessment Method tool once physician practices are able to collect and report on measures that assess patient complexity and identify areas of intervention. We believe the Minnesota Complexity Assessment Method tool represents the best approach to assess complexity that is not captured through a review of disease burden, and it can better direct care teams in patient management.

Whichever risk adjustment methodology is selected, we strongly encourage CMS to provide enhanced educational opportunities for family physicians so they can understand how it will impact quality and cost comparisons, and ultimately, payment adjustments.

CMS is especially interested in comments regarding methods to align quality of care with cost measures and welcomes recommendations and suggestions. Considerations for aligning episode groups with quality measurement are described in this document, but are not intended to be an exhaustive list of options. We welcome comment on these methods, as well as any other strategies that could be used to align quality of care considerations with cost measures.

By statute, MIPS is constructed with four components (quality, cost, advancing care information, and improvement activities) therefore quality and cost are already taken into consideration. By performance year 2019 (payment year 2021) these two components will equal each other at 30%.

We again urge CMS to beware of creating new measures that they hope will work before the agency has data on how well the existing ones are functioning. Additionally, CMS should analyze how improved quality affects cost.

CMS wishes to avoid any unintended consequences of using cost measures in MIPS, and seeks comment on issues of concern in this regard, such as taking steps to avoid disadvantaging clinicians who assume the care of complex patients such as by applying episodes for comparison of complex patients (i.e., comparison of like-patients of different clinicians).

Please refer to AAFP examples of unintended consequence found throughout this response.

COMMENT 17 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Caroll Koscheski, Member, ACG Board of Trustees, American College of Gastroenterology

Text of Comment:

The American College of Gastroenterology (ACG) appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services' (CMS) solicitation for public comment to the December 2016 publication, "Episode-Based Cost Measure Development for the Quality Payment Program."

Founded in 1932, ACG is a physician organization that currently represents 14,000 clinical gastroenterologists and other gastrointestinal specialists. We focus on the issues confronting the gastrointestinal specialist in delivering high quality patient care. Our members practice in a range of settings, and are faced with an increasing array of federal, state, and nongovernmental complexity to navigate. The primary activities of the ACG have been, and continue to be, promoting evidence-based medicine and optimizing the quality of patient care.

MIPS: Resource Use Performance Category

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), enacted on April 16, 2015, repealed the Medicare sustainable growth rate (SGR) formula and created a new

reimbursement system, the Quality Payment Program (QPP), beginning for the 2017 reporting year. The QPP has two components: the Merit-based Improvement Payment System (MIPS) and Advanced Alternative Payment Models (APMs). MACRA also requires the development of care episode and patient condition groups, and classification codes for the patient condition groups. MACRA requires the care episode and patient condition groups to account for a target of an estimated one-half of expenditures under Parts A and B (with this target increasing over time as appropriate). While MACRA passed with significant bipartisan support, the law must be improved.

In comments to the proposed rule, the College urged CMS to make changes to the Resource Use component, including: delaying the episode of care measures until there is a 2 year temporary trial and review period; and excluding Medicare Part D drug costs for attribution (as ACG Members have little to no control over drug costs).

While CMS reweighted Resource Use to 0% for the 2017 transition year, in the final rule, CMS expressed its intention to move forward with this performance category in 2018 despite a reliability score of 0.4 for these measures. These measures have yet to be reviewed by the National Quality Forum (NQF) and are subject to change. While CMS urges stakeholders to go through the NQF process, it remains to be seen whether the NQF will endorse a measure with such a low reliability score and ACG questions whether it is appropriate to hold a clinician accountable and base payment on results that may inaccurately represent performance 60% of the time. Detailed information, such as attribution, construction, and risk adjustment is not readily available at this time.

The ACG believes CMS should delay implementing this category until this information is available and publicly vetted. Thus, we urge CMS to keep the Resource Use category weights at 0% to the extent which the Secretary of Health and Human Services has the authority to do so.

Episodes

ACG appreciates the opportunity to be part of the clinical workgroup vetting and reviewing the various episodes of care proposals in gastroenterology. We welcome the opportunity to work with CMS on these important issues.

This review and episode-selection process may be improved by starting with the procedural episodes of care already developed by CMS and in a provider's quality and resource use report (QRUR). Currently, the clinical and technical workgroup panels find the current assignments and guidance to be lacking clear definition, with limited background data and rationale for the episodes proposed by CMS and its contractor. ACG recommends the clinical workgroup take one step at a time, starting with clinicians and CMS' contractor dissecting and reviewing the details of each episode in the QRURs, instead of trying to develop new episodes for many services. These episodes would provide clearer direction and assignments for clinical workgroup members. One of the most important components of the development of these episode groups is meaningful feedback to the clinician on costs for which they are directly responsible.

In the final rule, and for the CY 2017 performance period, CMS finalized episode-based measures, which have been previously reported in the 2014 supplemental QRUR and met reliability thresholds (0.4). "Colonoscopy and Biopsy" is among this list of 10 finalized episode-

based measures.¹ CMS further notes that the agency selected episodes from the 2014 QRUR because these measures have been included in 2 years of QRURs (2014 and 2015). According to CMS, this provides clinicians the opportunity for initial feedback before the MIPS performance period begins, although the feedback does not contain any scoring information, nor does it contain the updated attribution changes. This is a good place for the technical expert panel and clinical committee to begin, via reviewing QRURs for accuracy, providing feedback, and reviewing/discussing any updated attribution methodologies. This initiative will also help CMS simplify the QRUR report itself. While CMS believes the 0.4 reliability threshold is sufficient, a collaborative review may also improve the reliability threshold of the data and episodes. For example, CMS and a panel of gastrointestinal clinicians should review the trigger codes for this episode prior to delving into any new episode. A complete audit or review of the episode may also help to explain why there is a 0.4 reliability score. It is very important to ensure that already developed episodes of care are correct, instead of moving forward with new episodes and potentially using the same faulty logic or data.

Episode Groups for Gastroenterology

Acute groups: ACG believes the draft “esophagitis, gastroenteritis, and miscellaneous digestive disorders” is much too broad of a category to use as individual episodes in clinical practice. This group includes too many specific diagnoses for a meaningful assessment to be made, including identifying triggers, episode windows, and attributing providers, etc.

Gastrointestinal Hemorrhage: ACG also believes that this is too broad, and instead suggests separating this episodes out to “Upper Gastrointestinal Hemorrhage” and “Lower Gastrointestinal Hemorrhage.”

The rationale for these suggestions is this terminology is consistent with clinical guidelines, and notes that management and evaluation are distinctly different.

Chronic Condition Episode Groups: ACG believes there must be a thorough discussion and detailed plan on chronic care episode groups, as many Medicare beneficiaries have multiple comorbidities, and thus, would be assigned to multiple episodes of care among multiple clinicians. Accurately allocating costs to the correct provider is an important area for CMS and clinical workgroups to review and study.

Among the major concerns for ACG regarding accurate attribution of costs to providers is treating chronic conditions, including being involved in major aspects of care. MACRA requires that claims submitted for items and services furnished by a physician or applicable practitioner on or after January 1, 2018, as determined appropriate by the Secretary, include the applicable codes established for care episode groups, patient condition groups, and patient relationship categories, as well as the National Provider Identifier (NPI) of the ordering physician or applicable practitioner (if different from the billing physician or applicable practitioner).² These forthcoming patient relationship codes have the potential to help with cost attribution in both acute and chronic episodes of care, but require evaluation and testing prior to implementation. For example, resource use for treating chronic liver disease depends primarily on the individual ordering or managing the patient’s diagnosis. Recent payment models, however, emphasize the

value of a multi-specialty approach for best outcomes in these complicated patients. The trial period evaluation can be another major role for CMS and episodes of care clinical work groups.

Patient risk adjustment is of critical importance as well. Multiple comorbidities or medical noncompliance increases this potential risk of inadvertent consequences, as well as the likelihood of complicated or noncompliant patients being discharged from a practice or referred to another group due to financial reasons. Further, there are varying costs for patients at different stages of the same disease. This could apply to cirrhosis but also to Crohn's disease (with or without fistulae, abscess, infection, etc.). ACG urges CMS to review and consider lessons learned from state initiatives on risk-adjustment and risk-stratification. For example, Ohio and Tennessee are both currently going through this process. This review and feedback is another crucial role for clinical expert panels.

ACG believes the "chronic liver disease" episode is too diverse to pull cost data to accurately compare clinicians due to the broad spectrum of diseases involved (ranging from simple fatty liver to decompensated, advanced cirrhosis). Instead, the ACG suggests CMS look at a "cirrhosis" episode.

ACG believes that the "inflammatory bowel disease" episode should be divided into "ulcerative colitis" and "Crohn's disease" to account for any variances in costs.

Acute Inpatient Medical Condition Episode Groups: ACG appreciates the opportunity to raise the question of whether it would be appropriate to include outpatient events with acute, otherwise inpatient measures.

Site of Service: ACG believes that CMS should distinguish the place of service for a procedure in an acute episode group. Place of service has a significant impact on cost, specifically when comparing an ambulatory surgical center (ASC) and an outpatient hospital department. An independently owned ASC is generally less costly than a hospital owned ASC or hospital outpatient site of service. ASCs provide a safe, convenient and cost-effective environment for gastrointestinal procedures provided to Medicare beneficiaries. CMS recognizes this in the Medicare outpatient facility final rule:

"First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a) (1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPSS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services) [for example screening colonoscopy with no polyp removal]. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPSS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPSS copayment amount for the same services."³ Cost Measure Development: CMS stated in both the proposed and final rule that lower costs represent better performance in the Resource Use category. However, one systematic review on the association between cost and quality found inconsistent results.⁴ In addition, evaluating costs in the absence of quality is not meaningful information and may lead to inappropriate interpretations on whether a clinician is providing the highest quality of care when based solely on cost data (there

is no connection to corresponding quality data for same services). Currently, there is no methodology within provider billing systems that allocates a specific component of spending toward a selected quality measure, so as not to penalize the provider for adherence to a quality parameter. Likewise, there is no mention of an adjustment of resource use towards certain required amounts of spending to account for the quality measures. In addition, many questions remain both on the construction of the individual episodes (e.g., which costs will be included in each episode, the risk adjustment methodology including both clinical and sociodemographic factors) and what judgments will be made based on quality and costs together, including how CMS will address those episode groups for which quality measures do not currently exist, how attribution methodologies will be aligned across cost and quality, and how cost and quality data will be displayed on the Physician Compare website.

In many cases, the goal should be more resource use when it is clinically appropriate. For example, the U.S. Preventive Services Task Force, the U.S. Centers for Disease Control and Prevention, and many other organizations have labeled hepatitis C as a public health priority, especially in Medicare. Overall, approximately 3 million Americans are infected with hepatitis C, and up to 3 out of 4 do not know they are infected. The vast majority of those affected are baby boomers, or those born from 1945 through ^{5 6} Left untreated, hepatitis C can cause serious liver damage, including liver cancer. Screening and treatment are crucial to resolve this public health epidemic, but the drugs are expensive, and Medicare Part B and D costs are out of the physician's control. There must be recognition that higher costs and utilization may lead to better quality/performance. To address the costs of Medicare drugs (out of the provider's control) ACG suggests an improved and more clinically relevant Clinical Practice Improvement Activity performance category. Providers could be allowed to attest to the use of a number of approved resources in drug prescribing compliance. This could include any of several antibiotic prescribing resources, as well as online resources available specifically for prescribing medicine within acceptable clinical guidelines. During the Resource Use technical expert panel, there was discussion on the use of online resources which may warrant further evaluation. The approval of such resources would hopefully encourage specialty societies to establish online resources on appropriate drug use for their members to use and reference. AS CMS considers incorporating Part D cost for these patients, we have grave concerns regarding the risk of inadvertent consequences to these patients. We do not want to see physicians refusing to treat these patients due to this factor. We further believe that by utilizing an online treatment resource, we would instead be working toward making sure that these patients are treated with the most appropriate drug(s) and for the appropriate and approved duration.

Another example is that, according to the American Cancer Society, screening 80% of eligible American screened for colorectal cancer by 2018 would prevent 277,000 new cases and 203,000 deaths from colon cancer by 2030.⁷ The New England Journal of Medicine findings suggest that colonoscopy with polypectomy results in 53% reduction in deaths from colorectal cancer, as well as a 90% reduction in incidence rates.⁸ More services, thus more resource use, should be encouraged for important preventive services such as colorectal cancer screening.

MACRA requires the development of patient relationship categories and codes that define and distinguish the relationship and responsibility of a physician or applicable practitioner with a patient at the time of furnishing an item or service. According to CMS, these categories shall

include different relationships between the clinician and the patient and reflect the various types of responsibility for and frequency of furnishing care. As noted above, ACG believes that these patient relationship codes should be implemented on a trial basis, providing the opportunity for clinical and expert workgroup panels to review the data with CMS prior to fully implementing the Resource Use performance category. This would result in more accurate assignment of costs of services and help resolve the issue of attribution, where one provider may order the services but providers performing those services (specialty care) are assigned the costs. For example, ACG members have been designated as a patient's primary care physician when they self-refer for a screening colonoscopy. Trials and testing are needed to define and demonstrate the connections between providers, especially when there may be variations in coding among practices and when there are questions regarding the validity in the current measures' reliability.

Episodes of Care and Correlation with Proposed Advanced Alternative Payment Models under MACRA

It is important to convey ACG's strong belief that there must be consistency among episode of care in MIPS (and Resource Use) when compared to advanced payment models (APMs) in similar services. Without consistency, there will be no ability to compare quality and costs between the two payment models and across programs. For example, the American College of Surgeons (ACS)-Brandeis Advanced Alternative Payment Model (APM) proposal is episode-based and built on an updated version of the Episode Grouper for Medicare (EGM) software currently used by CMS for measuring resource use. This proposal can potentially include GI procedures such as colonoscopy and EGD (upper endoscopy). In April 2017, the Physician-Focused Payment Model Technical Advisory Committee (PTAC) recommended that this model move forward on a limited scale basis. Since this model is based on episode groupers, there must be alignment between any episodes of care in MIPS and any episode-based APM.

Conclusion

The stated goals of the QPP include improving healthcare outcomes, promoting smarter spending, minimizing burden of participation, and providing fairness and transparency in operations. While we are certainly appreciative of this commitment, efforts to attain these goals can easily become mired in the focused design of any of these working components of MIPS. Therefore, not losing sight of this centrally targeted commitment is paramount to the success of this endeavor.

1 Colonoscopy and Biopsy: Episodes are triggered by the presence of a trigger CPT/HCPCS code on a claim when the code is the highest cost service for a patient on a given day. Medical condition episodes are triggered by IP stays with specified MS-DRGs.

2 <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/macra-mips-and-apms/patient-relationship-categories-and-codes.pdf>

3 Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Nonexcepted Off-Campus Provider-Based Department of a Hospital; Hospital Value-Based Purchasing (VBP) Program; Establishment of Payment Rates Under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by an Off-Campus Provider-Based Department of a Hospital. [CMS-1656-FC and IFC]. https://oascahps.org/OAS_CY2017FinalRule.pdf

4 Hussey PS, Wertheimer S, Mehrotra A. The association between health care quality and cost: a systematic review. *Ann Intern Med.* 2013;258:27-34. 1965.

5 Centers for Disease Control and Prevention: Vital Signs Report on Viral Hepatitis.

<https://www.cdc.gov/media/releases/2013/p0507-hepc-testing.html>

6 Jemal, Ahmedin. Recent Hepatitis C Virus Testing Patterns Among Baby Boomers. Journal of Preventive Medicine. March 2017. [http://www.ajpmonline.org/article/S0749-3797\(17\)30092-2/abstract](http://www.ajpmonline.org/article/S0749-3797(17)30092-2/abstract)

7 National Colorectal Cancer Roundtable. <http://nccrt.org/tools/80-percent-by-2018/>

8 Sources: Zauber AG, Winawer SJ, O'Brien MJ et al. Colonoscopic polypectomy and long-term prevention of colorectal-cancer deaths. N. Engl. J. Med. 366(8), 687–696 (2012).

COMMENT 18 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Sharad Lakhanpal, President, American College of Rheumatology

Text of Comment:

The American College of Rheumatology (ACR), representing over 9,500 rheumatologists and health professionals, appreciates the opportunity to respond to the proposed Patient Condition Groups and Care Episode Groups and “Episode-Based Cost Measure Development for the Quality Payment Program”, released by the Centers for Medicare & Medicaid Services (CMS) on December 23, 2016. We welcome the opportunity to provide our concerns on the impact these proposals will have on our ability to provide quality care to the 50 million Americans living with rheumatologic diseases.

Rheumatologists provide ongoing care for Medicare beneficiaries with complex chronic and acute conditions that require specialized expertise. Rheumatologists provide face-to-face, primarily non-procedure-based care, and serve patients with serious conditions that can be difficult to diagnose and treat, including rheumatoid arthritis (RA), systemic lupus erythematosus, and other debilitating diseases. Early and appropriate treatment by rheumatologists slows disease progression, improves patient outcomes, and reduces the need for costly downstream procedures and care that is complicated and made more expensive by advanced disease states.

The ACR is dedicated to ensuring that our providers have the resources they need to work with CMS and to provide patients with high-quality care. We believe that for CMS, clinicians, and patients to all achieve their objectives, payment programs must be designed to reflect the way practices treat patients.

A. Care Episode and Patient Condition Groups

i. Episodes Must Recognize Physicians Treating Unique Patient Conditions

Episode groupers that will be used for payment or to align with quality measures should be designed to be clinically coherent so as to avoid unintended consequences or perverse incentives. In order to create coherent measurements, representative physicians and providers must be involved in all stages of grouper development.

In developing care episodes, we encourage CMS to utilize quality grouping mechanisms already in place, such as ACR’s Rheumatology Informatics System for Effectiveness (RISE) Registry. RISE is officially recognized as a Qualified Clinical Data Registry by CMS and is designed to

provide superior quality reporting and quality improvement capabilities. RISE helps practicing rheumatologists and rheumatology health professionals who are active ACR/ARHP members benchmark performance on key rheumatology clinical-quality measures and align with best practice standards.

We encourage CMS to build on existing National Quality Forum (NQF)-endorsed quality measure cohorts for guidance on defining groupers that are harmonized with quality measures. These measures employ a patient-centric approach to grouping episodes. Where and when possible, we encourage CMS to favor episode groupers that promote shared accountability for management of complex chronic diseases over those that encourage siloed care.

ii. Distinct Codes Should be Provided for New and Existing RA Patients

For the outpatient chronic disease code of rheumatoid arthritis, we believe distinct codes should be provided for new and existing rheumatoid arthritis patients, or at a minimum the RA code should distinguish and/or stratify by disease duration. Providing this distinction will produce a far more meaningful set of robust data--as initial treatment of patients for rheumatoid arthritis is more prototypical and consistent with rheumatologic guidelines.

By contrast, measurement of established RA patients can be very challenging, whether it is a clinical outcome or cost -- established RA patients represent a broad variety of clinical disease severity and risk categories, including patients with highly treatment refractory disease. Creating and more importantly adequately risk adjusting episode groupers for such clinically distinct patient groups is as yet beyond the reach of available national data sources.

In light of the above, we request that CMS provide additional information on what would exactly trigger the new patient evaluation and initial treatment for an early RA patient. In addition, what triggers the subsequent payment codes for patients after the initial 6 months of therapy? Further, how does CMS propose to account for clinically coherent explanations of cost differences within disease groups, such as RA?

As an alternative to the above, the ACR recommends that there should be mechanisms for a provider to actively exclude patients from care episode groups and patient condition groups where the patient otherwise meets the classification criteria. The broad spectrum of patients rheumatologists provide care for often defy classification and systems that force patients into ill-fitting groups. Pushing patients into ill-fitting groups distorts the groups and undermines the purpose of grouping them in the first place.

The ACR acknowledges variation in clinical care and its associated costs that do not reflect variation in disease severity and is eager to work with CMS to explore how robust data sources, like the RISE registry, may be able to fill this important gap and move the nation towards meaningful value-base payment.

iii. Episode Sub-Groups

The draft list does not currently include specifications for episode sub-groups for rheumatologic conditions or episodes. The ACR recognizes that sub-groups may be helpful for the measurement of complex conditions, but this must be done in a way that accurately assesses physicians and

balanced against the need to have an adequate number of cases that can be attributed to a given clinician. RA is a systemic disease, which involves multiple joints at any one time, thus it would be difficult, or impossible, to code for “RA, right ankle”, etc. By way of example, the RA Advanced APM model does not define by anatomy. It is imperative that episode groups accurately recognize how physicians treat patients.

Diagnosis Related Groups (DRGs) may offer an existing methodology for capturing and quantifying costs, but they do not replace the need for risk adjustment or stratification to account for clinically coherent variation in care and costs. We previously provided CMS and Acumen with recommendations on the acute inpatient DRG codes and recommended subgroups which we believe provide one path for CMS to use. CMS’s recent list of codes under development do not include our recommendations and we urge CMS to provide further consideration to our proposal.

Further, the proposed DRGs for the Connective Tissue Disorders (CTDs) acute episode encompass conditions managed by a variety of medical and surgical specialties that will make it challenging to attribute costs or clinical outcomes to a specific group of clinicians. We therefore request that CMS remove the acute-care episode for CTD in order to ensure proper attribution occurs. We also request that, in general, clinicians should be allowed to have control over attribution of episode groups to them.

Finally, it is important to note that many rheumatologists in the United States no longer consult or follow patients who are hospitalized. We would caution CMS on attributing hospital outcomes and costs to individual providers without clear evidence that the provider influenced those costs and outcomes. In particular, we note that if a patient is sick enough to be admitted to a hospital, there is likely to be multiple issues happening with the patient and therefore it is very difficult to assign outcomes and cost to a single specialty group. It would not be appropriate for providers to be penalized for those things which they cannot control, especially given that quality outcomes are not established and diseases can often be too complex to adequately track.

B. Cost Measure Development

i. Cost is Not a Measure of Quality and Should be Kept Scored at Zero

As physicians, our treatment of patients is driven by achieving the best treatment for their condition. While we are cognizant of cost when seeking the best treatment for our patients, it is critical to emphasize that when CMS evaluates providers and their clinical outcomes, cost is not an indicator of quality or measure of quality, and further that clinicians are in no way penalized for the high cost of specialty drug treatments. Cost may be an outcome, but it is not a quality measure. The ACR acknowledges that there is likely high value and low value rheumatologic care currently occurring in the United States. However, there are currently no scientifically acceptable tools that adequately account for disease complexity and severity to measure value for patients with rheumatologic disease. The ACR would eagerly like to engage with CMS to develop such measures.

Therefore, we urge CMS keep the cost category’s weight in the composite score at zero in 2018. In the final MACRA rule, CMS set the weights at zero in year one and 10 percent in year two. There are tremendous problems with the various methodologies, such as risk adjustment and attribution. CMS’s own data has shown that the current methodology discriminates against

physicians who treat the sickest patients. The agency needs time to develop better risk adjustment and attribution. CMS has the statutory authority to reduce the second year weight to zero and we urge it to do so.

ii. CMS Should Adopt a Flexible Gradual Transition Period

We believe that in years three through five of MACRA CMS should create and expand a pilot program. In the pilot, the cost score would be calculated only for physicians who volunteered to test new measures that are based on episodes of care, adjust costs to reflect patient condition, and use patient relationship categories to attribute costs within the episodes.

The ACR urges CMS to establish a more gradual transition period. MACRA provides flexibility to CMS in how it structures the MIPS program for 2017 and 2018. CMS has limited this flexibility to 2017 without providing guidance for what will occur in future program years. CMS should take advantage of this flexibility and adopt a similar transition year for 2018 to allow physicians to become more familiar with the program and keep program requirements stable.

CMS can set the MIPS performance score threshold to promote successful participation by ensuring a greater number of physicians are held harmless from penalties. Specifically, the agency should be flexible about the data used to set performance and should maintain a substantial low-volume threshold that exempts physicians with few Medicare patients or little revenue.

iii. Rates Should Reflect the Unique Characteristics of Rheumatology Practices

We request that CMS provide additional information regarding its proposal to use the CMS-HCC Risk Adjustment Model used in the Medicare Advantage program to determine rates.

We are concerned the CMS-HCC Risk Adjustment Model provides insufficient risk adjustment for the granular episodes CMS has proposed in MIPS. We ask CMS to evaluate the validity of the predictive model in the proposed episode groups and sub-groups using clinical adjudication to determine whether it adequately accounts for disease complexity and severity. We also have concerns that the use of the past year of data may not necessarily capture the actual complexity involved in a new diagnosis such as rheumatoid arthritis.

In order to measure risk adjusting episode groups, any risk adjustment model should include all the diagnoses such as DM and CHF. Use of such a model would depend on all physicians being able to see patient coding. Additionally, in order for episode group costs to be appropriately risk adjusted, more codes are needed for variables that are outside the clinician's control. These codes should account for variables such functional limitation, patient non-adherence, comorbidity-drug interactions (e.g., abnormal LFTs preventing MTX use), and financial barriers to care and treatment. We encourage CMS to identify a way to capture the risk adjustments without increasing the burden on the provider.

iv. Cost Measures Must Reflect the Cost of All Drug Costs

In future years, we believe that all drug costs should be included in any performance and/or cost measure. MACRA provides that Part D should be included “as appropriate and as feasible and applicable”. We believe it is not only appropriate and feasible, it is fundamental that Part D costs

are included. Without Part D costs included, the measure cannot capture an important, medically necessary benefit on which our patients rely. Excluding Part D costs also leaves an important source of cost variation unmeasured, further undermining the validity of any comparative cost assessments. Until Part D drug costs are included in cost measurement, and CMS can demonstrate that those Part D drug costs can be captured properly, the cost component of the MIPS scoring formula should remain at zero percent.

The ACR is presently investigating issues related to Part B and Part D costs in the RISE registry for treating rheumatologic diseases and we are eager to work with CMS going forward to share our findings in order to better inform the policy making process.

C. Patient Relationship Codes

We agree with CMS' suggestion that categories of classification which include combinations of categories would be most appropriate in properly classifying patient relationship categories. At the same time, CMS should recognize that patients and physicians relationships may change over time as health conditions and the corresponding care provided change.

We encourage CMS to allow providers to select a patient relationship category as the patient relationship changes. One possibility may be to allow providers to select multiple patient relationship codes for those episodes of extended duration or complexity.

In particular, we request that CMS emphasize a reduction in administrative burdens and streamlining of reporting tasks so that the delivery of patient-centered care is the principal focus in all clinical settings. We ask that CMS provide stakeholders a clear idea of how the agency proposes treating patient and physician relationships and how attribution will be handled. It will be important for physicians to understand what this will look like in practice.

D. Concerns Related to Alternative Payment Models

We ask that CMS recognize that many of the concerns that must be addressed in the development of episode-based cost measures are also concerns and needs in the development of Alternative Payment Models. Therefore we request that CMS seek input from those groups such as the ACR that are developing Alternative Payment Models, so that it can be determined how care episode groups and patient condition groups can best support APMs. Further, CMS should specifically seek out episode groupings and patient categories that have been developed by societies such as ACR that are working to develop Alternative Payment Models, and ensure those are consonant with that which CMS develops.

The ACR further recommends policies that would make APM development and participation easier for interested groups. CMS should make a significant effort to improve accessibility of claims data, so that the data is more readily available to serve as benchmark data for those groups developing APMs. Additionally, the start-up costs of becoming involved in an APM should suffice for risk in APM participation, and further financial risk should not be required.

E. Additional Considerations

As CMS recognizes, not all patient episodes will fall into clear-cut episode categories, particularly in cases where the treatment is truncated. In cases of truncated episodes, cost should be measured distinctly from non-truncated episodes.

Most importantly, episode groups should ensure patient access to therapies and to rheumatologists and rheumatology health care professionals.

COMMENT 19 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Dale N. Schumacher, President, Rockburn Institute

Text of Comment:

Attached please find our comments in response to Episode-Based Cost Measures, 12-23-2016. Comments relate to:

1. Quality measures -It will be difficult to establish a priori quality measures for these complex episodes. Rather we suggest that quality measures focus on the episodes resulting beneficiary's pathway.
2. Dual eligibles and Medicaid - Depending upon the beneficiary's state Medicaid benefits will vary and could substitute for or add to Medicare costs. Unfortunately, we can suggest no easy answer.
3. HCC Percentile Ranking - If multiple admissions during the performance year, the beneficiary has the identical HCC ranking based on the prior year HCCs. We suggest using 2 years HCC data and perhaps consider the 2 year "trend."

Thanks for the opportunity to respond. Please contact me if clarifications are necessary.

MSPB 30-Day Care Pathways

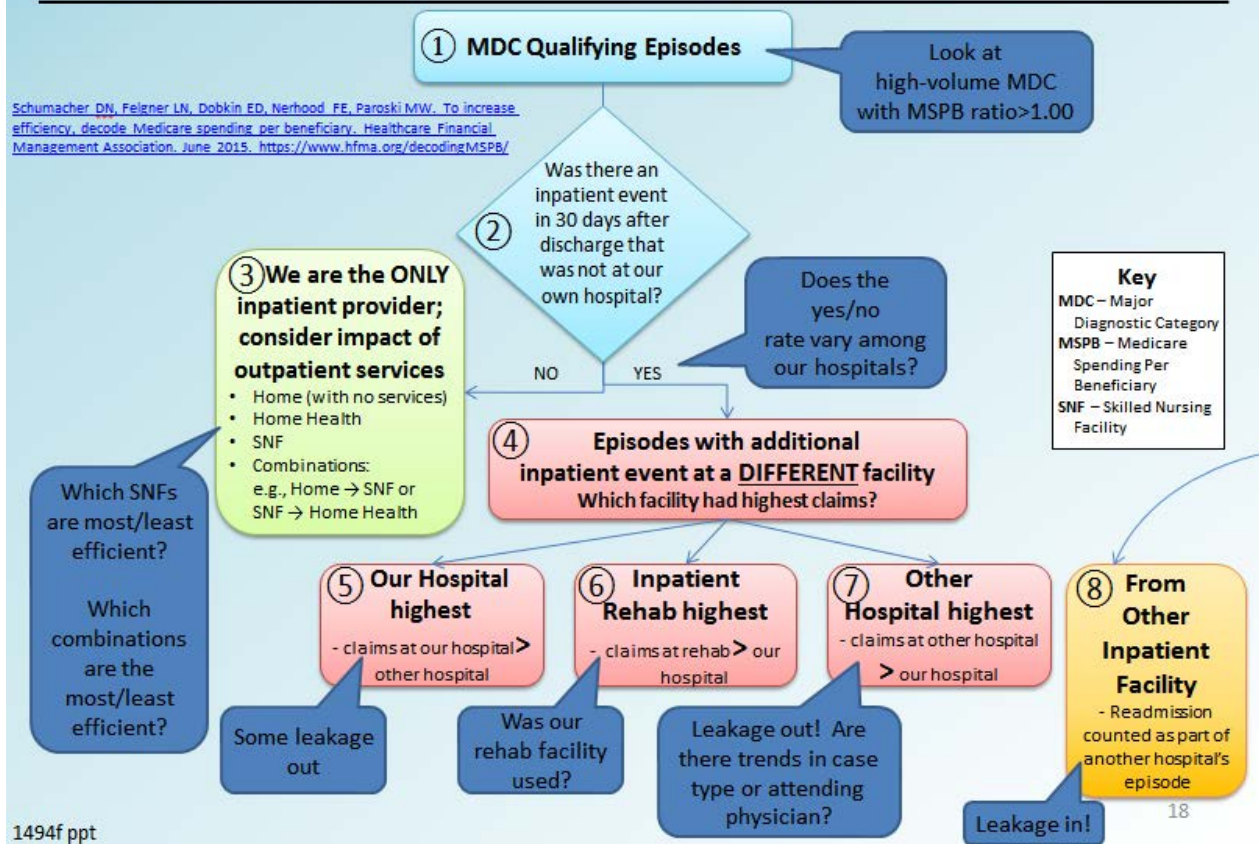


Figure 1 MSPB 30-Day Care Pathways

Chronic conditions and dual eligibles

The 21st Century Cures Act raises dual eligibles to a new level of prominence as a possible stratification metric in IPPS 2018. Consider sorting proposed episodes based on their dual eligible status.

Post-Stay Service, by Pre-Inpatient Stay Services, CY 2012

Pre-Stay Service	Medicaid Post-Stay Services			Medicare Post-Stay Services					Other	
	HCBS	Hospice	NF	ED	Home Health	Hospice	Inpatient	SNF	No Post Services	Died
Medicaid HCBS	85%	<1%	2%	29%	24%	4%	26%	24%	1%	8%
Medicaid Hospice	<1%	57%	50%	22%	<1%	59%	17%	29%	0%	<1%
Medicaid NF	<1%	5%	59%	22%	<1%	8%	22%	49%	1%	19%
Medicare ED	12%	2%	15%	34%	12%	4%	28%	35%	16%	8%
Medicare Home Health	16%	1%	5%	39%	19%	7%	34%	51%	6%	12%
Medicare Hospice	7%	23%	23%	28%	4%	54%	23%	28%	1%	27%
Medicare Inpatient	9%	2%	11%	79%	14%	4%	43%	39%	3%	10%
Medicare SNF	3%	3%	27%	43%	5%	7%	32%	78%	1%	17%
No Previous Service	<1%	<1%	2%	6%	10%	<1%	10%	9%	19%	1%

Figure 2 Dual Eligibles

	Medicaid Expenditures	Percentage of Medicaid Expenditures	Medicare Expenditures	Percentage of Medicare Expenditures	Total Expenditures	Percentage of Total Expenditures
Dental	\$121,004	<1%	\$0	<1%	\$121,004	<1%
Durable Medical Equipment	\$385,725	<1%	\$32,917,711	2%	\$33,303,437	1%
Home Health Services*	\$642,478,730	40%	\$28,625,905	2%	\$671,104,636	23%
Hospice	\$21,928,227	1%	\$30,334,906	2%	\$52,263,133	2%
Inpatient	\$49,440,570	3%	\$574,994,940	43%	\$624,435,510	21%
Outpatient/Carrier	\$136,000,050	8%	\$502,592,047	38%	\$638,592,097	22%
Pharmacy	\$8,025,303	<1%	\$0	<1%	\$8,025,303	<1%
Nursing Facility	\$734,315,146	45%	\$157,470,123	12%	\$891,785,270	30%
Special Programs	\$29,749,404	2%	\$0	<1%	\$29,749,404	1%
Total	\$1,622,444,159	100%	\$1,326,935,634	100%	\$2,949,379,794	100%

* Includes Medicare home health services and Medicaid state plan and home and community-based waiver person care services.
Notes: Medicare pharmacy expenditures do not include Medicare Part D claims. Medicaid may cover some prescription costs. Medicare does not cover most dental care, dental procedures, or supplies. Medicare Part A (Hospital Insurance) will pay for certain dental services performed while in the hospital.
Source: MMIS₂

Figure 3 Dual Eligible Expenditures

For dual eligibles, Medicaid expenditures exceeded Medicare expenditures. Maryland Medicaid is generous compared to some other states. Are these Medicaid payments taken into account in generating Medicare episode costs?

Refine HCC Percentile Ranking

Table 1: Refine HCC percentile ranking – Example.

Beneficiaries have diverse clinical pathways if multiple admissions, but have same HCC Percentile Rank. Beneficiary	Date of Admission - Admitting Hospital	QRUR HCC Percentile Ranking – Table 5D
123456789A	01/22/2015	47
123456789A	06/04/2015	47

Currently if a beneficiary has multiple admissions in the performance year the beneficiary is determined to have the same HCC Percentile Ranking using prior year’s data. Recommendation is to use two years rather than one year to set the HCC at percentile average. Alternatively, for performance year, use higher percentile if year 2 greater than year 1 and lower percentile if year 2 less than year 1. This could capture what might be a trend.

COMMENT 20 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: James L. Madara, Chief Executive Officer & Executive Vice President, American Medical Association

Text of Comment:

The AMA appreciates CMS’ recent efforts to engage with the AMA and medical specialty societies to garner further input from the physician community on the episode measures and to move toward a system that holds physicians accountable only for costs and outcomes that they can truly control or influence. The AMA and medical specialty societies have worked hard to

enlist practicing physicians to donate their time to helping develop the episode measures. CMS cannot design appropriate episode measures without significant clinical input from all specialties involved in a particular episode, so improving the communication between CMS, its contractors, and the physician community is vital.

While the AMA appreciates the recent efforts on behalf of CMS to better engage physicians in the episode-based cost measure development process, we still have significant concerns with the process, timeline, and implementation of the episode-based cost measures. We recognize the challenges put on CMS by the MACRA statute; however, developing the majority of episode-based cost measures by 2019 is unrealistic. In addition, CMS and its contractor (Acumen, LLC, LLC) must incorporate and respond to clinical feedback provided by physicians and specialty societies. Other areas of substantial concern include the approaches being discussed to align quality and cost measures, the lack of progress in the development of an appropriate risk adjustment methodology, and limited information on how CMS will use the episode-based measures to attribute cost to physicians. These issues must be addressed before any episode-based cost measures can be tested.

Previous programs, such as the Value-Based Payment Modifier program, that have attempted to attribute cost to physicians have major flaws and a new method to evaluate cost must be developed. Therefore, while significant work is needed to improve the cost measures and the measure development process, we continue to believe the construction and refinement of appropriate episode measures could offer an improved way to measure physician costs. We provide further details below on what is necessary for CMS to improve the episode-based cost measure development process in order for it to be successful.

Incorporate Feedback

The AMA and other medical specialty societies have repeatedly provided comments on the episode measures and patient relationship codes, yet the comments have not been adequately reflected in later versions of the measure development documents. In order to ensure all stakeholders views are adequately considered and addressed, CMS and/or Acumen, LLC should respond specifically to previous comments submitted by stakeholders. In addition, all public comments that have been submitted to date on episode-based cost measures and patient relationship codes should be publically accessible on CMS' website.

Furthermore, the AMA has heard significant concerns from medical specialty societies that the clinical input their members have provided is not reflected in the latest version of the episodes. The physicians who reviewed the draft cost episodes reported that there were numerous mistakes and logical inconsistencies within the draft episode-based cost measures. In addition, physicians reported that many of the trigger codes they were asked to review had Current Procedural Terminology® (CPT®) Process descriptions that were incorrect, which could lead to misclassification or inclusion of costs that should not be part of the episode. These mistakes illustrate the need for physicians to be intimately involved with the development of the episodes. The physicians who are working with Acumen, LLC to develop these measures understand the importance of that work and want to continue providing their clinical input. The work is resource intensive, takes time away from patient care, and typically involves reimbursement only for expenses. CMS and Acumen, LLC must make improvements based on the clinical input they receive from these physicians if they expect physicians to be willing to continue to volunteer their time and clinical guidance in the future.

Improve Timeline Issues

The AMA recognizes the statutory deadlines and resource limitations that CMS faces in developing the episode-based cost measures, and we appreciate the steps CMS has taken to incorporate stakeholder feedback into its episode-based cost measure development process. For example, as noted earlier, we strongly support CMS' efforts to identify which specific costs within an episode of care are attributable to a particular physician rather than attributing all direct and indirect costs from an episode of care to a single physician. However, we still have significant concerns regarding the time it will take to perfect the episode measures and the scope of the measures that are moving forward.

It has taken over a year for CMS and physicians to produce the published list of 119 potential episodes and initially identify codes that may trigger each episode. We anticipate that specialties will suggest additional modifications to episode trigger codes. Additional work will also be required to determine which services should be included in the episodes and whether episodes should be split into narrower subgroups. The episode developers will also face methodological challenges as they address issues, such as, risk adjustment, attribution, and alignment of quality measures.

Therefore, a timeline that envisions finalizing a majority of the proposed episodes for use by 2019 is unrealistic. Instead, the AMA urges CMS to focus on a very limited number of episodes initially. Acumen, LLC should work with the medical specialties that treat patients accounting for a large share of Medicare spending to determine which episodes they believe should be developed and tested first within that specialty. These may be episodes already being developed by CMS or they may need to develop new episodes depending on feedback from the relevant specialties. We understand that CMS and Acumen, LLC intend to create seven clinical panels that will each identify one episode to be refined and put through a "dry run" that could help inform work on later measures. We agree that a "dry run" on a limited number of episodes would be useful. A number of participants in earlier clinical panels recommend that initially work should focus just on procedural episodes where it should be easier to define the episode, identify the trigger code, and determine which physician is responsible for costs within the episode.

In addition, CMS must more narrowly define the episode-based cost measures. For example, the COPD and Asthma episode measure incorporates two different conditions with dimorphic patient populations. While we appreciate and support CMS' discussion of the future development of subgroups, we believe that these two conditions are so different that they should simply be separated into two episodes from the beginning rather than combined and later divided into subgroups. We also recommend that episodes requiring subgroups be developed in a later wave. Instead, the initial measures should be defined narrowly and should use exclusions for any conditions or patients that would complicate the episode.

Once a few episodes are developed, tested, and refined, CMS should work with additional medical specialties to develop further episode-based cost measures, and refine the existing measures to create subgroups out of some of the conditions that were previously excluded. While this may delay the ability for all physicians to have relevant cost measures, the AMA believes it is more important to have accurate episode-based measures than to have inaccurate measures covering a larger number of physicians.

Develop a Pilot Program

As discussed above, the cost measures used in the Value-Based Payment Modifier program are highly flawed but the episodes posted for public comment to date are not ready for widespread use. Therefore, the AMA again urges CMS to postpone the adoption of any cost measures other than as a voluntary pilot program at this time. As we have stated previously, we believe CMS should continue to assign a zero score for the cost portion of MIPS and allow volunteer physicians to pilot test episodes and be rewarded for their participation with bonus points for the next few years of the Quality Payment Program.

Physicians will be significantly more likely to accept cost measure reporting if they know the measures have been tested and proven to successfully and accurately attribute cost to physicians. In addition, we have repeatedly emphasized the need for episode-based cost measures to be tested for use in physician settings, not hospitals and other settings. Otherwise, CMS runs the risk of losing physician buy-in, as occurred with the Value-Based Payment Modifier program.

Possible Process Improvements

As illustrated by our comments above, the episode-based cost measure development process needs significant improvement. While we appreciate CMS' recent efforts in this regard, it seems clear that more clinical input is needed from the outset of any effort to construct an episode. The AMA believes the best way to get that input and to instill physician confidence in the process and the episodes is to work from the beginning with the all relevant medical specialties and sub-specialties.

One way CMS could consider getting adequate engagement and input from physicians and specialty societies is to create a process similar to the AMA/Specialty Society Relative Value Scale Update Committee (RUC) or CPT. The RUC and CPT processes have been refined over many years, and already have buy-in from all physician specialties. This approach would also provide more continuity and consistency among episode measure development than the clinical panels CMS is creating. In the future, it might also provide an avenue for updating and refining episodes. The AMA would be happy to assist CMS in pursuing the development of a RUC-or-CPT-like process to develop the episode-based cost measures.

Quality Alignment

The AMA reviewed the proposal presented at the Technical Expert Panel (TEP) March 2017 meeting, and we have concerns how the proposal would align quality and cost measures. First, the proposal implies that there is a correlation between lower cost and higher quality. There is no data to support this assumption, and results would likely vary based on the type of care being provided, patient and payer mix, and availability of applicable quality measures. Significantly, no practice received a score of both high quality and low cost in the Value-Based Payment Modifier program within the results reported to date.

Furthermore, we are concerned with the potential of requiring physicians to report on a random number of quality measures that are prioritized by domains. Prioritizing selection by domain is counter to the direction of the MIPS program and may prohibit physicians from reporting on measures that are most relevant to their practice. We are also concerned with the implication that physicians must be "continuously improving" the quality of care they provide. Many physicians already deliver extremely high quality care and have very little room for improvement.

Yale's proposed methodology of mapping quality measures to episode groups includes many quality measures that are not applicable to the episode and many episode-based cost measures that do not have relevant quality measures. For example, the Coronary Artery Bypass Graft episode measure includes ambulatory care measures and the heart failure episode measure includes diabetes A1C control and breast cancer screening measures. It is imperative that specialty societies are able to provide extensive input and review alignment of quality and cost measures. Otherwise, a CMS contractor will be determining which measures physicians are expected to report on based on groupings and trigger codes that are not always the most appropriate, much like what has occurred with CMS' Measure Applicability Validity process.

A better approach to consider is reinstating the concept of measures groups that was part of the Physician Quality Reporting System (PQRS) program. Measures groups have the ability to better assess a physician's quality tied to a specific episode since they follow a continuum of care, as opposed to Yale's proposal, which randomly maps quality measures to an episode and prioritizes quality measures by domains. Yale's current approach does not provide a full picture of measuring quality and efficiency of care for a particular condition or procedure. As we have stated in earlier MACRA-related comments, some episode-based cost measures have relevant quality measures, while others may require the development of new quality measures that appropriately correspond with an episode.

Finally, there are additional issues CMS must consider and questions CMS must answer related to how they would implement Yale's proposal, as well as any new proposal to align quality and cost measures. These issues include:

- Attribution: The current proposal does not appear to have considered attribution.
- Quality measure selection: Unless the intent is for the quality measures mapped to episodes to stay static, CMS will need to implement a process for reviewing quality measures similar to our proposed episode review process to ensure the best possible measures are being used.
- Quality measure trigger codes: How will a mapped quality measure to an episode be triggered? Is it by billing and being captured by an episode or by reporting on a quality measure? For purposes of scoring a quality measure under MIPS, a physician must have a minimum of 20 cases. Therefore, what happens if a physician reports on a quality measure but does not have enough cases to the relevant mapped episode?
- Patient population: Episode and cost measures are based on Medicare Part B patients only; however, quality measures are reported on all patients, regardless of payer (with the exception of claims-based reporting). Therefore, the cost and quality measurement would not be assessing the same patient population. CMS must develop a more robust risk-adjustment methodology to account for different patient populations or only measure quality in conjunction with cost for Medicare Part B patients. We highly recommend that CMS test both recommendations in a transparent manner and allow the TEPs to evaluate and provide input, as well as the public through comment period before finalizing a policy.
- Qualified Clinical Data Registries (QCDRs): How will the proposal impact QCDRs? Will QCDRs be forced to adopt traditional PQRS measures? We would not support any proposal that would force QCDRs to adopt traditional PQRS measures, as Congress intended to incorporate flexibility for QCDRs in MACRA.

- **Group reporting:** How would the proposal work for group reporting options such as Group Practice Reporting Option (GPRO) web-interface? For example, a specialist may be part of a multi-specialty group practice that reports as a group through the web-interface. The specialists that are part of the group may have an applicable cost episode, however the practice may not be reporting on the associated mapped quality measure. The same issues may occur with physicians who are reporting as a group through one of the other reporting options (electronic health record, registry, QCDR).
- **Reduce regulatory burden:** The AMA urges CMS to implement a proposal that would not increase physicians' regulatory burden. Specifically, we have concerns with some items that were mentioned in Yale's proposal such as reinstating the National Quality Strategy domains. CMS should work to simplify the Quality Payment Program instead of increasing complexity.

Improve Risk Adjustment and Attribution Methodologies

The AMA is concerned that CMS is still at the beginning stages of developing risk adjustment and attribution methodologies for the episode-based cost measures. The AMA urges CMS to use concurrent rather than prospective risk adjustment. Without including current comorbidities and diagnoses, CMS cannot properly risk adjust patients.

In addition, the AMA continues to urge CMS to risk adjust beyond clinical adjustment. As the AMA has stated previously, we believe it is very important to include socioeconomic and demographic factors in any final risk adjustment methodology. In addition, factors such as a patient's functional status and barriers to accessing health care services (such as living in a rural area) should be included in a risk adjustment calculation.

The AMA understands the complexity around developing appropriate and accurate risk adjustment and attribution methodologies. The agency will need detailed clinical input from across medical specialties to improve risk adjustment and attribution going forward, and we urge CMS to utilize its clinical committees to develop these methodologies. CMS will also need to consider a strategy that is not overly burdensome and dependent upon physicians collecting and documenting a significant amount of information and data.

Exclude Medicare Part B and Part D Drug Costs

The AMA strongly urges CMS not to include Medicare Part B or Part D drug costs in the episode-based cost measures. There are factors outside of a physician's control that affect the cost of drugs that they provide to patients. For example, a physician may not have access to cheaper compounded drugs, depending on their state. A physician in a state that does not allow compounding and requires physicians to use a more expensive alternative should not be penalized.

Finally, the AMA believes that stakeholders must be provided another opportunity to review and comment on a revised version of all episode-based cost measures, including the first ten developed, prior to their use in the Quality Payment Program.

COMMENT 21 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Gail J. Richard, President, American Speech-Language-Hearing Association

Text of Comment:

The American Speech-Language-Hearing Association (ASHA) is the national professional, scientific, and credentialing association for 191,500 members and affiliates who are audiologists; speech-language pathologists; speech, language, and hearing scientists; audiology and speech-language pathology support personnel; and students. ASHA has actively engaged in the process to develop and refine episode groups because we recognize that they have significant implications for our members in at least two areas: (1) the resource use category under the Merit-Based Incentive Payment System (MIPS) and (2) alternative payment models (APMs). As our members intend to be included in both MIPS and APMs, we have a strong interest in ensuring the episode groups are developed in a way that is inclusive and reflective of the scope of practice for our members. ASHA's comments focus on the following main concerns:

- The need to ensure that as the episode groups evolve and are adopted, the role of nonphysician clinicians, such as audiologists and speech-language pathologists (SLPs), are considered.
- The episode groups need to be specified to ensure that nonphysician clinicians, such as our members, are able to readily determine if they are part of one or more episode groups.
- As currently drafted, ASHA is forced to make assumptions about the appropriate inclusion and exclusion of our members in the revised 117 episode categories.

The role of nonphysician clinicians needs to be considered in the development of episode groups.

ASHA understands that these episode groups are a critical element of the Medicare Access and CHIP Reauthorization Act (MACRA), as they could be used for a variety of purposes including the development of resource use measures for one of the four MIPS categories and in the development of APMs. Successful participation in MIPS and/or APMs will be critically important to ensure the long-term viability of our members in treating not only Medicare patients, but also patients covered by private insurance if and when private insurers adopt similar initiatives.

As CMS is likely aware, audiologists and SLPs have a specific role in treating Medicare beneficiaries (and patients more generally) that does not often include primary care or care management. To date, many APMs and resource use measures focus on clinicians, such as primary care physicians, who serve a larger care coordination role. Therefore, it would be inappropriate to apply the same resource use measures to audiologists and SLPs as those that are applied to their physician colleagues. Instead, action should be taken to ensure that when the episode groups are defined, Current Procedural Terminology (CPT) codes and International Classification of Diseases (ICD) codes reflecting our members' services are included. Further, the resource use should only be attributed to our members for the procedures and diagnoses within their scope of practice—rather than the larger episode—given their limited influence on the overall episode of care, such as the inability to refer for specialty services. In addition, ASHA recognizes that speech-language pathology services are typically included under the “rehabilitation services” category along with occupational and physical therapy. We request that, when allocating costs for rehabilitation services, CMS only attribute costs for speech-language pathology services under rehabilitation services to an SLP, and not count occupational or physical therapy costs to the SLP because each provides distinct services focused on different functional goals.

Episode Groups Need to be Specified to Ensure Nonphysician Clinicians are Able to Easily Determine if They are Part of One or More Episode Groups

In a previous iteration of the episode group concept, which was released for public comment in mid-2016, there were 57 episode groups that have now been refined and expanded to 117 episode groups. At that time, CMS released detailed lists of CPT and ICD codes, including sequela ICD codes, which indicated that we might be part of six of the 57 episode groups. However, we did not agree with our inclusion in the rheumatoid arthritis episode group. In our comments, we sought clarification as to when codes typically used by audiologists and SLPs would trigger the initiation of an episode group. Would only primary ICD codes, typically used by a physician, trigger the initiation of the episode? Or, could sequela diagnostic coding also trigger the episode? This level of clarity is extremely important for nonphysician clinicians, such as audiologists and SLPs, who typically list sequela ICD codes.

It is our understanding that CMS has undertaken a fundamental reevaluation, which has led it to modify many of the episode group titles from the previous list of 57 to nearly double the number of episode groups under consideration. As part of this reevaluation, a significant level of detail associated with the 57 episode groups does not appear to be part of the new 117 episode groups. For example, it appears that only the CPT and ICD codes typically used by physicians are currently available. While CMS intends to issue a more detailed list, including sequela ICD codes, in the future, this lack of specificity has made it challenging to provide thorough and complete feedback.

Based on the revised episode groups, ASHA is prepared to make suggestions about the inclusion of our members in several episode groups.

Even though our procedural and diagnostic codes are not part of the current iteration of episode groups, we reviewed the revised list of 117 episode groups to make preliminary recommendations to CMS for potential inclusion in specific groups. The following table outlines our recommendations based on the current list; however, our recommendations may change as further details on these groups become available:

Type of Episode Group	Episode Group Name
Acute Inpatient Medical Condition	Acute Ischemic Stroke with Use of Thrombolytic Agent
Acute Inpatient Medical Condition	Acute Myocardial Infarction, Discharged Alive
Acute Inpatient Medical Condition	Fracture of Hip & Pelvis
Acute Inpatient Medical Condition	Gastrointestinal Hemorrhage
Acute Inpatient Medical Condition	Gastrointestinal Obstruction
Acute Inpatient Medical Condition	Heart Failure and Shock
Acute Inpatient Medical Condition	Intercranial Hemorrhage or Cerebral Infarction
Acute Inpatient Medical Condition	Major Gastrointestinal Disorders & Peritoneal Infections
Acute Inpatient Medical Condition	Peripheral Vascular Disorders
Acute Inpatient Medical Condition	Diabetes

Type of Episode Group	Episode Group Name
Acute Inpatient Medical Condition	Poisoning & Toxic Effects of Drugs
Acute Inpatient Medical Condition	Pulmonary Edema & Respiratory Failure
Acute Inpatient Medical Condition	Respiratory Infections & Inflammations
Acute Inpatient Medical Condition	Respiratory System Diagnosis with Ventilator Support <96 hours
Acute Inpatient Medical Condition	Respiratory System Diagnosis with Ventilator Support >96 hours
Acute Inpatient Medical Condition	Simple Pneumonia & Pleurisy
Acute Inpatient Medical Condition	Transient Ischemia
Chronic Condition	Asthma/Chronic Obstructive Pulmonary Disease (COPD)
Chronic Condition	Diabetes
Chronic Condition	Gastroesophageal Reflux Disease
Chronic Condition	Heart Failure
Chronic Condition	Major Depressive Disorder
Chronic Condition	Migraine
Chronic Condition	Parkinson's Disease
Procedural	Coronary Artery Bypass Graft (CABG)
Procedural	Laryngectomy
Procedural	Treatment of Spinal Fracture or Deformity
Procedural	Spinal Fusion

COMMENT 22 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Jeffrey Plagenhoef, President, American Society of Anesthesiologists

Text of Comment:

The American Society of Anesthesiologists® (ASA), on behalf of our over 52,000 members, appreciates the opportunity to comment on the draft episode-based cost measure framework posted on the CMS website. The creation of Episode Groups for use in the Cost Performance Category was included in the Medicare Access and CHIP Reauthorization Act (MACRA) statute. Episode grouper software aggregates claims data into episodes to assess condition-specific or procedure-specific utilization and costs. It is anticipated that this data will help inform the Cost Performance Category, one of the four components of the Merit-based Incentive Payment System (MIPS).

As reflected in many of our comments and interactions with the Agency, ASA has embraced the underlying goals of MACRA. ASA has invested heavily in initiatives aimed at improving the safety, quality and efficiency of care for the surgical patient. We have developed a clinical registry, operated by the Anesthesia Quality Institute (AQI) that contains detailed files on millions of anesthetic administrations by thousands of physician anesthesiologists in hundreds of care settings. Additionally, we have sponsored the Perioperative Surgical Home (PSH)

Collaboratives in almost 60 large and small health care institutions. PSH is a patient-centered delivery system that aligns with the National Quality Strategy (NQS) to achieve the triple aim of improving health, improving the delivery of healthcare and reducing costs. These goals are met through patient-centered shared decision-making and seamless continuity of care for the surgical patient, from the moment the decision for surgery is made, during the acute episode, all the way through recovery, discharge and beyond.

The development of cost measures is critical in the implementation of MIPS as well as the further advancement of value-based purchasing. It is also an area where CMS has limited experience. For these reasons, ASA urges CMS to consider the following factors which we believe impact the development and implementation of cost measures:

- Methodological Issues: Methodological issues such as attribution and risk adjustment including a recognition that the development of cost measures is inherently iterative—one cannot simply develop episode groups in a vacuum and then consider attribution and risk adjustment; these must be considered in an integrated fashion throughout the development of the cost measure component;
- Collaborations with Private and Other Payors: Collaborations outside of Medicare that attribute cost to an individual or a team of physicians should be an inclusive process that includes all stakeholders impacted by the measure or methodology, including specialty societies, to allow sharing of experience and avoidance of duplication or incompatibility; and
- Pilot Testing: A transition period for any new cost measures should be established to allow both CMS and physicians to better understand cost measures.

Methodological Issues

The methodological approach CMS will take in constructing episode groups will determine their robustness and the capacity of the agency to fulfill its mandate to measure the resource and costs of services and attribute them to Eligible Clinicians. Clear, precise and accepted standards and methods for measuring physician resource use do not exist. Nor does CMS have significant experience in this area. For these reasons, we urge CMS to take a transparent, iterative and careful approach in the development and implementation of episode groups.

Attribution

Attribution is a process that aims to clarify relationships and assign accountability for a patient's costs to a clinician, groups of clinicians, or a facility. They are an essential component of cost measure development, design and implementation. A core principle of attribution is that it should be shared and team-based.

CMS should develop rules and policies around attribution in the cost measure environment that are clear and transparent. They should be consistently applied, tested and monitored. Attribution models should attribute costs only insofar as entities can influence the costs of care and outcomes.

ASA supports the principles and approaches to attribution defined by the NQF in their report: *Attribution: Principles and Approaches*¹ published in December 2016.

- Attribution models should fairly and accurately assign accountability.
- Attribution models are an essential part of measure development, implementation, and policy and program design.
- Considered choices among available data are fundamental in the design of an attribution model.
- Attribution models should be regularly reviewed and updated.
- Attribution models should be transparent and consistently applied.
- Attribution models should align with the stated goals and purpose of the program.

ASA encourages CMS to adhere to these principles in their attribution methodology.

- *Unique Role of Physician Anesthesiologists as It Relates to Attribution of Costs*

Because of the unique role that physician anesthesiologists play when providing anesthesia services during surgical procedures, ASA wishes to explain the role physician anesthesiologists play in providing services to their patients and provide recommendations on how costs should be attributed to them.

In the typical practice environment for physician anesthesiologists, purchasing and acquisition decisions and the availability of choices of equipment and supplies are most often not within the control or discretion of the anesthesiologist. As such, ASA believes it would be most appropriate that these resources and their accountability be shared with the surgeon and the facility.

ASA recommends that these resources are proportionately attributed to all providers and facilities involved in rendering the service. We believe such a methodology is aligned with the concept of shared accountability.

The spectrum of roles that physician anesthesiologists play in providing services to their patients is described below.

- Providing anesthesiology during surgery
 - *Traditional practice:* This includes assessment of patient’s condition prior to anesthesia, preoperative management of chronic medications, review of diagnostic studies, determination of available anesthetic options, creating a plan with the patient and obtaining consent; intraoperative management of anesthesia, monitoring and maintenance of physiologic functions and immediate postoperative care.
 - *Advanced, more comprehensive practice:* This includes the above but with deeper engagement in preoperative preparation including optimization of medical conditions including nutrition, tobacco use, diabetes control – often weeks ahead of planned surgery; postoperative management of pain with interventional procedures or pharmacologic therapy during hospitalization and after hospital discharge, and fluid management. This is the model of practice promoted in the Perioperative Surgical Home (PSH) initiative described earlier.
- Providing critical care
 - *Critical care of patients with respiratory or surgical disease:* Anesthesiologist intensivists function as consultants to admitting physicians or, in many facilities, as the admitting attending physician themselves.
- Providing pain medicine services

- *Acute (post surgery)*: This includes multimodal pain management, prescribing oral or injected narcotic and nonnarcotic analgesics and/or by providing interventional pain management utilizing epidural or nerve block techniques. The goal is to minimize the use of opioids, alleviate patient discomfort and optimize recovery.
- *Chronic pain management*: This includes care of patients with the full spectrum of painful disorders including musculoskeletal disease, malignancy or traumatic pain. Similarly, approaches include pharmacologic therapy, especially management and prevention of opioid dependency and interventional injection procedures.

An individual physician anesthesiologist is often one member of a larger team of healthcare professionals providing services to a Medicare beneficiary. Depending on the needs of the patient and the other providers involved, the physician anesthesiologist may play a different role with different patients. These varying roles will impact the resources or costs that can be attributed to the Eligible Clinician. Any measure or method developed to estimate costs attributed to a provider should be nuanced enough to differentiate among the varying roles that a physician anesthesiologist may play as a member of a larger team. The use of Patient Relationship Categories of codes could help address these differences.

ASA urges CMS to develop Patient Relationship Categories that will create a pathway for CMS to be better able to measure and more accurately attribute costs to physician anesthesiologists.

Quality Resource Use Reports (QRURs) are feedback and benchmarking tools provided by CMS as part of the Physician Feedback Program. They offer information about the costs and quality of care provided by physicians or groups to certain Medicare patients. The Affordable Care Act also authorized CMS to use some of the information in the QRURs to calculate the Physician Value-Based Payment Modifier (VM), which is used to factor neutral, increased, or decreased payments. Risk adjustment is used for select measures in the (QRURs). The risk adjustment reflects the clinical complexity of the patient.

ASA heard from members who had difficulties with the QRUR reports. Some members had difficulty accessing the reports, while other had difficulty understanding the reports once they had been accessed. Some members were concerned that they were not being appropriately evaluated.

The QRURs are the most significant example of CMS's having attempted to attribute and measure costs to an individual physician. ASA recommends CMS closely evaluate this experience and apply lessons learned from it to the establishment and implementation of cost measures under MIPS.

Risk Adjustment

Risk adjustment can account for differences in beneficiary-level risk factors that can affect quality outcomes or medical costs, regardless of the care provided. CMS has limited experience with risk adjustment.

In the Medicare Physician Fee Schedule, in the measures included in the QRURs and Value Modifier calculations, risk adjustment generally involves estimating a Tax ID Number's (TIN's)

expected performance on a quality or cost measure based on the TIN's beneficiary case mix and then comparing that estimate to the TIN's actual performance.²

The Medicare Advantage (MA) program utilizes the CMS-HCC risk adjustment model. One advantage of this model is that it calibrates for different populations (e.g. disabled, aged population). CMS uses a risk adjustment model for the Medicare Part D program which adjusts payments to reflect the health status of plan enrollees. Many State Medicaid programs utilize risk adjustment as well.

The Affordable Care Act created a permanent risk adjustment program for the State-based Marketplaces and the Federally facilitated Marketplaces (the Marketplaces). The HHS risk adjustment model uses an individual's demographic data and diagnoses to determine a risk score, which is a relative measure of how costly that individual is anticipated to be to the plan (i.e., a relative measure of the individual's actuarial risk to the plan). Since this risk adjustment applies to the private insurance market it is unclear if this approach for risk adjustment would be appropriate for a Medicare population.³

In applying the risk adjustment in the fee-for-service (FFS) environment, physicians might be at a disadvantage. A provider is incentivized to document all of the services provided (because this results in incrementally greater reimbursement) but not necessarily all of a patient's diagnoses (which does not impact reimbursement in the current system). Recognition of this reality is reflected in the coding intensity adjustment applied to the MA environment. MA spending is aligned with FFS spending and to account for any up-coding that may occur in the MA environment a coding intensity score is applied. The specificity and intensity of coding may also vary by condition.

ASA strongly believes that socioeconomic factors should be considered in risk adjustment because patient outcomes and compliance may be influenced by patient health status, clinical, and sociodemographic factors, in addition to the quality and effectiveness of healthcare services, treatments, and interventions.

Risk adjustment methodologies are evolving and developing throughout the various Medicare and Medicaid payment systems, with other public payors, and in the private payor environment. No one methodology has emerged as best explaining variations in cost or quality outcomes related to patient factors. ASA recognizes that CMS may not be able to identify the perfect methodology that addresses all concerns and avoids potential pitfalls. ASA believes that the best way to move forward is to identify one that is tested and validated in a transparent and data-driven manner. The methodology should be clear and understandable to providers. Important criteria in the selection of a risk adjustment methodology should identify one that can be applied as consistently as possible across different payment systems. ASA believes strongly that the same risk adjustment methodology should be used for professional services throughout Medicare.

Specifically, ASA recommends that:

- ***CMS should conduct a thorough comparison of the various risk adjustment models used in Medicare, Medicaid and the private sector market. Models that best explain variations in costs and quality outcomes based upon medical, social, and demographic factors relevant in the Medicare population should be identified. This review should be conducted in a clear and transparent manner.***

- *The limitations of the administrative data available in a FFS environment should be factored into any analysis.*
- *Any methodology should be validated thorough and transparent testing prior to implementation.*
- *Risk adjustment that is performed throughout the Medicare program should be consistent. Specifically, CMS should align risk adjustment methodologies for professional services throughout the Medicare program as practically as possible.*

Our recommendations for risk adjustment align well with the intent of the MACRA statute. MACRA was designed to bring alignment and agreement across Medicare physician payment, to reduce costs and administrative burden while enhancing quality of care and outcomes. The approach we are recommending hews to those same goals.

Collaborations with Private and Other Payors

The trend towards value-based healthcare purchasing and delivery is impacting all payors professionals and healthcare systems not just Medicare. Some highly-developed integrated delivery systems may be further down the road in cost measurement than Medicare. Standardizing cost measures (or at least approaches to cost measurement) across Medicare and private payors may also be valuable in making comparisons for research and analysis. CMS participated in the Core Quality Measure Collaborative which included public and private payors to develop a core set of quality measures. This initiative is designed to reduce the number of quality measures. The value of this approach in the quality arena may also be valuable in the cost measure environment. While this was a worthy effort, ASA believes that participation of all stakeholders, including specialty societies, impacted by the measures would have enhanced and improved the process. A core goal of these efforts should be to ensure that the methodologies used by CMS and various private payors are aligned. We believe it would be very burdensome on providers and would not support the most accurate method of cost measurement, if different methodologies for measuring costs were developed.

Alignment among public and private payors takes on greater importance when considering the All-Payor Advanced Alternative Payment Model (APM) Combination option. Starting in 2021 (2019 payment year), some arrangements with non-Medicare payors can count towards becoming a qualifying APM participant. While this does not directly impact MIPS, it does reflect a potential future trend of greater alignment between Medicare and the private payor market.

ASA urges CMS to consider and evaluate models outside of Medicare, and we urge the agency to be inclusive in this process and include all stakeholders, including specialty societies, impacted by the measure or methodology being developed and evaluated. A central goal of these efforts should be alignment of cost measure methodologies across payors.

Pilot Testing Cost Measures and Episode Groups

Given the complexity and detailed nature of the cost measures, ASA believes there are a number of benefits that can be obtained through pilot testing any episode groups and cost measures prior to implementation. Through pilot testing, CMS will be able to assess the appropriateness of the proposed measure, address logistical and other problems prior to implementation, and provide an opportunity for participating clinicians to better understand the intent of the initiative and understand how they are being measured. Similar to how CMS approached MACRA in 2017 with a “pick your pace” option, we suggest a similar roll out for cost measures and episode groups. Since CMS will be testing methodologies and it will be a learning period for both CMS

as well as Eligible Clinicians, during this period Eligible Clinicians should not be at financial risk.

In addition to pilot testing, once they are established, ASA urges CMS to review them on an annual basis. Episode groups are composed of diagnosis and procedure codes. Each year new codes are created and existing codes are revised or deleted. In order to ensure the ongoing robustness of the episode groups, they will need to be maintained to assure they comprise the most current diagnosis and procedure codes. This will require the episode groups to be reviewed on an annual basis to ensure the ongoing accuracy of the episode groups.

Through pilot testing cost measures, CMS can ensure their feasibility, reliability and validity across specialties, practice setting and medical conditions. ASA offers its support in assisting CMS with pilot testing and conducting an annual review of episode groups and cost measures.

ASA recommends CMS pilot test of the cost measures and episode groups prior to implementation and review them on an annual basis to ensure their ongoing accuracy. The pilot testing period should be non-punitive for Eligible Clinicians.

1 National Quality Forum (2016). *Attribution: Principles and Approaches*. Retrieved from NQF on 4/18/2017: http://www.qualityforum.org/Publications/2016/12/Attribution_-_Principles_and_Approaches.aspx.

2 Centers for Medicare and Medicaid Services (CMS). (2015). *CMS Fact Sheet: Risk Adjustment*. Retrieved from CMS on 4/18/2017: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/Risk-Adjustment-Fact-Sheet.pdf>.

3 Centers for Medicare and Medicaid Services (CMS). 2016. *Discussion Paper: March 31, 2016 HHS-Operated Risk Adjustment Methodology Meeting*. Retrieved from CMS on 4/18/17: <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/RA-March-31-White-Paper-032416.pdf>.

COMMENT 23 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Henry W. Lim, President, American Academy of Dermatology Association

Text of Comment:

On behalf of the 13,500 U.S.-based members of the American Academy of Dermatology Association (AADA), I am writing to provide comments to the Centers for Medicare & Medicaid Services (CMS) about the Episode-Based Cost Measures that are intended to be used to improve cost measurement under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). We appreciate the opportunity to provide comments on the proposed cost measures and hope that CMS will take these recommendations and concerns into consideration when finalizing the measures.

The AADA is committed to excellence in the medical and surgical treatment of skin disease; advocating high standards in clinical practice, education, and research in dermatology and dermatopathology; and supporting and enhancing patient care to reduce the burden of disease. The AADA appreciates CMS's efforts to create Episode-Based cost measures under MIPS to more accurately measure medical resource utilization. Since these episode groups will be an important part of the MIPS score and consequently of physician reimbursement, it is very

important to create episode groups that accurately capture all clinically-vetted relevant services associated with the treatment of the given disease processes.

General Comments Related to CMS Development of Episode-Based Cost Measures

Grouping Services

After reviewing the proposed episode groups, we have identified significant flaws in many of them. For example, the Asthma episode is grouped with Chronic Obstructive Pulmonary Disease, which conflates a disease that primarily diagnosed in children (potentially a lifelong disease) with a disease primarily diagnosed in older patients (potentially near end of life disease).

For this reason, we urge CMS to work closely with the medical specialty societies to refine each episode group.

Episode Trigger Codes

Episode groups should have clinically relevant and easily understood triggers. CPT codes by themselves may not be sufficient to define the episode because of use of medical services to treat more than one disease process. ICD-10 codes also lack specificity in certain areas to appropriately capture a triggering event. This lack of specificity may lead to over- or under-inclusion of services within the episode. CMS should define the triggering rule clearly and ensure its sensitivity and specificity. If CMS depends on the chronological order of the services to determine the episodes, then CMS needs to clarify which triggering codes would apply for patients with multiple triggering services.

Attributing Episode Groups to Clinicians

Attribution of episode groups should be clear to all the physicians that are involved in the care of patients with the episode-defined disease process. CMS has not yet explained how it intends to address the attribution problem when multiple providers are involved in the care of the patient. However, providers should only be responsible for the cost of the service that is directly under their control. For instance, dermatologists frequently refer skin cancer patients to oncologists for further evaluation after surgical care, and they do not have control over the costs of tests that are ordered by the other specialists. We remain concerned that this is going to be a big challenge, especially for dermatologists who take care of patients with many chronic diseases.

We strongly urge CMS to address the attribution issue before moving forward with implementing the cost category under the Merit-based Incentive Payment System (MIPS) for 2018 and beyond. Assuring correct attribution is critically important for numerous alternative payment models as well. An episode group should allow for treatments requiring significant coordination among providers to include bundled payments that work across multiple clinicians and provider types. Therefore, we ask CMS to map out the process that it uses to identify the provider who is the responsible for the cost.

Risk Adjusting Episode Groups

The AADA is concerned with the lack of severity scales and risk adjustment tools that can be used for the proposed episode groups. Episodes of care need to be risk adjusted to be more

homogeneous as appropriate for the intended purposes. The episodes must be appropriately risk-adjusted to facilitate comparisons across providers by accounting for factors that are outside the influence or control of the providers. The episode grouper should not punish providers due to severity of the patients they treat.

Episode Definition

We encourage CMS to more clearly define what services are included in an episode. Clarity is needed as to whether the services provided due to complications that occur right after the episode period is over are considered as part of the episode. Furthermore, the episode group needs to be flexible to accommodate the patients' needs. We recommend for CMS to create model episodes that allow the physician to be able to provide both anticipated and unanticipated services based on the patients' needs.

Comments Related to Melanoma Destruction/Excision Episode Group

- We recommend CMS consider changing the name of the episode group by removing the word "Destruction", since destruction of melanoma is clinically contraindicated and it is not standard of care for modern melanoma treatment. We propose, "Excisional Treatment of Melanoma" to be an acceptable name for this episode group.
- The listed episode trigger code for the Melanoma Episode group is also used in the treatment of other skin cancers, so just using this set of CPT codes as a trigger will result in capturing costs unrelated to melanoma treatment. Linkage of the trigger codes to melanoma specific ICD-10 codes will be critical for the specificity and sensitivity of the episode. CMS has yet to provide the relevant ICD-10 codes. The AADA recommends the CPT codes 17312 and 17314 be deleted because they are add-on codes. The AADA recommends that the following additional procedure/codes to be used as trigger codes for the melanoma episode group: 17311 and 17313, as well as CPT codes 14000, 14001, 14001, 14020, 14021, 14040, 14041, 14060, and 14061 because the excision codes are bundled into the skin flap codes.

Many patients who have melanoma also have synchronous and metachronous non-melanoma skin cancers. Non-melanoma skin cancer treatment employs many of the same procedure codes as melanoma treatment but is unrelated. Careful and sophisticated cost inclusion logic will be required to exclude the cost of non-melanoma skin cancer treatment in this episode.

- It is also not clear if the cost of drugs is part of the overall cost which physicians would be responsible for, as drugs are an integral part of the treatments such as melanoma. However, due to the unpredictable nature of drug prices, it would be unreasonable to penalize the physician for something which they do not have control over.
- We recommend CMS consider splitting the melanoma episode into subgroups based on staging and body site to create a more homogenous model. The most important pathologic risk factor for poor patient outcome for cutaneous melanoma is histologic (Breslow) depth. However, thin and thick melanomas are coded with the same ICD-10 code with huge resulting variation in resource utilization and cost for the same diagnosis code. Body location of the melanoma (head and neck versus other sites) also portends significant differences in intensity of treatment. Using subgroups based on body site and

whether lymph node sampling is performed will allow for much more homogeneous groupers and consistent comparison of cost.

- **MIPS 224/NQF 0562** - Melanoma: Overutilization of Imaging Studies in Melanoma
- **MIPS 138** - Melanoma: Coordination of Care
- **MIPS 137/NQF 0650** - Melanoma: Continuity of Care – Recall System

We recommend for CMS to consider linking these three quality measures to the melanoma episode group. These measures are designed to reduce waste and increase coordination.

Conclusion

The AADA appreciates the opportunity to provide comments on the proposed episode groups. We encourage CMS to continue to work with the medical societies and other stake holders in a transparent manner during the development and implementation phases of the cost measures. CMS needs to continue to refine the episodes further as it is critical for future payment models that these episodes are correct, have clear rules delineating what is included and what is excluded, and are clinically appropriate. We urge CMS to test the episode groups prior to implementation, to ensure they are viable and appropriate.

We also request CMS develop a process that allows CMS to provide a timely performance feedback to the providers. This would give providers the opportunity to avoid penalties from lack of understanding CMS expectations.

COMMENT 24 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Amanda Cassidy, Health Policy Advisor, VisionCare, Inc

Text of Comment:

On behalf of VisionCare, Inc., we appreciate the opportunity to comment on CMS' proposals regarding development of episode-based cost measures for the Quality Payment Program (QPP). VisionCare is the manufacturer of the Implantable Miniature Telescope (IMT), an implantable medical device that has been demonstrated to improve vision and quality of life in individuals with end-stage age-related macular degeneration (AMD). It is not a treatment for cataracts. Furthermore, there are not quality measures related to use of the IMT for treatment of AMD and quality measures for treatment of cataracts are not relevant to treatment of AMD.

We urge CMS to adopt recommendations from stakeholders regarding alignment of episode groups and quality of care measures. In particular, we recommend that CMS ensure that the Lens and Cataract Procedure episode group is not more broadly defined than the quality measures related to that episode. Specifically, CMS should exclude CPT code 0308T Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis as a trigger code for the Lens and Cataract Procedure episode group because it describes insertion of the IMT and is not a cataract procedure. The costs and post-operative care for this procedure are

entirely different from those of cataract procedures. As importantly, 0308T is not included in the codes used to measure the quality of care for cataract patients; therefore, it should not trigger an episode related to cataract care or be included in the cost of caring for cataract patients.

It is critical that the episode groups developed by CMS appropriately capture resource use by physicians treating similar patients so that comparisons of cost and quality are reliable. We understand that CMS suggested that the development procedure described in the posting is proposed to only apply to the development of future episode groups which means it would not apply to the development of the Lens and Cataract Procedure episode group. We strongly disagree with this approach. Cost measures and episode groups already included in the QPP, such as the Cataract and Lens Procedure Group, should be evaluated against these proposed development standards and be refined as needed to be consistent with stakeholder feedback. All episode groups should be developed against the same standards or else CMS risks introducing significant bias into the evaluation, measurement and comparison of different physicians in the cost and quality domains of MIPS.

One of the key aspects for measure development identified in the posting is that in developing cost measures, it is essential for episode groups to align with quality measures. VisionCare urges CMS and its contractor, Acumen, to ensure that this standard applies to both current and future cost measures. The purpose of holding physicians accountable for costs of care provided during a specific episode is to encourage physicians to limit spending by better coordinating care and avoiding provision of unneeded services. The services that are triggers for the episode group should therefore be aligned with the triggers for the quality measure so that the cost and quality measures capture information on the same patients for the same episodes. In the case of 0308T, there are no quality of care measures related to the IMT. Therefore, quality of care for patients receiving the IMT cannot be measured.

Without simultaneously measuring the quality of care provided during the episode - as will happen with 0308T because there are no measures related to use of the IMT to treat AMD - establishment of cost measures for an episode that include a procedure for which quality is not being measured can create an incentive to inappropriately limit the services provided during the episode to improve performance on the cost measure.

Therefore CMS should remove 0308T from the Cataract and Lens Procedure Episode Group. This code is not included in any of the six quality measures related to cataract care that CMS included in the quality performance category. The IMT is a highly sophisticated implantable device that projects images in the patient's field of view onto healthy areas of the central retina outside of the degenerated macula. It is significantly different in function and cost from an intraocular lens used in a cataract procedure. The resources needed to provide this service, which is the only treatment option available to patients with end-stage AMD, should not be included in an episode group related to cataract procedures. Including 0308T in the Cataract and Lens Procedure Episode Group would present an inaccurate and distorted picture of the relative resource use of physicians providing this service.

Therefore, we urge CMS to remove 0308T as a trigger code for the Cataract and Lens Procedure Group in to order to appropriately align the cost measure with the cataract quality measures.

COMMENT 25 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: James C. Denny III, Executive Vice President and CEO, American Academy of Otolaryngology - Head and Neck Surgery

Text of Comment:

On behalf of the American Academy of Otolaryngology Head and Neck Surgery (AAO-NHS), I am pleased to submit the following comments on CMS's Request for Information (RFI) on Episode-Based Cost Measure Development for the Quality Payment Program.

On December 23, 2016, CMS released the RFI, asking for input from "episode groups." stakeholders on care episode and patient conditions groups, referred to as The Academy shares CMS' desire to develop cost measures which provide clinicians with actionable information to reduce healthcare spending and promote the delivery of high-value care. However, the Academy believes the desire to develop these measures should not overshadow the necessity for providing clinicians with accurate, actionable information.

In 2019, as CMS notes in the RFI, the cost category is weighted at zero percent of the MIPS final score and the cost category will be weighted at 10 percent for the MIPS final score in 2020 and 30 percent in 2021. As we stated in our comments on the MIPS final rule, the Academy was pleased to see the reweighting of the cost category. In 2016, the Academy was asked to participate in a Clinical Committee to provide input on the development of episode-based resource use measures, led by Acumen. Through this process, the Academy provided direct input in the development of several measures, including Laryngectomy, Tracheal Repair, and Tracheostomy. The Academy is pleased CMS continues to engage stakeholders throughout the development of the episode-based cost measures to ensure our concerns regarding the methodology and implementation of these components is considered.

The following comments represent answers to questions within the RFI on episode groups that are a priority to the AAO-HNS and the patients we serve.

Episode group Selection

- **In selecting the episode groups to be considered for development, CMS used criteria including an episode's share of Medicare expenditures, clinician coverage, and the opportunity for improvement in acute, chronic, and procedural care settings. We welcome comment on these episode groups and potential additional episode groups that should be considered for development.**

As currently constructed, there are no applicable chronic episode groups directly available for Otolaryngologist Head and Neck Surgeons to report. Depending on specific requirements CMS develops for the cost performance category, this could exclude Otolaryngologist Head and Neck Surgeons from participating due to a lack of applicable measures. We fear in this case, Otolaryngologist Head and Neck Surgeons would either be scored on episode groups that are not applicable to the specialty or will have an insufficient number of episode groups to ensure sound

scoring methodology. The lack of applicable measures can disproportionately negatively impact our physicians and result in negative payment adjustment. We seek clarification from CMS on how it intends to score specialists such as Otolaryngologist Head and Neck Surgeons that either have a dearth of episodes, or entire lack of applicable episode groups. There are, however, several episode groups that Otolaryngologist -- Head and Neck Surgeons may indirectly treat by addressing specific components of the treatment, including Asthma/ Chronic Obstructive Pulmonary Disease (COPD), Atrial Fibrillation, Rheumatoid Arthritis, and Lower Extremity Deep Vein Thrombosis (DVT) requiring anticoagulation. As currently constructed, it is not clear to Otolaryngologist Head and Neck Surgeons that they may be scored on components of these and other episodes they may encounter. While the Academy understands further rulemaking and clarification from CMS on patient relationship categories and codes and other components of the cost performance category, the Academy encourage CMS to make it as clear as possible to clinicians to indicate they can participate in the episode groups. The Academy fears CMS will create an opaque system determining episode applicability that will only reinforce perceptions and distrust that processes like the Measure Applicability Validation (MAV) have created. It is essential that CMS develop a transparent process that reimburses clinicians and correctly attributes cost in an easy way to report.

Additionally, in reviewing the initial list of chronic condition episode groups, the Academy believes there are chronic conditions missing which would serve as excellent opportunities for the development of additional episode groups including, chronic rhinosinusitis, allergy, dysphagia, chronic pneumonia, the treatment of oral cancer, and obstructive sleep apnea. While these conditions affect patients of all ages and demographics and are treated by many Otolaryngologist Head and Neck Surgeons, they specifically are conditions that are sources of large annual expenditures for Medicare, making them model conditions for future episode group development.

Finally, the Academy seeks clarification on whether CMS will measure inpatient care for episode-based cost measures, as was the case under the Value-based Modifier program. We believe the development of episode-based cost measures for chronic conditions that are treated in an outpatient setting are vital to allowing specialists such as Otolaryngologist Head and Neck Surgeons to participate in the cost performance category. Otolaryngologist - Head and Neck Surgeons disproportionately treat patients in an outpatient setting where they typically manage the care of the patient as compared to the inpatient setting where Otolaryngologists typically act as consultants. The movement of patient care from the inpatient to outpatient settings necessitates the development of chronic condition episode measures that are treated in the outpatient setting. As CMS works to develop episode-based cost measures for outpatient conditions, the Academy would be pleased to provide additional measure development recommendations in the future.

Episode Group Definition

- **The episode groups that accompany this posting are defined by the listed trigger events and codes (CPT/HCPCS for procedural episode triggers, evaluation & management codes combined with ICD-10 diagnostic information for chronic**

episode triggers, etc.). CMS solicits comment on the inclusion or exclusion of specific service codes used to identify each episode group.

The Academy thanks CMS for allowing our physician experts to review and provide comments via the process led by Acumen, on the composition of specific trigger events and codes last year. Specifically, the Academy provided comments on proposed Laryngectomy, Tracheal Repair, and Tracheostomy episode based cost measures. While the Academy appreciates the ability to provide input on multiple episode based cost measures, as previously mentioned, Otolaryngologist - Head and Neck Surgeons need additional applicable cost measures to ensure our physicians are fairly and appropriately scored by CMS. For our specialty and others, many applicable measures are in the outpatient setting for chronic conditions that represent a significant cost to Medicare. The previously identified episode-groups provide CMS the opportunity to work in the outpatient setting, which is especially important as CMS actively works to shift care to outpatient management. As this process moves forward, the Academy encourages CMS to apply episode-based measures to outpatient services.

Acute Inpatient Episode Groups

- **The acute inpatient medical condition episode groups that accompany this posting include only inpatient events. CMS seeks comment on outpatient events that could be considered candidates for development as acute condition episode groups, which could include chronic condition exacerbations that require acute care but not inpatient hospitalization. Acute episodes of care might occur on either an inpatient or outpatient basis and may or may not include surgery. CMS is considering a single Acute Episode Group type that does not distinguish the place of service or the performance of a procedure and welcomes comment on this approach.**

As previously mentioned, the Academy believes CMS should consider developing episode-based cost measures that will allow the greatest number of Otolaryngologists- Head and Neck Surgeons to accurately report on the cost performance category for MIPS. Similarly to the concerns stated in the episode group selection above, it is not clear to Otolaryngologist Head and Neck Surgeons that they may be scored on components of these and other episodes they may encounter. Under the list of Acute Inpatient Medical Condition Episode Groups, there are several episode groups that Otolaryngologist Head and Neck Surgeons may indirectly treat by addressing specific components of the treatment, including Acute Ischemic Stroke With Use of Thrombolytic Agent; Acute Myocardial Infarction, Discharge Alive; Acute Myocardial Infarction, Expired; Allergic Reactions; Cardiac Arrhythmia & Conduction Disorders; COPD; Endocrine Disorders; Esophagitis, Gastroenteritis & Miscellaneous Digestive Disorders; Peripheral Vascular Disorders' Pulmonary Edema & Respiratory Failure;

Pulmonary Embolism; Respiratory System With Ventilator Support < 96 Hours; Respiratory System With Ventilator Support > 96 Hours; and Simple Pneumonia & Pleurisy. The Academy once again calls on CMS to ensure correct episode attribution methodology and develop clear guidance for clinicians so they understand episode group applicability.

Specifically, the Academy believes CMS could consider the development of outpatient events that could be considered candidates for development as acute condition episode-based measures. Examples of acute condition episode-based measures include acute exacerbations and

complications of chronic and acute rhinosinusitis; peritonsillar abscess; epistaxis; angioedema; dizziness (exacerbation); sudden hearing loss; aspiration pneumonia; and facial trauma including structural and soft tissue. The Academy believes these examples correspond to the acute inpatient episode group regardless of a presence of a chronic component. The development of additional such measures would greatly expand the number of episodebased cost measures available to the Academy's diverse and specialized members, and allow them to more accurately report under the cost performance category.

Chronic Condition Episode Groups

- **Should we develop a chronic condition episode specific to the management of patients, i.e., a patient condition group to better compare cost to treat like patients?**

The Academy appreciates CMS' acknowledgement of the challenges associated with the construction of episode-based cost measures for chronic conditions. The Academy is concerned about the aggregation of all conditions in the development of episode-based cost measures. It would seem impossible to ensure proper attribution of cost to individual clinicians with aggregated condition cost measures. The Academy believes physicians should only be scored for the care they are directly responsible for. Additionally, the Academy cautions CMS against the aggregation of conditions that are not directly related. By aggregating unrelated conditions, CMS risks ensuring the proper attribution and scoring of clinicians cost. Instead, CMS should pilot how cost attribution for existing individual measures works before increasing the aggregation of conditions.

Cost Measure Development

- **We comment on the use of the CMS-HCC Risk Adjustment Model or an alternative for risk adjusting episode groups in the construction of cost measures. In addition, should concurrent or prospective risk adjustment be used, and should a full year of data or more targeted data from before the episode be used to adjust?**

The Academy is supportive of CMS' use of the CMS - HCC Risk Adjustment Model for severity adjusting chronic conditions. While the Academy is supportive of this risk adjustment model, we recommend CMS continue to update risk adjustment methodology based on data gathered and input from clinicians. Given issues with risk adjustment and attribution in legacy reporting programs such as the Value-based Payment Modifier (VM), the Academy recommends CMS pilot alternative risk adjustment methodology. CMS can use piloted data to make necessary modifications to ensure proper risk adjustment. Throughout any pilots or CMS-HCC Risk Adjustment models, it is pivotal that CMS maintain regulatory flexibility for risk adjustment and allow for adjustments in coming years to ensure proper cost attribution.

- **CMS acknowledges that prescription drug costs are a large driver of the cost of medical care for Medicare beneficiaries. What would be the best way to incorporate Part D costs into the episode group development?**

The Academy appreciates CMS' acknowledgment that prescription drug costs are a large driver of the cost of medical care for Medicare beneficiaries. Without the incorporation of Part D costs into episode groups, CMS, patients and clinicians will not have a full understanding of the true costs of care for different episodes. This information could be beneficial in helping drive down

the cost of care without sacrificing quality. The Academy encourages CMS to work to develop methodology to incorporate these costs into episode groups; however, when developing this methodology, we caution CMS to ensure clinicians are not unfairly punished for the cost of prescription drugs within episodes of care. It is incredibly important to ensure drug cost price transparency at the provider level. **CMS will not be successful incorporating Part D prescription drug costs into episode groups unless providers know the cost of drugs.** Prescription drug prices are factors outside of a clinician's control and CMS should not develop policies that may adversely influence patients care by forcing clinicians to choose between a better cost score or decreased quality of care.

Cost Measure Development

- **CMS is especially interested in comments regarding methods to align quality of care with cost measures and welcomes recommendations and suggestions. Considerations for aligning episode groups with quality measurement are described in this document, but are not intended to be an exhaustive list of options. We welcome comment on these methods, as well as any other strategies that could be used to align quality of care considerations with cost measures.**

It is vital for CMS to develop alignment between quality of care and cost measures to ensure patients are protected, ensuring clinicians deliver high value care at the most appropriate cost. As clinicians are scored for cost in future years, CMS must link the quality and cost of care to avoid under and overutilization of services. Protections must be put into place through the incorporation of quality metrics to ensure clinicians do not simply cut the cost of care at the expense of the quality of care a patient receives. CMS should link cost to known standards of care. Disease severity or staging information can be built into the treatment quality measurement to ensure the continued alignment of quality of care. Currently, appropriate use criteria and clinical practice guidelines are tools CMS can use to further align quality of care with cost measures. As the healthcare system continues to move towards outcomes measures with the development of additional and future quality measurement tools, the Academy believes CMS should continue to emphasize the alignment of cost with quality of care.

- ***CMS seeks input on the degree of responsibility of attributed services in episode-based cost measures.***

The Academy supports the concept of proportional shared accountability and believe that more work needs to be done to stratify risk and share accountability across provider, patient, and system groups in episode-based cost measures. As CMS promotes team based care, it is critical for CMS to ensure clinicians are score only on the cost they are directly responsible for. Additionally, the Academy believes patient compliance should be considered as an additional element to consider in developing cost measures, as patient non-compliance to a recommended treatment plan could lead to increased costs and decreased outcomes. CMS should consider the development of positive incentives to encourage patients to follow prescribed treatment plans.

Procedural Episode Groups

- **We solicit comment on the procedural episode groups that accompany this posting, including the service and diagnosis codes used to identify the existence of the procedural episode groups. We also welcome comment on additional procedural episode groups to consider for future development.**

The Academy appreciates the inclusion of two procedural episode groups applicable to Otolaryngologist Head and Neck Surgeons, Laryngectomy and Thyroidectomy Partial or Complete. The Academy believes these are appropriate episode groups for inclusion. As CMS considers expanding procedural episode groups in the future, the Academy reiterates comments that CMS should consider the shift to outpatient care settings. Chronic rhinosinusitis, additional cancer surgeries, cochlear implantation, positional vertigo, glottic insufficiency, and treatment of eustachian tube dysfunction are all procedural episodes linked to the management of a condition and are treated in an outpatient setting. We believe these examples provide the ability to add episodes to ensure the greatest number of clinicians can report

Cost Measure Development

- **Cost measures are being considered for development from episode groups after adding additional context, such as expenditure assignment, attribution, risk adjustment, and consideration of quality. We welcome comment on each of these elements and whether there are additional elements to consider in developing cost measures from episode groups.**

As CMS considers the development of cost measures from episode groups, it is important for CMS to ensure clinicians are only be scored for the care they are directly responsible. Proper attribution for the cost of care will help clinicians buy into cost measurement methodology. It is equally as important to ensure there is sufficient risk adjustment in place to protect clinicians that treat patients with multiple comorbidities compared to those that treat relatively healthy patients. Adverse selection of patients driven by cost considerations would have a detrimental impact on the health of Medicare beneficiaries. Parallel to this, CMS must incorporate safeguards through quality measurement consideration to ensure protections against under or over-utilization of care. CMS also should consider the number of times a procedure is performed annually when converting to an episode group. Many procedures Otolaryngologist Head and Neck Surgeons perform that have high cost have relatively low utilization. Due to this low utilization, it is possible these procedures will never be able to be converted to episode groups. The Academy seeks clarification from CMS on the minimum utilization threshold for conversion to episode groups.

- **The draft list does not currently include specifications for episode sub-groups (a subgroup is intended to achieve greater clinical comparability and is a subdivision of an episode group that further refines the specifications of episode trigger codes and grouping rules to yield more clinically homogenous cohorts of patients with similar expected cost). An example is an episode group for spine surgery with sub-grouping for number of levels and anatomic location. CMS solicits public comment on these draft episode groups and potential subgroups.**

As previously mentioned, due to low utilization, we do not feel we are currently candidates for episode sub-groups now. As CMS considers sub-groups, the Academy cautions CMS to ensure

accurate data is still obtainable with enough cases and patients, coupled with appropriate risk adjustment protections. The Academy also believes the list of clinical subcommittees CMS is currently soliciting volunteers for is appropriate. The Academy is interested in following developments from these subcommittees in the coming months and looks forward to working with CMS in the future on possible sub-groups.

- **CMS wishes to avoid any unintended consequences of using cost measures in MIPS, and seeks comment on issues of concern in this regard, such as taking steps to avoid disadvantaging clinicians who assume the care of complex patients such as by applying episodes for comparison of complex patients (i.e., comparison of like-patients of different clinicians).**

As previously mentioned, CMS must ensure that there are sufficient protections in place to ensure the quality of patient care does not suffer due to under or over-utilization of care. Furthermore, CMS should safeguard cost protections without stifling clinical innovations. CMS should incorporate quality metrics that safeguard levels of patient care to protect from drops in quality in the name of cost savings. Additionally, CMS must develop appropriate risk adjustment mechanisms that protect patients from adverse selection by clinicians trying to maximize their cost and quality scores. CMS must adjust for patients with multiple comorbidities to ensure these patients receive the appropriate care they deserve without decreased reimbursement for the clinician charged with treating them.

COMMENT 26 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Andrés Rodríguez, VP, Clinical Affairs, Infectious Diseases Society of America

Text of Comment:

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to provide comments on the development of Episode Groups for use in cost measurement as required by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. IDSA represents over 10,000 infectious diseases physicians and scientists devoted to patient care, disease prevention, public health, education, and research in the area of infectious diseases. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, HIV/AIDS, serious health care acquired infections, antibiotic resistant bacterial infections, as well as emerging infections such as Middle East Respiratory Syndrome coronavirus (MERS-CoV), Ebola virus disease and Zika virus disease.

IDSA members are committed to improving the quality and safety of patient care in a manner that accurately values the benefits of cognitive care that ID physicians provide to patients with severe infections. Under section 101(f) of MACRA, the Centers for Medicare & Medicaid (CMS) is required to establish episode groups, patient condition codes, and other classification codes that will be used to measure resource use in the Merit-based Incentive Payment System (MIPS) and the Alternative Payment Models (APMs). When CMS is developing episode groups, the agency will “consider the patient’s clinical problems at the time that items and services are furnished during an episode of care, such as the clinical conditions and diagnoses, whether or not

hospitalization occurs, and the principal procedures or services furnished.” IDSA provides the following comments related to the development and implementation of episode groups with the aim of ensuring that these episodes appropriately account for the valuable care provided by infectious disease (ID) physicians.

As CMS has noted with the release of the draft set of episode groups, there are no specifications outlined that could be used for subgroup development; however, it is our understanding that CMS may develop episode subgroups in the future. We note that CMS has stated that it does not want to disadvantage physicians who assume care of complex patients. ID physicians often treat the most complex of patients on a regular basis. The treatment an ID physician provides does not fall into discreet episodes based on organ systems or procedures, or even acute episodes of care as currently defined. An infection can occur within any organ, after any procedure, or during any acute inpatient stay. We believe that ID physicians are unique and therefore will require careful consideration during the creation of episode groups.

Per documents released by CMS, episode groups will be developed from claims data that identifies typical cases for various types of medical conditions. Many episodes of care that involve an inpatient stay may also involve infection that may lead to significant resource use.

This is especially true for infections such as carbapenem-resistant Enterobacteriaceae (CRE), methicillin-resistant Staphylococcus aureus (MRSA) and vancomycin-resistant Enterococci (VRE). IDSA is concerned with the episode group development process that is focused on items and services furnished during an episode of care (those that are easily accounted for by their respective billing or procedure codes), and that may not recognize the provision of more system-based services such as infection prevention and antimicrobial stewardship. It appears that the episode group development process resembles a direct cost-based accounting methodology and does not account for underlying services that would be captured in indirect costs. We raise this point here as we believe it is relevant context as the episode groups are defined and subsequently applied in the cost performance category of MIPS, and potentially adopted for use in alternative payment models (APMs), such as bundled payments. IDSA believes that when CMS is creating episode groups, system-level activities such as infection prevention and antimicrobial stewardship should be considered, given that episodes of care with low total resource use may be due to these underlying activities. The ID physician plays a vital role in leading these programs that contribute to low infection rates within healthcare settings, yet there is no way to appropriately attribute that effort.

As CMS moves forward with the development of the episode groups, IDSA would also like to raise concern about physician attribution within the episodes. We understand that CMS will issue future postings and have additional stakeholder outreach to solicit feedback on attribution as well as other aspects of cost measure development, but the issues we raise may inform how the episodes are defined. Within the inpatient setting, ID physician involvement in the care of patients with severe infections has been well-documented to lead to decreased mortality, reduced length-of-stay, fewer readmissions, and lower costs.¹ ID physicians are called to provide consultations by a patient’s attending physician, but it should be noted that the timing of this consult is out of the control of the ID physician. This is important because, despite evidence which shows that earlier ID consultation leads to improved outcomes, some ID consults are ordered “late”, which may lead in turn to increased resource utilization due to the “rescue care” that ID physicians must then provide. In addition, given the consultative relationship between ID physicians and attending physicians, it is possible that treatment recommendations provided by

the ID physician may not be followed by the attending physician in a timely manner, if those recommendations are followed at all. In these instances, the patient's condition may worsen and the episode may show higher resource utilization relative to the baseline case. These factors are outside the control of the ID physician and can place him/her at a disadvantage when episode attribution occurs, resulting in ID physicians having higher resource utilization cases attributed to them. CMS's work on patient relationship categories and codes is expected to mitigate some concerns about attribution; however this work has yet to be completed.

Finally, risk adjustment that incorporates socio-economic status will be an important component of the resource attribution, as there are patients with social risk factors that could predispose them to high resource utilization for their care. Patients' pre-existing conditions may also lead to poor outcomes, and this is where risk-adjustment could mitigate the attribution of high resource utilization to the ID physician. For instance, an ID physician may provide treatment to a diabetic, alcoholic, injection-drug using patient who presents to the hospital in florid septic shock from staphylococcal endocarditis with septic emboli to brain, epidural abscess, and multiple septic joints. The treatment of this patient would most likely result in high resource utilization, which is out of the control of the ID physician due to the patient's pre-existing conditions.

1 Schmitt et al, *Infectious Diseases Specialty Intervention is Associated with Decreased Mortality and Lower Healthcare Costs*, Clinical Infectious Diseases 2014; 58(1):22-8.

COMMENT 27 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Jacqueline W. Fincher, Chair, Medical Practice and Quality Committee, American College of Physicians

Text of Comment:

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Centers for Medicare and Medicaid Services' (CMS) request for information on Episode-Based Cost Measure Development for the Quality Payment Program (QPP) under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 148,000 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.

Delay in Implementation

The College urges CMS to delay implementation of the episode-based cost measures in the Cost Performance Category until the new system has had sufficient time for development and testing/refinement, followed by extensive education of clinicians on the new system and how it will impact their QPP score. The draft episode groups are still in the development process and are not yet ready for testing. Implementing the episode-based cost measures before they are ready and fully vetted, especially if they are weighted in the composite performance score, may unnecessarily result in a negative impact the performance scores of some clinicians without achieving the intended goal of aligning cost and quality with the clinician providing the

care, and it will cause confusion among clinicians who are just starting the process of learning the new system under QPP. The College also urges CMS to ensure that the implementation of these categories and codes is carried out in a manner that fully considers and minimizes the impact of reporting burden on the participating clinicians and that has appropriate flexibility to allow for learning and improvement in the approach by both the Agency and the clinicians. It is a certainty that the initial implementation of these categories and codes will identify necessary areas of improvement in terms of the category definitions, the methodology by which they are submitted, how they are used to attribute cost and patient outcomes to physicians and other clinicians, and potentially other unintended and unexpected impacts—and it is critical that clinicians not be unfairly penalized as this learning process gets underway.

Given the need for a delay until proper development, testing, refinement, and education on the episode-based cost measures has occurred, ACP reiterates its comment from the MACRA final rule that CMS zero out the cost performance category in the second performance year (2018) and continue to focus on the development and refinement of the new code sets to ensure that when cost is accounted for in the composite performance score, it is done in a more appropriate manner that factors in components such as patient condition and the costs associated with clinicians in the role in which they treat each patient.¹ Recognizing that a new cost measurement system needed to be developed, Congress specifically allowed flexibility in weighting of the cost performance in the first two performance periods of QPP, and CMS must use this flexibility to weight the cost category at zero to allow for further development and testing of the cost measures before they directly impact clinicians' composite performance scores.

Additionally, under Section 1848 of the Social Security Act (42 U.S.C. 1395w-4), subsection (q)(5)(F) as added by the MACRA law gives the Secretary the authority to assign different scoring weights (including a weight of zero) in any year if there are not sufficient measures and activities applicable and available to each type of eligible clinician involved. The College further recommends that CMS consider using this authority to reweight performance categories in the third performance period and subsequent years to reduce the weight of the Cost Performance Category to zero until the pilot referenced below has been conducted; the Agency has had time to review the results and make modifications to the codes and measures; and clinicians have had thorough education on the cost measures, any reporting requirements for new categories and code sets, and the impact these will have on their performance. As recommended in ACP's recent position paper, *Putting Patients First by Reducing Excessive Administrative Tasks in Health Care*,² CMS must also make every attempt to minimize any reporting or administrative burden on clinicians as it develops and implements the new episode-based cost measures. The paper outlines a cohesive framework for analyzing new and existing administrative tasks through several lenses to better understand any given administrative task and the potential impact of the task on practicing clinicians. This framework provides the foundation for a set of detailed policy recommendations aimed at various stakeholders, including regulatory agencies, to reduce excessive administrative tasks and requirements that are deemed unnecessary and burdensome.

Episode Groups Pilot Program

In order to test the system prior to implementation, ACP recommends that CMS conduct a voluntary pilot program on episode-based cost measures once an operational set of episode groups and subgroups is fully ready for testing, no earlier than in 2018, that includes a representative sample of practice types, sites, geographic regions, etc. Clinicians who volunteer to test the episode-based cost measures, which would also incorporate CMS' proposed patient condition groups and patient relationship categories, would receive feedback reports on the cost measures but it would not be counted toward their composite performance score in the Merit-based Incentive Payment System (MIPS). Additionally, clinicians would receive full credit within the Improvement Activities Performance Category for participating in the pilot.

The pilot would provide the opportunity for CMS to collect and review data over the course of a year (or multiple years) to help further answer some of the outstanding questions for how to best develop and implement these episode-based cost measures without inappropriately penalizing physicians. The outstanding questions of particular interest to ACP include approaches to developing single episode groups for chronic conditions; duration of the episode group and potential overlap; and risk-adjustment methodology – our initial thoughts on these concepts are described in greater detail below.

Chronic Condition Episode Groups

The Agency requested comments on the approach of a single episode group for outpatient chronic care with adjustment for comorbidities and demographics of the population served by the clinician. The College would favor this approach. A single episode group for outpatient chronic care could be constructed as a “Chronic Condition Episode Group” for patients with at least two or more chronic conditions as defined by CMS. This would allow for flexibility in treating patients that may have numerous chronic conditions. At one visit, the primary clinician may be attending to three chronic conditions for 80 percent of the time and effort and attending to the other chronic conditions for 20 percent of the time and effort. The next visit may be entirely different. For example, a primary clinician may see a patient on a particular day for diabetes mellitus (DM), congestive heart failure (CHF), chronic kidney disease (CKD), atrial fibrillation (Afib), hypertension (HTN), and hyperlipidemia. The next time the clinician sees that patient, she may see him for DM and CHF, and at yet another visit may address mainly CHF but the patient also has an acute problem of back pain. The single “Chronic Condition Episode Group” for patients with at least two or more chronic conditions would capture all the combinations of chronic conditions seen and treated by the primary clinician. The duration of the episode group could span between three to six months to a full year, whatever is deemed adequate to capture the typical episode of care for patients with two or more chronic diseases.

The second part of the single episode group for outpatient chronic care would be the “adjustment for comorbidities.” International Classification of Diseases (ICD)-10 diagnosis coding could be used to address “comorbidities” that increase severity and complexity of the visit. This approach would require more accurate staging of patients through the course of their disease. Greater granularity and specificity of the ICD-10 diagnosis coding would distinguish the patient with CHF or CKD from among other conditions that are in an advanced stage (and more complicated, costly, and time consuming) from the patient in an early stage. This process would further help

identify the primary clinician's contribution to the patient in a global surgical period who has a medical complication or exacerbation (e.g. pneumonia, CHF, DM out of control, renal failure, etc.) of the primary diagnosis for the visit. Additionally, this process could lead to better aggregation/disaggregation of costs with overlapping episodes. **In order to accurately capture the many chronic conditions a patient may have, ACP recommends CMS ensure that all ICD-10 codes reported on claims forms (up to 12) are recognized.**

The College believes this approach for a single episode group for chronic conditions could prove beneficial to providing flexibility without overly burdening clinicians with additional administrative responsibilities. Moreover, the use of ICD-10 diagnosis coding to provide more granularity and specificity for each chronic condition will align with the proposed use of the CMS-Hierarchical Condition Categories (HCC) risk-adjustment model discussed in greater detail in the next section.

Cost Measure Development – Risk Adjustment and Unintended Consequences of Using Cost Measures in MIPS

When risk adjusting episode groups to construct cost measures the College believes that using an already established risk-adjustment model, such as the CMS-HCC methodology used in the Medicare Advantage (MA) program, is logical and promotes alignment across the different Medicare programs. ACP recommends that the Agency require uniform coding requirements for any HCC risk-adjustment to ensure that HCC Model Categories are consistent across all plans and programs so that the episode of care is clinically homogenous for the entire beneficiary population. Anecdotally, it is believed that different MA plans use varying HCCs based on the benefits the plan provides and their specific beneficiary population. As the health care system evolves to one based on value, this uniformity will help to further align the Medicare programs, promote transparency among health plans, and lessen the administrative burden for participating physicians.

The Agency also requested feedback on whether the risk-adjustment model should be concurrent or prospective and the amount of patient data required for the risk adjustment model. **The College believes that using a prospective risk-adjustment model with a full year of patient data, as done in the MA program, is an appropriate approach in developing cost measures for episode groups.**

To further enhance the CMS-HCC risk adjustment methodology and address some unintended consequences of using cost measures in MIPS, the College recommends that CMS require the patients' socioeconomic status be considered 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. CMS has begun to address this within the MA program risk-adjustment methodology to account for beneficiaries who are eligible for both Medicaid and Medicare, but further incorporation of social determinants of health is necessary. 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 for 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.

1 https://www.acponline.org/acp_policy/letters/avp_comment_letter_to_cms_on_macra_final_rule_2016.pdf
2 <http://annals.org/aim/article/2614079/putting-patients-first-reducing-administrative-tasks-health-care-position-paper>

COMMENT 28 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Christine M. Jackson Sr., Director, Global Health Policy, Reimbursement, and Health Economics, Medtronic

Text of Comment:

Medtronic welcomes the opportunity to respond to the solicitation for comments on the development and implementation of episode groups, which will inform the cost component of the Merit-based Incentive Payment System (MIPS) as required by section 101(f) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA.) We appreciate CMS’s efforts to gather stakeholder input on the development of the episode groups.

While the comment solicitation is specific to the draft episode groups and the “trigger codes” associated with the episode development, we offer several broader comments on the topics of transparency, episode group details, the alignment of cost and quality measurement, and episode group selection. Addressing these areas while the Quality Payment Program (QPP) is still in the early stages of development will allow CMS to gather more substantive comments from stakeholders and further the program. Our comments are as follows:

- **Dedicated Resource Site is Necessary for Stakeholders.** Throughout the development of the episode groups and other aspects of the QPP, CMS has engaged in efforts to gather public input at various intervals. Medtronic appreciates this spirit of transparency and engagement. Nevertheless, the information regarding the QPP has been difficult to navigate from a stakeholder perspective, with information relative to the detailed episode groups, Physician-Focused Payment Model Technical Advisory Committee (PTAC) proposals, and other broad policy proposals of MACRA being housed at multiple websites inside and outside of CMS. Therefore, **Medtronic recommends CMS develop a dedicated site from which stakeholders may access various links related to MACRA, QPP, PTAC, and other resources.**
- **Greater Details on Episode Group Constructs are Critical for Appropriate Stakeholder Input.** As CMS continues to develop the episode groups, greater details surrounding the construct of these groups is necessary for stakeholders to provide substantive comments. Specifically, CMS should provide all trigger codes, procedures codes, and diagnosis codes proposed to be included in each episode group. In addition, alignment of each episode groups with specific quality measures should also be discussed. Without this level of information, it is difficult to assess the potential impacts for physicians and the patients they

serve. Therefore, **CMS should provide greater detail on the episode group construct when soliciting comments from stakeholders.**

- **Cost and Outcome Measurement Should be Aligned.** The purpose of the cost category under MIPS is to inform clinicians on the costs for which they are directly responsible, as well as the total costs of their patients' care. CMS intends for the information on cost to be actionable by clinicians in targeting areas for smarter spending. Medtronic encourages CMS to align measurement of costs with specific patient outcomes. Patient outcomes should be at the center of cost measures. Care improvements cannot be appropriately 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 clinical outcome for the patient or overall value to the healthcare system. Properly aligning quality with cost measurement is a value-based approach to assessing care improvement. Therefore, **CMS should study how to best link cost and outcome measurement to better assess overall value under MIPS.**
- **Episode Group Selection -- CMS Should Focus Episode Groups on High-Volume, High-Cost, Well-Studied Conditions.** When developing the episode groups under MACRA, CMS should target high volume, high cost, well-studied medical conditions and disease states with significant variation in treatment costs and outcomes. By focusing on conditions and patients with high costs and a wide range of variation, episode groups can help identify potential opportunity for meaningful improvements in cost and outcomes. In this interest, Medtronic has identified a few additional conditions with high volume and significant variation for CMS' consideration as episode groups. Specifically, **we recommend developing episode groups for thoracic (lung) procedures (MS-DRGs 163, 164, and 165) and certain Medicare-prevalent obstetrics/gynecology procedures (MS-DRGs 734-735, 736-738, 739-741, and 742-743.)** These conditions have high volume and vary in both cost and quality, making them potential candidates for episode groups.

In the addendum to this letter, we have more specific comments on select episode groups. These comments and recommendations focus on the details surrounding the trigger codes and the specific codes included in certain episode groups.

In addition, given the complexity of the cost component of MIPS, Medtronic recommends that CMS work closely with physician specialty societies to evaluate the number and types of episode groups included for expansion of the cost component for future years, and to assess clinician readiness overall. Given that the cost component will attribute a growing percentage of the overall MIPS score for physicians, input from societies is critical.

ADDENDUM

Specific Comments Regarding Episode Group Construction

Medtronic has reviewed the workbooks relevant to our therapy and device areas. The information below outlines specific comments regarding the construction of individual episode groups. In general, it appears that relatively rare, high-cost services are excluded from the episode groups. Medtronic supports this approach since including rare, high-cost services would skew the results and make determining a reasonable "average" cost difficult.

Episode Group Title: Hernia Repair (Incisional or Ventral)

Under this episode group, there is a key trigger code that should be included under this episode. Specifically, CPT 49653 (Laparoscopy, surgical, repair, ventral, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); incarcerated or strangulated) should be added as a trigger code for this episode group. The absence of this code is likely an oversight given that all other relevant laparoscopic hernia repair codes are included. Therefore, Medtronic recommends CMS include CPT 49653 as a trigger code for the Hernia Repair (Incisional or Ventral) episode group.

All Acute Inpatient Episode Groups with a Procedural Component

Medtronic recommends inclusion of the full list of surgical site infection (SSI) ICD-9-CM diagnosis codes for Potentially Avoidable Conditions (PAC) – Type 1, as defined in Prometheus HC13 ECR. Some of these codes are included in the proposed definition, but the list is not comprehensive. Given the importance of avoiding these complications, capturing the full list is essential, and the Prometheus definitions are widely used in a range of bundled/episode-based payment models. The PAC-Type 1 codes are defined to ensure applicability to physicians, as opposed to the facility.

COMMENT 29 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: William J. Maloney, President, American Association of Orthopaedic Surgeons

Text of Comment:

On behalf of the 18,000 board-certified orthopaedic surgeons who comprise the membership of the American Association of Orthopaedic Surgeons (AAOS), we are pleased to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Request for Comments on the Episode-based Cost Measures for the Quality Payment Program (QPP).

The AAOS thanks CMS, in advance, for its solicitation and consideration of the following comments and concerns. We are generally supportive of CMS' efforts to improve patient care and efficiency through quality measurement and payment evaluation.

Streamline the QPP RFI process

We are appreciative of CMS' efforts to engage the patient and provider communities while developing these important metrics as mandated by the Medicare Access and CHIP Reauthorization Act (MACRA, 2015) and are keen to participate in the process. We also understand that this is an iterative process involving clinicians and various other stakeholders involved in transforming the health care delivery system in this country. However, we note that several requests for information and subsequent iterations of the proposed design elements are difficult to pursue for full-time clinicians heavily engaged in patient care. Hence, we request that the QPP-related RFIs and rules be more streamlined such that all stakeholders can keep track of the multiple requests and also respond to these important queries from CMS.

In the past, CMS has indicated that there will be yearly rulemaking in the QPP program as the implementation is gradually scaled up. We recommend that an annual request for comments such as the annual Medicare Physician Fee Schedule or the Inpatient Prospective Payment System proposals be instituted for MACRA/QPP related rules.

Clarify the Type of Episode Groups and Episode Group Selection

CMS needs to further clarify the criteria used to determine the type of episode groups and subsequently group the episodes. The CMS White Paper explains that the acute inpatient episodes focus on disease exacerbations, injuries or illnesses and are expected to be resolved within the pre-defined episode period. The procedural episodes, on the other hand, are related to medical and surgical procedures. We noted that hip and femur fractures are included under both ‘Acute Inpatient Medical Condition Episode Groups’ as well as under ‘Procedural Episode Group’. Moreover, there was no mention of other inpatient fractures such as, femoral shaft; periprosthetic; tibial plateau, tibial shaft (open or closed fracture); pilon fracture, supracondylar femur fracture, etc. under Acute Episode Inpatient Episode Groups. Thus, CMS needs to clearly define the type of episode group that different kinds of lower extremity fracture treatments will be included in.

There is also a need for greater clarity on how two types of episode groups occurring concurrently be handled. Examples for this could be a syncopal episode (or an acute MI or stroke) resulting in a fall and a major injury (“fracture of hip or pelvis”) or if while driving, a motor vehicle collision and consequent multiple injuries. Another example might be cancer with metastasis to bone requiring treatment (with or without fracture).

Appropriate Episode Trigger

The AAOS disagrees with several of the enlisted episode triggers for orthopaedic procedures. For example, revision hip (listed on one of the hip arthroplasty triggers) and revision knee (listed on several of the total knee triggers) should not be triggers for episode based cost measures. Though it may be reasonable to try to define costs for primary hip and knee arthroplasty if the measures are thoughtfully risk adjusted, we do not think that revision arthroplasty can be neatly placed into an episode for cost measures. These are **highly variable** procedures. The current reimbursement system treats all these procedures uniformly and has resulted in ‘cherry picking’ of patients in some facilities and towards some procedures. Further tying these procedures into cost measures is certain to exacerbate these problems and will negatively impact access to care for high-risk Medicare beneficiaries.

Need for Risk Stratification

While we acknowledge that primary hip and knee arthroplasty are high cost and high volume procedures, it will be difficult to correctly measure resource use in episodes triggered by these procedures. We need to have more reliable and appropriate risk stratification strategies. The consequence of improperly developed cost measures in this arena will be to limit care to perceived higher risk patients in the Medicare program. The AAOS strongly believes that any application of cost measures should not be endorsed until evidence-based risk stratification is available and applied to the measure.

COMMENT 30 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Raymond Russell, President, American Society of Nuclear Cardiology

Text of Comment:

The American Society of Nuclear Cardiology (ASNC) appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services' (CMS) solicitation for comment on Episode-Based Cost Measure Development for the Quality Payment Program. ASNC is pleased to provide comment on the role of episode groups in the Quality Payment Program and hopes to work with CMS to ensure accurate, robust episode groups are implemented.

ASNC is a 4,500 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology and cardiovascular computed tomography, develops standards and guidelines for training and practice, promotes accreditation and certification within the nuclear cardiology field, and advocates for furthering research and excellence in nuclear cardiology and cardiovascular computed tomography.

As CMS continues to develop episode groups we hope that they will continue to consult with all relevant stakeholders. We are pleased to learn that CMS, in collaboration with Acumen, developed an online tool that will enable physicians to provide feedback on specific episodes that are pertinent to their specialty. ASNC hopes to have a number of members provide feedback using the online tool and appreciates the continuing commitment to the importance of incorporating specialty expertise in the episode-based cost measures.

Clinical Committee on the Development of Episode-Based Cost Measures

ASNC is encouraged that CMS is continuing its work with focused clinical committees and technical expert panels to develop episode-based cost measures in the Quality Payment Program. ASNC leaders have taken part in the clinical committees and hope to continue their work as the development of episode-based cost measures moves forward. We look forward to staying engaged on this initiative and are pleased that CMS is developing an extensive network of physicians to construct episode-based cost measures.

Episode Group Priority

The Medicare Access and CHIP Reauthorization Act (MACRA) requires CMS to establish episode groups and patient condition groups to measure cost for inclusion in the Merit-Based Incentive Payment System (MIPS). In particular, the CMS seeks feedback on cost measures based on Episode Groups. CMS describes cost measures as having five essential components: (i) defining an episode group; (ii) assigning costs to the episode group (iii) attributing the episode group, in whole or in part, to the responsible clinician(s); (iv) risk adjusting episode group costs, and (5) aligning episode group costs with quality. ***We strongly encourage CMS to prioritize procedural or acute episode groups in the initial phase of the program leaving the more***

complex chronic care episodes to be implemented when difficulties with risk adjustment and attribution can be better understood.

For example, developing procedural episodes for cardiac conditions such as Coronary Artery Bypass Graft (CABG) and Percutaneous Coronary Intervention (PCI) are less challenging given that they allow for more straightforward attribution methodologies. Quality metrics and methodologies are well established and there is existing procedural data which should provide more confidence in accounting for patient level demographics in the episode and subsequently choosing the appropriate methodology for risk adjustment. Moreover, chronic cardiovascular conditions or those that are heavily symptom-driven, including chest pain, arrhythmia, and syncope, are more complicated given the complexity associated with properly accounting for medical co-morbidities and demographics that contribute to the costs of an episode. Symptom-driven episodes also tend to have a vast array of resource inputs depending on the severity of the patients' co-morbidities. Accuracy in calculating benchmarks for these episodes is a complex task and should be implemented when clinicians have more experience with episode groups generally rather than at the initial stage. ***ASNC urges CMS to begin cost measures based on episode groups using procedural or acute episodes rather than chronic or symptom-driven episodes.***

Attribution

ASNC supports the use of expert clinical committees to address many of the challenges presented by proper attribution. ASNC looks forward to examining the list of patient relationship categories and codes in April 2017 that will contribute to how CMS plans to develop methodologies to handle attribution. As nuclear cardiologists we have particular concerns regarding how a patient who receives an item or service only as ordered by another physician will have patients attributed. It is essential that the clinical judgment of physicians is paramount in deciding what modality is needed in a particular patient and that the modality with the lowest cost does not become the default diagnostic test.

Another challenge of particular concern is accounting for an item or service when episodes run concurrently. For example, a patient who receives a coronary artery bypass graft (CABG) might subsequently experience post-operative acute atrial fibrillation. It is important to be sure that the Single-Photon Emission Tomography (SPECT) scan that patient receives is only included in one of the two concurrently running episodes of care.

Risk Adjustment

Proper risk adjustment is essential to include in cardiac care episodes given that cardiovascular comorbidities such as age, diabetes, chronic kidney disease, hypertension, hyperlipidemia, etc., can have a significant effect on costs. If episode groups do not properly account for comorbidities and other patient characteristics, physicians will have a disincentive to care for the sickest patients, as they will become *de facto* insurers of the risk of complications in complex patients. ASNC is pleased to see that CMS recognizes that Hierarchical Condition Categories (HCCs) might be more appropriate for adjusting total expenditures for care for a population but not appropriate for more specific condition based episode groups.

In the event that CMS moves forward with episode groups for chronic conditions the risk adjustment for those episodes will be particularly important given that the cost of providing care for a chronic condition in a given period may vary widely from patient to patient.

COMMENT 31 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Josanne K. Pagel, President and Chair of the Board, American Academy of Physician Assistants

Text of Comment:

The American Academy of PAs (AAPA), on behalf of the more than 115,000 PAs (physician assistants) throughout the United States, appreciates the opportunity to provide comments on the Episode-Based Cost Measure Development for the Quality Payment Program (QPP) report. AAPA welcomes CMS' efforts to seek meaningful input from the health professional community and other interested stakeholders into the development of cost measures as part of QPP. AAPA has participated in recent CMS listening sessions on this issue, and we value the CMS outreach to health professionals, including PAs, regarding potential participation on clinical subcommittees that will assist in determining some of the technical details of episode groups, trigger codes, and other aspects of cost measure development. We believe that regular opportunities for the public and health policy stakeholders to provide comments encourages an ongoing discussion that allows new and significant policies, like those being implemented under the QPP, to adapt and improve. AAPA encourages CMS to continue to find additional opportunities for stakeholder engagement as the QPP is evaluated and refined.

AAPA understands CMS' goal to identify accurate metrics of a health professional's resource use so that those metrics can be paired with quality measures, and assessments of value of care can be made. However, we caution that the actual development and implementation of such measures is extremely complex and, if not done properly, can lead to inaccurate data collection and erroneous conclusions. AAPA is particularly concerned about the effects of current policies on CMS' gathering of cost data, as well as a continued lack of clarity surrounding the mechanics and use of the resource cost information.

Existing Policy Unfavorable to Cost Data Collection Efforts

Billing Mechanisms

In the report titled, "Episode-Based Cost Measure Development for the Quality Payment Program," CMS assigns five essential components to the building of cost measures:

1. Defining an episode group
2. Assigning costs to the episode group
3. Attributing the episode group to one or more responsible clinicians
4. Risk adjusting episode group resources or defining episodes to compare like beneficiaries

5. To the extent possible, aligning episode groups with indicators of quality

Many of these essential components were developed or affirmed out of previous stakeholder comments received from CMS on the issue. For example, CMS' stakeholder input cited in the report indicated that "Attribution of episode groups to clinicians should be clear and credible," and "The information provided by cost measures should be actionable and timely," which can directly be seen to have influenced component three (attributing the episode group to one or more responsible clinicians). CMS further expounds, "The cost category of MIPS provides an opportunity for informing clinicians on the costs for which they are directly responsible, as well as the total costs of their patients' care," and, "We intend for the information on cost to be actionable by clinicians in targeting areas for improving the delivery of high-value care and resulting in smarter spending and improved patient outcomes and experience."

AAPA concurs with CMS' numerous affirmations of component three, and believes accurate attribution of services to the appropriate health professionals is in the interest of transparency, accountability, and the potential to drive beneficial change in the system, as well as to reward those who are delivering high quality, cost-effective care. However, we find the existence of "incident to" billing within Medicare threatens the stated objective of this component. Billing mechanisms such as "incident to" force health professionals who are considered Eligible Clinicians (ECs), specifically PAs and nurse practitioners (NPs), to be "hidden providers," with all or some of their personally provided services billed to and attributed to another health professional who may not have been involved in a particular patient care encounter. When health professionals are "hidden providers" the data collected is not accurate and the feedback reports may not go to the health professional who personally delivered the care.

If a health professional's services are hidden under another professional's name and National Provider Identification (NPI) number, accurate depictions of quality of care or resource utilization for both health professionals will be imprecise. With improper attribution, collected data will be incorrect and determinations of resource use will necessarily be flawed. In 2014, Medicare's Provider Utilization and Payment Data public use file, or the so-called "Medicare data dump," provided a concrete example of the detrimental effects of billing mechanisms such as "incident to" on data collection activities. Public review of the information elicited shock at the revenue of some physicians, provoking some to question how this was possible. The answer in many cases was that some services provided by other health professionals, such as PAs, were being captured under the physician's name and NPI number, biasing the data and effective comparisons, while also obscuring some or all of the work done by PAs and NPs. CMS should make every effort to prevent this same spurious data collection problem from impacting data gathered as part of the QPP.

Concerns regarding "incident to" billing extend beyond a potential biasing of cost data to other aspects of the QPP as well. Other examples include whether a health professional, such as a PA, reporting individually, will be deemed as a QPP low-volume threshold professional and what information will appear on the health professional's Physician Compare profile. In addition, improper data obscuring a health professional's true output can affect not only their MIPS score, but also influence future employment pursuits if a potential employer chooses to evaluate and factor in MIPS scores in their hiring decisions.

As part of determining cost allocation, CMS will have to decide how resource cost responsibility will be divided among different health professionals who treat a patient during the same episode of care. Currently, CMS has suggested the concept of identifying health professionals as the “direct” vs. “indirect” provider of care, depending on the type and level of care delivered. We are interested in seeing additional clarity regarding how that distinction is made. The conceptual framework for “direct” and “indirect” providers may offer some insight in addressing the problem of “hidden providers.”

Restrictions on Range of Treatments

An essential function of the anticipated cost measures is to allow comparability of resource use between health professionals for similar patients and clinical scenarios. However, any comparison between physicians and PAs or NPs from a resource utilization (and outcome) perspective may well be flawed. Currently, CMS restricts PAs and NPs from ordering diabetic shoes, medical nutrition therapy, and home health and hospice services, despite the fact that PAs and NPs are qualified by education and training to order and/or perform these same services. Health professionals who are restrained by CMS regulations in the care they can provide will be compared to physicians who are able to deliver a more comprehensive set of services to similar patients.

For example, take a situation in which a PA is treating a diabetic patient in a clinic that is located in an underserved community, physically remote from the PA’s collaborating physician. The patient suffers from diabetes mellitus, has diabetic neuropathic foot ulceration and needs diabetic shoes to prevent the formation of additional ulcers. Since current Medicare coverage policy does not authorize PAs (or NPs) to order diabetic shoes, that patient will have to find a physician (who has never treated the patient and is not familiar with that patient’s medical history), travel to the physician’s office (which may be a logistical challenge) in order to have a physician order diabetic shoes. The longer a patient waits for diabetic shoes the greater the risk of the formation of additional calluses, foot ulcers, and even the potential of toe or foot amputation. This is clearly detrimental to the interests of the patient, and will certainly drive up the total cost of care for no logical reason except for outdated and irrational coverage policies that limit the provision of medically necessary care. CMS should eliminate such barriers to care, giving patients timely access to needed services which produce the highest quality outcomes, while also ensuring that comparisons between health professionals are accurate and fair based on their ability to provide the full range of necessary care to patients.

Conclusion: Needed Clarifications

AAPA is concerned that a lack of clarity from CMS regarding certain policy specifics of the forthcoming cost measures may lead to confusion detrimental to health professionals and the healthcare market at large. AAPA requests further public clarification from CMS regarding the specifics of how its cost measures will be both developed and used in the assessment of health professionals and their cost-category score. AAPA requests greater transparency surrounding the expected role of patient-relationship codes (themselves still requiring greater refinement and clarity), the role of episode groups, how the various components fit together, which types of actions by health professionals will affect a practitioner’s score, and what type of information will appear in feedback reports.

While CMS has slowly revealed more about the various components that will make up the MIPS cost measures, a clear depiction of the complete product remains shrouded. AAPA recommends further elucidation and greater clarity regarding the “big picture” be provided before CMS’ first anticipated feedback report.

AAPA is also concerned there may be continued confusion among health professionals surrounding the issue of comparability of health professionals based on patients, episodes and risk adjustment. We perceive that there exists a persistent interpretation that someone who provides services that incur more costs (e.g., referrals to specialists or imaging services) will be disproportionately penalized due to the increased cost of patient care. Consequently, AAPA requests that CMS clarify the important point that there is nothing inherently wrong with ordering additional services if that’s what is required in the specific context of doing what is best for the patient. Rather, it is the comparative assessment, that is, how a health professional’s ordering, referring and treatment costs compare to those of other health professionals with similar patients and clinical scenarios that matters.

COMMENT 32 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Michael X. Repka, Medical Director for Government Affairs, American Academy of Ophthalmology

Text of Comment:

The American Academy of Ophthalmology (the Academy) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Request for Information (RFI) on Episode-Based Cost Measure Development, Episode Groups. We offer our input on this RFI and we appreciate the detail that has been provided on the groups that CMS has developed for the new Quality Payment Program (QPP).

The American Academy of Ophthalmology is the largest association of eye physicians and surgeons in the United States representing 93 percent of all ophthalmologists nationwide. A community of nearly 20,000 medical doctors, we protect sight and empower lives by setting the standards for ophthalmic education and advocating for our patients and the public. We innovate to advance our profession and to ensure the delivery of the highest-quality eye care. For more information, visit www.aao.org.

The Academy encourages continued review by CMS/CMMI of the use of episode groups. Using such a tool to assess cost is an improvement over using such methods to determine payments overall. We appreciate the great difficulty in measuring cost and in developing methods to appropriately assign attribution and undertake risk adjustment. The Academy has not seen any risk adjustment or attribution methods from CMS or private payers that adequately account for the high level of health disparities and minority populations that impact the most chronic eye diseases such as glaucoma and diabetic retinopathy. Attribution methods such as who submits claims for the majority of a patient’s office visits are arbitrary and have no relevance to actual patient care.

We would like to emphasize that the episode groupings will be difficult to successfully

implement. Even with the limited number of patient relationships now envisioned, it will take a year or more of carefully coordinated efforts by CMS in conjunction with the specialty societies to educate physicians and their staff on how to use these codes correctly.

Additionally, the use of such codes on claims will be difficult for claims processing. We believe there is a better way to do this that would simplify and streamline cost measurement and carefully align such efforts with quality improvement, a key goal CMS has emphasized (see section VI.).

In light of the problems seen with the Value Based Modifier (VBM), CMS has acknowledged the need to rework cost measurements and has helped by assigning the Cost category zero weight under the first year of MIPS. These episode groups are not only new, but are also still under development. This report refers to “the future development of episode groups to be considered as building blocks in developing the cost measures for potential future use in the QPP.” We believe this underscores the need for CMS to provide more time to transition while the Cost category is under development. This time is provided under statute as the Secretary can assign the Cost category weight for both 2017 and 2018. We urge CMS to consider the implications of inaccurately classifying clinicians as high-cost providers based on flawed or untested measures.

While we applaud the continuing efforts of CMS and its contractors toward developing a more reliable set of cost metrics through collaboration, we were concerned at the notion presented in this RFI that 80% of healthcare costs are under physician control. Studies published in peer-reviewed publications (JAMA, NEJM), articles in the Economist, and several books, have shown that this is not the case. While the physician may recommend the tests, procedures, consultations and hospitalizations, they do not control the actual cost or charge for those services. As the most regulated industry in America (per the Economist), physician practices already operate on small margins due to the cost of compliance and other administrative burdens. This is further compounded by the time required to achieve compliance (2/3 of physician time is spent on paperwork/computer work)¹. We are concerned that the misconstrued notion that the onus for healthcare cost increases is on physicians will focus further healthcare regulation on providers, taking more time away from care and treatment of patients.

Questions:

I. Episode Group Selection

1. In selecting the episode groups to be considered for development, CMS used criteria including an episode’s share of Medicare expenditures, clinician coverage, and the opportunity for improvement in acute, chronic, and procedural care settings. We welcome comment on these episode groups and potential additional episode groups that should be considered for development.

The Academy appreciates the additional clarification of the categories seen in this RFI, however, we remain concerned about clarity of episode groups when cases are not clearly acute vs chronic. For instance, it will be complicated to categorize episodes that are acute conditions complicating a chronic disease process or exacerbations. How will CMS ensure that the costs for care of an exacerbation is compared with other exacerbations, rather than with the cost of the chronic care

problem?

II. Episode Group Definition

1. *The episode groups that accompany this posting are defined by the listed trigger events and codes (CPT/HCPCS for procedural episode triggers, evaluation & management codes combined with ICD-10 diagnostic information for chronic episode triggers, etc.). CMS solicits comment on the inclusion or exclusion of specific service codes used to identify each episode group.* The agency must keep foremost in its deliberations regarding surgical care that it not create incentives for physicians and payers to take shortcuts that would jeopardize high quality eye surgery. There are several modifiers currently utilized in conjunction with surgical procedures that signify needed but unplanned services that may be related or unrelated to the surgery being performed. The same would be true for unrelated evaluation and management services. While the patient condition and relationship codes seek to help with risk adjustment and attribution, it is important that the use of such modifiers are tracked and excluded from the surgical episode. Ophthalmologists must not be punished because of the complications and complex issues that arise because of the disease process especially advanced or complex diseases. Accountability for costs and quality that are within the physician's control is an important and achievable goal, but it cannot come at the expense of providing necessary, emergent or a different line of treatment when other options are failing. **To this end, all complications that are excluded from quality reporting measures should also be excluded from episode group cost measurement, especially since CMS has not demonstrated a reliable means for risk adjustment of any episode group.** Not doing so will create an incentive for physicians to refer more complex/sicker patients out of their practice. A list of those exclusions is included at Appendix A of these comments.

Cataract Group The Academy applauds the removal of problematic trigger codes from the cataract group based on what we read in the latest report. Significant strides have been made toward transparency with the TEPs and the new Episode-Based Cost Measures Clinical Subcommittees, we would like to encourage further efforts toward transparency and collaboration throughout the cost measurement development process. Cataract surgery is one of the most common surgical procedures covered by Medicare. The care and costs associated with the surgery, while appearing relatively easy for CMS to identify, may be complicated by several issues. These components include preoperative testing (medical and surgical), IOL power determination and purchase, physician charges (surgeon and anesthesia), facility charges and drug charges.

During the episode time period, costs for other ophthalmic procedures and treatments are likely to be wrongfully attributed to the original cataract surgery. Most patients require bilateral cataract surgery but, for safety reasons, they are typically done at least two weeks apart. This is well within the first episode period and would be wrongfully attributed to the original procedure. It is, thus, necessary to identify laterality for surgery, either by using CPT modifiers or collecting ICD-10 laterality data. To date, CMS has not utilized such data.

Finally, based on data from IRIS, our clinical data registry, the Academy has found that 35 percent of ophthalmic patients have 3-5 ophthalmic conditions that require treatment, and others may develop acute conditions such as pink eye. This is important to note because CMS currently

is unable to measure the modifiers that denote a visit as unrelated to a procedure (-24, -25). Such procedural code modifiers must be taken into account to avoid penalizing physicians caring for sicker patients.

Diabetic Episode Groups with Ophthalmic Complications The Academy seeks further clarification on the intended application of these episode groups. Although the diabetes episodes were not considered to be ophthalmic measures in the clinical subcommittee call for nominations, diabetes with various ophthalmic complications are included as part of the chronic condition category list of episodes included in this RFI. We are concerned that our clinicians will trigger an episode or be attributed a patient that is seen for another reason, but carries a diagnosis code for diabetes in their medical record. Or, even more troubling, be attributed the cost of all of the patient's diabetes care for appropriate office based monitoring of conditions like diabetic retinopathy. This is especially true given that Medicare Advantage plans are constantly pushing providers to be sure that they report diabetes diagnosis codes for each ophthalmic service a patient with diabetes has, regardless of whether or not the patient is being seen on that day for diabetes.

III. Acute Inpatient Medical Condition Episode Groups

1. *The acute inpatient medical condition episode groups that accompany this posting include only inpatient events. CMS seeks comment on outpatient events that could be considered candidates for development as acute condition episode groups, which could include chronic condition exacerbations that require acute care but not inpatient hospitalization. We do not believe that episode groups for more complex chronic ophthalmic conditions should be developed until CMS has demonstrated success in reliably measuring costs in straightforward procedure groups, such as cataract.*

2. *Acute episodes of care might occur on either an inpatient or outpatient basis and may or may not include surgery. CMS is considering a single Acute Episode Group type that does not distinguish the place of service or the performance of a procedure and welcomes comment on this approach. The number of procedures done on an inpatient basis in ophthalmology is very low, However, those that are done on an inpatient basis are most likely provided in that setting because of the severity of comorbid conditions such as ocular trauma or other non-ophthalmic systemic diseases. In such cases, the patient usually has other injuries and medical needs that require hospitalization. The Academy strongly believes that this would be inappropriate. Site of service has a significant impact on the cost of care that is outside of physician control. Likewise, procedures done in an ASC versus a hospital outpatient department are not under the control of the physician in many cases. There are areas around the country that have strict Certificate of Need (CON) requirements which limit the availability of ASCs and force surgeons to operate in the hospital outpatient department as opposed to an ASC. Even in areas without this requirement, it is important to remember that ophthalmic patients are visually impaired and have difficulty with transportation to ASCs that are 20+ miles away, forcing physicians and practices in such areas to perform procedures at nearby HOPD in order to provide adequate patient care. CMS*

should consider separate cost episode groups for HOPD and ASC cataract surgery.

IV. Chronic Condition Episode Groups

1. *CMS is aware of many challenges in constructing episode groups for chronic conditions. These include coding habits that may obscure some chronic conditions and over-emphasize others. In addition, it may be difficult to assign a given treatment to a single condition for patients with multiple comorbidities. For example, are the resources for treatment to reduce cholesterol for a patient with diabetes, hypertension, and coronary artery disease to be assigned to only one of those diagnoses, to all of them in proportion, or should we develop a chronic condition episode specific to the management of patients with diabetes, hypertension and coronary artery disease, i.e., a patient condition group to better compare cost to treat like patients? An extension of this approach might be a single episode group for outpatient chronic care with adjustment for comorbidities and demographics of the population served by the clinician. We welcome comment on these and any other options for constructing episode groups for chronic conditions. **We share the concern that the difficulty in analyzing the costs of treatment when multiple conditions are treated within the episode time frame may lead to care fragmentation and inappropriate cost attribution.** It may be difficult to create enough patient condition groups to address this concern, so we suggest including comorbidities in risk stratification or simply eliminating patients with specific comorbid conditions from the cost analysis.*

2. *Certain specific conditions, such as cancer, present other challenges. The costs of caring for patients at different stages of disease are likely to vary. For instance, a single episode for a type of cancer is likely to differ in a predictable manner depending on the stage of the cancer. Information on disease staging is not easily or predictably available from claims. CMS welcomes comment on methods to incorporate disease severity or staging information to improve meaningful comparison of cost and quality of care furnished to patients, both generally and for specific clinical conditions. For example, how could a disease staging code be reported on claims to facilitate comparison of episodes for patients at like stages of cancer?*

The Academy has taken the effort to allow clinicians to stage two chronic eye conditions, glaucoma and diabetic retinopathy, and created corresponding ICD-10 codes. This will allow far more precise estimates of expected costs for patients with these conditions. CMS should encourage and work with other societies to do the same thing. It requires significant collaboration and consensus but we have shown it is possible. Until such efforts are undertaken, it will be extremely difficult to incorporate staging into the episode group process.

V. Procedural Episode Groups

1. *We solicit comment on the procedural episode groups that accompany this posting, including the service and diagnosis codes used to identify the existence of the procedural episode groups. We also welcome comment on additional procedural episode groups to consider for future development. Please see cataract episode comments above.*

VI. Cost Measure Development

1. *Cost measures are being considered for development from episode groups after adding*

additional context, such as expenditure assignment, attribution, risk adjustment, and consideration of quality. We welcome comment on each of these elements and whether there are additional elements to consider in developing cost measures from episode groups. The Academy applauds the effort to include crucial context in the development of these cost measures prior to their implementation. Further context must include the patient's clinical history at the time of the visit. The clinical picture can include the stage or severity of illness, the rate of progression, current or recent exacerbations, and comorbidities, recent hospitalizations and/or surgeries. Through the Academy's IRIS Registry, we are already beginning to get a better picture of the numbers and types of eye conditions faced by ophthalmology patients. Thirty-five percent of nearly 7 million patients whose data was reported in 2013 through 2014 had three to five eye conditions, and twelve percent had six or more such conditions. Additionally, of those reporting through IRIS Registry, 16.5 percent of their patients 65-74 years of age also had been diagnosed with diabetes. At a minimum patient condition codes must be able to accurately depict patients that face multiple conditions both systemic and of a specific nature for the physician providing the patient care. **We are also skeptical that patient relationship and condition codes will be able to account for the impact that socioeconomic status and health literacy have on compliance and other patient actions that impact their healthcare.** Cataract surgery is a prime example. There are important patient compliance issues with the medications used at the end of surgery. The antibiotic and anti-inflammatory drops required that prevent infection and promote healing have seen, like many other drugs, dramatic price increases. Many patients are faced with significant out of pocket expenses that they may not be able to afford. And other elderly patients may have difficulty instilling their medications properly. All of these can contribute to problems in post-operative care and higher cost, and there is not information provided on how patient condition codes can capture such impacts.

CMS must determine how these and other factors should be accounted for in risk adjustment and then be certain a mechanism is available to capture such information. How is race determined for patients of mixed race/ethnicity? These questions must be looked at very carefully, and how they are used as a factor in physician payment must be studied more thoroughly. Furthermore, many patients do not want to or decline to share socioeconomic data, and if that is the case, they must not be included for accountability or attribution purposes.

2. As described above, the degree of responsibility of attributed services might be considered separately. Those services furnished by the attributed clinician for the clinical purpose of the episode group might be differentiated from the services provided by others for the same clinical purpose. The services furnished by the attributed clinician might be considered directly attributable services. These could be correlated with the services delivered by others for the same clinical purpose, which might be considered indirectly attributed services. The consideration of both directly and indirectly attributed services might be weighed in reporting both the provision and the coordination of care within the episode group relative to each clinician contributing to the care. An alternative approach would be to obtain recommendations from multi-specialty panels about percentages of the resources for an episode that could be attributed to physicians serving in different roles. We welcome comment on these concepts of differential attribution or alternative methods to align attribution with the clinical activities of

clinicians.

Co-management is a practice seen frequently in the medical field, including in Ophthalmology. The attribution of post-op or post-procedural co-management costs to the surgeon has confounded cost measurement under VBM. The outdated percentages currently in use by CMS for physician payment purposes do not accurately reflect the actual share of the costs of the episode among co-managing providers. The Academy encourages CMS and Acumen to take steps to correctly measure and attribute co-management costs billed with the appropriate modifiers.

*3. The Medicare Advantage program uses the CMS-HCC Risk Adjustment Model to determine rates. We seek comment on the use of this model or an alternative for risk adjusting episode groups in the construction of cost measures. In addition, should concurrent or prospective risk adjustment be used, and should a full year of data or more targeted data from before the episode be used to adjust? **We do not believe that the HCC model, which was developed for the Medicare Advantage program, adequately accounts for risk when analyzing physician cost.*** The HCC was designed to risk adjust large patient populations for insurance rate determination and was never designed for group or individual eligible clinician evaluation. For example, the HCC considers patient factors such as age, gender, prior year diagnoses, and Medicaid dual-eligible status. We do not believe that Medicaid dual-eligible status alone adequately captures differences in patient risk due to socioeconomic factors. Risk adjustment should be based on targeted data from before the episode to determine the patient's true clinical and social picture at the time of presentation. As described above, the clinical picture should include the stage or severity of illness, the rate of progression, current or recent exacerbations, and comorbidities, recent hospitalizations and/or surgeries; all of which can be collected in the Academy's IRIS Registry. But medical conditions, treatments, and procedures do not fully depict a patient's risk status. Two leading indicators of a patient's ability to adhere to treatment and avoid complications are the patient's socioeconomic status and health literacy. Even with Medicare coverage, many patients cannot afford their medications, even those of lower cost, allowing conditions to progress and complications to arise. This is one of several factors that arise from lower socioeconomic status that is outside of physician control.

4. The draft list does not currently include specifications for episode sub-groups (a sub-group is intended to achieve greater clinical comparability and is a subdivision of an episode group that further refines the specifications of episode trigger codes and grouping rules to yield more clinically homogenous cohorts of patients with similar expected cost). An example is an episode group for spine surgery with sub-grouping for number of levels and anatomic location. CMS solicits public comment on these draft episode groups and potential sub-groups. The Academy believes that the use of sub-groups could assist in more accurate cost comparisons and strongly encourages collaboration and transparency during the development of any sub-groups to ensure viability. For ophthalmology, the following sub-groups may be useful: bilateral vs unilateral procedures, hospital outpatient department vs ambulatory surgical center site of service, procedures that are performed in tandem, and severity of illness and other risk factors.

5. CMS is especially interested in comments regarding methods to align quality of care with cost measures and welcomes recommendations and suggestions. Considerations for aligning episode

groups with quality measurement are described in this document, but are not intended to be an exhaustive list of options. We welcome comment on these methods, as well as any other strategies that could be used to align quality of care considerations with cost measures.

Cost Aligned with Quality is Possible

The initial vision of AQA, SQA and NQF was to tie resource use to specific quality measures. Resource and quality must be linked in order to achieve value by improving health, increasing quality and lowering costs. For groups, there should be quality measures and process measures to ensure the ability to improve and quantify quality improvement within a group.

Clinical data registries hold great potential to improve the accuracy of cost data. There are numerous specialty society clinical data registries including more than a dozen of the major specialties that share a common vendor, FIGMD. This new breed of registry is EHR agnostic and uses a systems integrator to pull outcomes and measure performances from the electronic record. The Academy’s registry, IRIS (Intelligent Research In Sight), is based on such an infrastructure and also has access to the practice's administrative database. We do believe common ophthalmological diseases and conditions could be appropriately measured for cost within registry reported data.

Through the IRIS Registry, many practice expenses, visits, procedures, testing pre-operative evaluations, lab results, and returns to the operating room are captured. For resources accrued outside the registry and/or office administrative data base, there are facility costs that can be normalized to regional costs. All registries have the ability to calculate cost specific to an episode group. CMS must acknowledge the utility and use of this manner of cost measurement so that specialties can begin the process of analyzing the data and working with CMS to determine appropriate cost.

Appendix A

Significant ocular conditions that should be excluded from any cost measures and calculations. Significant Ocular Condition	Corresponding ICD-9-CM Codes
Acute and Subacute Iridocyclitis	364.00, 364.01, 364.02, 364.03, 364.04, 364.05
Amblyopia	368.01, 368.02, 368.03
Burn Confined to Eye and Adnexa	9340.0, 940.1, 940.2, 940.3, 940.4, 940.5, 940.9
Cataract Secondary to Ocular Disorders, Central Corneal Ulcer	366.32 366.33 370.03
Certain Types of Iridocyclitis	364.21, 364.22, 364.23, 364.24, 364.3
Choroidal Degenerations	363.43

Significant ocular conditions that should be excluded from any cost measures and calculations. Significant Ocular Condition	Corresponding ICD-9-CM Codes
Choroidal Detachment	363.72
Choroidal Hemorrhage and Rupture	363.61, 363.62, 363.63
Chorioretinal Scars	363.30, 363.31, 363.32, 363.33, 363.35
Chronic Iridocyclitis	364.10, 364.11
Cloudy Cornea	371.01, 371.02, 371.03, 371.04
Corneal Opacity and Other Disorders of Cornea	371.00, 371.03, 371.04
Corneal Edema	371.20, 371.21, 371.22, 371.23, 371.43, 371.44
Degeneration of Macula and Posterior Pole	362.50, 362.51, 362.52, 362.53, 362.54, 362.55, 362.56, 362.57
Degenerative Disorders of Globe	360.20, 360.21, 360.23, 360.24, 360.29
Diabetic Macular Edema	362.07
Diabetic Retinopathy	362.01, 362.02, 362.03, 362.04, 362.05, 362.06
Disorders of Optic Chiasm	377.51, 377.52, 377.53, 377.54

I Sinsky C, Colligan L, Li L, Prgomet M, Reynolds S, Goeders L, et al. Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties. *Ann Intern Med.* 2016;165:753-760. doi: 10.7326/M16-0961

COMMENT 33 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Annie Purcell, Chair, Reimbursement and Policy Review Committee, American Academy of Physical Medicine and Rehabilitation

Text of Comment:

The American Academy of Physical Medicine and Rehabilitation (AAMP&R), a membership organization representing more than 10,000 physiatrists, appreciates the opportunity to submit comments on Episode-Based Cost Measure Development. Physical medicine and rehabilitation (PM&R) physicians, also known as physiatrists, treat a wide variety of medical conditions affecting the brain, spinal cord, nerves, bones, joints, ligaments, muscles, and tendons. PM&R physicians evaluate and treat injuries, illnesses, and disability, and are experts in designing

comprehensive, patient-centered treatment plans. Psychiatrists utilize cutting-edge as well as time-tested treatments to maximize function and quality of life.

AAPM&R appreciates that the Centers for Medicare & Medicaid Services, Acumen, and RTI are continuing to engage stakeholders in the process of developing episode-based cost measures. This letter contains our comments on both the draft list of MACRA episode groups and trigger codes as well as the document titled Episode-Based Cost Measure Development for the Quality Payment Program.

I. General Comments Regarding Cost Measurement

The Academy continues to assert that the use of untested episode measures is premature and must be delayed. Though CMS has previously implemented aspects of cost measurement in its Value Based Modifier program, the concepts for cost measurement outlined in the Quality Payment Program (QPP) are new and require testing prior to widespread implementation. Furthermore, the episode-based measures currently under review will still be in the early stages of development in mid-2017. AAPM&R contends that such measures would be inappropriate for use in the 2018 cost category of the QPP. *We recommend a pilot program in which the cost score would be calculated only for physicians who volunteered to test new measures that are based on episodes of care, adjust costs to reflect patient condition, and use patient relationship categories to attribute costs within the episodes.* A pilot program could potentially be initiated for certain episode groups in 2018 and others in subsequent years depending on the work of the Episode-Based Cost Measure Subcommittees.

The Academy encourages CMS to continue to be transparent as episode groups are developed in the coming months. However, we are concerned that the timeline for finalizing episode groups for implementation in 2018 is too tight to allow for thoughtful clinician and specialty commentary. Although trigger codes and proposed principles have been released, to achieve true transparency and facilitate insightful input, additional information must be made available. Rather than a generic discussion of the risk adjustment methodology, for example, *CMS must release the variables, coefficients, and equations used for the risk adjustment process, as well as the predictive accuracy of the methodology, especially when HCCs are utilized in post-acute care settings.* We recognize that this information is likely not yet available; however, it is challenging to provide thoughtful commentary on the trigger codes in the absence of additional information regarding the context of the episode and the methodological adjustments that will be applied. This further highlights the need for more time prior to implementation.

In the final MACRA rule, CMS set the cost category weight at zero in year one and 10 percent in year two. *We recommend that CMS weight the cost category of QPP at zero for the 2018 reporting year.*

AAPM&R is aware that the American Medical Association has submitted comments about the QPP including cost measurement. We echo those comments and urge CMS to take the time it is allowed under the statute to effectively implement the cost category of QPP.

II. Specific Comments Regarding Episode Groups and Trigger Codes

The Academy submitted names of several members to serve on the Episode-Based Cost Measure Subcommittees. We look forward to participating in this process to select episode groups for implementation and further expand upon the episode definitions.

AAPM&R encourages CMS to continue to adhere to a transparent process when defining episode groups. Additionally, while we recognize that episode grouping and attribution methodologies can be complex, we encourage CMS to consider making this information as simple as possible so that clinicians can understand at the time of service whether an episode's costs and outcomes will be attributed to them.

A. Acute Inpatient Episode Groups

Upon review of the acute inpatient medical condition episode groups, AAPM&R has concern that "chest pain," as an example, may be too broad for a single episode. It would be incredibly difficult to risk adjust for a category such as chest pain in which there is such a range of possible care plans for the range of patients presenting with that problem. If chest pain is to be included, an episode for back pain might arguably be appropriate as well. However, we would suggest that, like chest pain, back pain would be too difficult for risk adjustment and should therefore be broken down into more appropriate episodes. ***Therefore, AAPM&R recommends episodes that are more specific and therefore more homogenous, thereby more accurately portraying costs.***

B. Procedural Episode Groups

Upon review of the list of procedural episode groups, ***AAPM&R recommends the addition of an episode for carpal tunnel release.***

III. Specific Comments Regarding Episode-Based Cost Measure Development for the Quality Payment Program Document

AAPM&R appreciates and acknowledges that Acumen has specifically highlighted the role of the physiatrist in its proposal. In the discussion of attribution, it is noted that post-acute care is often managed by a physiatrist. We appreciate that the complexity of including post-acute care in episode based cost measurement is noted.

A. Episode Group Definition

In the Episode-Based Cost Measure Development document, it is suggested that episodes may need to be separated into subgroups. ***AAPM&R agrees that many of the proposed episodes would have a substantial range of appropriate cost due to the differences in patient needs. One suggestion regarding subgrouping for surgical services would be to sub-group based on complexity of the surgery.*** For example, within a group for hip arthroplasty, procedures may be more complex in instances in which the patient has more potential complications, requires more time to complete the procedure, and may ultimately require more intensive services in the postoperative period.

B. Cost Measure Development

Successful implementation of episode-based cost measures requires decisions on several important aspects including but not limited to: which services are included in the episode; how patients are attributed to clinicians; how risk adjustment is calculated and for what; and how cost measurement is tied to quality performance. Below are our comments on these issues.

i. Services Included in Each Episode: Because of the variability among patients, there is a wide range of possible services that could be included in each episode group. On pages 7 and 8 of the document, a procedural episode that is surgical in nature is described. In this description, the document suggests that treatment related to hypertension would be excluded as it is an "unrelated

condition or event that is not clinically relevant to the procedural episode group.” This is a perfect example of the nuances of correctly attributing services to an episode. Hypertension can be exacerbated due to surgery, anesthesia and/or post-operative pain management. It is not easy to tease out whether treatment for hypertension would appropriately be included in an episode. Such an example raises concerns about how episodes will be defined. ***AAPM&R recommends that CMS solicit feedback from a range of clinicians in determining the services that will be included in each episode.***

Furthermore, we would like to highlight that the physician does not always control the procedures provided to patients. Patients can elect to receive care which is counter to the recommendation and expertise of the clinician. In such a case, the clinician may be penalized for decisions out of their control. If possible, ***AAPM&R recommends accounting for this type of outlier associated with beneficiary preference or noncompliance.***

ii. Attribution: ***AAPM&R recommends that CMS take a more incremental approach to attribution, allowing for feedback and time to analyze success and accuracy.*** For example, CMS could start by assigning attribution only for procedures and services for which costs are directly attributable to a “lead” physician, rather than trying to assign varying levels of accountability at this early stage. We recognize that CMS is planning to implement patient relationship modifiers, which may potentially make attribution easier. However, the patient relationship modifiers have not yet been implemented, so it is difficult to know whether clinicians will use them properly and whether they will be an accurate mechanism for determining attribution when multiple providers care for the patient throughout the episode.

Furthermore, we note that the methodology for attribution of advanced imaging as well as drugs will be critical to the accuracy of episodes. Particularly in the post-acute stage, imaging and drugs, especially those without a generic version, are significant drivers of cost. ***AAPM&R urges CMS to consider attribution of advanced imaging and drugs with caution to avoid unforeseen complications such as reduced access to services.***

AAPM&R discourages CMS from attributing episodes to clinicians based on the amount of time they are responsible for managing a patient. Following this method of attribution would inappropriately attribute episodes to clinicians in the post-acute setting, where hospital stays are far longer than the acute inpatient setting. For example, an episode for hernia repair might include a lengthy post-acute hospital stay. If cost is assigned based on the length of time an individual clinician manages the patient, the entire episode might be assigned to the clinician responsible for post-acute care. AAPM&R disagrees with this methodology.

iii. Risk Adjustment: ***AAPM&R encourages CMS to account for comorbidities such as cognitive and psychological impairment as well as social determinants of health in calculation of risk adjustment of all episodes.*** We would also note that it is difficult to comment on risk adjustment given the limited discussion of the intended methodology in the document. Without more information about what is planned, it is a challenge to submit meaningful feedback.

iv. Quality Performance: ***AAPM&R encourages CMS to be closely attentive to the linking of quality measure performance to cost measurement.*** Without accurately monitoring quality performance, the cost measurement component of QPP appears to be solely driving down cost with no concern for its impact on patient care. In the proposed document, this linking of cost measurement to the quality of care assessment is described in general terms. The Academy recommends transparency about the specifics of how these aspects of the QPP are implemented.

Specifically, CMS should allow clinicians and specialties to comment on proposed pairings of episode group costs with quality measures.

AAPM&R encourages CMS to consider how quality will be attributed to clinicians. Specifically, if multiple clinicians are involved in an episode, it must be determined how the quality of care will be attributed. Currently, clinicians are embracing team-based care more and more; in such an environment, the concept of attributing quality to a single clinician is problematic.

COMMENT 34 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: James Gardner, Medical Science Officer, Vice President Reimbursement, Cook Medical

Text of Comment:

Cook Medical (Cook) appreciates the opportunity to comment on the Episode-Based Cost Measure Development for the Quality Payment Program Report, 12-23-2016 posted on the Centers for Medicare and Medicaid Services' (CMS) MACRA feedback page.

The report outlines some specific questions on which input is requested. Cook comments relate specifically to the questions regarding Procedural Episode Groups and the development of cost measures for those groups.

- We understand the general reasoning for Episode Groups but would appreciate a further explanation on why and how the Episode Groups specifically posted in this document were identified and selected. We think this would be helpful for all stakeholders in the future work further defining these groups.
- We recognize that some of the suggested Episode Groups are broad in scope while others are not. Some of the proposed groups seem very broad in scope, thinking about the complexity of the patient episodes in those groups both when it comes to the condition of the patients, the difference in procedures being performed and associated costs. We appreciate the continued effort by the clinical committee enabling a meaningful comparison within the Episode Groups potentially by developing sub-groups, by risk adjustments or redefine the scope of the groups. • We believe that the determination of the episode window, or length of the episode, will be crucial in order to avoid unintended consequences using cost measures. Again we would like to stress the importance of clinical input so treatments that provide the best long term outcome both clinically and economically will not be disadvantaged by treatments that are less expensive initially but in the long run are more expensive and have worse clinical outcomes.

In addition to our overarching comments above, we would like to draw attention to two specific Episode Groups under consideration which reflect our concerns noted above: (1) Abdominal Aortic Aneurysm (AAA) Repair; and (2) Lower Extremity Peripheral Artery Disease (PAD) Treatment. Abdominal Aortic Aneurysm repair has evolved considerably over the last two decades. Historically, open surgical repair had been the gold standard for treating these patients. However, over the last 15 or so years, with the advent of endovascular stent grafts, the standard of care has changed significantly, with minimally invasive stent-grafting procedures now being

used in approximately 80% of AAA repairs in the U.S. However, what may not be well-recognized at the moment and within the analysis of Episode Groups to-date is that the endovascular stent-grafting options for treating AAA are also evolving significantly with the development of "fenestrated" or "branched" stent grafts to treat more complicated aortic aneurysms. These types of procedures, currently described by "trigger codes" 34841-34848 (Note: 0078T-008T are no longer active CPT codes), involve a group of patients with distinctly different anatomies than those able to be treated with "standard" endovascular stent-grafts, which may very well result in additional imaging, secondary interventions, etc. which could alter their cost structure compared to more standard AAA repairs. As such, we would suggest further consideration should be given as to whether these particular procedures should be included within this Episode Group.

Consideration of Lower Extremity PAD Treatments as an Episode Group may very well offer some unintended consequences which should be closely considered. PAD patients, by their nature, are quite heterogeneous as can be the approaches to treatment of this disease. Like AAA repair treatment, the treatment of lower extremity PAD has evolved significantly over that last two decades. Open surgical bypass had been the traditional gold standard, but is being steadily replaced by minimally invasive treatments. However, the minimally invasive options themselves are very heterogeneous with physicians able to treat these patients with angioplasty, atherectomy, stenting, or some combination of the three. The treatment option chosen for any given patient will be based on a number of factors, including that patients overall health status, the character of the lesion(s) being treated (location, length, degree of narrowing, degree of calcification, etc.), and whether or not this is an initial intervention or a reintervention of some sort. Balloon angioplasty is the simplest and least expensive (when looking at episodic costs) of the treatment options, and it may very well be successful in opening up a lesion at the initial treatment. However, it is well-recognized that angioplasty's long-term success is sub-optimal for many lesions in the lower extremity. Short, discrete lesions may be well-treated with angioplasty, but longer lesions are likely to re-narrow ("restenose") with many patients requiring a reintervention within 12 months. On the other hand, initial treatment of these lower extremity lesions with a stent, for example, will result in a more expensive initial procedure, but with a significantly lower likelihood of patients required re-intervention in the future. We feel it is important to draw attention to this issue, since establishing an Episode Group in this way for Lower Extremity Treatment would encourage physicians to: (a) provide a less expensive initial treatment (angioplasty) for patients, that would ultimately result in higher overall spending for CMS since a significant portion of these patients would require reintervention in the future, outside of the Episode Group "window"; and (b) result in a lower quality of care for patients, since with angioplasty they're more likely to have a recurrence of their symptoms (claudication, rest pain, etc.) and to have to undergo additional procedures.

COMMENT 35 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Kenneth C. Anderson, President, American Society of Hematology

Text of Comment:

I am writing on behalf of the American Society of Hematology (ASH) regarding the request for comments on the document entitled, Episode-Based Cost Measure Development for the Quality Payment Program (QPP). As we work with our members to prepare to participate in the new QPP, we appreciate the opportunity to work with the Centers for Medicare and Medicaid Services (CMS) to ensure that the cost measures, episode groups, and associated episode triggers apply to the work performed by our members; and most importantly, accurately reflect the challenges of treating patients, many of whom have complex hematologic disorders.

ASH represents over 16,000 clinicians and scientists worldwide, who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists were pioneers in demonstrating the potential of treating various hematologic diseases; and we continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians who are providing care to patients in diverse settings including teaching and community hospitals, as well as private practices.

ASH greatly appreciated CMS' decision not to include the cost component in the scoring for the Merit-Based Incentive Payment System (MIPS) for 2017. We believe it is critical that the required risk adjustment, attribution methodologies, and episode measures should be finalized, and that the public should have an opportunity to comment on cost components, prior to their being used to calculate a physician's MIPS score. While we appreciate the work being done to address these issues, we remain concerned that these methodologies and measures will not be ready for 2018, specifically as they apply to the complex and rare hematological conditions that we treat. For our patients, addressing the cost of care requires having a complete understanding of the patient incorporating clinical risk data, which are not currently captured in routine billing coded data. Importantly, measures should normalize guideline adherence and meaningful outcomes to ensure that the patient is protected.

All physicians, regardless of specialty, must be meaningfully measured under the cost component, and physicians should have adequate time to understand how these tools work in practice, before such time as they impact physician reimbursement. ASH continues to urge CMS to provide physicians with an opportunity to review their cost scores based on at least one full year of performance using the new measures, before they impact a provider's MIPS composite score.

After reviewing the draft list of care episodes and episode groups, ASH believes that our members will be at an unfair disadvantage in 2018, based upon the progress to date to develop episode care and patient condition groups and codes. Our members treat patients with conditions such as acute leukemia, chronic lymphocytic leukemia, and myeloma, which cannot be adequately captured and measured by the list of episodes and groups currently available. We appreciate that hematologic disorders are a topic for a future clinical subcommittee. Until this group is formed and their work is completed, our members will be at a distinct disadvantage

when being assessed on the 10 existing cost measures and additional measures under development.

Patients with malignant and non-malignant blood disorders represent diverse patient populations, whose cost of care assessment requires a carefully-nuanced analysis that extends far beyond what is feasible with coded billing data. For patients with acute leukemia, the cost per patient may vary by *orders of magnitude* based upon disease status (therapy-responsive vs. refractory to standard treatment modalities), genetic/molecular/genomic risk assessments, age, performance status, and the intent of treatment (curative vs. palliative). For patients with adverse-risk genetic and genomic features (such as the presence of duplications of the *FLT3* gene), blood/bone marrow stem cell transplant represents best practice. Those undergoing transplant represent a very high-cost population of patients, whose high-cost care results in better survival outcomes and represents high-value care. Unfortunately, the clinical risk data used in this clinical assessment cannot be gathered through CMS' standard data abstraction methods. This deficiency creates a paradox, since those institutions that offer the best therapeutic approach to this patient population are likely to be unfairly penalized when compared to other institutions which fail to follow best practice.

Similarly, patients with chronic lymphocytic leukemia with unmutated heavy chain genes or with deletions of chromosome 17 have much worse survival outcomes and higher care costs than those chronic lymphocytic leukemia patients without these abnormalities. These high risk patients may benefit from hematopoietic cell transplantation, which therefore represents best practice and incurs greater care costs. CMS's current data abstraction and cost assessment methods again fail to capture this level of differentiation.

As specialists in internal medicine, hematologists may see a patient once in order to diagnose and recommend treatment, may take over care for long period of time in the event of a newly diagnosed disease such as leukemia, or may serve as a long-term primary care physician for patients with a lifelong blood disease such as sickle cell disease. Their level of influence on a given patient may differ substantially on the basis of that role, and this must be reflected accurately in episode groups, and ultimately in cost measures. Moreover, measuring the work of hematologists differs substantially from physicians whose work is procedure-based and easily broken into defined episodes. The type of cognitive work that is required by hematologists in making complex diagnoses or in serving as a primary physician for the patient for either the short or long term of their illness requires a more nuanced accounting of physician role and responsibility. CMS must take steps to ensure that they recognize these roles of caregivers for hematologic disorders when comparing cost of care.

The above described considerations are particularly critical for the cancer patients treated by our members. We appreciate that CMS recognizes that this patient population poses unique challenges to assess cost and resource use, particularly as it relates to cancer staging. Cancer and other complex hematological diseases will require CMS to carefully weigh the role of costs and risk stratification as these episode groups are developed. In an abstract presented at the 2016 ASH meeting, the impact of clinical risk upon cost of care was described for patients undergoing allogeneic transplant for acute leukemia. In this analysis, the patients' care costs rose based upon their age, disease status, performance status, intensity of transplant therapy, and the choice of

transplant donor. These are data that are not routinely reflected in billing data, but reflect the complex decisions necessary to ensure that patients achieve the best survival outcomes. Without rigorous risk/cost adjustments, we risk incentivizing the under-treatment or suboptimal treatment of patients with advanced blood cancers.

While the agency requested comments on the best way to incorporate Part D drug costs into the episode groups, ASH is particularly concerned about how Part B drug costs will be incorporated. Our members rely on Part B drugs to treat patients, including those with cancer. There are a limited number of opportunities to substitute similarly effective, lower cost, alternative drugs for these patients without adverse health effects. The MIPS cost measures must be developed and implemented in a manner such that physicians are not penalized for prescribing higher-cost drugs which have lower toxicity and incremental benefit. Furthermore, a treatment regimen cannot be judged on the Part B drug cost alone, as many cancer patients require supportive care medications that may fall outside of Part B. ASH discourages CMS from constructing measures, episode groups, and triggers that would drive decisions about care based upon any data other than the best available medical evidence. We encourage you to consider this concern, as you are finalizing a risk adjustment methodology.

COMMENT 36 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Anders Gilberg, Senior Vice President, Government Affairs, Medical Group Management Association

Text of Comment:

The Medical Group Management Association (MGMA) is pleased to submit the following comments in response to the Centers for Medicare & Medicaid Services' (CMS') draft framework for development of episode-based cost measures for the Quality Payment Program, released Dec. 23, 2016. In addition to upholding the highest standards of valid measure development through a transparent and stakeholder-inclusive process, CMS should pilot test new episode-based cost measures through a voluntary program to demonstrate their intended effect and mitigate unintended consequences. To facilitate a voluntary pilot program, MGMA urges CMS to continue to zero out the cost component of MIPS.

MGMA and its 50 state affiliates comprise more than 33,000 administrators and executives in 18,000 healthcare organizations in which 385,000 physicians practice. MGMA represents physician groups of all sizes, types, structures and specialties, and has members in every major healthcare system in the nation. As the leading association for practice administrators and executives for nearly 90 years, MGMA produces the most credible medical practice economic data in the industry and provides the education, advocacy, data and resources that healthcare organizations need to deliver the highest-quality patient care.

Utilize a transparent methodology and integrate provider feedback

MGMA recognizes the draft development process includes multiple levels of clinician feedback and stakeholder engagement, and we strongly urge CMS to fully incorporate the recommendations and concerns that result from the stakeholder engagement process. In addition, MGMA offers the following principles to guide the agency as it develops cost measures:

- Measure specifications should be fully transparent and available for public review.
- Measures should be evidence-based, broadly accepted, clinically relevant, actionable, continually updated and developed by practicing physicians.
- Measures must never stifle or restrain clinical innovation.
- Emphasis should be placed on statistically significant cases to minimize the margin of error. Insufficient sample size should be clearly noted in an unbiased manner.
- Data should be risk-adjusted to consider variables that affect health outcomes, including patient demographics, severity of illness and comorbidities.

Promote consistency across MIPS and APMs

We urge CMS to harmonize its construction methodologies for episode groups, where appropriate, across the Merit-Based Incentive Payment System (MIPS) and alternative payment models (APMs). Several specialties have developed or are 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.

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 therefore would not 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 services provided in an APM and 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.

Support the group practice team-based model of care

MGMA urges CMS to ensure the episode-based cost measures reflect the group practice model of care where multiple practitioners utilize a team-based approach to treating patients. In fact, the fundamental advantage the group practice model offers is the coordination of a wide range of physician and related ancillary services in a manner that is seamless to patients. Physician practices have a goal of collectively improving care through coordination, efficient use of resources, investment in effective health information technology and employment of practice improvement initiatives. This holds true whether the group is single- or multi-specialty, physician-owned or non-profit practice, or part of an integrated health system. By establishing a group practice reporting and assessment option in MIPS, the agency recognized the value of analyzing quality and cost under the umbrella of a group practice and should do so going forward in developing the episode-based cost measures.

Further, as physician practices transform in preparation for APMs and increased financial accountability, these organizations are adopting physician-led multidisciplinary teams that focus on coordination across the care continuum to guide patients through an acute episode of care or to provide care to patients with ongoing, complex care needs. For example, CMS' new Comprehensive Primary Care Plus demonstration requires group practices to "develop a personalized plan of care for high-risk patients and use team-based approaches like the integration of behavioral health services into practices to meet patient needs efficiently." MGMA strongly urges CMS to explore ways to account for a physician-led, multidisciplinary team approach to patient care. CMS should work closely with the developers of care episodes and physician specialty organizations to determine best practices for distributing the costs of care within episodes to ensure accurate attribution.

Weight the cost component of the MIPS score at zero

In the final rule with comment entitled, "Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models," CMS weighted the cost component of MIPS to zero in the 2017 performance period, 10% in the 2018 performance period and 30% in 2019 and beyond. MGMA strongly urges CMS to use the Secretary's authority under section 1848(q)(5)(F) of MACRA to reweight the cost performance category to zero until the agency has extensively tested the new episode-based measures, reformed and fully tested the patient attribution methodology, and implemented key aspects of this category, including risk- and specialty-adjustment recommendations from the congressionally-mandated report by the ASPE.

Further, it is critical that the agency provide timely and clinically-actionable information regarding these measures. On pages 5-6 of this posting, CMS itself states, "[t]he cost category of MIPS provides an opportunity for informing clinicians on the costs for which they are directly responsible, as well as the total costs of their patients' care." However, as currently implemented, physicians and groups will only receive feedback information six months after the conclusion of the performance period, which could be up to 18 months after the point of care. Because of this significant delay in feedback, group practices and physicians do not have an opportunity to adjust their work flows and spending patterns until partway through the following performance period. We urge CMS to consider delaying measurement of clinicians and groups on cost until it is operationally feasible to provide cost and attribution feedback on at least a quarterly basis.

Create a voluntary pilot program to test new episode-based cost measures

To demonstrate benefit in terms of cost-effectiveness, mitigate any unintended consequences of new episode-based cost measures and ensure their alignment with the new patient relationship codes, CMS should create a voluntary pilot program to test these new measures. In the pilot, CMS would provide feedback to physicians and practices who volunteered to test new measures that are based on episodes of care, adjust costs to reflect patient condition and use patient relationship categories to attribute cost within the episode. We do not believe it would be appropriate to score participants' performance on cost measures during the pilot program, as it could deter participation and skew the sample. Optimally, a pilot should include practices of varying sizes, medical specialties and technical capabilities.

A pilot program could provide an analysis of the implementation issues facing providers, including outreach and training, assignment of patient relationship codes, clinical-administrative

system integration and required workflow and process modifications. Most importantly, a pilot could focus on the challenge of assigning costs within a group practice environment where multiple clinicians could be participating in the patient's care delivery.

Provide sufficient opportunity for review and appeal of final cost measures

MGMA urges CMS to establish a robust and efficient review and appeals process that would allow providers and practice administrators to submit clinical or other relevant data to supplement and correct inaccurate data and cost attributions. To facilitate this process, CMS should provide detailed information about each attributed episode of care.

COMMENT 37 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Lisa Miller Jones, Regulation, Policy Manager American, Urological Association

Text of Comment:

The American Urological Association (AUA), representing nearly 15,000 members in the United States, is a leading advocate for the specialty of urology, providing invaluable support to the urologic community as it pursues its mission of fostering the highest standards of urologic care through education, research and the formulation of health policy.

The AUA commends the Centers for Medicare & Medicaid Services (CMS) on its efforts to seek stakeholder input on development of resource use (i.e., cost) measures for implementation in the Merit-Based Incentive Payment System (MIPS) of the Quality Payment Program. We are closely reviewing the proposed criteria for the three general types of episode groups to determine whether the components identified for development of cost measures would accurately distinguish resources used in furnishing specific urological services during an acute, chronic and procedural episode of care. We will provide detailed comments at a later date on attribution, risk adjustment and alignment with quality measures for accurate cost assignment across all three sites of service.

In the interim, we would like to offer general comments on the draft list of episode groups and their corresponding episode trigger codes for potential development of urological cost measures. As a starting point, to ensure the respective items and services for the Procedural Episode Groups are correct, we recommend appropriately cross-walking and matching each code with the descriptors in the Current Procedural Terminology (CPT®) code book, the standard procedure coding system maintained by the American Medical Association.

For example, in the Prostate Cancer Treatment (680) section, CPT code 55866 (Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed) incorrectly shows "endoscope" in the descriptor. This procedure is performed with a laparoscope" as specified in the CPT code book. In addition, HCPCS codes C9739 (Cystourethroscopy, with insertion of transprostatic implants; 1 to 3 implants) and C9740 (Cystourethroscopy, with insertion of transprostatic implants; 4 or more implants) are incorrectly mapped to the section for Prostate Cancer Treatment (681 and 682). HCPCS codes (9739 and

C9740 are for treatment of benign prostatic hyperplasia (BPH) and should be cross-walked to the section for Procedure for Benign Prostatic Hyperplasia (658-668) to ensure accurate ambulatory patient classification (APC) resource use.

As previously mentioned, additional comments will be provided at a later date. Thank you for the opportunity to comment on the development of episode-based cost measures and for the opportunity to participate in future efforts that focus on urologic disease management.

COMMENT 38 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Thomas A. Buchholz, Executive Vice President and Physician-in-Chief, The University of Texas MD Anderson Cancer Center

Text of Comment:⁶

On behalf of The University of Texas MD Anderson Cancer Center (MD Anderson), I am pleased to submit comments in response to the Centers for Medicare & Medicaid Services' (CMS) request for input on the development and refinement of evidence-based cost measures that are part of the Merit-based Incentive Payment System (MIPS) for eligible professionals. Founded in 1941 and located in Houston, Texas, MD Anderson is one of the world's most respected centers devoted exclusively to cancer care, research, education, and prevention. The institution is one of the nation's original three comprehensive cancer centers designated by the National Cancer Act of 1971 and is one of 47 National Cancer Institute-designated comprehensive cancer centers today. Additionally, due to its exclusive focus on cancer care, research, and education, MD Anderson is one of the nation's eleven Medicare Prospective Payment System-Exempt Cancer Hospitals (PCH).

Since 1944, over 1,000,000 patients have turned to MD Anderson for cancer care in the form of targeted therapies, surgery, chemotherapy, radiation and proton therapy, immunotherapy, or combinations of these and other treatments. MD Anderson's mission is to eliminate cancer in Texas, the nation, and the world through exceptional programs that integrate patient care, research, and prevention and through education for undergraduate and graduate students, trainees, professionals, employees, and the public. Underlying MD Anderson's mission is a strong focus on delivering high-quality cancer care, via a workforce of over 1,600 clinicians that have dedicated their careers to the prevention, treatment, and elimination of cancer.

In this letter, we offer specific comments regarding the proposed episode-based cost measures as they relate to cancer. We believe that our comments will provide an important perspective to CMS and will assist the agency in finalizing appropriate cost measures for the MIPS program. We would be happy to provide additional background or input as needed.

Complexities within Cancer Costs

⁶ This commenter has submitted a separate attachment accompanying the comment. (Attachment file name: *38_b Buchholz Thomas MDAndersonCancerCenter.xlsx*)

MD Anderson appreciates CMS' request for public comment on several oncology specific "trigger" procedures in the proposed rule, and how oncology services might affect the inpatient acute and chronic conditions also included in the proposed rule. Analyzing cost for cancer related services is a complex endeavor because tumor-specific *factors-site, histology, stage, and markers-and* patient-level *factors-demographics, comorbidities, psychosocial status, and performance status-influence* resource utilization and, therefore, the costs of cancer care. The term "cancer" itself encompasses multiple diseases, with costs, outcomes, and risk factors varying significantly among patients. High costs of care are common among cancer patients, making oncology a logical target to develop benchmark costs for a variety of treatments. Cost measures adopted for oncology care should account for these dynamics, along with variation associated with receipt of novel cancer therapies, treatment in different care settings, utilization of different evidence-based treatment pathways, and patient preference. As research continues to develop new and better ways to cure cancer, these variations will continue to change and present more complications for CMS as it manages the overall cost of oncology services to the Medicare program.

The complexity of cancer care and its prevalence within the Medicare population necessitate a clinically and statistically valid method of cost measurement, as well as reporting requirements that are standardized, clear, and actionable for clinicians. Within cancer, episode-based cost measures should be developed to span the entire treatment cycle (prevention, intervention, and survivorship), while offering sufficient flexibility to account for variation within and across patient subgroups. Most importantly, these measures should support meaningful cost comparisons across providers.

Complexities with Claims-Based Episode Definition for Cancer Services

"Episodic" Illness Design - MD Anderson notes that CMS has focused the proposed episodes on acute hospitalizations that are short-term and chronic conditions that are long-term. However, cancer is more of an "episodic" illness, which may not last over 12 months like a chronic condition, but are not as short in duration as traditional acute care episodes. Cancer treatment is often characterized by diagnosis, acute treatment, and resolution or the progression to second- and third-line treatments and the potential development of additional cancers. Therefore, MD Anderson suggests that CMS create separate episode-based cost measures to best represent episodic treatments like cancer for comparison with "like" services. Finally, in building these episodic cost measures, MD Anderson suggests CMS review the National Cancer Care Network (NCCN) guidelines and build the episodes to match the manner in which cancer is treated. NCCN guidelines are freely available to the public and document the exact medical methodology for treating a patient. CMS must fully understand these complexities in order to design appropriate episodes for cancer care.

Multiple Procedure Code Services- Many cancer services have multiple CPT codes involved in the same treatment. Therefore, assigning a global oncology event to one code - as CMS has proposed -could generate unreliable comparisons. When a single-code strategy is used, typically this is done by taking the code with the highest RVU and making it the lead. For example, in common oncologic practice, a large percentage of services having oncoplastic reconstruction (*e.g.*, mastectomy with immediate reconstruction) are assigned to the reconstruction because it

has the highest RVU. If a single CPT strategy is used, these cases would be ascribed to plastic surgery (rather than breast cancer surgery), creating erroneous attribution and multiple imbalances. Likewise, when a minor hepatectomy is provided at the same time as a major colon resection, the liver RVU dominates, with costs (and potential complications) of the colectomy ascribed to the liver service. Existing risk models (e.g., Hierarchical Condition Categories, or HCCs) were not designed to account for the complex, multi-team surgeries in oncology. Thus, we recommend that CMS create subgroups for any oncology procedures requiring subsequent reconstruction or multiple surgical teams to support meaningful comparisons.

Term of Global Periods- MD Anderson also has concerns about the global period that will be assigned around the oncologic procedures in the proposed measures, as the specific number of days before and after the procedure that are pulled into the global period are not designated for each procedure. In addition, there are different/clinically valid approaches to providing neoadjuvant services (services provided before a surgical procedure) to cancer patients, making national comparisons across providers complicated. MD Anderson highly recommends that these issues be investigated more thoroughly before any Medicare payments for oncology are tied to these criteria.

Regarding the global period, generally a 30-day pre-operative and 90-day post-operative period is the standard global period; the vast majority of charges within this 120-day window are relatable to surgery and its complications. However, this may be truncated if a subsequent oncologic therapy starts after surgery. For example, it is standard of care for many patients with non-metastatic breast or colon cancer to begin adjuvant chemotherapy within 120 days of diagnosis. Additionally, some providers are using "return to intended oncologic therapy (RIOT)" as a metric for cancer surgery quality. These providers strive to recover the patient as quickly as possible so they can move onto adjuvant systemic therapy, radiation therapy, and/or further surgery. When this occurs, the patient is, by definition, recovered from the index operation and the next modality assumes the cost/outcomes.

Use of Appropriate CPT Codes - MD Anderson's clinical review of the procedural codes in the proposed evidence-based cost measures showed several procedures that are clinically inappropriate as "trigger" events. For example, several "parent" procedures were missing, while other services were included on the proposed list that would only be provided as an add-on service to those "parent" procedures. In Attachment A, we have noted some of these issues for CMS' review.

Attribution

In preparation for the MACRA requirement that new patient relationship categories and codes be reported as of January 1, 2018, MD Anderson reviewed the five proposed categories of relationships issued for public comment in January 2017. Unfortunately, these categories are still vague and do not give clear direction to providers regarding the appropriate provider relationships for complex cancer related services and comorbidities. We understand that a new list of patient relationship categories and codes will be made available by CMS in April 2017, but since the final information has not yet been released, MD Anderson is unable to provide meaningful feedback to CMS on how the codes should best be incorporated into its attribution model. We ask that CMS provide another comment period after it releases the latest patient

relationship codes in order for stakeholders to provide meaningful input on use and attribution of the codes.

In addition, the method for how providers will be assigned to the proposed measures is not clear in the proposed rule. Will all measures be mandatory? MD Anderson recommends that CMS provide a list of many cost-based measures to providers and allow them to select a subset of those measures for their cost score in MIPS. This will avoid risks that inappropriate measures could influence clinical treatment or add unnecessary reporting burden on providers.

Risk-Adjusting Episode Groups

In order to ensure actionable feedback to providers through the MIPS program, MD Anderson agrees that it is vital for CMS to risk adjust for factors that are outside a clinician's direct control but that still have a notable effect on the total cost the Medicare program incurs for that patient. It is critical to ensure that providers are not penalized when they treat particularly complex or unhealthy patients, like cancer patients. CMS's risk adjustment methodology must also account for differences in patient severity of illness, function, age, type and number of comorbidities and/or chronic conditions, etc. MD Anderson urges CMS to ensure that only "like" patients be compared. For example, cancer patients should only be compared to other cancer patients. These comparisons should be made after CMS creates sub-groups or specialty groups to facilitate comparisons within cancer types (e.g., comparing breast cancer patients only to other breast cancer patients). Due to the complexities of the different types of cancer, comparisons across different types of cancers are inappropriate. For instance, comparing lung cancer patients to breast cancer patients would be misleading.

We understand that CMS uses the Hierarchical Condition Categories (HCCs) risk-adjustment methodology to adjust episode-based costs for its Medicare Advantage population, but also believe that CMS should apply a different risk-adjustment methodology to cancer services that is concurrent, rather than retrospective. Risk scores based on retrospective patient information may be of little use in the case where a previously healthy patient is suddenly diagnosed with cancer. Concurrent risk-adjustment methodologies would allow for a true representation of the acuity of such patients and better track the rapid changes that may occur during their treatment. MD Anderson recommends that once Medicare receives a claim including a cancer diagnosis, the risk adjustment methodology should shift to a concurrent risk adjustment.

MD Anderson also recommends that CMS create subgroups for providers reimbursed under a different inpatient payment methodology than traditional Diagnosis Related Group (DRG) classification. While acute care hospitals are paid under Inpatient Prospective Payment System using DRGs specific to the type of service provided to the specific patient, specialty hospitals and critical access hospitals are paid on a per-diem that cannot reliably be compared to DRG reimbursement. For example- as a specialty hospital, MD Anderson is reimbursed on a per-diem representing the "average daily cost of all inpatient oncology services provided" at MD Anderson for a fiscal year. It is not reasonable to compare that per-diem reimbursement to the DRG reimbursement an acute care hospital may have received for a specific service, such as a Colonic Resection. Subgroups based on the inpatient reimbursement methodology of the hospital at which an inpatient service occurred would ensure that all cost comparisons are made with appropriately matching service types.

Alignment of Cost and Quality

We agree with CMS' comments regarding the complexity of aligning episode group costs with quality of care measures. Cost measurement-in the absence of quality measurement provides an incomplete view of resource utilization at best. At worst, it can lead to care rationing and suboptimal care. Care that is truly value-driven and patient-centered prioritizes optimal outcomes and patient experience, along with patient safety, treatment efficacy, timely delivery, and efficient resource use. Measurement of meaningful outcomes and patient experience is needed to contextualize cost comparisons. The known challenges of aligning cost and quality measures are amplified in conditions, such as cancer, that are heterogeneous by nature. Cancer presents as both an acute and chronic condition, with significant variation between patients. Existing cancer quality measures are largely process-focused and are limited to high-prevalence cancers (e.g., breast and colon cancer). These measures often lack the flexibility to account for novel, life-prolonging therapies and less toxic treatment approaches (e.g., treatment on protocol, neoadjuvant treatment, and hypofractionated radiation therapy schemes).

To measure the value of healthcare, cost measures are best viewed within the context of outcomes that are meaningful to patients, caregivers, payers, and providers. However, many cancer outcomes (i.e., disease-free and progression-free survival, cancer recurrence, functional status, and quality of life) are not measurable via claims data. Likewise, many patient risk factors (e.g., psychosocial support, treatment preferences, health literacy, and frailty) and clinical factors (e.g., tumor resectability, treatment intent, and poor response to previous treatment) are not captured within claims. The most meaningful outcomes are often longitudinal in nature-measured in years, rather than weeks or months. The asynchronous relationship between these outcomes and the costs to achieve those outcomes yields misaligned comparisons at specific points in time. Cancer outcomes (and appropriate performance targets) can vary significantly, depending on tumor stage and histology, availability of effective treatments, and patient factors (including age, baseline performance *status*, and treatment preferences). In particular, functional status outcomes differ across cancer sites (for example, sexual and urinary function are appropriate for prostate cancer, whereas cosmetic satisfaction and arm mobility are appropriate for breast cancer). Finally, because oncology care is delivered by treatment teams-and patients frequently move between care settings appropriate attribution for both the outcomes and costs of cancer care is problematic. Thus, significant work is needed to develop and validate attribution models in cancer.

Together, these measurement challenges suggest that multi-stakeholder collaboration (including patient representatives) and a well-defined framework are needed to align and risk-adjust cost and quality measurement within cancer. Such an approach, while time- and resource-intensive, will do much to promote accurate, equitable, and meaningful performance comparisons within the MIPS program.

Collection of Cancer Stage and Patient Complexity Information

CMS requested public comment regarding how cancer staging can be tracked through data available on Medicare claims or other sources. MD Anderson supports this goal and thinks it would be a meaningful way to track the acuity of a specific cancer patient's treatment in relation to the costs of the treatments they actually receive. Clinicians determine cancer staging making a

medical determination based upon a several sources of information, including examination of the patient; pathology and other diagnostic tests; medical and radiation oncology treatments; and definitive surgery. It is possible to report cancer stages on inpatient and outpatient institutional claims, as well as on professional claims, using a variety of methods.

MD Anderson is currently working with the Alliance for Dedicated Cancer Centers (ADCC) to vet some proposed approaches to demonstrating cancer stage through data available on a Medicare claim. We would be very interested in sharing this with CMS at a later date once the methodologies have been more fully investigated.

Implementation Timing

As outlined above, there are many critical details that have not been communicated by CMS about how the proposed evidence-based cost measures will be applied to cancer services. As a result, MD Anderson recommends that CMS remove all cancer-related "trigger" procedures that are shown in the proposed rule and suggests that the cost category not be factored into the final MIPS score until payment year 2022 (performance year 2020) for specialty hospitals for cancer. In the interim, we encourage CMS to weight the cost category at zero percent (0%) of the MIPS final score for cancer related procedures until appropriate data is available to ensure proper comparison of oncology services across providers.

In summary, we appreciate the opportunity to provide input on the proposed evidence-based cost measures and CMS' thoughtful consideration of public comments on the measures proposed for the MIPS program. We believe that our comments offer a useful perspective for CMS regarding the complexities of creating appropriate comparison measures for oncology services and would be glad to discuss them with you directly.

COMMENT 39 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Krishna Komanduri, President, American Society for Blood and Marrow Transplantation

Text of Comment:

The American Society for Blood and Marrow Transplantation (ASBMT) is an international professional membership association of more than 2,200 physicians, scientists and other healthcare professionals promoting blood and marrow transplantation and cellular therapy research, education, scholarly publication and clinical standards. ASBMT is dedicated to improving the application and success of blood and marrow transplantation, which ensuring access to all patients who need hematopoietic cell transplants.

ASBMT appreciates the opportunity to comment on Episode-Based Cost Measure Development as part of the Quality Payment Program. We commend the efforts by CMS to make the methodology of this important new policy transparent to all parties.

ASBMT members have decades of experience in providing intensive, high-resource utilization care to individuals with very high risk hematologic malignancies, as well as understanding the

costs of this care. Blood and marrow transplantation (also known as Hematopoietic Cell Transplant – HCT) is usually paid for within case rates or other payments that shift financial risk to the provider. In November 2016, ASBMT providers were given separate specialty designation by CMS to distinguish our clinicians from hematology and oncology because our practices were very different in resource consumption. This long-term experience in understanding costs of care creates the lens through which we evaluate potential reimbursement models, including CMS proposal on Episode-Based Cost Measures.

Concerns with Episode-Based Cost Measure Methodology

We have three general concerns, as well as several concerns specific to the cost measure categories currently proposed.

1. Episode Groupers: We are concerned where episode groupers are kept broad and are not acuity risk-adjusted. It is rare that one individual provider will see a volume of cases sufficient enough to establish a bell-shaped curve to be used for fair comparisons. Any consumption and outcomes measures should not be used. While it would be ideal that episode groupers also link to outcomes measures, we worry that such linkage for every grouper will promote processes and episode grouper selection that increase risk of being very selective in one's patient population.

Episode triggers, and the appropriate codes to reflect them, will be important. For chronic and acute diseases, the ideal trigger is a clear diagnosis established pathologically or radiologically. For pathological-confirmed diagnoses, the trigger date cannot be the date when pathological samples were obtained but rather must be the date when results are available to confirm the diagnosis, and as such, that clinicians are comfortable engaging in clinical interventions. We also recognize that certain diagnoses are clinical diagnoses; these will be problematic to set up a trigger mechanism and will rely on a relevant clinical note stating sufficient grounds for moving forward with a diagnosis-based treatment plan.

2. Adjustment for Clinical Acuity and Patient Socio-Economic Status: The development and implementation of episode groupers will be important in preventing decreased access to care for those beneficiaries with advanced disease, patients with complex psychosocial situations, and patients with multiple comorbidities, especially those in which treatment for one disease adversely affects outcomes for other diseases.

Providers need to be encouraged to document diagnoses coding in detail, particularly while in the learning phase of a new compensation system. Proper documentation and coding of these details takes time and will likely be without additional compensation. All factors affecting outcomes must be documented both in physician notes and in problem lists that are then translated into claims data. Many things that in the past have not been in progress notes, problem lists and claims data must be recorded for risk adjustment, such as family concerns, lack of transportation and other significant SES indicators. At the recent PTAC meeting, Dr. Gajewski, an ASBMT member physician, noted that for proper acuity adjustment in the COPD alternative payment model, acute exacerbation and chronic disease need to be listed in both the physician notes and the problem list, yet this would not be common physician practice.

Providers often do not document or code noncompliance with therapy or factors leading to noncompliance, like family dynamic problems, marital stress, mental health issues especially

those with personality disorders, cognitive decline, early signs or suggestion of dementia, inability to afford medications, opioid abuse even in those patients with clear sources of pain, and/or inability to get to therapy due to distances or mobility issues. For risk adjustment to be effectively done, these factors need to be coded and be part of the episode risk adjusters, yet they can jeopardize the physician/patient relationship when they appear in the patient's electronic medical record. There may need to be restricted sections of patient chart for providers to document such healthcare problems; if we do not address this, patients with these added afflictions may not find providers willing to care for them and the result will be limited access to care. Providers caring for the sickest most complicated patients are already documenting with the highest level of inpatient and outpatient evaluation and management codes; they need to be compensated for the additional time for doing the additional documentation time for comprehensive coding. There may need to be modification of the prolonged service non-face-to-face CPT codes (99358 and 99359) to accommodate this need.

3. Attribution: Our providers utilize team-based care and a patient may have 2-3 different inpatient attending physicians during his or her month-long transplantation hospital stay. Attributing a clinician for purposes of these efforts will be problematic due to the structures of providing intensive care over a prolonged period of time. This may be easier to deal with for surgical and radiological proceduralists, but for our member physicians, attribution of costs of care will be difficult based. Acuity and resource consumption are determined by where the patient is in the clinical course of disease, so assignment of a provider other than by team is meaningless. MACRA legislation encourages practices to have a team of physicians and advance practice professionals. The advance practice professionals will sometimes see a patient independently, but while seeking advice of a physician and using a split/shared visit. Current databases also do not segregate advanced practice professionals by specialty; those treating complex patients in a team based environment may be severely disadvantaged. Team based reporting measures must be included. The common tax ID may work, but warrants a trial period.

Concerns on Specific Grouper Proposals

None of the diseases identified for the first rounds of measures are the principle focus of ASBMT physicians, but our physicians often provide on-going care for the entire patient for 1 to 2 years post-HCT. Thus, the proposed measures do occur during the times our providers are responsible for care.

Acute Care Episodes:

- **Acute Myocardial Infarction:** The presence or absence of heart failure determines resource consumption and length of stay. The location of myocardial infarction determines both resource consumption and length of stay, with an inferior wall MI requiring less monitoring than an anterior wall MI. Patients on coronary angiography having left main disease or severe triple vessel disease will likely have an emergency CABG surgery.

- **Bronchitis and Asthma:** Patients with CO₂ retention and on chronic steroids will not do as well as others, so there needs to be acuity adjustment. Specialists are likely to see more advanced disease. Pediatric patients with poor home situations are also likely to have more prolonged course.

- **COPD:** Patients with carbon dioxide retention, on chronic steroids, and/or on continuous oxygen will do worse so there needs to be acuity adjustment. Patients with FEV1 less than 1 liter will also do worse than relatively uncomplicated patients. Specialists are likely to see more advanced disease.

- **Diabetes:** This needs to be risk adjusted for patients with Type 1 or Type 2 diabetes, diabetes secondary to steroid usage, and “brittle” diabetics. Patient with diabetic complications like renal disease, vascular disease, neuropathy will do worse. Patients with long term diabetes and cerebral vascular disease will likely have cognitive impairment that will create compliance issues. Patients with a noncompliant with diet will have longer stays.

- **Gastrointestinal Hemorrhage:** Site of gastrointestinal hemorrhage, presence of thrombocytopenia or other coagulopathy will determine outcomes and resource consumption.

- **Renal Failure:** Stage of renal failure, underlying etiology and need for dialysis as well presence of heart failure will drive resource consumption.

Chronic Care Episodes:

- **Asthma/COPD:** These two entities should be separated. Asthma is often a younger population than the COPD population. Asthma is often triggered and exacerbated by environmental allergens. COPD typically occurs in older patients and often secondary to smoking. Older patients with a history of smoking may have ischemic heart disease or vascular disease, both peripheral and cerebral, complicating care. Some of the medications for heart disease, such as beta blockers, will worsen COPD.

- **CAD:** Coronary artery disease has different resource consumption based on severity of disease or vessel involvement, proximal vs. diffuse distal disease, presence of heart failure, and presence of diabetes. The latter patients often do not have chest pain or angina as warning of impending decompensation. CAD must have acuity adjustment

- **Lupus:** Lupus is a clinical diagnosis without a defined pathologic biopsy or radiologic diagnostic criteria. It is very hard to diagnose so identifying the correct way to trigger an episode will be problematic. This disease has heterogeneity of complications and morbidity, with those having CNS lupus or severe joint disease having more resource consumption and often requiring different monoclonal antibody or immune modification therapy.

Procedural Grouper Proposals:

- **Melanoma Destruction/Excision:** Proper therapy of a new melanoma or recurrent melanoma lesion is always excision and never destruction. Destruction would make staging of melanoma and confirmation of total removal impossible. Destruction of melanoma must be taken out of episode grouper definition. Patients presenting with metastatic melanoma have different procedure and resource consumption than those with simple skin lesion.

- **Prostate Cancer Treatment:** There are many patient specific factors governing therapy options for prostate therapy including patient choice and local availability of some therapy. Local disease stage, Gleason score, presence of metastases and comorbidities play a role in determining therapy and treatment. Different providers will advise and complete varying types of therapy,

with urologists performing surgery, radiation oncologists providing radiation therapy and medical oncologists treating mostly metastatic disease.

• **Simple and Modified Radical Mastectomy:** Simple mastectomies are often done for prophylaxis or where there is only Stage 1 disease, whereas modified radical mastectomies are done where local disease is more extensive. Complications and post-operative pain, and corresponding treatment, are different for both procedures.

COMMENT 40 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Ronald Fairman, President, Society for Vascular Surgery

Text of Comment:

The Society for Vascular Surgery (SVS), a professional medical society composed of 5,400 specialty-trained vascular surgeons and other medical professionals who are dedicated to the prevention and cure of vascular disease, is very concerned regarding the initial draft list of episodes and the associated triggers for a patient to be attributed to said episodes and their lack of specificity and clinical homogeneity. Our comments below detail these concerns.

Episode Group Selection

Using percentage of Medicare expenditures as the main episode group selection criteria would appear to over target some medical specialties versus others. SVS would instead urge Acumen, LLC to use a criterion of at least one clinical area by specialty or disease episode being completed and rigorously tested for each physician specialty prior to these episodes being used in the Merit-based Incentive Payment System (MIPS) for the measurement of costs.

Episode Group Definitions and Procedural Episode Groups

The episodes proposed in the draft excel document dated December 23, 2016 are too general and need to be further divided into episodes that have the following type of categories as triggers:

- Single Procedure Code by Method (e.g. open, endovascular, etc.), No Device
- Single Procedure Code, Plus any Add-on Code(s) and No Device
- Single Procedure Code and then a Specific Type of Device (episodes would be type of device used, specific)
- Single Procedure Code Plus an Add-on Code(s) and then a Specific Type of Device (episodes would be type of device used, specific.).

Given that Medicare Part A costs are currently included in the cost measure calculations, although, SVS has disagreed with that premise since the beginning of the Value-based Payment Modifier Program, episodes for the purposes of measuring costs and comparing costs need to be this granular as SVS has proposed.

Using the Abdominal Aortic Aneurysm Repair Episode Groups, the Dialysis Access Episode Groups, and the Lower Extremity Peripheral Vascular Disease Treatment Episode Groups proposed in the December 23, 2016 file as an example, that list only has episodes per the first trigger category that SVS believes is appropriate to compare clinical same patients and their episodes of care. For example, the Abdominal Aortic Aneurysm Repair Episode Group should be sub-divided into open abdominal, endovascular abdominal, and endovascular visceral episode groups. Also, the Peripheral Vascular Disease episodes are not homogeneous in their current form. This is a wide group of disorders that require different diagnostic and treatment processes. The acuity of the condition also significantly affects the resources invested during hospitalization. Dialysis Access Procedure Episode Groups need to first be divided into creation and Maintenance episodes.

Therefore, SVS would propose that Acumen work directly with the SVS to further develop the other three categories of episodes and triggers for these three proposed procedural areas. SVS would be happy to convene an in-person meeting as soon as is convenient where SVS physician leaders could work with Acumen staff, directly, to complete this task and then assign additional, relevant CPT codes to each episode.

Cost Measure Development

Risk/Severity adjustment is essential in cost measure development. SVS would recommend that Acumen, LLC create a specific set of Clinical Subcommittees exclusively for developing the list of conditions and complications that should be taken into consideration in a risk/severity adjustment methodology that would-be episode specific.

Furthermore, Acumen could work to have the available quality measures and the performance on such measures contribute to the risk/severity adjustment methodology. Many quality measures that are considered outcomes-based need to be included in the discussion regarding the lower or elimination of some type of complication or adverse event for the patient. This is the case with the measures developed by the SVS for Abdominal Aortic Aneurysms and the complication of not being discharged alive by day seven.

Rigorous testing and direct medical society involvement in the creation of the cost measures is imperative. Acumen needs to agree to the SVS offer to convene our leaders and work directly with us starting with a multi-day face to face meeting and then continuing with calls and webinars to construct these costs measures and then to test the costs measures and review the testing results. Without specific testing and transparent evaluation of the results, the medical society community will not be accepting of the cost measure results in the MIPS program.

SVS is also nominating several individuals for the Acumen, LLC Clinical Subcommittees for the Cardiovascular Disease Management, and Peripheral Vascular Disease Management separately and we would encourage Acumen to select all the SVS nominees. **And, we would like to stress that the work regarding refining episode triggers from the draft list of episode groups posted by CMS in December 2016 needs to consider the need for these additional episodes and triggers to be developed for Peripheral Vascular Disease by that Clinical Subcommittee.** Only after that has occurred should the Clinical Subcommittee move forward with recommending what services should be included in the episode's costs.

The SVS appreciates the opportunity to provide comments on this December 23, 2016 list of Episodes.

COMMENT 41 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Ellen Flaherty, President, American Geriatrics Society

Text of Comment:

The American Geriatrics Society (“AGS”) greatly appreciates the opportunity to provide feedback to Acumen, LLC on the development of episode-based cost measures for the Quality Payment Program (QPP) as defined by the Medicare Access and CHIP Reauthorization Act (MACRA). The AGS is a not-for profit organization comprised of nearly 6,000 physician and non-physician practitioners (“NPPs”) who are devoted to improving the health, independence, and quality of life of all older adults. The AGS provides leadership to healthcare professionals, policy makers, and the public by implementing and advocating for programs in patient care, research, professional and public education, and public policy.

Our mission is to advance efforts that promote high quality of care, quality improvement, and increased payment accuracy for providers (physicians and other professionals) paid under Medicare.

Most geriatrics clinicians identify themselves as primary care providers. We provide primary care to the sickest and most complex Medicare beneficiaries, a population characterized by the presence of multiple, co-existing chronic conditions and a high prevalence of frailty. Patients with multiple chronic diseases cannot be treated as though these conditions exist independently of one another.

A “whole patient” orientation is a core principle of geriatric primary care, indeed of all primary care. We treat patients, not diseases. It is our job to provide and/or coordinate substantially all the medical care our patients need. We aspire to deliver “person-centered care”¹. By understanding the full picture, patient's values and preferences, we strive to balance the benefit and burden of recommendations across the whole of an older person's well-being. Ultimately this supports patients and their families and caregivers in making informed medical decisions that are consistent with their health and life goals.

The nature of our work corresponds to the “continuous/broad” patient relationship category that CMS has proposed. An approach to evaluating cost performance that looks at the cost of treating patients, rather than diseases, will align better with the mission and goals of geriatric care.

What is the scope of accountability relevant to primary care and how should Medicare determine costs attributable to primary care providers? Payments to primary care providers account for only about 5% of the Medicare dollar, making these payments an unlikely source of significant savings. But primary care providers have an outsize influence on overall costs through the downstream impact of their decisions.

Incentives that promote reduction in payments to primary care would result in less primary care engagement with patients and higher overall costs, and would be inconsistent with the expectations and roles of primary care in health reform. Incentives that reward good stewardship of system resources, efforts to avoid unnecessary high cost and/or low value services, and more effective chronic disease care and management would address the sphere of influence of primary care on cost. Although primary care providers do not “control” downstream costs like hospitalization, imaging, and procedures, there can be no doubt that they exert substantial influence on utilization.

As Upton Sinclair noted: “It is difficult to get a man to understand something when his salary depends on his not understanding it.” Similarly, cost-containment efforts which focus exclusively on reducing costs (i.e., payments) for services furnished directly by a provider are unlikely to generate enthusiasm or engagement. When feasible, episodes should incorporate services influenced by the provider’s decisions and orders for further care. In this way, effective clinical care and prudent stewardship of resources each offer pathways to high performance.

Chronic Care Episode Groups

The diagnosis and procedure-focused model of defining episodes described is relatively well-suited to the procedural and acute medical episode types that have been the focus of the cost measure development work thus far. We believe that extending this concept to chronic disease care will be exceptionally challenging.

As described above, primary care providers play a central role in chronic disease care, and meaningful assessment of their cost performance in that role is important. However, very few chronic episode groups are likely to include a sufficient number of patients of a primary care provider to allow for valid conclusions. With small sample sizes, case-mix differences may make it impossible to obtain valid comparative data on per capita cost. Risk adjustment approaches such as the Hierarchical Condition Category (HCC) system used in Medicare Advantage lose their predictive value when applied to a population defined by diagnosis to measure costs attributable specifically to that diagnosis. Subdividing episode groups (categorical risk adjustment) to reduce variability will produce yet smaller groups that may not provide valid data. Therefore, it may not be possible to define more than a very few episode groups which include primary care providers that are of sufficient size and reasonable homogeneity (or adequately risk-adjusted) to produce valid comparative cost data. Differences in cost attributed to providers based on such episode groups may reflect heterogeneity of small populations rather than differences in appropriate utilization and cost performance.

Furthermore, as a separate matter, due to the prevalence of multiple comorbid conditions, it will be very difficult to define a diagnosis-based episode for patients with chronic diseases. For example, in a patient with diabetes, hypertension, arthritis, and cognitive dysfunction, how would CMS determine which diagnosis-based episode to assign the patient? Or would the patient be assigned to multiple episode groups thereby creating the possibility for double counting cost?

In other words, attribution of costs to a particular disease- or condition-based chronic episode group will be problematic when, like most beneficiaries, the patient has multiple chronic diseases. Geriatrics clinicians usually address multiple diseases and conditions during a single

encounter. Diagnostic tests provide information relevant to multiple conditions in the same patient. Medications are prescribed for more than one condition; e.g., lisinopril may be prescribed for some combination of hypertension, heart failure, renal failure, and/or diabetes. Even in the treatment of an apparently unrelated condition, the care delivered must consider both how that care affects each comorbidity and how the treatments of the comorbidities influence the options available to treat a new condition.

The triggering event in a procedural or acute medical group will function as a kind of risk adjustment, creating a more homogenous sample than will be possible for chronic disease episodes, which lack this stratification mechanism. Patients are given a diagnosis of chronic disease at all stages of disease progression. One patient will have mild Chronic Obstructive Pulmonary Disease (COPD) when an episode is triggered by an ICD-10 code, while another has advanced disease when this event occurs. These patients will have very different clinical trajectories. In the absence of good risk adjustment, this will create opportunities for gaming, by, for example, aggressive diagnosis of patients with mild disease.

The AGS supports the continued development of chronic episode groups as long as they have the proper length, contain large populations of patients, and are properly risk-adjusted. However, we are concerned that these difficulties may limit the applicability of this approach.

Assessing Cost Performance Now

The AGS believes that the measure “Total per capita Medicare Part A and B costs/year,” which CMS has already finalized as a cost measure for the MIPS cost performance category, is the best initial metric for assessing the cost-effectiveness of primary care providers, including their care for patients with multiple chronic diseases. We believe this measure is the most accurate way to fulfill MACRA’s mandate to evaluate a primary care provider’s cost performance. This approach offers multiple advantages:

- It is consistent with the “whole patient” orientation of primary care.
- It is a measure that, if adequately risk-adjusted, reflects the influence of both the provider’s clinical effectiveness and his or her stewardship of taxpayer dollars. It encourages more effective chronic care, care coordination, and prudent use of costly downstream resources.
- It covers virtually the entirety of a provider’s practice and generates the largest available sample size, ameliorating to a degree the small numbers problem.
- It avoids entirely difficult issues of attribution of costs to individual disease-specific episode groups in patients with multiple chronic diseases. It permits the application of the HCC risk adjustment system, which has proven utility in Medicare Advantage and in CMS population based payment environments, and proven capability to provide meaningful risk adjustment.
- Similar measures of primary care cost influence have been used extensively by provider groups participating in Medicare Advantage, and enjoy widespread acceptance by providers as useful measures of performance.

With the advent of patient relationship codes, however, we recommend that the existing two-step attribution process for this measure be replaced. Specifically, a patient and his associated

Part A and Part B costs should be attributed to a provider who attests to having a continuous/broad relationship through claims data. This methodology will more accurately attribute patient costs to the provider— usually a primary care provider—that has a real, ongoing relationship with a patient rather than to the provider that merely has the largest share of allowed charges for primary care services. Primary care providers that have a continuous/broad relationship to their patients are much more likely to be able to influence those patients’ quality of care and the prudent stewardship of associated resources. Therefore, it is both fairer and more effective as a cost-containment approach to attribute a patient’s total Part A and Part B costs to those physicians.

However, in order to obtain comparative data, CMS must assure that providers across all specialties use the patient relationship codes consistently and accurately. If providers do not use these codes consistently and accurately then CMS will not be able to use the data to accurately compare utilization and cost among providers of the same specialty—let alone different specialties.

By itself, the “total per capita costs” measure does not provide actionable information to practitioners. Therefore, it is important to provide clinicians with additional information that can direct attention to areas of potential focus, such as the rate of hospital admissions and re-admission, ER use, per-capita use of imaging and diagnostic modalities, and costs related to particular specialties and services. We hope that episode group analysis will also contribute to a deeper understanding of care patterns and enable improvement in the quality and cost effectiveness of care.

For all of the reasons discussed above, however, we believe that chronic episode-based cost measures defined by disease category will present too many concerns regarding their applicability and possible unintended consequences for AGS to recommend their use as modifiers of physician payment unless and until they are much more thoroughly understood and tested. As Acumen works with CMS to develop chronic episode-based measures, we strongly urge that these measures be reported for multiple years without counting toward the MIPS cost category so that CMS and Acumen can test and adjust the measures as necessary and clinicians can have time to become familiar with them. This is the reasoned and thoughtful approach CMS has taken for the current finalized cost measures for Year 1 of MIPS and we believe it should be the approach taken for new cost measures going forward, especially in the new frontier of chronic episode-based cost measures.

We thank Acumen, LLC for the opportunity to comment and expect to continue our engagement with the technical advisory panels and clinical committees that will assist in this work.

¹ “Person-centered care” means that individuals’ values and preferences are elicited and, once expressed, guide all aspects of their health care, supporting their realistic health and life goals. Person-centered care is achieved through a dynamic relationship among individuals, others who are important to them, and all relevant providers. This collaboration informs decision-making to the extent that the individual desires. The American Geriatrics Society Expert Panel on Person-Centered Care. Person-Centered Care: A Definition and Essential Elements. J Am Geriatr Soc 2016;64:15-18.

COMMENT 42 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Karen Bird,
Executive Director, Alliance of Dedicated Cancer Centers

Text of Comment:

Introduction

The Alliance of Dedicated Cancer Centers (ADCC) appreciates that CMS has engaged the stakeholder community to develop and refine the Merit-based Incentive Payment System (MIPS) cost measures. As acknowledged by CMS in its proposal, stakeholder feedback to date has identified some key areas for continuing focus. We firmly agree that the following principles are critical to developing meaningful measures:

- Patient outcomes should be at the center of cost measures.
- Attribution of episode groups to clinicians should be clear and credible.
- Cost measures should account for patient complexity and the challenge of addressing overlapping conditions, i.e., accurate risk adjustment is necessary.

Effectively addressing these issues is essential to ensuring that the Quality Payment Program is designed to fairly and accurately assess resource use and outcomes, particularly for practitioners that tackle some of the most complex cancer patients in the country. Below, we provide specific feedback on several of the questions posed by CMS in its notice on “Episode-Based Cost Measure Development for the Quality Payment Program.” We hope that our comments will assist the agency as it works through this challenging topic.

Risk-Adjusting Episode Groups

The ADCC agrees that it is critical for CMS to adjust for factors that can influence expenditures but are outside a clinician’s control. For example, patients differ in their severity of illness, functional status, age, type and number of comorbidities and chronic conditions, etc. These patient-level risk factors must be taken into consideration in any risk adjustment methodology that is used. Accounting for patient complexity and health status, including chronic conditions, is necessary to ensure that clinicians who treat particularly complex patients, such as cancer patients, are not penalized.

CMS currently uses the Hierarchical Condition Categories (HCCs) risk adjustment methodology to adjust episode-based costs for its Medicare Advantage population. CMS states on page 12 of its request for comments that *“while HCCs may be appropriate for adjusting total expenditures for care for a population, specific conditions may confer higher or lower risk for certain episode groups.”* CMS then goes on to say that *“an alternative approach to reduce heterogeneity within an episode is to apply the episode to comparison of like patients, for example, diabetics with heart disease, with end stage renal disease, [or] with chronic obstructive pulmonary disorder, rather than to all diabetics.”¹*

We agree with this view and **urge CMS to implement a different risk-adjustment methodology in a way that ensures valid and reliable comparisons between providers based on “like” patients.** This is particularly important in cancer, given CMS’ proposal of a procedure-driven episode model. Several procedures in the proposed list, including colectomy, nephrectomy, cystectomy, mastectomy, and thyroidectomy, can be performed in patients with and without a cancer diagnosis and the costs can vary significantly. This is also true for the list of acute inpatient medical conditions and chronic conditions, which can occur in patients with and without a cancer diagnosis. To address these issues, CMS should apply a specialized risk adjustment methodology to cancer, grouping “like” patients based on procedure and cancer site. The term “cancer” represents multiple diseases, costs, outcomes, and comorbidity risks that inherently vary based on cancer site and type. Thus, we recommend that CMS create sub-groups or specialty groups to facilitate comparisons based on cancer site (e.g., comparing costs of patients with colon cancer as a distinct group). We believe that comparisons between patients with and without a cancer diagnosis as well as comparisons among patients with different cancer diagnoses can lead to erroneous conclusions about resource utilization and costs and are, therefore, inappropriate.

As noted above, to be accurate, CMS’ risk-adjustment methodology should account for factors beyond the clinician’s control, such as comorbidities, chronic conditions, severity of illness, function, and demographic factors, such as gender and age. The ADCC cancer hospitals are currently evaluating risk-adjustment methodologies that are more appropriate than HCCs for analyzing risk, including the 3M Health Information System’s Clinical Risk Groups (CRGs). We have found that CRGs, while imperfect, are a better risk adjustment methodology than HCCs for cancer. Therefore, we encourage the agency to consider utilizing CRGs when establishing a risk adjustment methodology. We continue to seek and refine other methods of accurately accounting for patient characteristics and will share our comments with the agency as our thoughts on this topic evolve.

Importantly, regardless of the risk-adjustment tools utilized (HCCs or CRGs), risk adjustment tools work best when they are applied concurrently. Our analysis has shown that risk scores based on retrospective patient information do not produce meaningful data in cases where previously healthy patients are suddenly diagnosed with cancer. Concurrent risk-adjustment leads to a significantly more accurate representation of patient acuity as well as recognition of rapid treatment changes that can occur. **Therefore, whatever risk adjustment methodology CMS ultimately uses should be applied concurrently.**

Finally, because risk adjustment is significant and a third of Medicare beneficiaries are covered by Medicare Advantage plans, knowing the risk adjustment score for each patient is an important factor. **Therefore, the ADCC recommends that the HCC score assigned to each patient be retained in the Common Working File and released with each eligibility response (i.e., 271 transaction) to providers.** This will enable providers to begin to understand HCCs and to compare CMS’ HCC score to the more current information held by the provider. CMS may wish to consider a form of an appeal or notification when a provider believes an HCC risk score is significantly different from what it should be based on more current data.

Attribution

We understand that MACRA requires new patient relationship categories and codes to be reported as of January 1, 2018. We further understand that CMS expects to release an operational list of these categories and codes for review in April 2017. Since the information has not yet been released, the ADCC is unable to provide meaningful feedback to CMS on how the codes should best be incorporated into its attribution model. **We ask that CMS provide another comment period after it releases the patient relationship codes in order for stakeholders to provide meaningful input on use and attribution of the codes.**

Additionally, we understand that CMS is likely to use new HCPCS modifiers to establish the patient-provider relationship. While providers are familiar with the use of modifiers, which constitute a relatively simple mechanism for collecting this information, it is unclear whether they are all being read appropriately during claims processing. There has been a rapid increase in required modifiers over the last several years. We have raised concerns with CMS about whether all of the modifiers reported are read by CMS during claims processing and also whether the modifiers must be reported in a specific order (i.e., payment modifiers first and then informational modifiers). **The ADCC requests that CMS verify that all reported modifiers will be read by all of its contractor and the pricer/editor systems being used, regardless of the number of modifiers and the order in which they are appended.** If this does not occur, CMS risks not being able to access important information on patient-provider relationships, or truncating important claims data from the reimbursement and rate-setting process.

Episode Definitions

The ADCC notes that CMS has focused episodes on acute hospitalizations that are short-term and chronic conditions that are long-term. However, episodes of care within cancer can vary tremendously in duration, intensity of services, and number. For some patients, the episode of care is characterized by diagnosis, acute treatment with curative intent, and cancer remission. For other patients, the episode reflects progression to second- and third-line treatments and the potential development of additional cancers. Still other patients may receive treatment with palliative intent for weeks or years. **Therefore, the ADCC recommends that CMS pay close attention in how it creates episode-based cost measures for cancer care and that these measures take into account the nature of episodic cancer treatments including the various interventions utilized. Finally, in building these episodes the ADCC suggests that CMS work with guidelines such as those from the National Cancer Care Network (NCCN) which are organized by cancer type and can help define more appropriate cancer episodes which can help ensure valid comparisons.**

We also request CMS disclose how it plans to define and treat outliers. For example, will outliers be excluded from the cost calculation? Will patients who die be included or excluded from episodes? Likewise, will patients who incur traumas or other accidents be excluded in the episode? Similarly, will patients on clinical trials be included, excluded, or treated as separate subgroups based on the presence of a National Clinical Trials (NCT) on the claim? Finally, will clinical trial patients be included in episodes, after a period of time after their participation in the trial ends? These are just some of the questions raised by cancer hospitals that indicate how critical it is for CMS to clearly define inclusion and exclusion

criteria and outlier provisions. These decisions will make a difference in whether episodes reflect good clinician management of patient care or a one-size fits all approach that does not allow the agency to truly make that distinction.

Collecting Staging and Patient Complexity Information

Cancer staging is determined by clinicians that make medical determinations based upon a synthesis of information, including: pathology and other diagnostic tests; examination of the patient; and/or definitive surgical, medical, and radiation oncology treatments. Cancer stages may be reported on inpatient and outpatient institutional claims, as well as on professional claims.

The ADCC agrees with CMS that certain conditions (including cancer) are likely to have significant variations in costs depending on the stage of the patient's disease and that it is important to account for these variations. The ADCC further agrees with CMS that it is critical to track cancer stages in order to effectively and accurately attribute cancer patients' cost of care. However, stage information is currently unavailable in claims data, hampering CMS' ability to incorporate that information into cost analyses, and preventing the agency from making meaningful cost comparisons between different stages of similar sub-groups of cancer patients.

We appreciate CMS' interest in investigating the capture of staging information through claims data and have been analyzing potential processes among our member institutions. Below, we present one potential method for collecting cancer staging information on claims.

As CMS is aware, claim form location definitions are the purview of specific standard-setting and operating rule organizations. For UB-04 or 837I institutional claims, that organization is the National Uniform Billing Committee (NUBC). For 1500 or 837P professional claims, the organization is the National Uniform Claims Committee (NUCC). These organizations must authorize any new claim codes to be reported, along with the associated definitions and instructions.

The ADCC believes new value codes could be created to indicate cancer. For example, CMS could instruct providers to report "CS", along with a numeric code (0 to 4) to reflect cancer stage and also to use "CR" to indicate a cancer recurrence, again along with stage information. For the NUBC, this information would be reported using form locator fields 39-41; for the NUCC, it would be reported on 1500 claims in item number 19 representing "additional claim information." For facility and physician claims, the new "CS or CR" codes would need to be accompanied by a numeric value related to the cancer stage as shown below. Additionally, we believe a separate value code, for example, "00" could be used to report that cancer is present but the clinician is unable to make a stage determination at the time of claim submission. We believe this is a better option than leaving the field blank or taking the risk that providers assume they are required to select a value absent a stage determination, which would only corrupt the data.

The ADCC is exploring the use of the TNM Classification of Malignant Tumors (TNM) staging system as described on the National Cancer Institute's website² where numeric codes could be reported on claims corresponding to different stages of cancer:

- Stage 0: Abnormal cells are present but have not spread to nearby tissue (carcinoma in situ); numeric code to report on claims = 0
- Stage I: Cancer is present; numeric code to report on claims = 1
- Stage II: Cancer is present; numeric code to report on claims = 2
- Stage III: Cancer is present; numeric code to report on claims = 3
- Stage IV: Cancer has spread to distant parts of the body; numeric code to report on claims = 4

There are many additional considerations to explore and operational issues to vet, but we are pleased to share our initial thoughts with CMS on how disease staging information could be captured and hope these early ideas will facilitate the agency's own exploration of collecting staging information using claims. We also encourage CMS to vet these ideas and suggestions with stakeholders and should CMS proceed, it is vital that CMS provide clear instructions so that providers completely understand any future reporting request and the analytics to which it will apply. As with most claims reporting requests, it will take time for providers to begin reporting. However, we believe reporting practices will improve as they realize the importance of the data and how it is being used. **Finally, regardless of the method used to collect staging information, the ADCC urges CMS to ensure that undue administrative burden on providers is minimized.**

QRUR Reports

In response to CMS' request for actionable ideas, **the ADCC suggests specific changes be made to the QRUR reports.** First, the reports must be provided to clinicians as close as possible to real time so that they are able to utilize the information to make actionable decisions that can meaningfully and quickly impact overall costs without compromising patient quality of care. Second, the ADCC believes the QRUR reports must clearly differentiate the various types of costs (i.e., inpatient, outpatient, drugs, post-acute care, etc.) being attributed to clinicians particularly since facility costs are being attributed to them and that these costs must reflect normalization as stated above. Third, our members are struggling to understand the QRUR reports and their current relationship to the value modifier. As we contemplate the implementation of MIPS, we believe more detailed QRUR reports from CMS are necessary. Reports must directly link the cost criterion being applied to physicians to their performance score in order to provide data that can truly lead to meaningful improvements in care.

Implementation Timing

Given the number and nature of the questions associated with the development and refinement of the MIPS cost measures, **the ADCC recommends that CMS delay inclusion of these episode-based cost measures in the calculation of the cost performance category score until clinicians have more experience with these measures.** Due to concerns about the adequacy of risk adjustment generally, we also recommend that the cost performance category score be weighted at zero in the final MIPS score until payment year 2021 or 2022. This will give clinicians more time to understand the cost measures and attribution methodology.

The ADCC sincerely appreciates the opportunity to provide input into the development of MIPS cost measures. If you have any questions, please do not hesitate to contact us.

1 Episode-Based Cost Measure Development for the Quality Payment Program; Centers for Medicare & Medicaid Services

2 <https://www.cancer.gov/about-cancer/diagnosis-staging/staging>

COMMENT 43 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Sharmila Sandhu, Counsel and Director of Regulatory Affairs, The American Occupational Therapy Association

Text of Comment:

The American Occupational Therapy Association (AOTA) is the national professional organization representing the interests of more than 213,000 occupational therapists, occupational therapy assistants, and students of occupational therapy. The science-driven evidence-based practice of occupational therapy enables people of all ages to live life to its fullest by promoting health and minimizing the functional effects of illness, injury, and disability. Occupational therapy services are reimbursed under the Medicare Physician Fee Schedule (MPFS) and are affected by Medicare Part B payment policies, including the policies and related changes anticipated under the Medicare Access and CHIP Reauthorization Act (MACRA). We appreciate the opportunity to provide input to CMS on the draft list of care episode and patient condition groups and codes.

I. Episode Group Selection and Definition

AOTA supports the inclusion of a number of the episodes identified in Appendix A as they represent some of the most costly conditions and patients would benefit from better quality and coordinated care delivery. As part of the interprofessional rehabilitation team, occupational therapy practitioners play a significant role in the care for patients recovering from orthopedic conditions such as knee and hip replacements, hip & pelvis fractures and dislocations, hand/joint repair, and various spinal surgeries. Additionally, under Medicare, occupational therapy services are provided throughout a number of the episodes listed for comment, including but not limited to: chronic obstructive pulmonary disease, pulmonary edema and respiratory failure, intercranial hemorrhage, cerebral infarction, disease, acute ischemic stroke, cardiac events, diabetes and mental health conditions such as major depressive disorder.

Although occupational therapists and other therapy professionals are not currently classified as “eligible professionals” for MIPS reporting purposes in CY 2017, it is important to note that occupational therapy CPT codes are billed for and reimbursed, for services provided during the aforementioned condition-based episodes. Therefore, going forward in this process, AOTA urges CMS to collaborate closely with therapy professional associations and specialty groups, including AOTA, APTA and ASHA, in order to gain accurate feedback with regard to these procedure codes and furthermore to avoid problematic and inappropriate groupings of conditions and codes. Based on AOTA’s August 2016 review of the condition episode group diagnoses and CPT code listings during the open comment period, we identified several code errors and

omissions that proved to be illogical and inconsistent with quality patient care for occupational therapy services. CMS must not leave out key medically necessary procedure codes that a rehabilitation professional, such as an occupational therapist, would use with a specific patient population during the course of one of the clinical episodes named in Appendix A. AOTA will be nominating several occupational therapy experts as part of the CMS Call for Clinical Subcommittee Nominations for the MACRA Episode-Based Cost Measures, and encourages CMS to utilize our experts to provide detailed guidance to the CMS panel regarding the most appropriate diagnoses and CPT codes to be included within relevant episodes.

II. Acute Inpatient Medical Condition Episode Groups

AOTA has reservations with the notion that expenditures that are assigned to an acute episode group only intend to include a few conditions that are associated with that diagnosis. At the same time, “procedure episodes” are a troubling concept as it may be challenging to identify all the resulting services within the episode, within a 90-day window for example, that must be linked to a procedure. AOTA recommends that CMS, with the guidance of expert therapy and other professionals, expand the list of acute episode group types that practitioners typically treat in the acute care setting.

III. Chronic Condition Episode Groups

AOTA recommends that if CMS decides to categorize chronic conditions into episode groups that it does so by representing several conditions that typically occur concurrently. CMS should look to its data and experts regarding common comorbidities and share this data with its technical expert panel for discussion and decision-making regarding how best to define chronic condition episodes. In addition, CMS may tap into patient and professional society registries for new sources of data and health care information. As noted, certain chronic conditions like cancer are progressive and staged. The costs and resources needed at different stages of disease vary widely and must be accounted for through this process.

IV. Cost Measure Development

AOTA believes that the cost measures should include risk adjustment that could account for comorbidities, severity of condition, cognitive impairment, and staging of condition. The patient attribution aspect will also be very important here as CMS determines how to attribute various services within the episode to health care practitioners. AOTA urges CMS to work with the relevant professional society to assure alignment while attributing the services provided within an episode.

Another critical aspect of developing cost measures involves how the measure specifications recognize the ICD-10 and CPT codes for the various professionals involved. AOTA believes that a wider range of ICD-10 codes may be necessary to “trigger” the episode. Many rehabilitation professionals choose to indicate a “treating” diagnosis on their claim form rather than (or in addition to) a “medical” diagnosis that the therapist receives from the physician.

Therapists often provide a diagnostic code to indicate the performance deficit for which the client is receiving therapy. While the medical and treating diagnoses may be the same at times, in other instances, they may differ in order to provide a better to illustrate why the patient is receiving the therapy services. For example, a client with a medical diagnosis of multiple

sclerosis (MS) may be receiving treatment for decreased muscle strength, and incoordination. In this case, it would be important to provide a more specific ICD-10 treatment diagnosis code in addition to the medical diagnosis of MS. AOTA advises occupational therapists to select an ICD-10 code that most closely reflects the condition for which they are providing intervention. If CMS uses administrative claims to gather the coding data associated with cost and episodes, AOTA requests that CMS consider expanding the list of trigger ICD-10 codes.

V. Pilot Testing

AOTA believes that in order to gauge if the episode groups CMS develops actually fulfill the intended purpose of accurately reflecting the correct episode of care for purposes of identifying Medicare costs, CMS must institute a pilot testing period of at least one year in order to collect data and monitor the accuracy of this process before finalizing any episode groups in MIPS. This start date should take into consideration that rehabilitation professionals such as OTs have not been included in the initial roll-out of MIPS, and thus in order to allow current ineligible professionals to be successful, CMS should make the proposed year begin at a minimum of one year after these practitioners are deemed EPs by statute. This pilot phase should be conducted in conjunction with a similar patient relationship categories pilot. The pilot phase should not involve penalties for claims that mistakenly label the episode incorrectly, but rather should provide the provider or facility with an explanation and pre-prepared educational training to remediate issues as they arise. Further, AOTA would recommend thorough periodic education on this topic, beginning with a formal announcement, and materials available in multiple mediums to include website fact sheets, webinars, in-person Q&A session and/or technologically-friendly applications (accessible via cell phones, tablets, etc.).

Thank you for the opportunity to comment on the Supplemental Episode Groups impacting future Part B payment policy. AOTA looks forward to a continuing dialogue with CMS on coverage and payment policies that affect the ability of occupational therapy practitioners to provide quality, cost effective outpatient therapy to Medicare beneficiaries.

COMMENT 44 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Debra Johnson, President, American Society of Plastic Surgeons

Text of Comment:

The American Society of Plastic Surgeons (ASPS) is the world's largest association of plastic surgeons. Our over 7,000 members represent 94 percent of Board-Certified Plastic Surgeons in the United States. ASPS promotes not only the highest quality in patient care, but also in professional and ethical standards. Our members are highly skilled surgeons who improve both the functional capacity and quality of life for patients, including treatment of congenital deformities, burn injuries, traumatic injuries, hand conditions, and cancer reconstruction. We appreciate the opportunity to provide feedback on the draft list of episode groups and trigger codes, as well as your report, *Episode-Based Cost Measure Development for the Quality Payment Program*, to help inform the agency's ongoing efforts in developing cost measures.

Episode-Based Cost Measure Development for the Quality Payment Program

Episode Group Selection

CMS considered Medicare expenditures, clinician coverage, and the opportunity for improvement in acute, chronic, and procedural care settings in selecting the episode groups to be considered for development. As a result, “lumpectomy or partial mastectomy” and “simple or modified radical mastectomy” continue to be targeted for episode group development. ASPS is eager to work with CMS and its contractor on further developing these episode groups into reasonable and appropriate cost measures, so that plastic surgeons can be held accountable for resource use that is within their control.

Episode Group Definition, Procedural Episode Groups & Cost Measure Development

As noted above, we understand how “lumpectomy or partial mastectomy” and “simple or modified radical mastectomy” have been targeted for episode group development and agree that the CPT codes identified as “trigger codes” represent those services. It would be helpful if CMS identified the ICD-10-PCS codes for these episode groups, cross-walked them to the CPT “trigger codes,” and made this information public and open for comment. That way, when episodes are being constructed in the real-time claims environment, stakeholders will have more confidence that the physician, hospital and/or ambulatory surgery center (ASC) claims are corresponding as they should.

In addition, we would strongly support the development of episode sub-groups for mastectomy with or without breast reconstruction, which drastically alters resource use for these services and should be parsed out, accordingly.

Unfortunately, we are limited in our ability to provide substantive comment outside of the above because key information about the episode groups are missing. Beyond the CPT “trigger codes,” what are the parameters under which these episodes intend to be developed? For example,

- When do the episodes begin and end?
- What are the associated ICD-10 diagnosis codes?
- How will surgeons and other providers participating in the patient’s continuum of care be attributed costs during the episode? We continue to await information on patient relationship categories and codes, which will be key to this effort, but concerns remain about their effectiveness, feasibility and utility.
- What, if any, are the exclusion criteria for these episodes?
- How will risk factors, including socio-demographic, be accounted for in these episodes?
- How will additional treatment modalities, such as chemotherapy (both neo-adjuvant and post-mastectomy) and radiation therapy, both known to increase risk of infection and healing complications, be accounted for in both length of episode and cost?
- How are device costs accounted for? This could be particularly important as new, innovative products become available and show superiority (i.e., clinical, outcomes and quality of life) over less-expensive predecessor products. In addition, the variety and availability of reconstructive implants or other medical devices (e.g. skin substitutes and other tissue grafts) may not be within the surgeon’s control. We understand that some

areas are appropriate for efficient resource use, however, CMS's cost measurement should not stifle or hinder advances in medicine and technological innovation.

- How are indirect activities that impact overall costs accounted for? For example, a surgeon may own and operate an ASC that maintains accreditation and engages in infection control and antimicrobial stewardship activities which improves overall quality and cost. How might this be factored into cost measurement?
- How frequently will the episodes be updated to account for changes in clinical practice? Changes in the medical inflation rate?

ASPS recognizes that CMS is conducting this work in phases, but it is very challenging to evaluate the suitability of episode trigger codes without any other context regarding the parameters of the entire episode. We urge CMS to provide these critical details sooner rather than later, so that ASPS may provide important feedback to the agency prior to the implementation of episode groups in the MIPS cost performance category.

We appreciate the opportunity to offer these comments, and we look forward to providing additional input on accurate cost measurement. Given CMS' current plan to increase the weight of the MIPS cost performance category to 10 percent for the CY 2018 reporting period, we encourage the agency to issue more detailed proposals as soon as possible. Our members are committed to taking all appropriate steps to ensure patients receive care that results in the best outcomes and value.

COMMENT 45 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: David B. Hoyt, Executive Director, American College of Surgeons

Text of Comment:

On behalf of the more than 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) document titled, "Episode-Based Cost Measure Development for the Quality Payment Program." The ACS is a scientific and educational association of surgeons, founded in 1913, to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. We first provide some overarching comments on the area of cost measurement within MIPS and as it relates to MACRA, followed by responses to the questions that CMS has set forth.

Cost Measures and the Transition from MIPS to APMs

Cost measurement is an important element of the Merit-based Incentive Payment System (MIPS) and is also a crucial aspect of any Alternative Payment Model (APM). The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) seeks to establish value as a measure of care by combining quality and cost data into a picture of care represented through a composite score. The composite score also incorporates credit for improvement and use of certified electronic health record technology (CEHRT). The apparent goal of increasing transparency and

awareness of the value of care provided is to provide incentives to optimize this value by improving quality and reducing waste and unwarranted variation.

It is also important to note that MACRA appears to be designed with a primary and secondary incentive structure. The first set of incentives rewards clinicians who, through moving toward higher value care, perform well in MIPS. The secondary incentives are more transformational, and are intended to transition physicians away from MIPS and traditional fee-for-service (FFS) care into APMs. Creating a pathway that allows for both of these aspects (MIPS performance and migration to APMs) calls for considering these two programs as part of a continuum that facilitates the movement to APMs. Use of a comprehensive cost measurement tool, capable of accurately accounting for every Medicare dollar spent and attributing this spending appropriately regardless of payment model will be key to streamlining this pathway.

Many believe that the FFS environment is highly siloed with no shared risk or accountability. However, APMs do share risk and accountability and are more closely aligned with the team-based nature of the practice of medicine. Care delivery today is more team-based, and efforts that seek to optimize value require patient centric information in quality and cost as much as is possible.

As noted in a recent CMS listening session on Episode Based Cost Measures, many stakeholder groups commented that cost measures should be limited only to those aspects of care with direct control by the individual provider. This would result in measures that are provider-centric and narrow. While we recognize the inclination to focus incentives on the costs most directly influenced by the provider, we fear that if focused too narrowly such measurement would fail to recognize the team-based nature of care delivery and would fail to achieve the buy-in and culture change necessary to drive meaningful improvement. Furthermore, to establish a truly clinician nonpatient centric cost profile would require clinical and socio-economic risk adjustment that limits the cost elements to only those costs plausibly due to immediate and direct actions of the provider in a manner that is not currently achievable. However, defining episode based cost measures that are broad enough to provide information to clinicians on all related services that are being provided to the patient in the course of care is currently achievable and would allow for optimization of warranted care and reduced unwarranted care.

A more patient-centric alternative to the narrow individual cost profiles requires grouping of claims in a manner that considers all costs associated with a patient's episode of care and attributing a portion of those costs based upon a provider's role in the specific episode for the specific patient. These episodes could consist of both Medicare Part A and Part B charges and could incorporate Part D spending if data become available. In such an "all cost" environment, clinicians would not wish to have all costs attributed to them that are not directly related to care provided for the specific condition being treated.

To account for this, each episode would require an episode-specific set of definitions for the series of relevant services plausibly associated with the given treatment or condition. This approach is ideal for episode-based APMs and is used in the ACS-Brandeis Advanced APM proposal which was recommended by the Physician-focused Payment Model Technical Advisory Committee (PTAC) at their April meeting.

To address the dual goals of MACRA (incentivizing value in the MIPS FFS arena as well as the transition to APMs) a cost measurement system that allows for a smooth transition from MIPS to APMs would be ideal. Instead of one program for MIPS and multiple programs for APMs, significant efficiencies and simplification could be achieved through a continuum with both programs nested within an overarching cost methodology.

Quality, Cost, Advancing Care Information (ACI), and Improvement Activities (IA) are the four pillars for the MIPS composites. Discernment in each of these categories is important, however, it is even more critical in the Quality and Cost categories, not only because they will account for the majority of the final MIPS score, but also due to the higher likelihood that scores in IA and ACI categories will tend to cluster at the extremes or eventually top out. The narrower the cost profiles, the more these will tend to cluster clinicians into tight profiles as well, leaving quality to be the lone discriminator. Yet, quality measurement is not at the point of serving as a discriminator. As such, a sound cost measurement system for both MIPS and APMs is essential.

QUESTIONS FOR PUBLIC COMMENT

Episode Group Selection

- **In selecting the episode groups to be considered for development, CMS used criteria including an episode's share of Medicare expenditures, clinician coverage, and the opportunity for improvement in acute, chronic, and procedural care settings. We welcome comment on these episode groups and potential additional episode groups that should be considered for development.**

CMS' current approach appears to use multiple different payment systems and incentives to migrate away from FFS. This could result, however, in several different competing payment systems that lead to confusion in the market. For example, surgeons are not typically engaged by ACOs despite the fact that ACOs are overall population based payment models, resulting in a lack of care transformation with respect to surgical patients.

Examining the total cost of care provided by FFS, ACOs, CPC + tracks, BPCI and new Advanced APMs creates overlapping complexities and accountability.

These fragmented payment models reveal gaps that can be closed as suggested in the question by share of Medicare expenditure; specialty coverage; and acute, chronic, or, procedural care.

An alternative course of action would be to develop APMs based on a cost methodology that incorporates the majority of patient care across all care settings, includes time windows of acute and chronic care, and is also inclusive of the multiple sites of service where care is delivered. We believe the CMS Episode Grouper for Medicare (EGM) can provide enormous range and flexibility to meet all these needs. A small percentage, 10-15 percent of all expenditures, would be excluded for their rare and esoteric nature. The remaining costs have various levels of accountability in the EGM and can be "packaged" with the sort of flexibility CMS requires to be as inclusive of the different payment environments it wishes. The ACS-Brandeis APM model is one small reflection currently dominated by procedural episodes. These can and should be extended to include condition episodes and rolled up into service line population health episodes or full ACOs or other total cost of care models.

Episode Group Definition

- **The episode groups that accompany this posting are defined by the listed trigger events and codes (CPT/HCPCS for procedural episode triggers, evaluation & management codes combined with ICD-10 diagnostic information for chronic episode triggers, etc.). CMS solicits comment on the inclusion or exclusion of specific service codes used to identify each episode group.**

In order to optimally define the costs of care in an episode, the creation of different levels of engagement of services for inclusion/exclusion could be required. The first level would include the costs attached to services that could plausibly be assigned to the trigger and that would directly be controlled by the provider being measured. It is important to draw a distinction between what are appropriate costs and what plausibly could be associated with the trigger.

Appropriate care as a measure will limit the scope of costs assigned to the trigger. While plausibly aligned with the trigger will define the services to consider for real costs. This entry level of services for inclusion which are directly and plausibly attached to a provider would potentially align more with part B for most providers.

The next level of inclusion relates less to what a provider controls in relation to the trigger, rather is more aligned with the patient and their total cost of care.

In this instance or episode, optimal cost tracking would include plausible costs from all aspects of care (Parts A, B, and D). We recognize that part D is not available for tables in an episode grouper but we could encourage efforts that seek to include these costs.

Acute Inpatient Medical Condition Episode Groups

- **The acute inpatient medical condition episode groups that accompany this posting include only inpatient events. CMS seeks comment on outpatient events that could be considered candidates for development as acute condition episode groups, which could include chronic condition exacerbations that require acute care but not inpatient hospitalization.**
- **Acute episodes of care might occur on either an inpatient or outpatient basis and may or may not include surgery. CMS is considering a single Acute Episode Group type that does not distinguish the place of service or the performance of a procedure and welcomes comment on this approach.**

When considering costs, the patient related costs are more helpful than a foundation tied to site of service. Also, total costs should be accounted for and attributed only once. The rules logic to be developed for episodes will require the ability to attribute and split or share costs in order to assign costs to all the shared partners who care for the patient. As such, we support counting every dollar once and assigning those dollars by patients, not solely by site of service.

Site of service can, however, have drastic implications on the cost and quality of care and should be accounted for. It is imperative that the rules logic capture sequelae or possible complications associated with procedures to help ensure that care is being provided in the most appropriate setting. For example, if a cost measure were targeted too narrowly, providing care in the

outpatient setting may appear to be cost effective, even if it resulted in complications, future hospital admissions or other costs that could have been avoided by performing the procedure in a different setting. Overall we support defining episodes beginning with procedures but believe this should be followed by episodes that are condition or disease based. Assuming appropriate rules logic is used and that risk adjustment that takes into account factors likely to influence the patient's outcome is in place, tracking patients across site of service will eventually become less important.

Also, CMS may wish to consider a cost basis that has consistency when providers move from MIPS to MIPS-APMs to Advanced APMs. In this continuum, having episodes tied to patients, procedures, and conditions will facilitate models built on the patient rather than on the site of service. For example, a BPCI episode launches once a DRG is triggered, which incentivizes more DRGs. Instead, the episode should launch based on optimal care or what is best for the patient, which could result in less use of DRGs for a given condition.

Chronic Condition Episode Groups

- **CMS is aware of many challenges in constructing episode groups for chronic conditions. These include coding habits that may obscure some chronic conditions and overemphasize others. In addition, it may be difficult to assign a given treatment to a single condition for patients with multiple comorbidities. For example, are the resources for treatment to reduce cholesterol for a patient with diabetes, hypertension, and coronary artery disease to be assigned to only one of those diagnoses, to all of them in proportion, or should we develop a chronic condition episode specific to the management of patients with diabetes, hypertension and coronary artery disease, i.e., a patient condition group to better compare cost to treat like patients? An extension of this approach might be a single episode group for outpatient chronic care with adjustment for comorbidities and demographics of the population served by the clinician. We welcome comment on these and any other options for constructing episode groups for chronic conditions.**

We agree with CMS that chronic conditions present challenges in the development of episodes. Regarding chronic conditions, our thoughts are still being developed and require input outside the scope of surgical care (input from primary care physicians (PCPs) would be extremely important). Many more medical specialties and primary care physicians provide chronic care support. That said, the methodology we would recommend involves building a panel of patients with chronic diseases and clustering those diseases with risk adjustment, so that, for example, a PCP could see their patients and associated costs from several different perspectives.

First, a PCP may wish to see all costs for their patients individually with their diseases clustered together. Second, they should be able to see all conditions individually with lists of patients and their related costs. It is also feasible to cluster conditions in selective groups which are related to track their costs. For example, such a cost group could include DM, HTN, and CRF. Third, as chronic disease patients move into other acute-on chronic episodes, no PCP should be accountable for "all" costs for those other episodes. Shared attribution schedules should become the norm since physicians share responsibility of care. As such, attribution is crucial.

- **Certain specific conditions, such as cancer, present other challenges. The costs of caring for patients at different stages of disease are likely to vary. For instance, a single episode for a type of cancer is likely to differ in a predictable manner depending on the stage of the cancer. Information on disease staging is not easily or predictably available from claims. CMS welcomes comment on methods to incorporate disease severity or staging information to improve meaningful comparison of cost and quality of care furnished to patients, both generally and for specific clinical conditions. For example, how could a disease staging code be reported on claims to facilitate comparison of episodes for patients at like stages of cancer?**

With respect to cancer, there are several aspects to the complexity of this disease. The stage, patient factors, multiple National Comprehensive Cancer Network (NCCN) acceptable treatment options, and patient preference will all influence the survival plan and the associated costs. We are currently working on a solution that would allow for establishing how various aspects of these factors can come together to establish a survival plan. Costs can then be based on phases of care for a given survival plan. For example, ACS is currently in the very early stages of efforts to use the triggering diagnosis to establish a stage and treatment plan that could exist within the CMS Episode Grouper for Medicare (EGM) cost tables. This would facilitate the development of a stage-specific and treatment plan-specific cost comparison. This effort is to provide a scalable solution for the CMS EGM to optimize tracking and resource use in cancer care, appropriate for stage and survival plan.

Cost Measure Development

- **The Medicare Advantage program uses the CMS-HCC Risk Adjustment Model to determine rates. We seek comment on the use of this model or an alternative for risk adjusting episode groups in the construction of cost measures. In addition, should concurrent or prospective risk adjustment be used, and should a full year of data or more targeted data from before the episode be used to adjust?**

We would seek clarity from CMS with respect to HCCs. We are unclear as to whether this question relates to setting an episode price and whether or not the cost data for setting expected prices come from national data, regional data, HCC data or some other source. The actual risk adjustments for the expected costs come from patient factors that influence the amount of services (and therefore costs) required to treat a condition.

- **The draft list does not currently include specifications for episode sub-groups (a subgroup is intended to achieve greater clinical comparability and is a subdivision of an episode group that further refines the specifications of episode trigger codes and grouping rules to yield more clinically homogenous cohorts of patients with similar expected cost). An example is an episode group for spine surgery with sub-grouping for number of levels and anatomic location. CMS solicits public comment on these draft episode groups and potential sub-groups.**

The inclusion of sub-categories or sub-groups is necessary to accurately assess whether the cost of care provided is greater than, less than, or equal to what might be expected for a given patient undergoing a given course of care. At the same time, subcategories could become a “slippery slope back toward FFS. As a result, appropriateness of categories requires multi-stakeholder input to govern the degree of subcategorization.

- **CMS is especially interested in comments regarding methods to align quality of care with cost measures and welcomes recommendations and suggestions. Considerations for aligning episode groups with quality measurement are described in this document, but are not intended to be an exhaustive list of options. We welcome comment on these methods, as well as any other strategies that could be used to align quality of care considerations with cost measures.**

In the ACS-Brandeis Advanced APM PTAC proposal we have developed an episode-based quality measure framework, which is tied to the specific episodes of care provided. That approach allows for shared accountability in team-based care, and for evaluating cost and quality simultaneously within the same clinical episode context. Please see the attached ACS-Brandeis A-APM submission that was recently recommended by the PTAC.

- **CMS wishes to avoid any unintended consequences of using cost measures in MIPS, and seeks comment on issues of concern in this regard, such as taking steps to avoid disadvantaging clinicians who assume the care of complex patients such as by applying episodes for comparison of complex patients (i.e., comparison of like patients of different clinicians).**

Risk adjustment and subcategories are both key in assuring apples-to-apples comparisons of cost. This risk adjustment should ultimately be both socioeconomic and clinical. More research is needed in the evolution of these elements of risk adjustment. The current Medicare EGM uses claims data to risk adjust. We believe that clinical registries may enable risk adjustment tables that could validate or even directly improve on the risk adjustments used in the EGM. For example, EGM will identify patients with DM, HTN or AMI but cannot quantify or qualify the degree of control in the DM or HTN or the level of cardiac function after the AMI. If these clinical parameters influence overall risk adjustment in costs, we should build the clinical tables to support more accurate cost comparisons.

- **CMS acknowledges that prescription drug costs are a large driver of the cost of medical care for Medicare beneficiaries. What would be the best way to incorporate Part D costs into the episode group development?**

Part D represents a significant part of overall expenditure and therefore a large opportunity to optimize care. Providing actual costs in the workflow of clinicians is an important “next step” which should be accomplished in the digital environment. In addition, providing comparative drug costs as a service line for prescribing physicians would be helpful for those who have met a minimum threshold of drug cost expenditures. Use of episodic cost measurement in private insurers who have available cost tables to enrich the measures as part of Medicare ACO work could be a place to begin research and understand the overall impact.

We appreciate the opportunity to provide comments as CMS develops episode-based cost measures for the QPP. The ACS looks forward to continuing dialogue with CMS on these important issues.

COMMENT 46 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Boyd R. Buser, President, American Osteopathic Association

Text of Comment:

On behalf of the American Osteopathic Association (AOA) and the nearly 130,000 osteopathic physicians and osteopathic medical students we represent, thank you for the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) *Episode-Based Cost Measure Development for the Quality Payment Program*.

The osteopathic profession strongly supported passage of the Medicare Access and CHIP Reauthorization Act (MACRA), and remains optimistic as we move towards 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. To further support these efforts, we offer the following comments on the questions posed by CMS.

Episode Group Selection

We support that use of the episode's share of Medicare expenditures; clinician coverage; and the opportunity for improvement in acute, chronic, and procedural care settings are considerations when developing an episode group. We would add that episodes must also have parameters for included services that are reasonable and likely for patient care. These parameters are not easily set; variation in patients' needs will undoubtedly generate a multitude of care scenarios. We caution that where this variation exists to a greater degree, CMS should reconsider the development of an episode group.

Further, we appreciate that CMS is compelled to create episode groups to address cost measurement under MACRA. However, we urge CMS to take a stepwise approach to this effort by creating and testing fewer episode groups, and adding to that list only when existing episode groups have been proven to reflect actual care. This approach will ensure CMS has a manageable set of episode groups which it can refine, and in doing so, perfect its methodology, before extending episode groups to other conditions.

Acute Inpatient Medical Condition Episode Groups

We appreciate CMS' efforts to identify acute inpatient episode groups. We agree that there may be overlap between some acute inpatient episode groups and chronic condition episode groups. For example, CMS lists an inpatient episode group for diabetes as well as a chronic condition group for it. As CMS has aligned "inpatient" and "acute" it is unclear on how acute care in an outpatient setting would be considered. For example, a diabetic patient may present in the

hospital emergency room and have their medical needs addressed there rather than as an admitted patient to the hospital. Based on CMS' approach, proposed categories for episode groups are insufficient to account for this care. We appreciate CMS' recognition of these challenges and its consideration of a single acute episode group category. The approach would better distinguish between ongoing care for chronic conditions and acute care that may be provided in a variety of locations including at a physician's office or acute care clinic.

Chronic Condition Episode Groups

We recognize challenges in assigning a patient with multiple chronic conditions to a single episode group. 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 cardiovascular disease, for example, the dominant condition would change to cardiovascular disease 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.

We also appreciate that current definitions of disease are too broad to capture clinical variation in disease severity or staging. For example, breast cancer alone does not identify the patient's condition or likely treatment pathway sufficiently to anticipate services in an episode group. Such an episode group should be informed by the stage of cancer at minimum. We suggest that a modifier be introduced so that claims can track this information and ensure an appropriate episode group is assigned. While this measure will aid in identifying a more appropriate episode group, we note that additional significant detail will still be illusive. For example, knowledge that a patient has Stage 2 breast cancer does not also provide information on the patient's known genetic information on the type of breast cancer which will also determine the patient's treatment pathway. In addition to a cancer staging modifier, we offer that disease severity modifiers may be useful in relation to chronic disease and we would support appropriate modifiers for these uses.

Cost Measure Development

We appreciate CMS' acknowledgement that several important variables should be considered when using episode groups to develop cost measures.

Regarding risk adjustment, we offer that patient classification should be based on at least two components:

1. Clinical factors including age, gender, condition, etc., as well as for non-clinical factors such as socioeconomic status and access to care, which can significantly 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).

Chronic conditions can impact patient health differently based on risk factors (age, gender, etc.) and disease management (controlled and stable, or uncontrolled and unstable), so both of these should be considerations moving forward.

Regarding attribution, we offer that robust methodology is needed to ensure appropriate pairings of providers and services, or proportions of services, in the episode group. This is particularly challenging as 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, and offer that the patient-centered medical home (PCMH) model provides an appropriate context for this care coordination. Additionally, 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.

Regarding the degree of responsibility of attributed services, we offer that proportions may change over time as the patient's condition improves or progresses. For example, a diabetic patient may be stable in the first quarter of the year, and have a precipitating event in the second quarter of the year that necessitates intervention by other care team members for the same illness. As such, a single and continuous attribution of services to providers would not be appropriate in this scenario. Any degree of responsibility of attributed services must provide enough flexibility to mirror real world care. We offer that for chronic diseases, annual adjustments are too infrequent and that quarterly changes to the degree of responsibility of attributed services are preferable.

Regarding subgroups, we support that they should be developed 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.

We also appreciate CMS' consideration of the use of cost measures in MIPS and the potential adverse impact this may have for physicians who assume the care of complex patients. We share these concerns and urge CMS to ensure appropriate risk stratification of all measures. In addition, we urge particular attention to ensure that chronic care measures appropriately reflect the resources used to care for patients. These resources may not be captured in current CPT codes, and therefore, be unaccounted for on claims. We urge CMS to ensure that care coordination is included in all episode groups for chronic disease.

We appreciate CMS' desire to include all costs in an episode, including prescription drug costs. However, we urge CMS to first establish a foundation of operational episode groups based on sound methodology. CMS may then consider analytics that test the incorporation of Medicare Part D costs into episode groups, and share the findings of that assessment with physicians' association and other key stakeholders who can make recommendations on the methodology. Only after these episode groups have proven to reflect actual care should CMS consider incorporating Medicare Part D costs into episode groups. At this early stage, we believe the incorporation of drug costs into episode groups will add undue complexity.

COMMENT 47 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Gregory B. Seymann, Chair, Performance Measurement and Reporting Committee, Society of Hospital Medicine

Text of Comment:

The Society of Hospital Medicine (SHM), on behalf of the nation's nearly 57,000 hospitalists, offers the following comments on the Episode-Based Cost Measure Development for the Quality Payment Program.

Hospitalists are front-line providers in America's hospitals, providing care for millions of hospitalized patients each year, many of whom are Medicare and Medicaid beneficiaries. As members of an interdisciplinary team, they lead the management of inpatient clinical care of their patients, while working to enhance the performance of hospitals and health systems. The position of hospitalists within the healthcare system affords a distinctive role in facilitating care both at the individual, provider-level as well as at the systems or hospital level.

SHM broadly supports the move towards episode-based cost measures as they may provide more actionable or useful information to providers and groups. However, we caution that there are serious impediments that need to be overcome to ensure that these measures are fair, equitable and appropriate for use in accountability programs. We offer the following three principles for consideration as CMS continues to develop these episode measures and deploy them in the Merit-based Incentive Payment System:

1. **Transparency:** It is vital that the episode cost measures, the trigger events, and the attribution methodologies be transparent and replicable so that clinicians can validate their performance.
2. **Connected to Quality:** Cost measures should be related to the quality measures reported by a provider to make meaningful Cost/Quality assessments. This is not the current reality for quality

measures. Providers select quality measures to report that are available to them, which in most cases are a different population of patients than those who would be administratively attributed to the provider under cost measures. We caution CMS against enacting cost measures without related quality measures as this would mean providers are scored on one set of patients for quality and another for costs.

3. Construction Mindful of Measures' Use: We urge CMS to develop cost measures mindful of the programs and policies that will use these measures. Since these episode measures are meant to be used for provider assessment in the Merit-based Incentive Payment System (MIPS), CMS must take into account the downstream impacts of a measure on provider performance and behavior. The measures must be constructed to ensure equity and fairness in performance assessments.

Attribution to Individual Providers

We have reservations about the ability for these measures to be meaningfully, or accurately, attributed to individual providers, particularly for the Acute Inpatient Medical Condition Episode Groups. Hospitalists function as part of a team in two distinct ways. First, their work schedules are shift-based and therefore several individual hospitalists may see a patient in each hospital stay. Second, there are numerous providers – specialists, nursing staff, case workers, support staff – who may provide care and services to a patient during their hospitalization. Because care teams within hospitals are multifaceted, it will be difficult to assign a beneficiary to an individual provider. We also encourage consideration of different practice structures, such as hospitalists employed directly in hospitals or integrated health systems and versus hospitalists with independent contracting models, that may warrant alternative attribution methodologies to accurately reflect their relationships and work.

For the Acute Inpatient Medical Condition Episode Groups, CMS notes that “episodes will be triggered by clinicians’ Evaluation and Management claims in combination with other billing information on Part A and Part B claims that is associated with the hospitalization.” Knowing the complexity and number of providers who see the patient during a hospitalization, we are concerned about the ability for CMS to structure trigger events and attribution methodologies that are transparent and easily understood.

Outpatient and Inpatient Episodes of Care

CMS indicates that it is considering developing a single episode group type for all acute events – both inpatient and outpatient, agnostic of place of service. SHM is opposed to creating an episode group type for cost measures that compare acute episodes of care across settings. We urge Acumen and CMS to prioritize constructing episode cost measures that would compare providers functioning in similar settings against each other. This would ensure measures provide meaningful, actionable information.

Costs between inpatient and outpatient settings, or facilities and offices, are structurally different. Inpatient or facility settings are inherently more expensive than outpatient settings. To create an episode group type that aggregates these costs would set up a distinct disadvantage for providers who practice predominately in the inpatient or facility setting. While it may be a worthwhile endeavor for CMS to explore and prioritize patients receiving care in the most cost-effective

setting for the Medicare Trust Fund, it would not be appropriate for CMS to structure physician assessments and therefore payments through these comparisons.

Hospitalists' experiences with cost measures under the Physician Value-Based Payment Modifier illustrates this dynamic and underscores the need for separate episodes and benchmarks for facility-based and office-based providers. Looking at performance on the Total Per Capita Costs measure, hospitalists are typically two to three standard deviations more expensive when compared against benchmarks that are built around inpatient and outpatient providers. Conversely, outpatient providers would not receive actionable information about their actual costs relative to their peers when being assessed on a benchmark that incorporates inpatient providers.

Trigger DRGs and Development of Sub-Groups

In framing the Acute Inpatient Medical Condition Episode Groups, CMS identified Diagnosis Related Groups (DRGs) relevant to the groups. We are concerned that an individual DRG contains heterogeneous ICD-10 condition diagnoses that may have very different treatment courses and therefore costs. DRGs are designed to separate patients into groups that are supposed to have different costs due to their underlying medical conditions. The Major Complication or Comorbidity (MCC) and Complication or Comorbidity (CC) designations allow hospitals to identify patients who have the potential need for more medical care and thereby higher medical costs. For example, the Allergic Reactions episode and its associated DRGs (915 and 916) could range from allergic dermatitis (L23.7 or L23.9) to anaphylaxis (T78 or T80) as identified by ICD-10 coding. The COPD episode and its associated DRGs (190, 191, and 192) is another example of differential in costs (2014 averages for each DRG nationally are \$7,088.08, \$5,672.03, and \$4,200.94, respectively) further marked by variances due to specific clinical circumstances as denoted by ICD-10 coding. This is a wide diversity of potential diagnoses with radically different expected costs. It is not clear to SHM that these differences would be accounted for in broad episode measures.

Although we acknowledge that risk adjustment may allay some of our concerns, we believe it will be difficult to risk adjust out all the differences between the DRGs within an episode to make fair comparisons. SHM encourages the development of sub-groups within episodes that provide more granular and homogenous comparison groups. We also encourage consideration of specialty-specific cost measures and sets of measures that would be meaningful to those providers. This would enable greater specificity of information, clearer benchmarks, and yield more actionable cost information.

We also encourage CMS to consider minimum number of DRGs per provider or, if appropriate, per group that would need to be reported to make valid comparisons. We believe there should be enough cases reported for each provider or group to make sure that no one is unfairly penalized or rewarded because of small sample size.

Conclusion

SHM stands ready to work with CMS as it continues exploring and developing episode-based payment measures.

COMMENT 48 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Tod Ibrahim, Executive Vice President, American Society of Nephrology

Text of Comment:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comments regarding the development of episode-based cost measures for the Quality Payment Program (QPP) created by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). ASN represents nearly 17,000 physicians, scientists, nurses, and other health professionals dedicated to treating and studying kidney diseases to improve the lives of people with kidney diseases. ASN is a not-for-profit organization dedicated to promoting excellence in kidney care. Foremost among the society's concerns is the preservation of equitable patient access to optimal quality care in the treatment of kidney diseases and kidney failure and the integrity of the patient-physician relationship.

ASN appreciates the Centers for Medicare and Medicaid Services' (CMS) commitment to the successful creation and implementation of the new QPP. The creation of a transition year for 2017 within the QPP along with a corresponding approach to reporting and scoring during that year has given physicians and their practices an opportunity to better understand the new program as the components related to cost measures are in development. ASN also applauds the work CMS and its related Technical Expert Panel (TEP) have put into the development of episodes over the last two years.

The society realizes that Congress passed MACRA with relatively proscriptive language on how the QPP should be structured, who should be included, what should be included in its components, how it should progress over time, and how the Secretary of Health and Human Services (HHS) should solicit and incorporate public input. Simultaneously, it is clear that much progress has been made to satisfy the statutory requirements of MACRA in general, and on episode-based cost measure development in particular, since the MACRA enactment in April 2015. Considering these observations, ASN respectfully offers comments for consideration as implementation of MACRA continues.

The QPP is designed to re-align physician reimbursement with quality-driven, value-based health care. This goal inherently includes efforts to contain costs and incentivize savings. ASN understands and supports those goals but, considering concerns about how those goals may interface with the care of the complex, vulnerable population of kidney patients, offers thematic recommendations to bear in mind as episode groups are developed in the coming months and years.

First, nephrology is heterogeneous by its very nature. Patients in need of nephrology care generally have very complex needs due to their high percentage of comorbidities. While kidney diseases can be the primary illness for some, for most patients their kidney disease accompanies, or is secondary to, coronary disease, hypertension, diabetes, obesity, etc. The scope of nephrology practice includes caring for complicated hospital inpatients; following a diverse

outpatient population with chronic kidney diseases, hypertension, kidney stones and other kidney related conditions including kidney transplant recipients and donors; and managing a modest number of complex dialysis patients, often at multiple dialysis facilities.

Second, due to their comorbidity burden, most kidney patients see a number of other physicians and specialists besides their nephrologists. These are necessary interactions for complex patients, but they inevitably create situations in which the nephrologist has little or no control over many of the factors that affect costs. Furthermore, it can be difficult—and can vary by patient—to discern when care is provided is pointedly related to a kidney condition (as opposed to a cardiovascular condition as opposed to a vascular condition, for example).

At the same time, care for patients with kidney diseases, kidney failure, and comorbidities is expensive. Therefore, ASN requests those working on episode-based measure development to use great care when developing nephrology episodes that could have the unintended consequences of incentivizing underserving patients with kidney diseases.

In support of that goal, ASN offers some high-level, thematic observations about the development of nephrology episodes.

- Heterogeneity and prevalence of comorbidities in the kidney patient population is the Achilles' heel of nephrology cost control. ASN recommends that episodes be distilled to the most homogenous patient population possible to ensure that the episode does indeed measure equivalent components.
- Maintain a clear delineation of kidney diseases across nephrology episodes. There are many types of kidney diseases for which measures must be appropriately calibrated such as acute kidney injury (AKI), chronic kidney disease (CKD) with multiple stages, kidney failure, and transplantation. As above, the more homogenous the episodes are, the more accurate the episodes are likely to be when capturing and evaluating costs.
- Attribution is the key. The functionality of the episodes for nephrology will significantly depend on how precise the episodes are at attribution. Multiple clinicians generally treat kidney patients along a continuum and at multiple locations. Capturing all those data points is essential.
- Episodes do not function in a vacuum. CMS is aware that very few nephrology-specific quality measures currently exist in the QPP. To properly align episode-based cost measures with quality measures, there needs to be a critical mass of both to achieve synergy. ASN is aware that CMS cannot wait until the well of nephrology-specific quality measures is full, but the society does encourage CMS to find a balance of the two before fully weighting the cost section of the QPP for a full performance year.

Again, thank you for the opportunity to comment on the development of episode-based cost measures for the QPP. ASN appreciates CMS's commitment to a robust, quality-driven physician reimbursement system and the Agency's efforts to engage the society and other stakeholders in the QPP implementation. The society looks forward to opportunities to work with CMS and its contractors in every possible capacity, and urges them to think of ASN as a resource.

COMMENT 49 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Bob Hussey, Wolters Kluwer Health

Text of Comment:

Wolters Kluwer Health appreciates the opportunity to comment on the development of new episode-based cost measures for the Quality Payment Program.

As way of background, Wolters Kluwer (WK) is a leading global provider of information, business intelligence and point-of-care solutions for the healthcare industry. Key brands include ProVation® Medical, UpToDate®, Emmi Solutions®, Medi-Span®, Lexicomp®, Facts & Comparisons®, Pharmacy OneSource®, Health Language and Medicom (China). Wolters Kluwer had annual revenues in 2016 of \$4.6 billion.

We strongly support the inclusion of *Septicemia or Severe Sepsis with Mechanical Ventilation > 96 Hours* as one of the proposed acute inpatient medical condition episode groups, and believe it meets all three criteria (i.e. share of Medicare's expenditures, clinician coverage and opportunity for improvement in acute, chronic and procedural care settings) used by CMS to select such episodes.

According to CMS' own data, over 550,000 Medicare beneficiaries were afflicted with sepsis in 2013 as a primary diagnosis, totaling more than \$8.1 billion in Medicare allowed amounts. A 2015 study¹ published in the *American Journal of Respiratory and Critical Care Medicine* found that older adults are three times more likely to develop sepsis in the first three months after leaving a hospital that at any other time, and that the risk of sepsis is 30% higher for patients whose original hospital stay involved care for infections such as pneumonia. A study² presented at the American Thoracic Society's annual conference in May 2014 concluded that sepsis contributes close to half of all hospital deaths in the United States. And a research letter³ published in February of this year concluded that sepsis is associated with more hospital readmissions than myocardial infarction and hearth failure.

Sepsis reduction and prevention is particularly relevant for outpatient and ambulatory settings. In August 2016 as part of its *Vital Signs* report⁴, the Centers for Disease Control and Prevention (CDC) concluded that approximately 7 in 10 patients with sepsis had used health care services recently or had chronic diseases that required frequent medical care. The report concluded that these ambulatory patient encounters represented opportunities for healthcare providers to prevent, recognize and treat sepsis long before it can cause life-threatening illness or death. Increased use of outpatient infection prevention strategies such as vaccination, and improved management of patients with chronic diseases were two of the strategies cited in the CDC report that can be used in ambulatory settings to reduce the onset of sepsis.

We note the inclusion of DRG 870 as the sole trigger code for this proposed cost measure, but we recommend adding DRG 871 *Septicemia or Severe Sepsis without Mechanical Ventilator > 96 Hours and With Multiple Chronic Conditions*, and DRG 872 *Septicemia or*

Severe Sepsis without Mechanical Ventilator > 96 Hours and Without Multiple Chronic Conditions as additional trigger codes. Though DRG 870 represents the most severe episodes of sepsis, these additional codes also capture very serious and costly episodes.

Thank you again for the opportunity to comment.

1 Am J Respir Crit Care Med. First published online 27 May 2015 as DOI: 10.1164/rccm.201503-0483OC

2 <http://www.thoracic.org/about/newsroom/press-releases/resources/Liu.pdf>

3 Proportion and Cost of Unplanned 30-Day Readmissions After Sepsis Compared with Other Medical Conditions, JAMA. 2017;317(5):530-531. doi:10.1001/jama.2016.20468

4 www.cdc.gov/vitalsigns/sepsis

COMMENT 50 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Howard Rogers, Physician, Advanced Dermatology

Text of Comment:

As a member of the MACRA Clinical Committee and a physician that treats melanoma frequently, I appreciate the opportunity to provide feedback on the melanoma treatment episode group and trigger codes, as well as your report, *Episode-Based Cost Measure Development for the Quality Payment Program*, to help inform the agency's ongoing efforts in developing cost measures.

Episode-Based Cost Measure Development for the Quality Payment Program

Episode Group Selection: Melanoma Episode

CMS' evaluation of episode groups resulted in the identification of melanoma treatment services to be considered for development. Specifically, CMS has included "Melanoma Destruction/Excision" on its draft list of MACRA Episode Groups.

I feel that CMS' terminology is not clinically accurate because destruction of melanoma is clinically contraindicated and not standard of care and there are no destruction codes in the trigger list. CMS should revise the name of this episode group to "Melanoma- Excision."

Episode Group Definition, Procedural Episode Groups & Cost Measure Development

CMS identified several CPT "trigger codes" as representing services associated with the melanoma episode group. I generally agree with the list of trigger codes; however, the codes 17312 and 17314 should be replaced because these are add on codes for Mohs surgery services and don't define the primary procedure and are thus not appropriate triggers. In their place, the Mohs surgery codes 17311 and 17313 should be used. I also believe the following CPT codes should be included as trigger codes: 14000, 14001, 14001, 14020, 14021, 14040, 14041, 14060, and 14061 because excision of cutaneous lesions is bundled within them. Exclusion of these cutaneous flap codes will result in missing many primary melanoma excisional treatments.

It is important to note that the listed episode trigger codes for the melanoma episode group are also used in the treatment of other skin cancers (e.g., non-melanoma), which means the episode trigger as listed will capture many treatments unrelated to melanoma. To address this, linkage of the CPT "trigger" codes to correct melanoma specific ICD10-CM diagnosis codes will be critical. Because CMS has yet to provide the relevant ICD-10-CM diagnosis_codes associated with the melanoma episode, it has inadequately defined the triggering rules to produce a homogenous disease model or a clinically relevant episode.

In addition, I recommend that CMS consider splitting the melanoma episode into subgroups based on staging and body site to create a more homogenous model. The most important clinical risk factor for poor patient outcome for cutaneous melanoma is histologic depth. However, thin and thick melanomas are coded with the same ICD-10-CM diagnosis code with significant variation in resource utilization and cost for the same diagnosis code. Body location of the melanoma {head and neck versus other sites} also portends significant differences in intensity of treatment and patient outcome.

Using subgroups based on body site and histological stage will allow for much more homogeneous groupers and consistent comparison of cost.

Attributing Episode Group Cost to Clinicians

Physicians that treat melanoma need a clear understanding of the attribution process. Dermatologists frequently diagnose melanoma and lead the care and management for the vast majority of their skin cancer. In addition, they often refer their melanoma patients to oncologists for further evaluation after surgical care. However, the dermatologist does not have control over what tests or treatments are performed by other specialists that become involved in the care. For physicians who take care of melanoma patients that require multispecialty management, attribution of costs could be a significant challenge. Physicians should only be held accountable for costs that are directly within their control.

Definition of Codes and Costs for Inclusion into the Melanoma Episode

Many patients who have melanoma also have synchronous and metachronous non-melanoma skin cancers. Nonmelanoma skin cancer treatment employs many of the same procedure codes as melanoma treatment but is unrelated.

Careful and sophisticated cost inclusion logic will be required to exclude the cost of non-melanoma skin cancer treatment in this episode.

Other issues

I recommend that CMS also provide more information about critical features of the melanoma episode including:

- The type of episode being considered (static or dynamic);
- What the exclusion criteria will be; and
- The length of the episode

With CY 2018 fast approaching and the weight of the cost performance category slated to increase, I urge CMS to provide answers to the aforementioned questions as soon as possible, which will afford a fair opportunity to review the planned cost measures and provide feedback to the agency prior to the implementation of episode groups in the MIPS cost performance category.

I appreciate the opportunity provide feedback and look forward to providing additional input on cost measurement for skin cancer care and treatment. I look forward to working with CMS and its contractor Acumen as part of the MACRA Clinical Committee on further developing this episode group into reasonable and appropriate cost measures of resource use by Mohs surgeons that is within their control.

COMMENT 51 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Steve Phillips, Senior Director, Global Health Policy, Johnson & Johnson

Text of Comment:

This letter is in response to the request from CMS for comments on episode group development included in the document “Episode-Based Cost Measure Development for the Quality Payment Program” as posted on the CMS web site <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Episode-Based-Cost-Measure-Development-for-the-Quality-Payment-Program.pdf>. CMS indicates 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). That 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). CMS indicates that this posting builds on feedback received in response to the prior solicitations on episode groups with a specific focus on episode construct, the codes that start the episode (“trigger codes”) and the overall concept of cost measure development.

J&J is the world’s most comprehensive and broadly-based healthcare company, delivering products and services for the consumer, pharmaceutical and medical devices and diagnostics markets. For more than 125 years, have we supplied the health system with a broad range of products and have led the way in innovation, beginning with the first antiseptic bandages and sutures. We are continuing this heritage of innovation today, bringing important new pharmaceutical products to market in a range of therapeutic areas, as well as developing important advancements in medical devices and new consumer products.

J&J is supportive of the movement toward value based reimbursement and recognize the importance in linking payment to efficient performance and the delivery of high quality outcomes. For example, we have been actively involved in the HHS Health Care Payment Learning & Action Network (LAN), and were the first life science products manufacturer to become a LAN Committed Partner. As we progress toward more value-based payment models

such as MACRA, it is important to maintain the proper balance between improved efficiency, quality care, and access to medical innovation. We believe there are several key principles that need to be included to ensure the ultimate reform goals are met:

- The goal of cost savings must be balanced with ensuring that quality patient care is not compromised;
- Ensuring patients have access to the care and providers most appropriate for their needs; and
- Maintaining access to innovative treatments.

We thank CMS for the opportunity to comment at this stage of the episode development process. In this solicitation CMS is requesting comments specifically on episode development for the MIPS cost category. Our responses below are primarily related to the specific questions listed in the solicitation document related to Cost Measure Development.

Approach to Soliciting Public Comment, Data Transparency and Pilot Opportunities

We appreciate the lengths to which CMS has gone to engage external stakeholders in MACRA education. J&J has participated in a number of CMS MACRA events and webinars and we appreciate the opportunity to ask questions and learn from the process. In regards to the episode development process there are a couple of areas that would benefit from improvement.

For example, while the new Quality Payment Program website <https://qpp.cms.gov/> is very well organized with a clear inventory of educational materials and indexed webinars, it's challenging to find the key documents on which CMS is currently seeking comment in regards to this solicitation on episode development. Many stakeholders were not aware of the release of this December, 2016 solicitation until well after December. Moreover, it is hard to tell when the companion episode Excel files were last updated and when a file is superseded by another, when both versions are on the web site (e.g., the Draft List of MACRA Episode Groups and Trigger Codes, compared to the Supplemental Episode Groups, at:

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

Importantly, we don't want key clinical stakeholders to miss the opportunity to nominate candidates for the sub-panels on episode development. Going forward, we recommend CMS also use the QPP website, and the associated email updates to sequentially post all the important work germane to the MIPS cost measures and episode development efforts.

In regards to data transparency, it's clear that CMS is spending a significant amount of time thinking through the components of episode development. It is far less clear how CMS is actually going to calculate the cost component score in 2018 and beyond. While, recognizing that episodes will only be one component of a blended cost composite score that also takes into account other traditional Medicare cost measures from the value based modifier, the precise calculation is not clear.

More generally, it remains unclear for many stakeholders how the final episodes will be constructed. These details were not disclosed on the recent MIPS Cost Component and Episode Development webinar. As CMS has decided to start with 10 episodes for the inaugural MIPS

year, with no weighting but for the purpose of data sharing, we recommend CMS provides a deep-dive on the approach to episode development for these ten measures, including walking through a couple of test cases of the complete calculation.

CMS Questions on Cost Measure Development

“Should concurrent or prospective risk adjustment be used, and should a full year of data or more targeted data from before the episode be used to adjust?”

CMS recognizes in the document the importance to not penalize physicians who treat sicker and more complicated patients than average. Sound risk adjustment methodology is needed to appropriately account for significant variation in cost of episodes that may in part be attributed to beneficiary demographics and health conditions (illness severity and complications) and other factors outside of the control of the attributed clinician being measured.

We understand the point raised by CMS that the Hierarchical Condition Categories may not accurately capture specific risk factors within discrete episodes. However, so far it has not been transparent how much variability exists within episodes that relates to patient characteristics and, therefore, whether risk adjustment is needed. We recommend CMS be much more transparent about the cost variability physicians face (risk) within episodes, and how it plans to adjust for that risk, before implementing future cost measure episodes.

“CMS is especially interested in comments regarding methods to align quality of care with cost measures and welcomes recommendations and suggestions.”

We appreciate that CMS acknowledges that “measures of quality need to be considered along with measures of costs in order to avoid the unintended consequences of incentivizing stinting on care (page 11 of the document).” In order to provide more transparency into CMS’ methods to align quality and cost measures, we recommend including a list of relevant quality measures for each episode cost measure. This would facilitate an assessment of whether there is sufficient alignment to protect patients from stinting.

We recognize in both the proposed and final MACRA rules, CMS has emphasized the importance of outcomes measures, as well as “high priority measures” in the approach to developing the overall MIPS composite score. However, within the overall MIPS composite score it remains unclear how the measures submitted to achieve success for the quality component are aligned, or measured against episodes that will be used to assess the cost component score to directly compare cost and quality outcomes for conditions and procedures.

For certain types of episode groups, for example, a procedural episode group where there are clearly defined available measure sets, the linkage of the cost and quality categories may be more direct. For procedural episodes where there is not a clearly defined measure set (i.e. hip fracture), the approach to directly measuring cost to quality outcomes is less straightforward. The same could be said for the acute inpatient and chronic care episodes. We recommend CMS continue to work with the appropriate clinical experts and medical societies to identify quality measure gaps and to develop verified measures, where no appropriate measure exists.

“CMS wishes to avoid any unintended consequences of using cost measures in MIPS, and seeks comment on issues of concern in this regard.”

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 recognized, however, that medicine is a quickly evolving field and any payment system needs to accommodate innovation. For example, breakthrough treatments that change, or even eliminate, the long-term course of treatment may be costlier within a short-term episode than existing therapies.

Episodes defined on the basis of historical costs could discourage adoption of a breakthrough treatment, thus some mechanism to recognize meaningful innovation is needed. We recognize this issue is not a primary consideration of the initial definition of clinical episode groups, but it is an important consideration that will need to be addressed as CMS goes forward. Specifically, we request that CMS provide more information on how episode pricing will account for meaningful innovation in defining episodes and specifically the methodology (add-on or other approach) CMS will use to account for breakthrough treatments. For an example of such an approach, we would point to the Adjustment for Novel Therapies under the CMMI Oncology Care Model.

“What would be the best way to incorporate Part D costs into the episode group development?”

Section 1848(q)(2)(B)(ii) of the Act recommends accounting for the costs of Part D drugs as appropriate and feasible under the resource use performance category. We understand per the Final MACRA rule that CMS is still analyzing how best to include Part D drug costs in episode development. We strongly recommend CMS begin to include Part D costs within the resource use performance category starting with the second performance year (2018).

Currently, all Medicare Part B costs, including Part B drug and drug administration costs, are included in the resource use measures, while Part D drugs are excluded. Such an inconsistency is problematic for two reasons. First, the exclusion of Part D drugs presents an incomplete picture of the true healthcare costs for many Medicare patients. Second, it complicates and distorts comparisons of resource use among providers treating patients with conditions for which both Part B and Part D medicines are available.

This problem has been illustrated in multiple specialty areas, especially rheumatology and gastroenterology where both Part D and Part B drugs have indications for treatment of the same condition. This is of particular concern when a patient receives a Part B drug for reasons of clinical efficacy, adherence and safety. Specifically, quality of care concerns over “non-medical switching” of therapeutic interventions are well-documented, particularly for biologics.

Considering the MACRA requirement to account for the cost of drugs under Part D as appropriate and feasible, and with the inaugural MIPS performance year looming, the time is now to get this right and implement a solution that will account for the costs of Part D drugs. We have met with CMS previously to present what we believe is a viable solution (originally described in the attached report by The Moran Company). Here is a description of the recommended approach from The Moran Company report, which could be implemented using data CMS will have available from the proposed 2017 benchmark period:

“We recognize that Medicare does not pay for Part D drugs at the level of an individual drug, in a manner comparable to payment for Part B drugs. The policy function performed by a national average valuation mechanism for Part D drugs is to incorporate the value of these drugs into total

per capita cost constructs that are used in value based payment resource use metrics, and in historical target pricing for APMs. CMS currently includes average negotiated price in its Part D data released to the public. This amount results from negotiations between plans and pharmacies, and reflects the gross amount paid for a drug by plans and beneficiaries. As a result, it is somewhat parallel to 106% of ASP for Part B drugs administered in the physician office.

Average negotiated price is limited in that it does not include retrospective rebates received by plans from manufacturers. While CMS receives some information from plans on rebates they receive from manufacturers, not all of these rebates are necessarily tied to specific drugs, and many rebates are used to reduce Part D premiums—rather than the price tied to particular drugs at the point of sale. Moreover, CMS is limited in its ability to use reports it receives on rebates from Prescription Drug Plans. Thus, even if the agency could calculate accurate average rebate amounts at the level of individual Part D drugs, it might not be able to use those amounts publicly.

One potential solution to this conundrum would be to apply national averages for Part D rebate amounts, at whatever level of granularity is accurate—and permissible in light of the agency’s statutory mission. For instance, it might be advisable to calculate different levels based on brand versus generic drugs or in other situations where market dynamics create materially different incentives for rebates. The agency could also consider whether rebates vary based on the costs of drugs in question or based on other factors that could be measured and reported without violating proprietary concerns of plans and manufacturers.”

According to the Medicare Payment Advisory Commission, 23% of Medicare beneficiaries have prescription drug coverage from a source outside Medicare (e.g., retiree coverage from a former employer). CMS has indicated its concern that including Part D data would incorrectly indicate higher costs for beneficiaries with Part D coverage relative to otherwise comparable beneficiaries without such coverage and for whom prescription drug costs cannot be measured directly by CMS. To address this issue, CMS could create benchmarks for resource use for beneficiaries enrolled in Parts A, B & D separately from those enrolled in Part A & B. This approach would facilitate comparisons across practices with different proportions of patients with Part D coverage.

We believe CMS can implement these approaches in the final rule subsequent to this proposed rule, and use 2017 data when the MIPS adjustments are calculated for 2019. Until CMS is able to include Part D costs it should not proceed with implementing episode-based models where patients are treated with both Part B and Part D drugs. This is particularly relevant in certain specialty areas such as rheumatology and gastroenterology.

Thank you for the opportunity to provide input into your process. We would welcome the opportunity to discuss MIPS cost measures in greater detail.

COMMENT 52 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Carolyn C. Ha, Director, Policy & Research, Pharmaceutical Research and Manufacturers of America

Text of Comment:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to provide our perspective in response to the request for input on Episode Groups and Cost Measure development published by the Center for Medicare & Medicaid Services (CMS). PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives.

The Merit-Based Incentive Payment System (MIPS) established by the Medicare Access and CHIP Reauthorization Act (MACRA) creates new demand for robust measures of both quality and resource use. PhRMA is committed to advancing solutions that promote the transition to a value-driven and patient-centered health care system. Development of sound measures of resource use and appropriately linking them to relevant quality measures is particularly important in view of the ways that these measures shape incentives for care quality, treatment selection, and patient access to care.

However, CMS continues to face a dearth of reliable, actionable, and consensus-based resource use measures for use in the MIPS program. While CMS has some experience with measures of resource use as part of its value-based modifier program, stakeholders have identified numerous methodological concerns with these measures, including that they are not meaningfully and actionably linked to relevant quality measures. Resolution of these challenges is imperative to ensure that the MIPS program is successful in driving towards high quality, patient-centered care.

Accordingly, we appreciate CMS' attention to the issue of meaningfully linking cost and quality through this comment solicitation. We agree that obtaining public input and feedback is of critical importance to these efforts. We respectfully offer the following comments for your consideration as you assess resource use measures for adoption in the MIPS program.

1. Link resource use measures to relevant quality measures.

As CMS implements the quality and resource use components of MIPS, it should ensure that when cost measures are used, they are appropriately balanced with robust measures of quality and patient outcomes. In particular, any cost measures used should be reported in the context of appropriate quality data as a means of providing a framework for interpretation so that the cost data are not misused or misunderstood. In such a framework, cost measures must be aligned with the reported quality data to make the comparison between quality of care provided at cost expended an apples-to-apples comparison. Application of raw cost measures in the absence of meaningfully linked quality data could result in reduced provision of needed care and decreased adoption of new medically beneficial treatments in an effort to stem costs, especially when applied in an incentive program.

As a first step to meaningfully linking cost and quality measures, CMS should consider being more prescriptive in the type, number, and caliber of measures that providers report under MIPS. Currently, providers choose from among the full set of MIPS quality measures, which makes it very challenging to consistently link quality scores to resource use measures in a meaningful and

actionable way. CMS also noted that another potential strategy for aligning cost measures with quality of care could pair episode group costs with quality measures sharing similar characteristics, and including indicators of patient outcomes, such as functional status, that are interpreted along with cost. We recommend that CMS conduct a crosswalk between the current landscape of quality measures with the three types of episode groups in order to determine measure gaps and identify priority areas for outcomes-based measure development.

It will be particularly important for CMS to continue to assess the availability and caliber of quality measures addressing episode group conditions as it develops policy in this area. For example, CMS is considering episode measurement for rheumatoid arthritis patients, and a recent analysis found that of 52 quality measures identified for rheumatoid arthritis, 100 percent were process measures and did not address patient outcomes, and only 6 measures had received endorsement from the National Quality Forum (NQF).¹

2. Select resource use measures that have achieved consensus endorsement.

In selecting resource use measures for MIPS, CMS should continue to rely on measures that are supported by multi-stakeholder consensus, such as those measures that have been endorsed by the NQF. Measures that have attained NQF endorsement have successfully undergone the rigor of careful testing, validation, and scrutiny to ensure that they provide accurate, reliable, and meaningful results; have been subjected to external review; and are published for public review and comment. Multi-stakeholder consensus endorsement processes, like NQF's, provide a validation of the rigor of the measure.

By the same token, we note potential room for improvement in the measure endorsement and adoption process. In particular, several stakeholders have expressed concern that recommendations issued by NQF and its Measures Application Partnership are not always addressed by measure developers prior to endorsement or adoption in a CMS program. To address this issue in part, NQF is piloting a mechanism to gain more feedback on the implementation experience with these measures. We expect this process to yield valuable input that can inform measure maintenance and future CMS policy.

In addition, PhRMA is cognizant that NQF-endorsed measures are not always available and that MACRA gives CMS significant flexibility to incorporate measures that are not NQF endorsed into the MIPS program. We also recognize and appreciate the promise of Qualified Clinical Data Registry (QCDR) measures as a new source of quality measures and data for the MIPS program and Alternative Payment Models (APMs). As more clinicians elect to use the QCDR reporting option, it will continue to be important to ensure that QCDR measures are methodologically rigorous and evidence-based. We remain concerned by the lack of opportunity for other stakeholders to provide input into the development of those measures. While we recognize that NQF endorsement is not a requirement for QCDR measures under MACRA, we encourage CMS to work with QCDRs to improve the transparency of the measure development and evaluation process for measures included in QCDRs.

CMS must seek to balance the need for the rapid development and deployment of measures for MIPS and APMs with the imperative that measurement be valid and accurate. In instances where non-endorsed measures are used, we believe that they should go through a rigorous, transparent

development and evaluation process like the one described above. Accordingly, we are pleased to see that CMS plans to provide several additional opportunities for public comment as its efforts to refine the episode groupers evolve.

3. Gradually phase-in MIPS resource use measures.

MACRA gives CMS the flexibility to adjust the quality and resource use weights to increase the quality weight and reduce the resource use weight in the first two years of MIPS. In year one, CMS must assign quality measures a weight between 50-60% of the MIPS composite score (with resource use weighted between 0-10%, such that the two weights total to 60%). In year two, CMS must assign quality measures a weight between 45-60% of the composite score (with resource use weighted between 0-15%, such that the 2 weights total to 60%). We recommend that CMS continue to exercise this flexibility to maximize the portion of the MIPS score derived from quality measures in the first two years of MIPS (60%). Doing so will give CMS the time it needs to develop a more sophisticated approach to resource use measurement with clear linkages to quality scores, and will help ensure that incentives based on these measures are well-aligned with high-quality, individualized care.

While we support a continued gradual phase-in of cost measures, we also note that there are still underlying methodological issues related to resource use measures that may take more than 2 years to fully address. For example, a number of challenges remain with attributing patients to physician practices for reliable resource use measurement; one study found that relatively few primary care physician practices are large enough to reliably measure 10 percent relative differences in common measures of quality and cost performance among fee-for-service Medicare patients.² In addition, we appreciate that providers would benefit from having some experience with reporting cost measures prior to CMS applying the full weighting of 30 percent. We encourage CMS to carefully consider these challenges and consider additional means of offering reporting flexibility for resource use measures as it continues implementation of the MIPS program.

4. Recognize patient heterogeneity within episodes.

PhRMA encourages CMS to carefully consider the level of complexity and patient heterogeneity prior to initiating development of new episodes. CMS should also ensure that episode-based resource use measures include mechanisms to account for patient heterogeneity, such as robust risk adjustment and adjustment for outlier cases. As CMS notes, Medicare beneficiaries often have multiple co-morbidities that complicate care episodes. Even within a single clinical area, it can be extremely difficult to define an episode of care and accurately attribute services to the episode. An analysis of commercial tools that created episodes for community-based diabetes and coronary artery disease care found significant differences between available tools, highlighting these challenges.³ The fact that care intensity for more complex conditions may be dependent on patient specific characteristics adds to the challenge of accurately defining episodes for many conditions.

5. Promote balanced incentives for use of medicines while avoiding disruptions to the Part D benefit.

Development of resource use measures for MIPS will require consideration of several complex issues, including how these measures reflect spending on medicines covered by Medicare Parts A and B, and potentially Part D. MACRA specifies that the resource use component of MIPS shall account for the cost of drugs in Part D, as feasible and applicable. As PhRMA has noted in previous comments, including spending for medications in resource use measures is challenging, particularly for medicines covered by the Part D outpatient prescription drug program. CMS must take care to avoid creating disincentives for patient access to medicines that are most appropriate for individual patients irrespective of whether those medicines are provided under Medicare Part A, B, or Part D, and also avoid creating uncertainties for Part D plans that would undermine the competitive bidding system. We urge CMS to work transparently and collaboratively with health care stakeholders as it wrestles with these difficult issues.

PhRMA appreciates the opportunity to provide input into the CMS episode groups and considerations for measuring resource use. Please do not hesitate to reach out if we can answer any questions about our comments.

1 Avalere Health, LLC. Quality Report for Rheumatoid Arthritis. August 2016. <http://avalere.com/expertise/life-sciences/insights/quality-report-for-rheumatoid-arthritis>

2 David J. Nyweide, PhD, William B. Weeks, MD, MBA2, Daniel J. Gottlieb, MS, Lawrence P. Casalino, MD, PhD, and Elliott S. Fisher, MD, MPH. "Relationship of Primary Care Physicians' Patient Caseload With Measurement of Quality and Cost Performance." JAMA. 2009 December 9; 302(22): 2444–2450. doi:10.1001/jama.2009.1810.

3 David J. Nyweide, PhD, William B. Weeks, MD, MBA2, Daniel J. Gottlieb, MS, Lawrence P. Casalino, MD, PhD, and Elliott S. Fisher, MD, MPH. "Relationship of Primary Care Physicians' Patient Caseload With Measurement of Quality and Cost Performance." JAMA. 2009 December 9; 302(22): 2444–2450. doi:10.1001/jama.2009.1810.

COMMENT 53 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Ira H. Kraus, President, American Podiatric Medical Association

Text of Comment:

On behalf of the members of the American Podiatric Medical Association (APMA), the national organization representing the vast majority of the estimated 15,000 podiatrists in the country, we welcome the opportunity to submit input on the proposals in the Episode-Based Cost Measure Development for the Quality Payment Program.

Acute Inpatient Medical Condition Episode Groups

We appreciate the broad nature of several of the Acute Inpatient Medical Condition Episode Groups such as "Cellulitis", "Diabetes", "Osteomyelitis", and "Peripheral Vascular Disease" and would like to clarify that there will be a place for podiatric physicians and surgeons to participate within those Episode Groups. For example, podiatric physicians and surgeons frequently provide care for acute inpatients with these conditions. Diabetic patients with a foot ulcer may be admitted to the hospital with any of the conditions listed above and may require intervention provided by a podiatric physician and surgeon. With future processes in Episode-Based Cost Measure Development, are there opportunities within the already selected Episode

Groups to narrow the scope to provide specific instances where podiatric physicians and surgeons can participate (e.g. cellulitis of the foot, diabetic foot infection, osteomyelitis of the foot, ulcer of the foot secondary to peripheral vascular disease)? With this, we would also like to clarify as to whether diabetic limb salvage fits or will fit into one of the already provided Acute Inpatient Medical Condition Episode Groups. Podiatric physicians and surgeons care for diabetic patients when complications associated with the foot and ankle arise. Diabetic foot complications, like foot ulcerations, are costly in and of themselves, but often lead to infection, hospitalization and amputation, which are also very costly to our system and result in poor quality of life for our patients. We would like to start the conversation regarding the overall cost of diabetic foot complications, as described above, as we believe it could be a significant share of Medicare's expenditures. Diabetic foot complications also likely offer opportunity for improvement in care, the establishment of multidisciplinary care teams and outcome measures regarding quality of life and healing (ulcer or amputation site).

We strongly support the idea of creating an Acute Outpatient Medical Condition Episode Group. An example would be "Cellulitis" to mimic the Inpatient Episode Group. Podiatric physicians and surgeons see cellulitis frequently and if caught early enough can treat this acute condition as an outpatient and avoid a more costly hospitalization or a worse patient outcome such as amputation. The cost savings associated with outpatient treatment of an acute condition should be considered in this program. If the condition is not treated as an outpatient, the patient may end up with a hospitalization and more costly and lengthy treatment. As above, we would like to see information on Medicare expenditures to see where there might be opportunity for podiatric physicians and surgeons to be involved in the program.

Chronic Condition Episode Groups

Regarding the Chronic Condition Episode Group and thoughts on assigning treatment to conditions and adjustment, we agree this will be challenging and are supportive of the discussion of adjustment. The single episode group for outpatient chronic care that could be adjusted for comorbid conditions and demographics sounds the most promising at this time. Trying to separate out by such specifics (like the example provided in the materials – diabetes, hypertension, coronary artery disease) limits the number of people in each category, which could lead to issues in the future of not having enough people in any one category to compare.

Like the example provided that addresses cancer staging and the differences in cost, diabetic foot ulcerations can also be staged, with higher stage ulcers being more costly due to their need for advanced modalities (frequent debridements, synthetic grafts, advanced imaging, IV antibiotics, incision and drainage, amputation, hyperbaric oxygen therapy, and peripheral vascular intervention). Staging ulcerations can aid in predicting healing and could potentially aid in predicting cost. A staging system such as The Society for Vascular Surgery's Wound, Ischemia, and foot Infection (WIFI) classification predicts wound healing and could help delineate cost based on stage of ulceration, with future cost data.. Adding an additional code would be possible, although burdensome, and providers will need to be appropriately educated and encouraged to participate.

Procedural Episode Groups

Regarding the Procedural Episode Groups, we would like CMS to consider adding procedural codes associated with caring for diabetic foot infections, such as incision and drainage, surgical debridements and amputations (diabetic limb salvage).

In addition to expenditure assignment, attribution, risk adjustment and consideration of quality, cost measures will need to be closely and appropriately associated with quality measures. We must ensure the quality or outcomes measures associated with the cost measures are actually measuring what they are intended to measure. Outcome and quality measures will need to be developed and refined carefully to ensure that care is not being withheld as a means of cutting costs. Regarding attribution, we ask that CMS consider a scenario where the provider triggering the code to begin a cost episode may not be the provider making decisions that could drastically increase the cost of the episode. For example, a podiatric physician and surgeon may be involved in a patient's care and use the procedural trigger code that starts the cost episode. In the acute inpatient setting, a hospitalist may take over all but post-operative care of that patient and be driving the cost of that episode. We ask for clarification on such a scenario. We feel as though each episode should be evaluated for attribution rather than having any fixed percentages of the overall episodes being attributed to a particular specialty.

We agree that aligning cost measures with quality measures could have the unintended consequence of stinting care and wish to be part of future conversations and quality measure development.

Risk Adjustment

We support the conversation regarding risk adjustment for comorbidities and demographic information but do not have any comment on the CMS-HCC Risk Adjustment Model or alternative models. Depending on location and patient demographics, podiatric physicians and surgeons could be disadvantaged regarding their cost measure reporting for the MIPS program. Incorporating information regarding socio-economic status, level of education, etc. in addition to medical complexity will be important regarding comparison of outcomes.

Sub-Grouping

For many of the procedural codes relevant to podiatric physicians and surgeons, the codes themselves provide fairly adequate sub-grouping. Similar to the example provided (spine surgery with multiple levels), we would like to see sub-grouping for instances where multiple foot bones might be fractured or multiple toes may have a procedure performed on them as this will increase cost associated with operating room time and equipment/implants. Another example would be for patients with cellulitis; a sub-grouping based on presence of ulceration or lack thereof would be helpful as well as sub-group based on presence or absence of diabetes. The presence of an ulcer and diabetes can change the length of treatment and outcome drastically. We do support the use of sub-grouping to ensure the patients being compared are as alike as possible.

Provider engagement and education will be imperative for successful participation and understanding of the Cost Measures. We thank you for the opportunity to submit comments regarding Episode-Based Cost Measures and look forward to future participation in the discussion.

COMMENT 54 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Stephen A. Tilles, President, American College of Allergy, Asthma, and Immunology

Text of Comment:

The Advocacy Council of the American College of Allergy, Asthma and Immunology (ACAAI), together with its sponsoring organization, the ACAAI, appreciate this opportunity to provide suggestions for improvements on the proposed Patient Condition Groups and Care Episode Groups that were posted on the CMS website on December 23, 2016.

The Advocacy Council and the ACAAI represent the interests of over 6,000 allergists-immunologists and allied health professionals. Allergists –immunologists specialize in diagnosing and treating patients with allergic diseases and conditions including chronic conditions such as asthma which affects approximately 24.6 million individuals and allergic rhinitis which affects over 50 million individuals in the United States. Therefore, we are very concerned that episode groups and patient condition codes be as accurate as possible when it comes to caring for patients with chronic disease.

We commend CMS for its efforts to implement the many complex requirements of the Medicare Access and CHIP Reauthorization Act within the short time frames established by the statute. However, we are concerned that CMS' proposed approach will not provide the type of detailed information that is needed to assess physician performance for purposes of the Merit-Based Incentive Payment System (MIPS) or provide the type of information needed by APMs.

Care Episode Groups

The episode groups proposed by CMS are based largely on current claims data including ICD-10 codes for chronic conditions, HCPCS codes for procedures, and DRG codes for acute inpatient medical conditions, with adjustments for demographics and comorbidities. While we appreciate the importance of not adding new layers of complexity to the coding process, we do not think that this approach will be sufficiently accurate or reliable for purposes of holding physicians accountable under MIPS or for helping APMs gather the information they need.

The CMS proposal would seem to establish a single episode group for all phases of care provided for chronic conditions. However, patients with chronic disease, such as asthma, need very different kinds of services depending on the phase of care or disease stage. Our organization is developing an alternative payment model (APM) focused on a bundled approach to patient-centered asthma care that we intend to submit to the Physician-focused Payment Technical Advisory Committee (PTAC) by June 1, 2017. (Our Letter of Intent was sent on March 10, 2017.) That APM would distinguish between two distinct phases of care: diagnosis and initial treatment and continued care with each being treated as a separate care episode for purposes of payment. We believe episode groups need to account for the different phases of care and urge CMS not to lump distinct phases of treatment into a single episode group.

Patient Condition Codes

Patient characteristics that impact costs of care differ depending on the condition being treated. For that reason, it is important to establish patient condition codes using comorbidities and other factors that are relevant to the particular condition being treated. We do not believe the CMS HCC risk adjustment system used in the Medicare Advantage program is the best way to identify risk or severity of the patient's condition. Rather, patient condition codes should be designed to

capture those comorbidities that impact patient severity with respect to the specific disease being treated.

In the asthma care APM being developed by our organization, we have stratified severity of disease into four categories for the “Continued Care for Difficult-to-Control Asthma” phase of care based, among other things, on the presence of specific comorbidities. Although not finalized, the subcategories in our working draft are the following:

Subcategory	Billing Code	Patient Characteristics
Level 1	xxx21	Well controlled asthma, but with comorbidities and/or medications requiring special management
Level 2	xxx22	Not well controlled asthma (symptoms > 2 days/week, etc.)
Level 3	xxx23	Very poorly controlled asthma (daily symptoms, etc.) or Not well controlled asthma with significant comorbidities
Level 4	xxx24	Very poorly controlled asthma with significant comorbidities

We believe these categories, which were created by experts in asthma care, are much better predictors of resource use than the HCC risk adjustment system. We strongly urge CMS to work with specialties that are developing or have submitted APMs and include any disease specific patient condition categories they have developed as it implements both the MIPS and APM pieces of MACRA.

We thank you for considering our recommendations and we look forward to working with CMS as this process continues.

COMMENT 55 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Robert Coughlin, Reimbursement Manager, Moffitt Cancer Center

Text of Comment:

Moffitt Cancer Center appreciates the opportunity to submit comments in response to CMS development of episode cost measures that are part of the Merit based Incentive Payment System (MIPS).

Moffitt Cancer Center is the only National Cancer Institute-designated Comprehensive Cancer Center based in Florida, a state which ranks #2 in the nation for cancer incidence and mortality. Moffitt provides cancer care to residents of all 67 Florida counties and all 50 states, producing superior outcomes for survival, quality of life and patient satisfaction. We treat more than 50,000 individual patients each year, a large percentage of which are Medicare beneficiaries. We also maintain active collaborations with health care providers and research institutions across the U.S. so that we might help elevate the standard of care for all those diagnosed with cancer.

Below is specific feedback to several questions CMS raised in its recent "Episode-Based Cost Measure Development for the Quality Payment Program" posting.

Risk-Adjusting Episode Groups

Moffitt agrees that it is critical for CMS to adjust for factors that can influence expenditures but are outside a clinician's control. For example, patients differ in their severity of illness, functional status, age, type and number of comorbidities and chronic conditions, etc. These patient-level risk factors must be taken into consideration in any risk adjustment methodology that is used. Additionally, accounting for patient complexity and health status, including chronic conditions, is critical to ensure that clinicians who treat particularly complex patients, such as cancer patients, are not penalized.

Although CMS uses the Hierarchical Condition Categories (HCCs) risk-adjustment methodology to adjust episode-based costs for its Medicare Advantage population, we agree with CMS' view stated in the document that an *alternative approach to reduce heterogeneity within an episode may need to apply with respect to this episode work so that comparisons of like patients can be made. We believe this is particularly true for cancer patients and therefore urge CMS to implement its methodology in a way that ensures valid and reliable comparisons between providers based on "like" patients. Moffitt further believes that CMS should apply a specialized risk adjustment methodology to cancer, grouping "like" patients based on procedures and cancer site. We believe that comparisons between patients with and without a cancer diagnosis as well as comparisons among patients with different cancer diagnoses can lead to erroneous conclusions about resource utilization and costs.*

Regarding the CMS-HCC Risk Adjustment, this model does not appear to adequately accurately capture and adjust for differences in patient acuity and complexity. This is especially true, when applied in the context of assessing the resource use of practitioners who are based at a tertiary cancer center with a highly complex patient population.

Equally concerning, is the failure of a prospective model to capture or adjust for the resources used by newly diagnosed cancer patients during the performance period. Patients with newly diagnosed cancer are all but guaranteed to significantly exceed the predicted costs assigned by prospective HCC risk adjustment.

Our review of the 2015 data for all Medicare beneficiaries attributed to Moffitt providers under the Value Modifier program (which employs prospective adjustment using the CMS-HCC methodology) demonstrate that the CMS-HCC model has very poor predictive value when applied to our patient population.

Given the poor ability of CMS-HCCs to explain variation in the total cost of care, Moffitt believe CMS must assess alternative risk adjustment methodologies - including but not limited to the 3M Clinical Risk Group (CRG) or HHS-HCC models- would present a more accurate and reliable solution. Both the CRG and HHS-HCC models offer greater specificity, i.e., more diagnoses and risk categories, than the CMSHCC model, which may allow for a more accurate comparison of like patients. Regardless of which methodology is employed, the use of concurrent data will help ensure the best possible level of accuracy.

Attribution

As noted in CMS 's recent document, attribution of inpatient episodes to a single provider is extremely challenging; particularly when a primary care physician, specialist and hospitalist all may have been involved in the patients care.

We understand that MACRA requires new patient relationship categories and codes to be reported as of January 1, 2018. Since the information has not yet been released, we are unable to provide feedback to CMS on how the codes should best be incorporated into its attribution model but would be pleased to do so once CMS releases the information.

Episode Definitions

Moffitt notes that CMS has focused the proposed episodes on acute hospitalizations that are short-term and chronic conditions that are long-term. However, cancer is more of an "episodic" illness, which may not last over 12 months like a chronic condition, but are not as short in duration as traditional acute care episodes. Cancer treatment is often characterized by diagnosis, acute treatment, and resolution or the progression to second- and third-line treatments and the potential development of additional cancers. We suggest that CMS create separate episode-based cost measures to best represent episodic treatments like cancer for comparison with "like" services.

We also request that CMS disclose how it plans to define and treat outliers. For example, will outliers be excluded from the cost calculation? We also question whether patients on clinical trials will be included, excluded, or treated as separate subgroups?

Finally, we are concerned that oncologists maybe held accountable for cost of cancer care for patients who are defined with another acute or chronic condition. This is not appropriate.

Moffitt is also concerned about how CMS proposes to define "complex cancer patients." These could be patients with multiple cancer diagnoses, with rare cancers, with a higher cancer stage, or a combination of these. It is difficult to assess these elements and to risk-adjust them appropriately at this time. Therefore, we recommend that CMS first implement systems to capture this information and test those systems using various risk-adjustment methodologies.

Implementation Timing

Given the number and nature of the questions associated with the development and refinement of the MIPS cost measures, we recommend that CMS delay implementation. We suggest that the cost category not be factored into the final MIPS score until payment year 2021 or 2022. In other words, we encourage CMS to keep the cost category weighted at zero percent (0%) of the MIPS

final score until it has better data to use. This would also give clinicians more time to understand the cost measures and attribution methodology.

The Moffitt Cancer Center appreciates the opportunity to provide input into the development of MIPS cost measures. We would be happy to answer any questions or provide additional details.

COMMENT 56 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Cynthia R. Moran, Executive Vice President, American College of Radiology

Text of Comment:

The American College of Radiology (ACR), representing more than 36,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the Request for Information (RFI) regarding episode-based cost measure development. The ACR remains committed to working collaboratively with CMS and others to develop and share meaningful recommendations on the episode groups and the role of radiology as episode groups evolve under the Merit-based Incentive Payment System (MIPS) cost category.

General Comments:

ACR supports high value, evidence-based care that aligns with the Triple Aim of better quality, lower costs and better care for patients. Therefore, for the value of care to improve across the healthcare delivery system, CMS must ensure that the role of specialists is recognized and incentivized. The ACR has developed, and will continue to improve clinical tools used to encourage the appropriate use of imaging and expand communication between radiologists and referring clinicians. These tools support radiologists in controlling costs and improving patient care, as well as contributing to the success of alternative payment models.

We have reviewed the Episode Groups in Appendix A and support the concept of expansion and diversification, as well as the subsequent process of including these into a physician's overall cost score for MIPS. The ACR has concerns that several of the suggested categories may be too broad, while others are too narrow for accurate comparison of clinician resource use. Given that the proposed episodes do not currently have associated relevant diagnoses, relevant service and sequelae codes assigned; it is difficult to comment further on whether these proposed episodes will provide an accurate and fair assessment of resource use. The ACR appreciates CMS' expansion of the episode groups to 119, almost twice those initially proposed; however, we are concerned that this rapid expansion could impact the quality of cost measurement. The process being used for episode group development lead by Acumen had multi-specialty input, however, this input occurred in silos without the ability for subject matter experts to collaborate. The ACR believes that collaboration in clinical practice will be key to controlling cost and necessary in developing episode group cost measures.

Radiologists and Episodic Cost Measures

The ACR believes it will continue to be a challenge for CMS to define and attribute costs to radiologists within any of the finalized or proposed episodes. However, radiologists contribute to resource use and cost in ways worthy of recognition under the Cost performance category which may inform future alternative measures for assessment. We provide the following examples for your consideration as CMS continues to work on further episode development:

Radiologist currently have two MIPS measures in the “Quality” category of MIPS which seek to encourage appropriate follow-up recommendations for incidentally detected lesions in the thyroid, liver, kidneys, and adrenal glands. Adherence to these guidelines can be measured, potentially providing a disincentive to more frequent and potentially inappropriate downstream advanced imaging studies. The concept of measuring a radiologist on the use of cost effective best practice guidelines is an area of potential opportunity not only in the “Quality” category of MIPS, but may also be of value in informing MIPS.

For resource use, CMS should recognize the role that a diagnostic radiologist plays in imaging clinical decision support (CDS) and associated consultation with a referring provider regarding the most appropriate imaging to utilize. Not only does this consultative service assist in stewarding of resources, it also promotes care coordination, and focuses on what is best for each patient. CDS can play a role to measure resource use, rewarding the radiologist for informing the provider to not order an inappropriate study, thereby saving resources.

- Appropriate imaging recommendations for “incidentalomas” (over-diagnosis) (too many, too often)
- Use of prior outside images from an unaffiliated institution to avoid duplicative exams
- Imaging appropriateness (actionable when done as a team with referring physicians, e.g. appropriate use of CT for headache in concert with neurologists using a similar measure, or in a facility setting)

Conclusion

The ACR supports the current and newly developed episode groups and appreciates being part of the process. We look forward to seeing more details about the episode groups and the episode-based cost measurements development process moving forward. The ACR offers the attached responses to the questions posed by CMS. We appreciate this opportunity to comment.

QUESTIONS FOR PUBLIC COMMENT

This posting seeks input on the accompanying episode groups recommended for development and their associated episode triggers. We also request comment regarding the approach to developing cost measures that are based on episode groups. Subsequent postings and stakeholder outreach will be used to solicit feedback on additional aspects of cost measure development, such as clinician attribution for care episodes. The following section presents some specific questions as examples of the topics on which we seek stakeholder input. CMS welcomes a wide

range of public comments. These specific questions are included to highlight some of the pertinent issues and are not designed to restrict or limit commentary

Episode Group Selection

- In selecting the episode groups to be considered for development, CMS used criteria including an episode's share of Medicare expenditures, clinician coverage, and the opportunity for improvement in acute, chronic, and procedural care settings. We welcome comment on these episode groups and potential additional episode groups that should be considered for development.

In order to suggest additional episode groups that would meet CMS requirements for development, we would greatly appreciate more insight into how exactly CMS used the criteria specified in the comment above to determine which episode groups should be developed.

Episode Group Definition

- The episode groups that accompany this posting are defined by the list trigger events and codes (CPT/HCPCS for procedural episode triggers, evaluation & management codes combined with ICD-10 diagnostic information for chronic episode triggers, etc.). CMS solicits comment on the inclusion or exclusion of specific service codes used to identify each episode group.

Comments on inclusion or exclusion of specific codes to identify episode groups should not be requested from each specialty independently. These codes can have a large degree of variation in usage across institutions and specialties. The inclusion and exclusion criteria for these codes should be broadly specified to provide a foundation on which a multi-disciplinary panel can discuss specific codes for inclusion or exclusion in each episode group and then provide a consensus recommendation to CMS.

Acute Inpatient Medical Condition Episode Groups

- The acute inpatient medical condition episode groups that accompany this posting include only inpatient events. CMS seeks comment on outpatient events that could be considered candidates for development as acute condition episode groups, which could include chronic condition exacerbations that require acute care but not inpatient hospitalization.
- Acute episodes of care might occur on either an inpatient or outpatient basis and may or may not include surgery. CMS is considering a single Acute Episode Group type that does not distinguish the place of service or the performance of a procedure and welcomes comment on this approach.

The costs of care can vary tremendously by site of service. In addition, many costs of care on the inpatient setting may not be in the direct control of the physician (e.g. overhead costs determined by an inpatient hospital). Therefore, combining these sites of services into a single Acute Episode Group will likely make it more difficult to make valid cost comparisons between providers who have varying proportions of inpatients vs. outpatients in their acute care episode groups.

Chronic Condition Episode Groups

- CMS is aware of many challenges in constructing episode groups for chronic conditions. These include coding habits that may obscure some chronic conditions and overemphasize others. In addition, it may be difficult to assign a given treatment to a single condition for patients with multiple comorbidities. For example, are the resources for treatment to reduce cholesterol for a patient with diabetes, hypertension, and coronary artery disease to be assigned to only one of those diagnoses, to all of them in proportion, or should we develop a chronic condition episode specific to the management of patients with diabetes, hypertension and coronary artery disease, i.e., a patient condition group to better compare cost to treat like patients? An extension of this approach might be a single episode group for outpatient chronic care with adjustment for comorbidities and demographics of the population served by the clinician. We welcome comment on these and any other options for constructing episode groups for chronic conditions.
- Certain specific conditions, such as cancer, present other challenges. The costs of caring for patients at different stages of disease are likely to vary. For instance, a single episode for a type of cancer is likely to differ in a predictable manner depending on the stage of the cancer. Information on disease staging is not easily or predictably available from claims. CMS welcomes comment on methods to incorporate disease severity or staging information to improve meaningful comparison of cost and quality of care furnished to patients, both generally and for specific clinical conditions. For example, how could a disease staging code be reported on claims to facilitate comparison of episodes for patients at like stages of cancer?

We agree that obtaining meaningful comparisons for diseases like cancer are challenging. In order to include a disease staging code on claims, consensus is needed on which staging system to use for each cancer type, as well as agreement on what objective criteria is required to assign each patient to a certain stage. It is also possible that each stage includes a heterogeneous clinical cohort.

For example, in hepatocellular carcinoma, the outcome and treatment options/cost for stage 4 (distant metastatic disease) varies between patients with numerous distant metastases and those with “liver-dominant” disease (where a few lymph nodes have metastatic deposits but the predominant disease burden is in the liver). Similarly, the outcome and treatment options of patients with stage 4 metastatic colorectal cancers are different if it is liver-dominant, liver-only, or lung-only metastatic disease.

Procedural Episode Groups

- We solicit comment on the procedural episode groups that accompany this posting, including the service and diagnosis codes used to identify the existence of the procedural episode groups. We also welcome comment on additional procedural episode groups to consider for future development.

The American College of Radiology and other radiologic specialty societies have been involved in making recommendations for procedural episode groups. It is unclear to us how those

recommendations were considered. Greater transparency in the process will help the ACR provide meaningful comments and recommendations.

Cost Measure Development

- Cost measures are being considered for development from episode groups after adding additional context, such as expenditure assignment, attribution, risk adjustment, and consideration of quality. We welcome comment on each of these elements and whether there are additional elements to consider in developing cost measures from episode groups.
- As described above, the degree of responsibility of attributed services might be considered separately. Those services furnished by the attributed clinician for the clinical purpose of the episode group might be differentiated from the services provided by others for the same clinical purpose. The services furnished by the attributed clinician might be considered directly attributable services. These could be correlated with the services delivered by others for the same clinical purpose, which might be considered indirectly attributed services. The consideration of both directly and indirectly attributed services might be weighed in reporting both the provision and the coordination of care within the episode group relative to each clinician contributing to the care. An alternative approach would be to obtain recommendations from multi-specialty panels about percentages of the resources for an episode that could be attributed to physicians serving in different roles. We welcome comment on these concepts of differential attribution or alternative methods to align attribution with the clinical activities of clinicians.

It would be invaluable to include indirect and/or downstream costs to the cost measurement model. This is the main area with the value of imaging and minimally-invasive image-guided procedures can be captured. For example, an abdominal CT scan to diagnose appendicitis will only be seen as a cost unless its effect in reducing the negative laparotomy rate or early recognition of a post-operative abscess is included in the overall episode of care and cost measurement methodology.

Moreover, we agree with obtaining multi-specialty panels on percentages of resources attributable to different physicians in different roles. We request that prior to convening such panels, ground rules are disseminated on what criteria will be used to ensure a patient-centered approach to decision making and what data (e.g. published literature) may be required to help the panel decide.

- The Medicare Advantage program uses the CMS-HCC Risk Adjustment Model to determine rates. We seek comment on the use of this model or an alternative for risk adjusting episode groups in the construction of cost measures. In addition, should concurrent or prospective risk adjustment be used, and should a full year of data or more targeted data from before the episode be used to adjust?

In the HCC model, diagnostic radiology has not been measured inside the episode. The ACR would like to work with CMS on finding ways to measure the work of radiologists within the episode, such as incidental findings and the use of CDS.

- The draft list does not currently include specifications for episode sub-groups (a subgroup is intended to achieve greater clinical comparability and is a subdivision of an episode group that further refines the specifications of episode trigger codes and grouping rules to yield more clinically homogenous cohorts of patients with similar expected cost). An example is an episode group for spine surgery with sub-grouping for number of levels and anatomic location. CMS solicits public comment on these draft episode groups and potential sub-groups.
- CMS is especially interested in comments regarding methods to align quality of care with cost measures and welcomes recommendations and suggestions. Considerations for aligning episode groups with quality measurement are described in this document, but are not intended to be an exhaustive list of options. We welcome comment on these methods, as well as any other strategies that could be used to align quality of care considerations with cost measures.

ACR strongly urges CMS to consider the option of counting quality measures designated in the efficiency/cost domain to serve also as measures under the Cost performance category. Examples are: 1) mammography/lung cancer screening abnormal interpretation rate or 2) appropriate use measures such as the 2016 PQRS measures on appropriate follow up imaging recommendations for incidentally found abdominal and thyroid lesions.

- CMS wishes to avoid any unintended consequences of using cost measures in MIPS, and seeks comment on issues of concern in this regard, such as taking steps to avoid disadvantaging clinicians who assume the care of complex patients such as by applying episodes for comparison of complex patients (i.e., comparison of like-patients of different clinicians).

CMS acknowledges that prescription drug costs are a large driver of the cost of medical care for Medicare beneficiaries. What would be the best way to incorporate Part D costs into the episode group development?

COMMENT 57 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Donald May, Executive Vice President, Payment and Health Care Delivery Policy, AdvaMed

Text of Comment:

AdvaMed appreciates the opportunity to respond to the posting by the Centers for Medicare & Medicaid Services (CMS) “Episode-Based Cost Measure Development for the Quality Payment Program” as noted on the CMS website.¹ Our comments touch on a number of topics in the posting including considerations on the following issues and components as discussed during the CMS Listening Session on Episode-Based Cost Measure Development on April 5, 2017: Opportunities for Stakeholder Engagement, Assigning Costs to the Episode Group, Aligning Costs with Quality, Risk Adjustment Episode Groups and Attributing Episode Groups to Clinicians.

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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). As the process of developing appropriate components of episode groups is extremely complex and ongoing, we continue to provide feedback on a number of high level issues that are essential in the development of these measures.

I. Opportunities for Stakeholder Engagement

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

As noted the recent CMS Listening Session on Episode-Based Cost Measure Development, prior feedback from stakeholders emphasized that broad stakeholder feedback is crucial to the development and implementation process of episode groups. 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. We urge CMS to seek stakeholder feedback more frequently.

We have previously advocated for using all 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 forums would also provide an opportunity for all interested parties to provide valuable — and early — feedback to CMS regarding these matters. To date, it appears that CMS has not utilized many of these wide-ranging input opportunities from stakeholders. As the clinical subcommittees working with CMS's contractor, Acumen, begin their deliberations, it is our recommendation that CMS facilitate more in-person and more wide-ranging occasions for stakeholder input into their discussions and findings.

We continue to 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 in order to receive adequate feedback for proper construction and implementation of this initiative. Additionally, in order to facilitate consideration of additional episodes from those CMS has identified, we recommend CMS work collaboratively with medical specialties, provider networks, and manufacturers to gain feedback on understanding which episode groups would be most appropriate

We continue to 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 accept requests to provide input into its process on an ongoing basis as it develops and refines various aspects of episode group construction. 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. We believe episode groups should be focused on high-volume, high-cost studies with significant variations in care delivery and quality outcome measures.

II. Assigning Costs to the Episode Group

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

While CMS has provided the code sets related to the list of episodes in the supplementary materials, AdvaMed urges CMS to provide more detail for external stakeholders to fully understand and assess the validity and reliability of the proposed episodes, including cost variation and longitudinal distribution of clinical events.

AdvaMed continues to believe that it would be helpful for stakeholders to see 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.

AdvaMed also recommends 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. Claims data provided in each episode should assess both homogeneous and heterogeneous patient populations to best address the generalizability of the data and impact of significant co-morbidities. In addition, if an acute episode is strongly associated with an underlying chronic condition, CMS should provide data on both the acute episode as well as the underlying chronic condition.

The analyses of resource use variability across clinical episodes and chronic conditions will likely help CMS to identify those clinical areas that require 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 again urges CMS to release episode variability statistics as soon as possible as part of this process. To date, it is our understanding that CMS has not made this information available. While this information may not have been shared publically, CMS should share this information with the clinical subcommittees that are forming in order to make informed decisions and accurately assign services and consider attribution for each episode. This information, in-turn, should be made publicly available and offered by CMS for input via in-person and other types of stakeholder forums.

III. Aligning Costs with Quality

A. Episodes Should Be Developed with Flexibility to Allow for Adoption of Medical Innovations and Breakthrough Treatments.

CMS acknowledges that alignment of indicators of quality is necessary to compensate for the information that is not adequately captured by episode costs. AdvaMed agrees that quality assessments, as noted in the recent CMS Listening Session, are very important to consider including the functional status of the patient, complications, re-hospitalizations, unplanned care, underuse and other consequences. 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 also 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. This is especially important as the newly formed seven clinical subcommittees begin evaluation of services that are being assigned to these episodes. **Specifically, these subcommittees should consider how the process will take into account breakthrough technology and medical innovation costs and how they will be assigned, if at all, to specific providers.**

We again 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 — which should include input to the clinical subcommittees — to ensure that CMS and the subcommittees have access to the most up-to-date information with regard to best practices for treating patients.

As emphasized by CMS, a key step in building a cost measure is to align it with quality to make these measures more meaningful to clinicians and encourage collaboration across all venues of care and those that provide this care. CMS has taken steps to increase use of episodes for payment and for quality in its value-based programs, including the hospital value-based program inpatient program, physician value-modifier which will be replaced by MIPS, ESRD Quality Initiative Program, Home Health Value Based Purchasing Program and a future SNF Value-Based Purchasing program in development. In addition, the use of condition-based episodes appears to be growing within and across programs. For example, the physician VBP and hospital VBP both incorporate measures related to heart failure and to chronic obstructive pulmonary disease. Also, because of the implementation of the QPP for physicians, the number of condition-specific episodes in MIPS is expected to grow substantially. Ultimately, these episode groups and cost measures may be aided by standardizing or having shared quality measures that are aligned with cost across many of the value-based programs in the future. CMS should inform stakeholders and the public to what extent that CMS is considering alignment of these various episodes across all quality-related programs, value-based programs and alternative payment models.

IV. Risk Adjusting Episode Groups

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

Risk adjustment for patient-related factors (e.g., comorbidity and illness severity) is needed to make accurate and fair conclusions about the quality of care patients receive. Risk 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.

Risk adjustment is a key element that must be valid, reproducible, sensitive and specific. 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 patient-specific factors, like those described above, 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. Also, CMS should consider the recent report from the Assistant Secretary for Planning and Evaluation (ASPE)² as they revise and propose risk adjustments that incorporate the range of social risk factors as applied to episode measures.

In addition, AdvaMed recommends that CMS and the newly formed clinical subcommittees 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. While the method of using HCCs may be appropriate for adjusting total expenditures for care for a population, specific conditions may confer higher or lower risk for certain episode groups and these will need to be explored thoroughly for each episode considered.

V. Attributing Episode Groups to Clinicians

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. This concept was emphasized during the recent CMS Listening Session which noted that one of the key points of stakeholder feedback was that the attribution of claims and episodes to clinicians should be clear and credible at the time of service.

To this end, the National Quality Forum (NQF) recently conducted an environmental scan and white paper using a multi-stakeholder Standing Committee, to examine the strengths and weaknesses of the attribution models identified in the environmental scan. The Final Report presents a set of principles and recommendations for applying the models within a complex healthcare delivery system. AdvaMed recommends that CMS and the newly formed clinical subcommittees consider the guiding principles, recommendations and proposed Model Selection Guide of the *NQF Attribution Principles and Approaches Project Final Report*.³

An important finding of this paper was the variability in approaches to attribution and the lack of rigorous evaluation of the methods used. The authors of the paper found that the quality measurement field has not yet determined best practices for attribution models, and importantly, there is little consistency across models, but there is evidence that changing the attribution rules can alter results. Currently there is often a lack of transparency on how care is attributed and no processes for an accountable unit to appeal the results of an attribution model that may wrongly assign responsibility. To address many of these concerns, the NQF Committee focused on developing principles, recommendations, and the Attribution Model Selection Guide to allow for greater standardization, transparency, and stakeholder buy-in with the goal of allowing evaluation of attribution models in the future and laying the groundwork to develop a more robust evidence base around this relatively unstudied measurement issue.

The NQF Committee agreed on the following set of guiding principles to address attribution challenges:

1. Attribution models should fairly and accurately assign accountability
2. Attribution models are an essential part of measure development, implementation, and policy and program design
3. Considered choices among available data are fundamental in the design of an attribution model
4. Attribution models should be regularly reviewed and updated
5. Attribution models should be transparent and consistently applied
6. Attribution models should align with the stated goals and purpose of the program

In addition, the Committee's recommendations build on the guiding principles and the Attribution Model Selection Guide. They are envisioned to apply broadly to those developing, selecting, and implementing attribution models in the context of public and private-sector accountability programs. The Committee's recommendations for selecting and implementing attribution models are:

1. Use the Attribution Model Selection Guide to evaluate the factors to consider in the choice of an attribution model
2. Attribution models should be tested
3. Attribution models should be subject to multi-stakeholder review
4. Attribution models should attribute results to entities who can influence care and outcomes
5. Attribution models used in mandatory public reporting or payment programs should meet minimum criteria

The NQF Committee recognized that an important first step to evaluating attribution models is to determine the necessary elements of an attribution model that should be specified. The Attribution Model Selection Guide is aimed to help measure developers, measure evaluation committees, and program implementers to specify the essential elements of an attribution model. It represents the minimum features that should be shared with the accountable entities and includes questions to answer in the development and selection of an attribution model. The intent of the Guide is to improve standardization across attribution models and increase the ability to evaluate attribution models in the future.

1 <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Episode-Based-Cost-Measure-Development-for-the-Quality-Payment-Program.pdf>

2 Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs; U.S. Dept. of Health and Human Services, Office of the Assistance Secretary for Planning and Evaluation. December 2016.

3 NQF Attribution Principles and Approaches; Final Report, National Quality Forum. December 2016

COMMENT 58 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Thomas Stasko, President, American College of Mohs Surgery

Text of Comment:

The American College of Mohs Surgery (Mohs College) represents more than 1,400 Mohs micrographic surgeons who have successfully completed extensive fellowship-training in Mohs micrographic surgery following their dermatology residency training. Mohs micrographic surgery is the most effective and efficient treatment for advanced or difficult to treat skin cancers. In line with its mission, the Mohs College sets and promotes the highest standards of patient care relating to Mohs micrographic surgery. We appreciate the opportunity to provide feedback on the draft list of episode groups and trigger codes, as well as your report, *Episode-Based Cost Measure Development for the Quality Payment Program*, to help inform the agency's ongoing efforts in developing cost measures.

Episode-Based Cost Measure Development for the Quality Payment Program

Episode Group Selection: Melanoma Episode

CMS explains that it considered Medicare expenditures, clinician coverage, and the opportunity for improvement in acute, chronic, and procedural care settings in selecting the episode groups to be considered for development. This resulted in the identification of melanoma treatment services for episode group development. Specifically, CMS has included "Melanoma Destruction/Excision" on its draft list of MACRA Episode Groups. We note that CMS' terminology is not clinically relevant because destruction of melanoma is clinically contraindicated and not standard of care. CMS should revise the name of this episode group to "Melanoma - Excisional Treatment."

Episode Group Definition, Procedural Episode Groups & Cost Measure Development

CMS identified several CPT "trigger codes" as representing services associated with the melanoma episode group. We generally agree with the list of trigger codes; however, we believe the codes 17312 and 17314 should be replaced because these are add on codes for Mohs surgery services and don't define the primary procedure. In their place, the Mohs surgery codes 17311 and 17313 should be used. We also believe the following CPT codes should be included as trigger codes: 14000, 14001, 14001, 14020, 14021, 14040, 14041, 14060, and 14061 because the excision codes are bundled within them. However, it is important to note that the listed episode trigger codes for the melanoma episode group are also used in the treatment of other skin cancers (e.g., non-melanoma), which means the episode group will capture costs unrelated to melanoma treatment. To address this, linkage of the CPT "trigger" codes to correct melanoma specific ICD-10-CM diagnosis codes will be critical for the specificity and sensitivity of the episode. Because CMS has yet to provide the relevant ICD-10-CM diagnosis codes associated with the melanoma episode, it has inadequately defined the triggering rules to produce a homogeneous disease model or a clinically relevant episode.

In addition, we recommend that CMS consider splitting the melanoma episode into subgroups based on staging and body site to create a more homogeneous model. The most important clinical risk factor for poor patient outcome for cutaneous melanoma is histologic depth. However, thin and thick melanomas are coded with the same ICD-10-CM diagnosis code with huge resulting variation in resource utilization and cost for the same diagnosis code. Body location of the melanoma (head and neck versus other sites) also portends significant differences

in intensity of treatment and patient outcome. Using subgroups based on body site and whether lymph node sampling is performed will allow for much more homogeneous groups and consistent comparison of cost.

Attributing Episode Group Cost to Clinicians

Attribution of costs should be clear to all physicians involved in an episode of care. CMS previously proposed patient relationship categories and codes that are continuous, episodic and “only as ordered by another clinician”, in an effort to capture the role of a physician in an episode thus allowing more precise analysis of attribution. Section 101(f) of MACRA requires that CMS post the operational list of patient relationship categories and codes by April 2017, however, this has not been posted.

Mohs surgeons need a clear understanding of the attribution process, given their role in skin cancer care and treatment. While Mohs surgeons often lead the care and management for the vast majority of their skin cancer patients, they often refer their *melanoma* patients to oncologists for further evaluation after surgical care. However, the Mohs surgeon does not have control over the costs of tests that are ordered by those specialists. For Mohs surgeons who take care of melanoma patients that require multispecialty management, attribution of costs could be a significant challenge. Mohs surgeons should only be held accountable for costs that are directly within their control.

Other Issues

ACMS would appreciate the opportunity to provide more meaningful and substantive comments, however, key information about the episode group is missing, including:

- When the episode would begin and end;
- What the exclusion criteria will be;
- How risk adjustment, including social risk factors, will be accounted for; and
- How CMS will set benchmarks for subspecialty providers, such as Mohs surgeons, to ensure they are not inappropriately compared to other providers that may be providing the services under this episode.

With CY 2018 fast approaching and the weight of the cost performance category slated to increase, we urge CMS to provide answers to our aforementioned questions as soon as possible, which will afford us a fair opportunity to review the planned cost measures and provide feedback to the agency prior to the implementation of episode groups in the MIPS cost performance category.

We appreciate the opportunity provide feedback and look forward to providing additional input on cost measurement for skin cancer care and treatment. ACMS is eager to work with CMS and its contractor on further developing this episode group into reasonable and appropriate cost measures of resource use by Mohs surgeons that is within their control.

COMMENT 59 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Joseph A. Hill, Chair, Advocacy, Heart Failure Society of America

Text of Comment:

The Heart Failure Society of America (HFSA) is writing to convey our concerns regarding the August – September 2016 Clinical Committee for the MACRA Episode-Based Resource Use Measures Project. In addition, we are sharing comments on the draft list of episode groups and trigger codes due to the CMS contractor Acumen, LLC, on April 24, 2017. The HFSA represents the first organized effort of heart failure specialists across America to provide a forum for all those interested in heart function, heart failure, and chronic heart failure research and patient care.

Process for Providing Input to Creation of Episode Groups and Trigger Codes

HFSA was pleased our nominee was chosen to provide clinical expert input into the MACRA Episode-Based Resource Use Measures Project. We look forward to ongoing participation with Acumen, LLC, the CMS contractor responsible for guiding this important work. However, we must note the experience was a frustrating one with a flawed process to date. It seems that members appointed to this project worked almost in a vacuum to provide input for the draft list of episode groups and trigger codes. We find this process to have been an unusual one, which required considerable effort, but which did not provide much confidence regarding the consideration of members' input to the project.

As you know, CMS contracted with Acumen to drive a process that would result in designation of specific "episode groups." These groups could be procedural events (e.g. CABG), inpatient diagnoses (e.g., heart failure) or ambulatory diagnoses (e.g., heart failure). Once these groups were identified, there was then a selection process related to the CPT or diagnostic codes that might trigger the associated "episode." Once the "Episode Based Resource Use Metrics" go into effect, the physician responsible for that "episode of care" would be accountable (in some way) for all of the related resource use that occurred over the course of that episode, until a yet-to-be-determined event (in some cases an elapse of time) terminated the episode.

It was concerning that throughout this process the group never met face to face. There were two webinars where the mechanics of the tasks were explained. The "committee members" then each, individually, participated in two sets of tasks on-line, to identify episode groups and the codes that would trigger them.

Throughout the process, members raised questions about a number of aspects of the task. For example, how does a stable outpatient diagnosis become an "episode"? If multiple providers are involved, how is the accountable provider identified? How easily can one distinguish the resources that are or are not related to that "episode"? (e.g., if a cath and PCI are done for angina in a patient who is amidst an "episode" or chronic heart failure as an outpatient, is the accountable MD accountable for that?). For a hospital inpatient with a complex condition like heart failure, how can risk adjustment methodology succeed in leveling the playing field related to the amount of resources that are utilized over a set period of time? All these questions were

raised with Acumen by multiple representatives but no satisfactory answers emerged by the rapid conclusion of this project.

The process of responding to queries on-line, without any opportunity for open discussion, was insufficient to even begin to address the inherent complexities of the tasks undertaken. This flawed process often meant that overly simplistic answers were provided to complex questions. These flaws, undoubtedly, had a negative impact on the results of this work. It also appeared that Acumen did not have the necessary resources or personnel to integrate the feedback and understand what was needed to thoroughly and accurately depict the clinical complexities involved.

Draft List of Episode Groups and Trigger Codes

In December 2016, Acumen, LLC posted a draft list of episode groups and corresponding trigger codes for acute inpatient medical conditions, chronic conditions and procedural episode groups. We offer the following comments and questions regarding the composition of the proposed episode groups and trigger codes.

First, we believe the episode groups need to be homogeneous with definable and circumscribed events. We do not support the proposed grouping of heart failure and shock under the acute inpatient medical condition list. Cardiogenic shock is a form of heart failure but the vast majority of patients do not have cardiogenic shock. Also, cardiogenic shock is just one type of shock. We encourage Acumen to group “like” conditions together and remove shock from a heart failure episode group.

We are concerned by the content of the proposed chronic conditions list. From the CMS document “Episode-Based Cost Measure Development for the Quality Payment Program,” we understand that chronic condition episode groups are meant to reflect patient conditions and their clinical history at the time of a medical visit along with their current health status. If this is the case, why are acute episodes listed in the chronic conditions list? Is there a way to better define chronic condition episode groups? How long are these episodes? The current 12-month administrative metric seems overly long and not reflective of a reasonable episode of care. Care for a chronic episode must have a definable end for the episode. How are costs to be attributed? What happens in the case of readmissions? Again, we urge Acumen to focus on episode groups with a sufficient degree of volume and events that are readily defined and circumscribed.

We understand from Acumen that there will be further opportunities to comment on the draft list of episode groups and triggers, define episode windows, selected group services, and further define risk adjustment. We would like to remain engaged in this important work but urge Acumen and CMS to refine the process for engagement in this project. More meaningful opportunities for comment will only serve to strengthen the result.

HFSA recently nominated two individuals to continue work with Acumen on this important task. We are confident their input will help inform this work. They look forward to the face-to-face interaction outlined by Acumen for the project going forward.

COMMENT 60 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: David B. Peden, President, American Academy of Allergy, Asthma & Immunology

Text of Comment:

Established in 1943, the AAAAI is a professional organization with more than 7,000 members in the United States, Canada and 72 other countries. This membership includes allergist/immunologists (A/I), other medical specialists, allied health and related healthcare professionals—all with a special interest in the research and treatment of patients with allergic and immunologic diseases.

We appreciate the opportunity to provide feedback on the draft list of episode groups and trigger codes, as well as your report, *Episode-Based Cost Measure Development for the Quality Payment Program*, to help inform the agency’s ongoing efforts in developing cost measures.

Episode-Based Cost Measure Development for the Quality Payment Program

Episode Group Selection

CMS considered Medicare expenditures, clinician coverage, and the opportunity for improvement in acute, chronic, and procedural care settings in selecting the episode groups to be considered for development. Therefore, it is no surprise that several conditions managed by allergy/immunology (A/I) professionals were targeted for episode development, including

- Bronchitis and Asthma,
- Chronic Obstructive Pulmonary Disease (COPD),
- Respiratory Infections and Inflammations, and
- Asthma/COPD.

Episode Group Definition, Chronic Condition Episode Groups & Cost Measure Development

As noted above, we understand why several A/I conditions have been targeted for episode group development and agree with the identified “trigger codes” CMS has included in each of the respective episodes.

Beyond that, we are limited in our ability to provide meaningful comments because critical information about the episode groups are missing. That is, we do not have information about the parameters under which these episodes intend to be developed. For example, when do the episodes begin and end? What, if any, are the exclusion criteria for these episodes? How will risk factors, including socio-demographic, be accounted for in these episodes? How frequently will the episodes be updated to account for changes in clinical practice and changes in medical inflation?

Moreover, how will A/I professionals and any other providers participating in the patient’s continuum of care be attributed costs during the episode? AAAAI continues to await information on patient relationship categories and codes, which will be key to this effort, but concerns remain about their effectiveness, feasibility and utility. We previously expressed concern that including a patient relationship code on every single claim would be an administrative burden, and that A/I practices may struggle with deciphering whether their care is “continuous” or “episodic” in some

instances. We also suggested that CMS ensure that specialists, such as A/I professionals, would not be attributed patients with diagnoses that are outside the scope of their specialty, as was the case in the VM cost measures.

We recognize CMS is planning to use clinical subcommittees to assist with the development of these episodes, and these episodes appear to be slated for consideration in “Wave 3”. As noted above, A/I professionals would much prefer to be held accountable for episodes where they have some opportunity to control resource use, versus the current measures that stem from the VM program, which have inappropriately attributed beneficiaries to A/I professionals when they may have only seen their A/I professional once for management of their allergy condition. We urge CMS to provide as much detail as possible so that AAAAI may provide important feedback to the agency prior to the implementation of these A/I-focused episode groups in the MIPS cost performance category.

AAAAI looks forward to working with CMS and its contractor on further developing these episode groups into reasonable and appropriate cost measures for A/I professionals. A/I professionals greatly prefer being held accountable for resource use associated with conditions within their clinical scope of expertise rather than the crude cost measures that carried over from the Value-Based Payment Modifier (VM) program, specifically the Total Per Capita Costs and Medicare Spending Per Beneficiary (MSPB) cost measures.

We appreciate the opportunity to offer these comments, and we look forward to providing additional input on accurate cost measurement. As the agency intends to increase the weight of the MIPS cost performance category to 10 percent for the CY 2018 reporting period, we encourage the agency to issue more detailed proposals for comment, as soon as possible.

COMMENT 61 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Michael Camilleri, Chair, American Gastroenterological Association

Text of Comment:

On behalf of the American Gastroenterological Association (AGA), I am pleased to provide comments on the Centers for Medicare & Medicaid Services (CMS) Episode-Based Cost Measures for the Quality Payment Program report and draft list of episodes and associated trigger codes. AGA is the trusted voice of the gastroenterology community. Founded in 1897, AGA includes more than 16,000 members from around the globe who are involved in all aspects of the science, practice, and advancement of gastroenterology.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) aims to reform how care is delivered and reimbursed under Medicare. AGA acknowledges that the Quality Payment Program (QPP) established under MACRA can benefit patients by improving care delivery and physicians by consolidating and streamlining existing programs, including the Physician Quality Reporting System (PQRS), the Value-Based Payment Modifier (VM) and the Electronic Health Records Incentive Program. In recent years, physicians nationwide have struggled to meet the

requirements of these fragmented, highly technical and sometimes redundant programs, which, at times, has detracted from patient care. AGA encourages CMS to create the QPP in a way that enhances care, reduces costs and maximizes available resources. AGA shares your commitment to improving the value, quality, and delivery of health care for Medicare beneficiaries.

To accomplish these goals, physician input is necessary. AGA members bring valuable perspectives to the implementation process by providing clinical expertise and real-world insights on ways to achieve higher levels of patient care. In March 2016, in response to an October 2015 request, we submitted comments on an initial set of episode-based cost measures. We appreciate CMS’s continued efforts to seek input from stakeholders on the development of episode-based cost measures and look forward to your careful consideration of the comments herein.

In the Episode-Based Cost Measures for the Quality Payment Program report, CMS reviews the cost measure development process and provides a draft list of episode groups and trigger codes that are intended to serve as a starting point for the future development of episode-based cost measures. CMS further indicates that the draft episode groups were identified using four criteria – (1) Medicare expenditure share; (2) opportunity for improvement; (3) clinician coverage; and (4) alignment with quality measures. Draft episode groups are categorized as either an acute inpatient medical condition, procedural, or chronic condition episodes.

AGA's comments focus on six acute inpatient medical conditions, two procedural, and three chronic condition episodes (**Table 1**).

Table 1. List of Episodes of Interest to AGA

Acute Inpatient Medical Condition	Cirrhosis & Alcoholic Hepatitis
Acute Inpatient Medical Condition	Disorders of the Biliary Tract
Acute Inpatient Medical Condition	Esophagitis, Gastroenteritis & Miscellaneous Digestive Disorders
Acute Inpatient Medical Condition	Gastrointestinal Hemorrhage
Acute Inpatient Medical Condition	Gastrointestinal Obstruction
Acute Inpatient Medical Condition	Major Gastrointestinal Disorders & Peritoneal Infections
Procedural	Diagnostic Colonoscopy
Procedural	Screening/Surveillance Colonoscopy
Chronic Condition	Chronic Liver Disease
Chronic Condition	Gastroesophageal Reflux Disease
Chronic Condition	Inflammatory Bowel Disease

Acute Inpatient Medical Condition Episode Groups

For each acute inpatient medical condition episode, CMS proposes that an episode would be triggered by Medicare-Severity Diagnosis Related Groups (MS-DRG). AGA has concerns with this approach. The MS-DRG is a statistical method used to classify hospital inpatient stays into groups for prospectively setting inpatient hospital payment rates. Although the MS-DRG framework requires patients within a DRG to be clinically coherent and to have similar resource intensity, variations and exceptions do exist within DRGs. Moreover, when establishing DRGs, clinical coherence and resource intensity are evaluated only in the context of an acute inpatient hospital stay. As such, patients assigned to the same DRG, although sufficiently similar for hospital payment purposes, may not be sufficiently similar either during the hospitalization or in the period after the inpatient hospital stay to be grouped in a single episode for cost measurement and comparison. Sub-groups will be required to improve the clinical homogeneity of patients within an episode and, thus, to improve the ability to make cost comparisons.

The draft “Cirrhosis & Alcoholic Hepatitis” episode may be used to highlight clinical and resource heterogeneity within DRGs. Trigger codes for this draft episode are three MS-DRGs (432 “Cirrhosis and Alcoholic Hepatitis with Major Complications or Comorbidities (MCC)”; 433 “Cirrhosis and Alcoholic Hepatitis with CC”; and 434 “Cirrhosis and Alcoholic Hepatitis without MCC or CC”). To be assigned to one of these three MS-DRGs, a patient’s inpatient hospital stay must be principally defined by one of 14 International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes, most of which identify alcohol-related liver disease, including alcoholic hepatitis, fibrosis and sclerosis, cirrhosis, and hepatic failure. There are however, a few principal diagnoses for these MS-DRGs that do not result from alcohol use, such as primary biliary cirrhosis (K74.3) – destruction of the bile ducts of the liver usually due to an autoimmune disease – and secondary biliary cirrhosis (K74.4) – destruction of the bile ducts because of prolonged obstruction, narrowing or closure of the bile duct from a tumor or other causes. For hospital inpatient rate-setting purposes, primary and secondary biliary cirrhosis are similar enough to alcohol-related liver disease to be grouped together, but these conditions are not sufficiently similar clinically or with respect to costs to be grouped into a single episode for cost measurement and comparison. Moreover, because primary and secondary biliary cirrhosis have different etiologies, post-acute care for these two conditions also differ, suggesting that it may be inappropriate to group together patients with these conditions for cost comparisons.

These concerns are not limited to the draft “Cirrhosis & Alcoholic Hepatitis” episode. Rather they apply to all the draft acute inpatient medical condition episodes of interest to AGA, including Disorders of The Biliary Tract, Esophagitis, Gastroenteritis & Miscellaneous Digestive Disorders, Gastrointestinal Hemorrhage, Gastrointestinal Obstruction, Major Gastrointestinal Disorders & Peritoneal Infections. In fact, this approach might be most problematic for the draft “Esophagitis, Gastroenteritis & Miscellaneous Digestive Disorders” episode, in which the proposed MS-DRG trigger codes (391 “Esophagitis, Gastroenteritis and Miscellaneous Digestive Disorders with MCC” and 392 “Esophagitis, Gastroenteritis and Miscellaneous Digestive Disorders without MCC) have more than 200 principal diagnosis codes that capture a heterogeneous set of gastrointestinal conditions, such as infectious enteritis, gastroesophageal reflux disease, and diverticulitis. Using only MS-DRGs to define, measure, and compare costs is extremely problematic.

As described, AGA is concerned that DRG triggered acute inpatient medical episodes are likely to result in heterogeneous clinical groups and inappropriate cost comparisons. This heterogeneity may be addressed by establishing clinical sub-groups and by ensuring measurement and comparison methods account for variability within the final episode groups. AGA urges CMS, its contractor, and the clinical subcommittees that will be tasked with developing cost measures to further evaluate whether DRGs are appropriate episode trigger codes and to examine how acute and post-acute care vary for conditions that share a DRG to understand if episode sub-groups are sufficient to address these concerns or whether a more granular approach to defining episodes may be needed.

Procedural Episode Groups

For each procedural episode group, CMS proposes that an episode would be triggered by one or more Current Procedural Terminology (CPT®) or Healthcare Common Procedure Coding System (HCPCS) codes. AGA supports this approach and below provides detailed comments on two procedural episodes – diagnostic and screening/surveillance colonoscopy – and their associated draft trigger codes.

Diagnostic and Screening/Surveillance Colonoscopy

CMS has proposed two distinct procedural episodes for colonoscopy – diagnostic colonoscopy and screening/surveillance colonoscopy. However, information on how CMS defines and plans to distinguish between diagnostic and screening/surveillance colonoscopies is absent from the draft report and episode lists. AGA assumes that diagnostic colonoscopy is specific to colonoscopy performed because of an abnormal finding, sign or symptom (such as abdominal pain, bleeding, diarrhea, etc.) and that screening colonoscopy is specific to colonoscopy performed on an asymptomatic person for testing for the presence of colorectal cancer or colorectal polyps. We further assume that CMS intends to distinguish diagnostic colonoscopy episodes from screening colonoscopy episodes using diagnosis codes and or CPT® or HCPCS modifiers. These assumptions influence the recommendations set forth below.

Diagnostic Colonoscopy

We recommend that CMS make several changes to the trigger codes for diagnostic colonoscopy:

Exclude CPT® code 45330 (“Sigmoidoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)”). Colonoscopy is defined as the examination of the entire colon, from the rectum to the cecum or colon-small intestine anastomosis, and, in certain circumstances, may include examination of the terminal ileum or small intestine proximal to an anastomosis. In contrast, sigmoidoscopy is defined as the examination of the rectum and sigmoid colon and, in certain circumstances, may include examination of a portion of the descending colon. Since, sigmoidoscopy is not colonoscopy, CPT® code 45330 should not be included as a trigger code for diagnostic colonoscopy.

Review inclusion of CPT® code 45381 (“Colonoscopy, flexible; with directed submucosal injection(s), any substance”). This procedure is predominantly performed as a secondary procedure. Additionally, total 2015 Medicare volume was only 103,995. CMS, its contractor, and the Clinical Subcommittee should further examine the appropriateness of including CPT®

code 45381 as a trigger code for diagnostic colonoscopy by examining the frequency with which this procedure is billed as a standalone procedure.

Exclude CPT® code 45383 (“Colonoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique”). CPT® code 45383 has been deleted, is no longer valid for billing and payment purposes, and as such, should not be included as a diagnostic colonoscopy trigger code.

Include CPT® code 45388 (“Colonoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)”). Procedures previously reported using CPT® code 45383 are now reported using CPT® Code 45388.

In addition to these recommendations, CMS should include CPT® codes that describe colonoscopy through a stoma, which is the examination of the colon from a colostomy stoma to the cecum or colon-small intestine anastomosis. The specific CPT® are listed below.

- **44388** (“Colonoscopy through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)”)
- **44389** (“Colonoscopy through stoma; with biopsy, single or multiple”)
- **44391** (“Colonoscopy through stoma; with control of bleeding, any method”)
- **44392** (“Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps”)
- **44394** (“Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by snare”)
- **44401** (“Colonoscopy through stoma; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre-and post-dilation and guide wire passage, when performed)”)

Screening Colonoscopy

We recommend that CMS make several changes to the trigger codes for screening colonoscopy:

Exclude CPT® code 45382 (“Colonoscopy, flexible; with control of bleeding, any method”). This procedure is predominantly performed as a therapeutic procedure and total Medicare volume is very low (26,596). There are circumstances under which this CPT® code would be billed to describe an aspect of a screening colonoscopy, however, these situations are rare. Moreover, in these circumstances, the screening colonoscopy would be identified by another trigger code for screening colonoscopy.

Exclude CPT® code 45383 (“Colonoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique”). CPT® code 45383 has been deleted, is no longer valid for billing and payment purposes, and as such, should not be included as a diagnostic colonoscopy trigger code.

Include CPT® code 45388 (“Colonoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)”). Procedures previously reported using CPT® code 45383 are now reported using CPT® Code 45388.

Chronic Condition Episode Groups

For each chronic condition episode group, CMS proposes that an episode would be triggered by one or more ICD-10-CM diagnosis codes. While AGA supports this approach, we urge caution in developing chronic condition episode groups. Measuring cost in chronic conditions without adequate risk adjustment and robust measures of quality and outcomes may generate imperfect information and worse yet, may create incentives to provide lower quality care.

Below we provide detailed comments on three chronic condition episodes – chronic liver disease, gastroesophageal reflux disease (GERD), and inflammatory bowel disease (IBD) – and their associated draft trigger codes.

Chronic Liver Disease

We recommend that CMS make several changes to the trigger codes for chronic liver disease:

Remove ICD-10-CM codes K70.3, K72.1, K73, K74, and K74.6. These ICD-10-CM codes are non-billable as they are non-specific codes.

Additionally, AGA recommends establishing subgroups that distinguish between compensated and decompensated cirrhosis. Decompensated cirrhosis is identified by the presence of complications, which may be identified by the primary ICD-10-CM diagnosis code or secondary diagnosis codes.

- **I85.10** (“Secondary esophageal varices without bleeding”)
- **I85.11** (“Secondary esophageal varices with bleeding”)
- **K65.9*** (“Peritonitis, unspecified”)
- **K70.31*** (“Alcoholic cirrhosis of liver with ascites”)
- **K70.40*** (“Alcoholic hepatic failure without coma”)
- **K71.10*** (“Toxic liver disease with hepatic necrosis, without coma”)
- **K72.10*** (“Chronic hepatic failure without coma”)
- **K72.90*** (“Hepatic failure, unspecified without coma”)
- **K75.1** (“Phlebitis of portal vein”)
- **K76.6** (“Portal hypertension”)
- **K76.7** (“Hepatorenal syndrome”)

In the list above, the asterisk identifies ICD-10-CM diagnosis codes that would both identify cirrhosis and the presence of complications. The other ICD-10-CM diagnosis codes would be secondary diagnosis codes.

GERD

We recommend that CMS make several changes to the trigger codes for GERD:

Remove ICD-10-CM code K21. This ICD-10-CM code is non-billable as it is a non-specific code.

IBD

We recommend that CMS make several changes to the trigger codes for IBD:

Remove ICD-10-CM codes K50, K50.0, K50.01, K50.1, K50.11, K50.8, K50.81, K50.9, K50.91, K51, K51.0, K51.01, K51.2, K51.21, K51.3, K51.31, K51.8, K51.81, K51.9, and K51.91. These ICD-10-CM codes are non-billable as they are non-specific codes.

Additionally, AGA recommends establishing subgroups that distinguish between Crohn's disease and ulcerative colitis. Additionally, ulcerative colitis should be further grouped to distinguish the extent of disease as pancolitis requires different management compared to proctitis and other types of ulcerative colitis.

Thank you for providing us with the opportunity to submit feedback on the proposed episode groupers. We look forward to continuing our discussions with CMS as you continue to implement MACRA and MIPS.

COMMENT 62 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Daniel F. Hayes, President, American Society of Clinical Oncology

Text of Comment:

The American Society of Clinical Oncology (ASCO) is pleased to submit comments on the Centers for Medicare & Medicaid Services (CMS) document soliciting comments on Episode-Based Cost Measure Development for the Quality Payment Program (QPP).

ASCO is the national organization representing more than 42,000 physicians and other healthcare professionals specializing in cancer treatment, diagnosis and prevention. ASCO members are also dedicated to conducting research that leads to improved patient outcomes and are committed to ensuring that evidence-based practices for the prevention, diagnosis and treatment of cancer are available to all Americans, including Medicare beneficiaries.

This notice provides an important opportunity for public comment on how to measure and compare oncologists and other health care providers on the basis of cost under the Merit-Based Incentive Payment System (MIPS). Although ASCO appreciates the Agency's efforts to seek feedback on episode groups for analyzing the cost of cancer care, there are foundational concerns that should be addressed prior to creating any oncology episode group. Until CMS has developed methodologies for collecting and analyzing data on cancer type, stage, genetic mutation and patient comorbidities, the Agency should use an alternative approach based on adherence to high-quality clinical pathways as a means to consider the value and cost of care provided by oncologists.

Proceeding without an adequate cost measurement methodology for cancer care would create perverse incentives and impose counterproductive penalties on providers serving Medicare beneficiaries with cancer. CMS should exempt cancer care from the cost performance category of MIPS until CMS produces a methodology that fairly and accurately assesses oncology resource use.

In the QPP final rule, CMS announced a policy to delay the application of cost measurement for all MIPS eligible clinicians until the 2018 performance period. This policy decision was critically important for cancer care providers because there is no existing cost measurement methodology that can be fairly or accurately applied to cancer care.

Cancer is not a single disease. Rather, the word “cancer” refers to many different diseases that are often complex to treat, requiring highly individualized treatments that are selected based on a patient’s cancer type, stage, genetic mutation and comorbidities. The variation in conditions and disease states creates tremendous difficulties in designing episodes of care that will fairly and accurately attribute costs to oncologists for cancer care. For example, individual physicians or oncology practices may specialize in treating patients with particular oncology diseases— comprised of cancer types, stages, genetic mutations, and comorbidities—that are especially complex and expensive to treat. Additionally, based on the subspecialty, the resulting expense may be different for similar levels of complexity depending on the specific disease treated. To protect the Medicare population, CMS must ensure that any cost methodology accounts for these considerations.

Clearly, no clinician should be penalized for giving the right treatment to the right patient at the right time. The cost measurement in MIPS must be refined to avoid violating this important principle in the area of medical oncology.

There are three primary considerations to establish a fair and accurate assessment of cancer costs for use under MIPS.

- First, data on the cancer type, stage, genetic mutation(s), and patient comorbidities must be used to create adequate risk-adjustment methodologies;
- Second, it is fundamentally unfair and counterproductive to include unadjusted Part B and Part D drug costs when analyzing the costs of cancer care (see discussion in next section below); and
- Third, CMS should directly take into account the added costs and vulnerabilities associated with disparities in the health care system that are associated with low-income and underserved populations.

Each of these elements are being studied in greater detail in the Center for Medicare and Medicaid Innovation’s Oncology Care Model (OCM), where early data demonstrate that substantial portions of OCM costs are related to the utilization of drug therapies. These costs are outside the control of oncology professionals and should be excluded from any analysis of the cost of cancer care.

Cancer episodes should be designed to assess oncologists on the use of the health care resources that are under their direct control instead of aggregate and unadjusted costs. We caution CMS from rushing to create episodes that are likely to result in diminished resources for providers who are willing and able to treat cancer patients who require particularly complex or expensive treatments, as well as those providers who are dedicated to treating individuals with cancer from rural and low-income communities.

We appreciate the Agency’s request for feedback on the appropriate design of episodes for chronic cancer care and the recognition that this notice lacks episode groups capable of capturing and assessing the nature and cost of oncology care. At present, we urge CMS to continue to refrain from calculating a cost measurement for medical oncologists in 2018. There are only two proposed episodes that may or may not involve patients receiving medical oncology services (the mastectomy episode and the prostate cancer treatment episode), and these episodes are unlikely to provide an accurate evaluation of the value provided by medical oncologists. These two episodes are related to surgical procedures rather than management of active and ongoing cancer treatment by a medical oncologist.

ASCO is available to assist the Agency in crafting episode-based methodologies, which must be refined to include the following:

- Appropriate triggering events *not necessarily limited to drug initiation* based on the relevant clinical factors for the specific condition and stage of cancer;
- Fair and transparent attribution methodologies that hold medical oncologists accountable only for the costs of care that are directly under their control;
- Recognition that significant variations in drug costs exist on the basis of the type, stage, and genetic mutations of an individual’s cancer and the patient’s personal preferences; and
- Account for the unique challenges in oncology treating populations in low income and rural areas in a manner that does not create disparities or exacerbate existing disparities.

CMS should promote the appropriate use of health care resources in oncology care by permitting oncologists to adhere to clinical pathways that meet ASCO’s “Criteria for High-Quality Clinical Pathways in Oncology” as a means to evaluate the value and cost of oncology services and drugs provided under MIPS. Pathways are evidence-based treatment protocols for specific conditions that focus on promoting value and eliminating unnecessary variations in care.

CMS should engage ASCO and other stakeholders in focusing on the use of high-quality clinical pathways as a means to assess and promote value and cost-savings through the appropriate use of drug therapies in cancer and by reducing variations in care that are not supported by the clinical evidence.

Oncology clinical pathways are gaining broad acceptance in the payer and oncology communities as tools to assess whether clinical resources are being appropriately used in the practice of cancer care—both oncology services and drugs. Oncology clinical pathways “are detailed, evidence-based treatment protocols for delivering quality cancer care for specific patient presentations, including the type and stage of disease.”¹ The increasing use of oncology clinical pathways by payers signals an approach to resource management in cancer care that focuses on reducing treatment variance for specific conditions instead of financially penalizing oncologists for providing the clinically appropriate care.

ASCO has partnered with a wide range of oncology stakeholders to include clinical pathways in the next iteration of the Patient Centered Oncology Payment (PCOP) model, which is ASCO’s

proposed Advanced Alternative Payment Model (APM) for cancer care. Integrating clinical high-quality pathways into MIPS scoring and assessment will facilitate smooth transitions for oncologists into Advanced APMs.

ASCO recently released a document entitled “Criteria for High-Quality Clinical Pathways in Oncology” that details the elements of well-designed pathways, which “can be an important tool for improving adherence to evidence-based medicine and reducing unwarranted variation in cancer care.”ⁱⁱⁱ These standards promote the development, use, and analysis of clinical pathways to assure the pathway is evidence-based and promotes high-value care for all cancer patients being treated on the pathway.

Pathways are often based on the type, stage and molecular subtype of the cancer involved, making pathways clinically appropriate tools for determining whether a provider adhered to a clinically appropriate course of care and eliminating incentives to use suboptimal treatments. By focusing on appropriate use of drug therapies and other health care services, pathways help address a key inequity in the measurement of oncology costs.

Measuring the cost of cancer care by directly calculating unadjusted drug costs is inappropriate and counterproductive. Oncologists have little or no control over the drug prices charged by manufacturers and distributors. In many instances, the best interests of an individual cancer patient are served by using specific drugs within their anticancer regimen because a single molecular entity provides a clear clinical advantage for a particular patient without another drug providing a clinically equivalent substitute. As a result, medical oncologists often are left with little flexibility to reduce overall costs by selecting less costly drugs.

The aggregate costs of drugs prescribed by many medical oncologists are often quite significant compared to other costs associated with other specialties. Within the specialty, the aggregate costs of cancer drugs prescribed by individual oncologists can vary significantly based on the sub-specialization of a particular oncologists and whether new, expensive drugs play a prominent role in the appropriate treatment of their patient population. Additionally, there are oncology disease states in which **no drug use** is either indicated or clinically appropriate. A cost model, which fairly compares all of these clinical realities, would thus need to exclude drug costs.

ASCO would welcome the opportunity to work with CMS to continue to explore how pathways may be used as episodes for assessing value and cost for oncology services and drugs under the MIPS cost performance category.

Reporting cancer type, stage and genetic mutation is critical to creating episodes of care that can be risk adjusted to ensure fair and accurate measurement of cancer resource use. CMS may wish to draw upon past efforts, explore existing data sources and work with ASCO to establish appropriate reporting mechanisms that are not overly burdensome to oncology providers.

We appreciate the Agency’s recognition that it is imperative to collect accurate and verifiable data on the type and stage of cancer to create appropriate cost measures under MIPS. Cost of care varies significantly on account of these factors. Leveraging existing resources beyond billing data may help avoid creating unnecessary administrative burdens and educate providers on new reporting obligations.

Fair and accurate cost comparisons in cancer care depend on collecting data that reflects cancer type, stage and molecular mutation that are granular enough to yield clinically appropriate comparisons. In 2006, CMS conducted a demonstration program that encouraged oncologists and hematologists to report clinical information on disease states by using G-codes. The Agency created eighty-one new G-codes that tracked care based on disease states, reason for visit, and adherence to clinical guidelines.ⁱⁱⁱ Creating new codes or modifiers in collaboration with ASCO could offer an appropriate means for data collection. However, these efforts will only be successful if reporting this data minimizes the burden on the practice and the provider.

In addition to focusing on how CMS may collect stage and disease state data through the Medicare billing system, CMS may also wish to explore mechanisms used in real-world big data applications such as ASCO's CancerLinQ program. ASCO remains willing and able to assist the Agency in creating mechanisms to collect this data as it is imperative to the development of episodes of care that fairly and accurately assess the cost of cancer care under MIPS.

i Zon, RT, Frame, JN, Neuss, MN, Page, RD, Wollins, D, Stranne S, Bosserman, LD: American Society of Clinical Oncology Policy Statement on Clinical Pathways in Oncology. J. Oncol Pract 12:261-266, 2016

ii American Society of Clinical Oncology Criteria for High-Quality Clinical Pathways in Oncology, <http://www.asco.org/sites/new-www.asco.org/files/content-files/blog-release/documents/2016-ASCO-Criteria-High-Quality-Pathways.pdf>

iii Doherty, J, Tanamor, M, and Goldber-Dey, J.: Oncologists' Experience in Reporting Cancer Staging and Guideline Adherence: Lessons from the 2006 Medicare Oncology Demonstration. J Oncol Pract. 6:56-59, 2010.

COMMENT 63 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Michael Stevens, President, Coalition of State Rheumatology Organizations

Text of Comment:

The Coalition of State Rheumatology Organizations, or CSRO, is a group of state or regional professional rheumatology societies formed in order to advocate for excellence in rheumatologic disease care and to ensure access to the highest quality care for the management of rheumatologic and musculoskeletal diseases. Our coalition serves the practicing rheumatologist.

We are pleased to provide input that will inform the development of episode groups for use in the cost performance category of the Merit-based Incentive Payment System (MIPS).

Episode-Based Cost Measure Development for the Quality Payment Program

Episode Group Selection

As outlined in the report accompanying the draft episode groups and trigger codes, CMS notes that it considered Medicare expenditures, clinician coverage, and the opportunity for improvement in acute, chronic, and procedural care settings in selecting the episode groups to be considered for development. Not surprisingly, rheumatoid arthritis (RA) and systemic lupus erythematosus have been identified by CMS for episode group development. CMS previously proposed resource use measures for RA and Osteoporosis – measures that CSRO opposed for inclusion in MIPS – which we assume will be replaced by these new episodes.

Rheumatologists would prefer being held accountable for the cost of care for conditions within our scope of clinical practice and for patients we routinely manage, instead of a broad range of medical conditions and beneficiaries we seldom see, as is the case under the current cost measures – Total Per Capita Costs and Medicare Spending Per Beneficiary (MSPB) – which were retained from the Value-Based Payment Modifier program.

Episode Group Definition, Chronic Condition Episode Groups & Cost Measure Development

CSRO agrees with the list of ICD-10-CM diagnosis “trigger codes” identified for the lupus episode group, but has significant concerns about the ICD-10-CM diagnosis “trigger codes” for the RA episode group. This is because most of the ICD-10-CM diagnosis codes listed are inappropriate for reporting the vast majority of RA conditions and are seldom, if ever, used. RA is a systemic disease and is not localized to a single joint.

CMS also notes its interest in public comment on where sub-groups could be created in the draft list of episode groups. CSRO believes the RA episode is prime for sub-groups parsed by disease progression and whether the pharmaceutical therapy chosen is covered under Part D or Part B. For example, Felty’s Syndrome is difficult to treat and the standard of care is directed against underlying RA with an additional goal of treating neutropenia and recurrent infections. Also, depending on how drugs are incorporated into the RA episode group, it will be important to differentiate between whether Part D or Part B drugs are chosen (see below). Given the above, it is critical to further subdivide the RA episode group to yield a more clinically homogeneous cohort of patients with similar expected costs.

To be able to provide more meaningful comment, we urge CMS to provide details about the parameters for these measures, including:

- When the episode would begin and end
- What the relevant ICD-10-CM codes for these episodes are
- What CMS anticipates as exclusion criteria for these episodes
- How the episode will be attributed to rheumatologists and providers participating in the patients care, such primary care providers
- How risk adjustment, including social risk factors, will be accounted for
- How frequently CMS anticipates these episodes would be updated to account for changes in clinical practice and medical inflation
- How Part D drugs are accounted for

To further elucidate on Part D drugs, CSRO has previously commented about this issue, urging the agency to appropriately and adequately account for pharmaceuticals in its resource use metrics in the Value-Based Payment Modifier (VM). When cost and resource use measures exclude Part D costs, it puts physicians who administer Part B drugs in their office at a significant disadvantage compared to those who order/prescribe drugs covered under Part D, since the former would appear to have higher Medicare expenditures than the latter. It may also disadvantage beneficiaries, as treatment options could become more limited when providers are inappropriately held accountable for costs beyond their control. CMS has previously noted that use of the Hierarchical Condition Categories (HCC) model may account for some conditions that require Part B drugs, however, it does not distinguish between the appropriateness of Part D

drugs v. Part B drugs and unduly punishes physicians who ultimately determine that Part B drugs are most appropriate for their patient. We continue to believe the current methodology has the potential to influence treatment decisions as physicians are perversely incentivized to prescribe Part D drugs when Part B drugs may be more appropriate for the patient. This must be addressed as CMS develops episode-based cost measures for use in the MIPS cost performance category.

Whether the solution is to remove Part B drug costs from resource use calculations or to incorporate Part D drug costs into these calculations, the most important thing is that cost-of-care measures not have an adverse impact on practice patterns and do not discourage treatments that best meet the needs of the patient. We emphatically request that CMS either remove Part B drug costs, or include Part D drug costs, as it evaluates resource use under the resource use performance category.

Timing

A review of CMS' Measures Management System web page suggests that CMS is carrying out the development of episode groups in "waves" and that rheumatologic conditions are likely slated for "wave 2". This is based on CMS' plans to convene future MACRA Clinical Subcommittees that may include "Rheumatologic Disease Management" in the next wave (a call for technical experts for the first wave is underway).

We are concerned that, with CY 2018 fast approaching and the weight of the cost performance category slated to increase, we will not have a fair opportunity to review the planned cost measures and provide feedback to the agency prior to the implementation of episode groups in the MIPS cost performance category. We are also concerned that the measures will not have enough time to be "field tested" prior to implementation, which is a critically important step prior to holding rheumatologists accountable. We ask that CMS provide more information about its plans for implementing the new episode-based measures in the MIPS cost performance category, as soon as possible.

COMMENT 64 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: James L. Gajewski, Individual

Text of Comment:

I am writing as a private citizen on these issues. As background, I recently have served as member of RVU Update Committee (RUC) on rotating internal medicine seat, was RUC representative to CPT Editorial Panel, chair healthcare finance committee for Oregon Medical Association, Council of Medical Directors of National Marrow Donor Program and am currently serving as president of Oregon Society of Medical Oncology. Recently I served on the initial Acumen working committee to develop episodes of care and attended as a participant the Physician Focused Payment Model Technical Advisory Committee (PTAC)

I appreciate the opportunity to comment on Episode-Based Cost Measure Development as part of the Quality Payment Program. I commend the efforts by CMS to make the methodology of this important new policy transparent to all parties.

My clinical experience is as practitioner of hematopoietic cellular transplantation (HCT). I have published on providing intensive, high-resource utilization care to individuals with very high risk hematologic malignancies, and the interactions with the costs of this care. HCT are usually paid for within case rates or other payments that shift financial risk to the provider. In 2015, on behalf of the American Society for Blood and Marrow Transplantation, I authored a request to have HCT providers to be given separate specialty designation by CMS to distinguish our clinicians from hematology and oncology because our practices were very different in resource consumption. This request was granted November 2016.

Concerns with Episode-Based Cost Measure Methodology

I have several general concerns, as well as several concerns specific to the cost measure categories currently proposed.

Episode Groupers: I am concerned where episode groupers are kept broad and are not acuity risk-adjusted due to concerns over inadequate numbers. It is rare that one individual provider will see a volume of cases sufficient enough to establish a bell-shaped curve to be used for fair comparisons. Any episode grouper that cannot be adjusted to reflect acuity and clinically needed resource consumption and outcomes measures should not be used. While it would be ideal that episode groupers also link to outcomes measures, we worry that such linkage for every grouper will promote processes and episode grouper selection that increase risk of being very selective in one's patient population, potentially creating beneficiary problems with provider access.

Episode triggers: and the appropriate codes to reflect them, will be important. For chronic and acute diseases, the ideal trigger is a clear diagnosis established pathologically or radiologically. For pathological-confirmed diagnoses, the trigger date cannot be the date when pathological samples were obtained but rather must be the date when results are available to confirm the diagnosis, and as such, that clinicians are comfortable engaging in clinical interventions. I recognize that certain diagnoses are clinical diagnoses; these will be problematic to set up a trigger mechanism and will rely on a relevant clinical note stating sufficient grounds for moving forward with a diagnosis-based treatment plan. That will require a clinician initiating an episode of care measurement. I do not see another way than physician self reporting. To date no one has determined who will identify episode triggers and who will attribute physician role to an individual provider. This determination needs separate public comment.

Adjustment for Clinical Acuity and Patient Socio-Economic Status: The development and implementation of episode groupers will be important in preventing decreased access to care for those beneficiaries with advanced disease, patients with complex psychosocial situations, and patients with multiple comorbidities, especially those in which treatment for one disease adversely affects outcomes for other diseases-such as treatment of cancer with steroids in a patient with diabetes mellitus where steroids will make diabetes worse.

Providers need to be encouraged to document diagnoses coding in detail, particularly while in the learning phase of a new compensation system. Proper documentation and coding of these details takes time and will likely be without additional compensation. All factors affecting outcomes must be documented both in physician notes and in problem lists that are then translated into claims data. Many things that in the past have not been in progress notes, problem lists and claims data must be recorded for risk adjustment, such as family concerns, lack of transportation and other significant SES indicators.

At the recent PTAC meeting, I commented for proper acuity adjustment in the COPD alternative payment model, CO₂ retention or mixed acid base disorder with hypercapnia need to be listed in both the physician notes and the problem list, yet this would not be common physician practice. The HCC coding adjustments are not as risk adjusted as needed for this to be success. For COPD and asthma, CO₂ retention and respiratory acidosis secondary to hypercapnia do not instigate HCC adjustment but these factors reflect the most severe COPD with the highest mortality risk. Greater specialty input into risk adjustment must happen to ensure the sickest beneficiaries have access to care as this example with COPD and mixed acid base disorder with hypercapnia illustrates a shortcoming of HCC adjustment for this diagnosis.

Providers have historically not documented or coded noncompliance with therapy or factors leading to noncompliance, like family dynamic problems, marital stress, mental health issues especially those with personality disorders, cognitive decline, early signs or suggestion of dementia, inability to afford medications, opioid abuse even in those patients with clear sources of pain, and/or inability to get to therapy due to distances or mobility issues. For risk adjustment to be effectively done, these factors need to be coded and be part of the episode risk adjusters, yet they can jeopardize the physician/patient relationship when they appear in the patient's electronic medical record. There may need to be restricted sections of patient chart for providers to document such health care problems; if these concerns are not address this, patients with these added afflictions may not find providers willing to care for them and the result will be limited access to care.

Providers caring for the sickest most complicated patients are already documenting with the highest level of inpatient and outpatient evaluation and management codes; they need to be compensated for the additional time for doing the additional documentation time for comprehensive coding. There may need to be modification of the prolonged service non-face-to-face CPT codes (99358 and 99359) to accommodate this need.

Attribution: HCT providers like me utilize team-based care and a patient may have 2-3 different inpatient attending physicians during his or her month-long transplantation hospital stay. Attributing a clinician for purposes of these efforts will be problematic due to the structures of providing intensive care over a prolonged period of time. This may be easier to deal with for surgical and radiological proceduralists, but for our member physicians, attribution of costs of care can only be team based. Acuity and resource consumption are determined by where the patient is in the clinical course of disease, so assignment of a provider other than by team is meaningless. MACRA legislation encourages practices to have a team of physicians and advance practice professionals.

The advance practice professionals will sometimes see a patient independently, but while seeking advice of a physician and using a split/shared visit. Current payment-claims databases also do not segregate advanced practice professionals by specialty; those treating complex patients in a team based environment may be severely disadvantaged. Team based reporting measures must be included. The common tax 10 may work, but warrants a trial period. Our providers problems with single physician attribution vs. team attribution are mirrored by many internal medicine specialty groups managing severe chronic diseases like congestive heart failure, chronic liver disease with ascites etc. where multiple physicians monitor these patient in outpatient and inpatient venues due to the high acuity of care.

Concerns on Specific Grouper Proposals

None of the diseases identified for the first rounds of measures are the principle focus of HCT physicians, but HCT physicians often provide on-going care for the entire patient for 1 to 2 years post-HCT. Thus, the proposed measures do occur during the times HCT providers are responsible for care.

Acute Care Episodes:

- Acute Myocardial Infarction: The presence or absence of heart failure determines resource consumption and length of stay. The location of myocardial infarction determines both resource consumption and length of stay, with an inferior wall MI requiring less monitoring than an anterior wall MI . Patients on coronary angiography having left main disease or severe triple vessel disease will likely have an emergency CABG surgery, providers who diagnose this severity early should not be penalized for high resource consumption.
- Bronchitis and Asthma: Patients with CO2 retention and on chronic steroids will not do as well as others, so there needs to be acuity adjustment. Specialists are likely to see more advanced disease. Pediatric patients with poor home situations are also likely to have more prolonged course.
- COPD: Patients with carbon dioxide retention, on chronic steroids, and/or on continuous oxygen will do worse so there needs to be acuity adjustment. Patients with FEV1 less than 1 liter will also do worse than relatively uncomplicated patients. Specialists are likely to see more advanced disease. Failure to segregate these high risk patients will cause access to care issues.
- Diabetes: This needs to be risk adjusted for patients with Type 1 or Type 2 diabetes, diabetes secondary to steroid usage, and "brittle" diabetics. Patient with diabetic complications like renal disease, vascular disease, neuropathy will do worse. Patients with long term diabetes and cerebral vascular disease will likely have cognitive impairment that will create compliance issues. Patients with a noncompliant with diet will have longer stays. Again acuity adjustment is needed here to ensure beneficiaries with advance disease have no access to care issues
- Gastrointestinal Hemorrhage: Site of gastrointestinal hemorrhage, presence of thrombocytopenia or other coagulopathy will determine outcomes and resource consumption.

- Renal Failure: Stage of renal failure, underlying etiology and need for dialysis as well presence of heart failure will drive resource consumption.

Chronic Care Episodes:

- Asthma/COPD: These two entities should be separated. Asthma is often a younger population than the COPD population. Asthma is often triggered and exacerbated by environmental allergens. COPD typically occurs in older patients and often secondary to smoking. Older patients with a history of smoking may have ischemic heart disease or vascular disease, both peripheral and cerebral, complicating care. Some of the medications for heart disease, such as beta blockers, will worsen COPD. Children with asthma both have exacerbations with environmental stimuli and psychological or family stress, but rarely have comorbidities as extensive as older adults with COPD.

- CAD: Coronary artery disease has different resource consumption based on severity of disease or vessel involvement, proximal vs. diffuse distal disease, presence of heart failure, and presence of diabetes. The latter patients often do not have chest pain or angina as warning of impending decompensation. CAD must have acuity adjustment

- Lupus: Lupus is a clinical diagnosis without a defined pathologic biopsy or radiologic diagnostic criteria. It is very hard to diagnose so identifying the correct way to trigger an episode will be problematic. This disease has heterogeneity of complications and morbidity, with those having CNS lupus or severe joint disease having more resource consumption and often requiring different monoclonal antibody or immune modification therapy.

Procedural Grouper Proposals:

- Melanoma Destruction/Excision: Proper therapy of a new melanoma or recurrent melanoma lesion is always excision and never destruction. Destruction would make staging of melanoma and confirmation of total removal impossible. Destruction of melanoma must be taken out of episode grouper definition. Patients presenting with metastatic melanoma have different procedure and resource consumption than those with simple skin lesion.

- Prostate Cancer Treatment: There are many patient specific factors governing therapy options for prostate therapy including patient choice and local availability of some therapy. Local disease stage, Gleason score, presence of metastases and comorbidities play a role in determining therapy and treatment. Different providers will advise and complete varying types of therapy, with urologists performing surgery, radiation oncologists providing radiation therapy and medical oncologists treating mostly metastatic disease. For initial therapy, I cannot emphasize enough, how much patient choice plays a role. We cannot penalize providers for allowing patient choice.

- Simple and Modified Radical Mastectomy: Simple mastectomies are often done for prophylaxis or where there is only Stage 1 disease, whereas modified radical mastectomies are done where local disease is more extensive. Complications and postoperative pain, and corresponding treatment, are different for both procedures.

Thank you very much for reviewing my comments as a private citizen. I am happy to continue the dialogue.

COMMENT 65 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Kenneth R. McQuaid, President, American Society for Gastrointestinal Endoscopy

Text of Comment:

The American Society for Gastrointestinal Endoscopy (ASGE), representing more than 14,000 members worldwide, appreciates the Centers for Medicare and Medicaid Services (CMS) solicitation of input from the physician stakeholder community on episode groups.

ASGE's comment letter is divided into two sections: 1) responses to CMS questions; and 2) analysis of episode groups assigned to gastroenterology.

We appreciate CMS' demonstrated commitment to ensuring the input of physicians in the development of episode groups that are specific to their specialty. Specifically, through Acumen's convening of a Clinical Committee to develop care episode and patient condition groups, and later this year through the creation of specialty specific clinical subcommittees.

Episode Group Development Prioritization

CMS asked whether the criteria proposed for prioritizing the development of episode groups (cost share, clinician coverage, opportunity for improvement and linkage to quality) are appropriate and how they should be ranked, and whether other criteria should be considered.

Section 101(f) of the Medicare Access and CHIP Reauthorization Act (MACRA) requires CMS to establish care episode groups and patient condition groups, and related classification codes, to measure resource use for purposes including the Merit-Based Incentive Payment System (MIPS) and alternative payment models (APMs), and that these groups should account for a target of approximately 50 percent of expenditures under Parts A and B (with such target increasing over time, as appropriate). ASGE has previously encouraged CMS to take a gradual approach to reaching this 50 percent target, which would better allow for the prioritization of episode groups for which: reliable information is attainable; provider burden is minimal; and cost can be easily and accurately attributed to providers.

CMS has determined that cost measure development will occur in waves based on clinical subcommittees for clinical areas. Included in wave one is gastrointestinal disease management. Within this clinical area, ASGE recommends the prioritization of colonoscopy screening and surveillance in the outpatient setting and non-variceal upper gastrointestinal (GI) bleeding (NVUGIB) in the inpatient setting. Because this service and this condition, respectively, account for a high volume of patients cared for by gastrointestinal endoscopists, they can serve as a good starting point for a physician's overall quality and resource use as episode groups for other conditions and procedures are developed, including complex chronic conditions.

In addition to expenditure share, clinician coverage, opportunity for improvement and linkage to quality, episode groups should be prioritized based on the ability to define appropriate trigger

codes and to determine episode duration and the services and care that are appropriate to include in a typical case scenario for each condition. Reaching consensus and clinical stakeholder acceptance of these variables are critical and should drive prioritization of incorporation of episode groups as a cost measure within the Medicare Quality Payment Program.

Episodes as Discrete Events or Clinical Conditions for which those Events Occur

CMS is considering whether the focus of episode development be on comparing discrete events, such as acute hospitalizations or procedures. Or, alternatively, whether the focus should be on the clinical conditions for which those events occur.

ASGE believes that whether an episode compares a discrete event or a clinical condition in which those events occur should be determined on an episode-by-episode basis. Initially, the complexity of episode groups should be minimized while attribution methods are tested.

When focusing on clinical conditions, clinical and risk stratification criteria must be well defined. For example, in designing a colonoscopy group, a colonoscopy done for episodes of colon cancer screening and surveillance must be distinguished from those done for other clinical diagnostic or interventional situations such as GI bleeding, stenting for bowel obstruction, diagnosis of inflammatory bowel disease or ischemic colitis due to the large differences in incurred resource utilization for these procedures and complex care management by numerous providers.

Certain condition-based episodes (for example, GERD) could become too complex based on certain factors, such as the duration of the episode, or the rules for when the episode is triggered. For example, is the episode based on a primary diagnosis or are there other triggering factors. Acute hospitalizations/procedures have a finite beginning and ending, making them more manageable starting points for measuring physician resource use.

CMS has also asked how cost measure development can take into account multiple options that might be available in the care of a particular clinical condition. For example, cirrhosis could be looked at as a chronic disease management issue, or as an episode when there is a decompensation or hospitalization for complication. The possible scenarios are similar for inflammatory bowel disease.

Direct and Indirect Service Assignment

CMS states that it intends to provide information on the resource use of each member of a clinical team, enabling one clinician's directly-performed services to be considered as well as another clinician's indirect services when performed in the same clinical context. CMS is asking how this concept can be used to determine accountability for each member of the clinical team as an alternative to the entire episode being attributed to a single clinician.

ASGE believes it will be important to test the submission of patient relationship categories, which will be used for assigning clinician responsibility to a patient's care when multiple clinicians are involved. As CMS considers how it will apportion the cost of care among physicians when they are attributed to the same episode of care, ASGE suggests that the following potential pitfalls be considered:

- Attribution by plurality of charges may inadvertently penalize physicians who engage in high-volume, low-intensity services that may attribute a higher percentage of total cost to them due to higher volume of services

- Attribution by percentage of total charges may inadvertently penalize physicians who perform high-quality, high-intensity, low-volume services
- A physician specialist may be participating in the care of a patient to remediate a complication caused by the care of another acute or chronic condition treated by the primary physician. The cost of caring for this complication may exceed the cost of all other care and should not be attributed to that specialist but rather the primary or other physician.
- Physicians may try to minimize their attribution or potential "downside" by documenting a less intensive relationship if they believe the patient is likely going to be high risk/cost. This would suggest that the attribution assignment needs to somehow be automated and driven by claims and associated diagnoses/procedures.
- There is also the more global problem of physicians avoiding predictably high cost cases or cases likely to have poor outcomes. Recent data on the experience of New York cardiac surgeons imply that no longer publishing individual outcomes data was associated with improved interventions and better outcomes. While CMS' proposed programs aren't identical to the New York program, physicians justly fear the directions of public outcomes data and outcomes linked to reimbursement when conditions or patient characteristics not in a physician's control may lead to adverse outcomes to the physician. There are also, unfortunately, situations in which high-quality physicians practice in a peer environment of lower quality care/or higher cost care provision, and can then get "dragged down" in performance ratings and reimbursement.

Linking Cost and Quality

We agree with CMS that considering the cost of clinical services needs to account for the effects of those services on the quality of care. ASGE suggests that it is important for CMS to look at what options are available now that enable consideration of quality, and what infrastructure improvements can be considered over time to improve the linkage between cost and quality.

As ASGE has previously commented to CMS, we believe the most informative resource use measure is one that is aligned with a clinical quality measure. Ideally, the aligned resource use and quality measures would measure the same outcome as co-variables. This would require the identification of specific outcomes related to the condition or service being measured. We acknowledge, however, some of the challenges of aligning cost and quality measures under the Merit-Based Incentive Payment System (MIPS) due to discrete classification of cost and quality performance categories. Initially, focusing efforts on the collection of data from an electronic health record and clinical data registries will be essential to appropriately aligning resource use measures with clinical quality measures.

Screening and surveillance colonoscopy is a good example of how resource use and quality can be more easily aligned because quality criteria are well-defined and evidence-based, and there are numerous, approved, and endorsed measures that track with outcomes, including adenoma detection rate (ADR) as related to colorectal cancer mortality. ASGE and ACG's GIQuIC Qualified Clinical Data Registry (QCDR) captures these metrics. GIQuIC has been adopted as a method to track outcomes related to benchmarking in state healthcare innovation initiatives. Costs of providing high quality screening and surveillance colonoscopy reflect best practices, including complete examination in a well-prepared colon, and avoidance of procedure-related complications. Similarly, desirable outcomes related to effective therapies of non-variceal upper GI bleeding, as we have proposed for a patient condition, also correlate with costs, including decreased length of stay and avoidance of surgery.

Streamlining the communication and data reporting to CMS from QCDRs would constitute an important infrastructure improvement that will help to better align cost with quality. Positive benefits will include more efficient and effective feedback to clinicians resulting in more timely practice improvement.

Risk Adjustment

We believe one of the greatest challenges of cost measurement is how best to account for medical complexity and other risk factors. We suggest that CMS utilize the hierarchical condition category (HCC) coding as a tool for risk adjustment for cost measures under the Quality Payment Program. Should CMS choose another risk adjustment method, it is crucial that the methodology be transparent.

As ASGE has previously commented, the method of data collection will be a critical factor when deciding if the clinical criteria and patient characteristics for risk adjustment can be accurately captured. The medical community and CMS experts, working together, should examine each potential episode condition and help define known predictors of outcome for risk adjustment, as well as disease severity criteria, supported by best evidence.

Appropriate risk adjustment can be addressed, in part, by splitting episodes into more granular categories; however, this is complicated by the use of ICD-10 codes. We have recommended screening and surveillance colonoscopy as a more narrow episode group rather than any colonoscopy procedure as an episode group because of the complexity associated with colonoscopy done for other clinical diagnostic or interventional situations.

We have also recommended non-variceal upper GI bleeding as a finer category than any upper GI hemorrhage or GI hemorrhage in general. Variceal and non-variceal upper gastrointestinal bleeding are very different in terms of diagnosis due to underlying conditions. Variceal bleeding would commonly occur in a context of decompensated cirrhosis, which is a complex, costly episode that overlaps with this and other complications. Non-variceal bleeding, occurring in a hospitalized patient, is often different in risk to the patient, potential outcome and associated comorbidities from cases that occur in the outpatient setting. Resource use is, therefore, vastly different in these two settings and this needs to be captured in the construction of this episode.

GI Hemorrhage Acute Inpatient Medical Condition Episode Group

We have reviewed DRG and ICD-10 codes for the GI Hemorrhage. CMS currently lists DRG 377, 378 and 379 for this episode for GI Hemorrhage. Although, these three capture most of the GI bleeding ICD-10 codes, the following two ICD-10 codes are listed under DRGs 380, 381, 382, 383, and 384 related to Peptic Ulcer but not in 377,378,379:

- K2211 – Ulcer esophagus with bleeding
- Q430 – Meckel’s diverticulum (displaced) (Hypertrophic)

We believe that esophageal ulcer bleeding is common enough that it should be included in the codes for the GI Hemorrhage Episode, via DRGs 380-384.

The following three ICD-10 codes located in the DRGs (368, 369, 370) related to Major Esophageal Disorders should also be included in the GI Hemorrhage Episode.

- I85.10 – Esophageal varices with bleeding
- I85.11 – Secondary esophageal varices with bleeding

- K226 – Gastro-esophageal laceration-hemorrhage syndrome

Again, bleeding from esophageal varices is a common condition and should be included in the GI Hemorrhage Episode, via DRGs 368-370.

Outpatient events that could be considered candidates for development as acute condition episode groups (which include chronic condition exacerbations that require acute care but not inpatient hospitalization) include such conditions as chronic anemia from small bowel angioectasia bleeding (ICD-10 K31.811), Heyde's syndrome, Gastric antral vascular ectasia (GAVE) syndrome (ICD-10 K31.819), Osler Weber Rendu Syndrome (ICD-10 I78.0) to list a few.

Colonoscopy Diagnostic Procedural Episode

Overall, we believe that the Colonoscopy Diagnostic Episode has the appropriate range of CPT codes. However, we believe that the equivalent colonoscopy through stoma codes should also be included.

Conclusion

ASGE appreciates the opportunity to provide feedback on episode group measure development for the Quality Payment Program.

COMMENT 66 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Carolyn Magill, CEO, Remedy Partners, Inc.

Text of Comment:

Remedy Partners is an Awardee Convener in the Medicare Bundled Payments for Care Improvement initiative, acting on behalf of over 100 health care organizations initiating bundled payment episodes at 1,400 sites of care. We are also rolling-out bundled payment programs for managed care organizations, serving their employer, self-insured, Medicare Advantage and Medicaid programs. We offer these comments on the episode-based cost metrics from the perspective of coordinating tens of thousands of episodes daily.

We appreciate the efforts by CMS and Acumen to propose a framework for holding providers accountable through episode-based cost metrics. In general, however, the framework and grouper proposed will increase the complexity of administering bundled payments and requires further refinement before being ready for use. Triggering logic, grouping logic, closing rules, an opaque comorbidity/risk adjustment schema, and nesting are all in need of further refinement. This is a good starting place for considering refinements, but the Episode Grouper for Medicare is far from ready for prime time.

We believe that episode-based payment models can serve as powerful tools for organizing more efficient delivery of care and for improving patient outcomes. But we also agree with Mr. Harold

Miller, who observed at the April PTAC meeting that a payment model should not merely describe care patterns; rather, the payment structure should follow from a defined care model that addresses specific deficits in care. As Dr. Marsha Gold cautioned nearly twenty years ago about physician-focused bundled payments, “In developing a payment model, it is important to consider what one is trying to accomplish.”¹

As the CMS designs its episode-based cost metrics for measuring performance under the Quality Payment Program, we encourage the members to recall the 2009 article written by former CMS Chief Scientist, Dr. Stephen Jencks². Much has been done by Medicare since then to improve readmission rates. But CMS should consider how to use the Episode Grouper for Medicare to increase the accountability of hospital-based physicians for patients experiencing transitions of care during acute events. As Dr. Jencks and colleagues remarked, “[a]lthough the care that prevents rehospitalization occurs largely outside hospitals, it starts in hospitals.”³

For the episode-based cost metrics, we believe that CMS should focus on episodes that emphasize efficiency and patient outcomes during acute exacerbations of chronic conditions. This initial focus will allow the model to best meet the core assumption of the Episode Grouper for Medicare: coding completeness. Marsha Gold noted that “[i]t can be difficult to construct an episode because of incomplete charting of diagnoses.”⁴ (Gold M. Common Sense on Extending DRG Concepts to Pay for Ambulatory Care. *Inquiry* 1988;25:281-289.) Hospital-based practices are relatively better positioned than community-based providers to accurately and comprehensively code billings. We believe that episodes focused on inpatient settings are more likely to satisfy the coding requirements of the Episode Grouper for Medicare.

Moreover, episode types that focus on transitions of care during acute medical events are frequent enough for Medicare to be able to draw statistically significant conclusions. All payment models experience trade-offs between the homogeneity of the care pathway and the statistical reliability of the model. Our hospital medicine and orthopedic partners have found nevertheless that episodes focusing on acute events are sufficiently frequent to draw actionable conclusions for quality improvement. We believe that CMS should focus use of the Episode Grouper for Medicare to analyze episodes covering acute exacerbations of chronic conditions.

We strongly urge CMS to refrain from using this episode framework until further stakeholder input and analysis can be collected. To help with the process, we nominate Dr. Win Whitcomb to serve on the Episode-based Cost Metric Clinical Committee.

Thank you for the opportunity to comment on the episode-based cost metrics.

1 Gold M. Common Sense on Extending DRG Concepts to Pay for Ambulatory Care. *Inquiry* 1988;25:281-289.

2 Jencks SF, Williams MV, Coleman EA. Rehospitalizations among Patients in the Medicare Fee-for-Service Program. *N Engl J Med* 2009;360(14):1418-1428.

3 *Ibid.*

COMMENT 67 OF 69

Date: 4/24/2017

Commenter Name, Professional Title, and Organizational Affiliation: Gary H. Swartz, Senior Advisor for Public Policy, American Academy of Home Care Medicine

Text of Comment:

The American Academy of Home Academy appreciates the opportunity to comment on CMS development of episode groups and cost measures as required under MACRA. The Academy represents physicians, nurse practitioners, and physician assistants who provide house calls to some of Medicare's sickest and most costly beneficiaries—those with multiple chronic conditions who are home-limited due to illness and disability.

Our overall observations are that CMS should conduct additional analysis to improve episode groups and cost measure approach to MIPS by incorporating the following considerations that are discussed in greater detail in this letter:

1. Use of place of service to enhance provider to provider comparison and assure “like populations.”
2. Inclusion of a factor for functional status.
3. Inclusion of a factor for the clinical instability of provider's beneficiary population.
4. Use of a risk-adjustment model that explicitly incorporates dementia.
5. Take advantage of the discriminating ability of the clinical criteria for Independence at Home demonstration beneficiary eligibility in identifying more cost-homogeneous subgroups for chronic episode groups.

We believe, based on significant analysis of the Medicare 5% file that we would be pleased to discuss with CMS staff involved on the development of this important Quality Payment Program work that the incorporation of the recommendations around these factors will greatly improve accuracy. Moreover, these factors will help to support the workforce required for the care of the sickest most vulnerable Medicare beneficiaries.

Episode Groups

Question 1. Requested comments re: inclusion or exclusion of specific service codes to identify each episode group.

Response - We understand the use of specific services codes to identify each episode group. We have concerns discussed below regarding interaction of encounters and the chronic episode groups and how acute vs chronic categories will be established. We are also concerned about potential double counting of cost in cases of multiple chronic conditions if CMS suggests that total cost could be attributable to more than one chronic episode group. Such a policy of attributing full cost to more than one episode could harm this group of providers who treat beneficiaries with multiple chronic conditions as compared to Part B providers who render more acute and procedural based service.

Establish a proxy for functional status, which is not currently reported in claims: in terms of the approach to obtain information from claims, it is important to note that functional status is not included on claims. There is sufficient and accepted analysis that functional status has a material impact on cost. CMS will have to establish methods to account/risk adjust episodes for this additional, predictable cost. One approach for CMS to consider would be use of a risk index that

is predictive of functional impairments, such as the JEN Frailty Index (JFI). The JFI organizes claims to predict long term care expenditures (primarily long term institutionalization), which results in predicting functional impairments, due to the strong relationship between LTI and ADL impairments. The Veterans Health Administration uses the JFI currently for targeting some non-institutional care services, and is evaluating its use to refine funding allocation through VERA. An alternative approach to include functional status is that used by the IAH qualifying criteria, where discharge functional status is recorded on post-acute care reported assessments (OASIS, MDS, and FIM).

Question 2. Outpatient events/exacerbations of chronic conditions that should be considered as candidates for acute conditional episode group.

Response - We appreciate the CMS request for comment on this topic. However, we believe it requires additional analysis. We also believe it will be difficult to establish bright lines of what is an acute conditional episode group versus chronic episode group. For example, management of pneumonia is acute and, yet, may be difficult to distinguish from an exacerbation of COPD.

Carving conditions which can be manifestations of exacerbations of chronic conditions out as acute conditions may disadvantage those who more effectively manage those chronic conditions, preventing exacerbations. This could serve to discourage those who are effectively managing such chronic conditions in the home and assisted living facilities. We are interested in working with you on this topic should CMS decide to proceed in this area.

Question 3. Requested comments re: Should an Acute episode group be developed – that is site agnostic and that does recognize the performance of a procedure or not.

Response - We would like to learn more this question and purpose and are interested in contributing after we gain more understanding.

Question 4. Chronic Condition Episode Groups – whether and how to allocate treatment cost across multiple diagnostic conditions; whether to develop episode groups that captures multiple diagnoses, or develop a single episode group for outpatient chronic care with adjustment for comorbidities and demographics of the population served by the clinician.

Response – We recommend additional analysis of the third option – that is, a single episode for chronic care with adjustment for co-morbidities and demographics of the population.

We have learned through analysis of the 5% file that the HCC risk adjustment for the frail, disabled home limited population with multiple chronic conditions is inadequate to accurately predict future cost for those who meet IAH qualifying criteria. We have also identified approaches to better align current CMS risk adjustment with these high risk individuals. We believe that CMS should incorporate the following into its risk adjustment for co-morbidities and demographics:

Functional status – as noted elsewhere in this letter CMS should incorporate functional status (using an index similar to the JFI, or an adapted version of the JFI) to factor in the currently unaccounted cost associated with deficits in activities of daily living.

Clinical instability. - CMS should incorporate a factor to reflect the share of a provider's practice that reflects clinical instability. We have found in analysis of the Medicare beneficiary population that meets Independence at Home criteria ("IAH Q") that beneficiaries that enter into home care medicine practices during periods of clinical instability can reflect per beneficiary per month cost for a period of time that are 20% the cost of IAH Q beneficiaries who follow a more stable clinical trajectory.

Home care medicine practices are often small in number with a limited population in the hundreds of beneficiaries. As small practices, home care medicine providers are more susceptible to the higher costs of clinically unstable patients, and might be more likely to be disadvantaged by groupings sensitive to those costs. However, what is driving this high cost is the percentage of clinically unstable beneficiaries in the practice as compared to stable beneficiaries.

Home care medicine practices, caring for the home limited population, by definition will be treating some material number of clinically unstable beneficiaries (approximately one third of home care medicine practice on average). Therefore, CMS is encouraged to adjust for this clinical instability ("clinical hysteresis"), so as to not systemically disadvantage the providers who are treating the home limited population.

CMS can make an adjustment in the single chronic care episode group by incorporating a factor to reflect the percent of the provider's clinical unstable population as compared to their total IAH Q beneficiary population.

CMS can validate these findings by review of the IAH Demonstration population, comparing the cost of care for those beneficiaries with a hospitalization in the 4 months prior to enrollment compared to those whose qualifying hospitalization occurred earlier than the initial 4 months before enrollment.

Additionally, we encourage CMS, to further improve the risk adjustment of the cost measures, could stratify the Medicare beneficiary population by IAH criteria and use this as another means to compare providers treating "like population" under the episode group approach to MIPS cost measure.

Incorporation of dementia diagnosis -. The generally used HCC model (V22) risk adjustment model does not include dementia as a condition, which is problematic for high-need Medicare populations, which have prevalences of dementia 5-15x greater than the general Medicare population. While we encourage the use of a risk adjustment model that uses dementia such as the V21 model, but we think more simply to include the dementia HCCs (51, 52) in re-estimating the V22 models.

Cost Measure

Question 1- What other elements beyond expenditure assignment, attribution, risk adjustment, and consideration of quality should be considered?

Response - This is an important question. Provider focus upon a distinct patient population and setting of care must be taken into consideration. We have experience with Part B analysis that providers who focus on the frail, disabled, multi-morbid population in the home setting are

disadvantaged, (and considered “outliers”), in utilization and cost comparison where only same specialty is considered for comparison. Other factors must be incorporated to produce a reasonable (“apples to apples”), comparison.

Accordingly, we recommend that CMS include:

- Provider place of service. We have learned that specialty designation by itself is not reasonable for an “apples to apples” comparison. Moreover, CMS’s own analysis has reflected that those who take care of the geriatric population are penalized more as a percent of specialty under the value based payment modifier that preceded this work. As a result, particularly for the field of housecalls where providers of various specialties render service, inclusion of place of service must be included so that providers who care for the high cost, frail, disabled home limited are not disadvantaged.
- Dementia condition categories for scoring in the HCC model that is used.
- Functional status – as previously mentioned functional status greatly influences cost of care and a means to incorporate functional status (such as the JEN Frailty Index) must be established.
- Confirmation that CMS will use payment without geographic adjustment. We have learned and has been confirmed by MedPAC that the high cost, high risk population is more homogenous in terms of cost than mean county costs. As a result, CMS must take steps to not disadvantage providers rendering services to high cost patients in “low cost” counties.

Question 2. How should the cost of attributable services for treatment of the same patient be allocated – weighted based on direct or indirect responsibility or percent determined in advance through work of multi-specialty panels?

Response - Given that the episode groups and cost measures will be new and that CMS is not collecting the patient relationship categories until 2018 there may not be data on direct on direct and indirect responsibility. CMS may want to consider the use of representative multi-specialty panels to begin with a transition to results that are informed by the patient relationship categories.

Alternative to cost allocation - CMS may also want to consider how much (after incorporating the risk adjustment improvements noted in this letter), the cost of a provider’s patients that are above the expected costs for that population of beneficiaries treated by the provider. With construction of a multi-morbidity chronic episode group, this would be a better fit with current risk adjustment models (total cost, across multiple conditions), yet would allow identification of providers whose attributed patients generate greater expenditures than expected. We feel it would be a challenging task to accurately, and convincingly, allocate costs within an episode group to particular providers, particularly for the multi-morbid. The share of an attributed group of patients with above or below expected costs would be a more believable measure of the cost performance of a provider, the goal of the cost component of MIPS. In comparing “like patients” CMS would look at the cost distribution of the provider as compared to what would have been expected for that provider.

Question 3. Use of the CMS-HCC Risk Adjustment Model. Should this or an alternative for risk adjusting episode groups be used in the construction of cost measures? In addition, should concurrent or prospective risk adjustment be used, and should a full year of data or more targeted data from before the episode be used to adjust?

Response- We have identified and CMS has agreed in review of the Independence at Home demonstration that the CMS-HCC risk adjustment model is inadequate to accurately and completely predict the future cost of care. This analysis is based on the Medicare 5% file from multiple years. There are fortunately, elements that can be applied to improve the accuracy of the CMS-HCC Risk Adjustment Model.

We recommend that CMS review the Independence at Home criteria as it continues its work on episode groups. Analysis of this data has been developed and shared with CMS in different forum. As mentioned above CMS should incorporate the following.

1. Factor for functional status – the JEN Frailty Index, as discussed above, has been validated for this purpose. CMS could use the JFI or other means to establish the factor for functional status on as accurate a basis as the JFI.
2. Factor for clinical instability as discussed above in Episode Groups – Question 4.
3. HCC model that incorporates dementia diagnosis in the HCC scoring. HCC models that do not incorporate dementia are inadequate to risk adjust for the frail elderly population.

More generally, HCC risk adjustment is for total cost of care, not cost within an episode group; and by themselves would not necessarily account for costs across multiple episode groups (for example, CKD, CHF, COPD, and diabetes chronic episode groups).

Concurrent vs prospective risk adjustment - We recommend that concurrent risk adjustment be used, as analysis supports that diseases and events in the current year drives futures cost. This is particularly the case for the acute episodes.

The role of risk adjustment here—to be used for performance comparison—reduces some of the gaming incentives of concurrent models where risk adjustment is directly related to payment, such as Medicare Advantage.

Amount of data – We recommend that two years of HCC data be used for chronic conditions, while for acute conditions 1 year (the concurrent year) is sufficient. Analysis has shown that 2 years of data improves the predictive power of the HCC model, particularly for well-managed patients with lower rates of hospitalization. This is because diagnostic coding is superior in hospitals than in outpatient practices, where it's easier for chronic conditions (among patients with multiple conditions) to fall off, when a claim is limited to 4-8 diagnoses.

Question 4. Request for comments re: considerations for aligning episode groups with quality measurement.

Response - We support CMS work in this area. We believe it may be easier to align episode groups with quality measurement than to decompose costs between groups and among providers. This would be particularly beneficial in support of the move to outcomes measures. It would be

beneficial to establish additional quality measures concurrent with the development of episode groups that are relevant for the treatment of frail, disabled beneficiaries with multiple chronic diseases.

The existing inventory of MIPS quality measures does not provide sufficient and relevant opportunity to compare the services of providers for this patient population. Accordingly, we look forward to working with you to develop and align quality measures with the episode groups.

Question 5. How to avoid unintended consequences of cost measures in MIPS; such as taking steps to avoid disadvantaging clinicians who assume the care of complex patients through the use of cost measure in MIPS such as by applying episodes for comparison of complex patients (i.e., comparison of like-patients of different clinicians).

Response - Our comments to this question are the same as for Cost measure Question 1.

Question 6. What would be the best way to incorporate Part D costs into the episode group development?

Response - Incorporation of Part D costs would produce a more comprehensive view of cost and of care. However, Part D is a complex program and definitional work needs to occur. There have been developments in past few years such as availability and use of biologics that are driving changes in care in areas such as outpatient chemotherapy and rheumatoid arthritis. Other settings and specialties may reflect opportunity and success in mitigating drug utilization (for example, polypharmacy management by those treating beneficiaries with multiple chronic conditions). Additionally, review of Part D cost could support analysis of the tradeoffs of treatment options and utilization under Part D.

This would produce additional support for the accurate and complete risk adjustment for episode groups and cost measures. Against this backdrop, the incorporation of Part D cost creates a number of foundational definitional issues that must be addressed.

These include:

- What cost will be considered Part D drug cost?
- Is this the cost by Part D plan to the Medicare program?
- Is this the cost of acquisition by Part D plan?
- What is the role and consideration of pharmacy benefit managers, operations and formularies?
- What roles does and should beneficiary co-insurance play in the determination and comparison of cost?

Once the definitional work is completed, the share of cost represented by Part D for each of the episode groups could be established, and those groups for whom Part D costs are a significant driver (e.g., biologics in the Rheumatoid Arthritis chronic episode group) might have pharmaceuticals included. Such ranking by cost and percentage to total cost could provide opportunities for additional analysis and treatment options.

Given the importance of this question and the foundational definition work that should first occur we recommend that CMS convene representatives of stakeholders to further develop this area of work.

We appreciate this opportunity to comment on the episode groups and cost measures and we look forward to providing additional contribution to CMS work in these areas.

COMMENT 68 OF 69

Date: 4/25/2017

Commenter Name, Professional Title, and Organizational Affiliation: Mary Norine Walsh, President, American College of Cardiology

Text of Comment:⁷

The American College of Cardiology (ACC) is providing the following comments to the Centers for Medicare and Medicaid Services (CMS) and its contractors on the draft list of episode groups as required under Section 101(f) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and the approach to develop cost measures detailed in the Episode-Based Cost Measure Framework document.

The ACC is a 52,000-member medical society that is the professional home for the entire cardiovascular care team. The mission of the College is to transform cardiovascular care and to improve heart health. The ACC leads in the formation of health policy, standards and guidelines. The College operates national registries to measure and improve care, provides professional medical education, disseminates cardiovascular research and bestows credentials upon cardiovascular specialists who meet stringent qualifications. The ACC also produces the Journal of the American College of Cardiology, ranked number one among cardiovascular journals worldwide for its scientific impact.

The ACC recognizes the value of developing episode groups to measure cost yet understands this is a challenging endeavor. Therefore, the ACC strongly urges the Agency to proceed thoughtfully and cautiously, taking time to gather input from all relevant stakeholders, including the medical specialty societies when ultimately creating new groups, refining existing groups and seamlessly implementing them into the Merit- Based Incentive Payment System (MIPS) and other payment programs. Such engagement should occur through transparent dialogue. The College has submitted comments throughout the episode group development process and has engaged in the clinical subgroups convened by Acumen; however, we remain unaware of how our prior recommendations have been considered or incorporated into the development of episode groups. Any episodes developed should be tested or phased into the Quality Payment Program (QPP) prior to being used to calculate a clinician's MIPS score. Therefore, the College is uniquely positioned to provide valuable input from the perspective of practicing clinicians and cardiovascular administrators. This perspective is crucial to the development of realistic and accurate episode groups as the needs and characteristics of the patients who will be attributed to these groups may vary widely. **Consequently, the College's comments focus on the *clinical***

⁷ The commenter submitted a comment after the close of the public comment period on April 24, 2017. The comment has been included in this report for completeness.

appropriateness of the cardiovascular episode groups. This refers to capturing a clinically comparable set of beneficiaries to allow for an accurate understanding of cost and quality as well as subsequent reasonable and appropriate care redesign.

The following comments focus on recommendations to specific cardiovascular episode groups from the draft list provided and the framework for developing cost measures as released in the Episode-Based Cost Measure Development for the Quality Payment Program document on December 23, 2016. The comments are organized into the following sections: general comments on episode groups in cardiology, selecting episode groups for development and implementation, comments on the draft list of episode groups, and comments on the overall cost measurement development framework.

General Comments on Episode Groups in Cardiology

Procedural vs. Acute and Chronic Condition Episode Groups

The ACC recommends prioritizing the refinement and implementation of procedural episodes over acute and chronic condition episode groups until improved methodologies can be developed. As conveyed in prior comments, procedural episode groups are the least difficult type of episode group to develop and implement due to the ease of defining episode elements and relative clinical homogeneity of the patient population when compared to acute and chronic condition groups. Procedural episodes, by definition, involve clear identifiable triggers and typically have well-defined expected outcomes in addition to a predictable window of time in which possible complications can occur. Some acute medical condition episode groups are similar to procedural episode groups in that they often have identifiable triggers. However, in contrast to procedural episode groups, patient heterogeneity makes the ability to predict outcomes and timeframes for defining an episode much less clear.

The ACC remains concerned about the development and implementation of chronic cardiovascular condition episode groups. The College strongly recommends that CMS proceed with caution in this area. Due to the clinical heterogeneity of the population for such chronic conditions, appropriate treatment pathways, costs, and outcomes may vary significantly. Patients with chronic conditions will likely present with a number of acute exacerbations and concomitant co-morbidities over the course of their lifetimes; these factors will contribute to the individual clinical treatment needs of each patient. In addition, it is difficult to create a time-limited episode for a chronic condition. CMS proposes that chronic episodes would last a calendar year. Most patients who have chronic conditions have them for many years. Their treatment and costs may vary greatly depending on the stage of their condition. For example, a patient newly diagnosed with heart failure will have much different needs from a patient who has *advanced* heart failure. Moreover, patients with heart failure who have preserved as opposed to reduced ejection fraction have fundamentally different conditions and treatment needs. However, based on the current methodology, all of these patients could be attributed to the *Heart Failure* chronic condition episode group. For these reasons, CMS should continue to evaluate whether it is appropriate to measure cost based on chronic condition episodes.

The ACC recommends that CMS and its contractors address how cases of overlapping episodes will be handled. CMS should minimize the occurrence of overlapping episodes as

it carries the unintended risk of artificially inflating or double-counting the costs attributed to a clinician. The College is concerned that a single patient attributed to a chronic condition group with simultaneous multiple co-morbidities will be attributed to additional condition or procedural episodes. CMS should provide clear instruction on the relationship of multiple episodes such as when new episodes are triggered or if certain conditions or procedures that occur become nested within an existing episode.

Piloting Episode Groups

The ACC recommends that CMS pilot a limited set of episode groups prior to wider implementation. Focusing on a smaller set of initial episode groups will allow CMS to analyze collected data and refine these episodes for long-term use. Prior to using any episode groups in the calculation of a clinician's MIPS score, CMS should conduct a minimum of one full year of data collection similar to that which is currently done prior to introduction of new quality measures. CMS should use this data to refine any episode groups or to eliminate any episode groups where it is difficult to create a benchmark cost.

Each episode must be anticipated to have sufficiently high patient volume to ensure statistically valid measurements and comparisons. The importance of sufficient patient volume for each episode selected cannot be overstated; the higher the patient volume for an episode, the greater likelihood that the data will be accurate, valid and generalizable. A large patient population will also support efforts for risk adjustment that is essential to the validity of the episode payment initiatives.

Site of Service

The ACC recommends at a minimum, factoring site of service when applying risk adjustment methodology to episode groups. While CMS is taking steps to neutralize payment rates across the Medicare Physician Fee Schedule and hospital and facility prospective payment systems, costs for services may still vary depending on the setting of care. A clinician should not be penalized as "high cost" for taking care of a high-risk patient who presents at a particular setting.

ICD-10 Coding Updates to Episodes

As CMS and its contractors update and develop episode groups based on ICD-10 coding, the ACC recommends vetting all ICD-10 codes so that they are not grouped together in a way that implies they are equivalent if that is not the intent. The learning curve for accurate coding to the specificity needed is still in evolution. There are a large number of ICD-10 codes in comparison to DRGs. The nuances of these codes may lead to vast differences in cost of care. In some cases, multiple ICD-10 codes seem to be duplicative when in actuality, they mean something quite different.

Administrative Burden and Overlap with other Medicare Programs

The ACC urges the Agency and its contractors to limit administrative burden to the extent possible when developing and implementing episode groups. Clinicians and administrators will need to understand how their current documentation, coding, and billing procedures are

impacted by these episode groups. In addition, EHRs may need to be equipped to collect the data necessary for triggering the appropriate episodes and attributing patients to the corresponding clinicians. CMS also has yet to release more information about the patient relationship codes and modifiers that will be used to attribute episodes to clinicians.

The ACC also recommends accounting for overlap between these episode groups, the Bundled Payments for Care Improvement program (BPCI), Episode Payment Models (EPMs) and other payment models such as Accountable Care Organizations (ACOs). Episode definitions used across these programs must be consistent to prevent confusion.

CMS must be attentive to issues of overlap including resulting attribution, otherwise there is great potential for unintended consequences. For example, such consequences may include double counting Part B service costs for clinicians who may be participating in MIPS as well as one of these episode-based payment models.

Selecting Episode Groups for Development and Implementation

The ACC recognizes the task of selecting episode groups for valid cost measurement is difficult. To assist CMS and its contractors, the College makes the following recommendations for inclusion in episode group selection criteria:

- **Sufficient clinical homogeneity of the patient population associated with the episode group for comparison purposes**
- **Anticipation of a high patient volume to ensure statistical validity**
- **Feasibility of defining elements of an episode and accurately attributing costs and providers to the episode group for operational success**

While this may not have been the intent, the selection criteria specified in the document do not *directly* capture the importance of a sufficiently clinically homogeneous patient population. This, however, is a *fundamental* requirement for an episode group. Sufficient clinical homogeneity of a patient population within an episode group forms the *basis* for clinical comparability between patients. Without it, the episode group lacks any real value from a clinical perspective. Joint replacement episode groups work well because the respective patients have sufficiently similar clinical characteristics allowing for clinical comparability. In terms of cardiovascular episode groups, elective PCI allows for a sufficiently clinically homogenous population and by extension could be a good candidate for an episode group pilot.

As mentioned above, clinical homogeneity is not the only requirement for an episode group as episode groups will not be practical without a sufficiently high volume of patients. Emphasis should be on anticipation of significant numbers of patients per clinician for comparisons among physicians. An episode group anticipated to consist of a low volume of patients will result in low statistical power rendering comparisons invalid.

Determining the feasibility of defining the elements of an episode and attributing cost and clinicians to the episode is critical. This will facilitate the process of constructing the episode in a clear and practical manner.

Comments on the Draft List of Episode Groups

Taking into account the above criteria as well as what included in the CMS document, the ACC is recommending changes to or elimination of the following episode groups:

<i>Procedural</i>	<i>Acute Medical Condition</i>	<i>Chronic Condition</i>
Percutaneous Coronary Intervention (PCI)	Cardiac Arrhythmia & Conduction Disorders	Coronary Artery Disease
Mitral Valve Procedure	Heart Failure and Shock	Heart Failure
Implantable Cardiac Defibrillator (ICD) Implantation	Acute Myocardial Infarction, Discharged Alive	
Right Heart Catheterization	Acute Myocardial Infarction, Expired	
Left Heart Catheterization	Chest Pain	
Pacemaker Implantation	Syncope and Collapse	
Ventricular Tachycardia Ablation	Peripheral Vascular Disorders	
Coronary Thrombectomy	No data	

The College provides rationale for each of these recommendations in the following sections of this comment letter. *As stated earlier, triggers for procedural episodes are fairly straightforward. However, this is not the case for condition episodes.* Some condition-based episodes can have multiple, even hundreds of trigger codes. Some of these trigger codes have very different cost implications. For example, the costs associated with heart failure presenting as pulmonary edema requiring intubation and mechanical ventilation in an intensive care unit are very different from heart failure presenting in the ambulatory setting as exertional dyspnea.

Procedural

Percutaneous Coronary Intervention (PCI)

The College recommends piloting the PCI episode group with changes. Within the PCI patient population, several subgroups exist which could create challenges within an episode. For this reason, it is *important* to exclude acute coronary syndrome patients since the urgency of intervention and the fact that myocardial damage is the default rather than a complication of the clinical condition creates a scenario that is quite different from that of a patient who is not suffering from a partial or full acute coronary occlusion, STEMI and NSTEMI patients, respectively; elective PCI patients are a much more homogenous group.

The following procedures consist of very heterogeneous patient populations, which may result in variable outcomes and, by extension, variances in costs that are heavily dependent on specific pathophysiology present and stage of underlying disease prompting the procedure. As such, the College recommends eliminating these episodes or refining them to

a degree that meets the criteria referenced above – homogeneity, volume and feasibility of defining episode elements and attribution.

Mitral Valve Procedure

The ACC recommends removing mitral valve procedure from the list in the absence of major refinement of the episode. Mitral Valve Procedure is an episode group that would consist of a clinically heterogeneous population as mitral valve dysfunction arises from multiple disease processes. For example, there are important clinical differences between primary and secondary mitral regurgitation as recognized in the current ACC/AHA Guidelines for Valvular Heart Disease. Among those with primary mitral regurgitation, there is heterogeneity in patients undergoing mitral valve procedures. Those with mitral regurgitation due to infection carry very different prognoses compared to those who have myxomatous degenerative changes. The ACC shares concern expressed in prior comments from the Society for Thoracic Surgeons (STS) that there is significant risk including an episode group such as these with multiple disease processes leading to the same procedure.

Implantable Cardiac Defibrillator (ICD) Implantation and Pacemaker Implantation

The ACC recommends removing Implantable Cardiac Defibrillator (ICD) Implantation and Pacemaker Implantation from the list. This is a very heterogeneous group. The approach to and costs of caring for patients with ICD implantation is largely driven by the underlying condition for which the ICD is implanted. For example, ICDs are indicated for patients with advanced heart failure that have reduced ejection fraction as well as for young patients with no heart disease other than a genetic predilection for malignant arrhythmias. The management plans for these groups differ widely. Equally wide disparities can be found in those undergoing pacemaker implantation which may be indicated as treatment for an otherwise healthy patient with congenital heart block or a patient with advanced heart failure having reduced ejection fraction for whom the driver is the need for ventricular resynchronization.

Right Heart and Left Heart Catheterization

The ACC recommends removing right and left heart catheterization from the list. Right heart catheterization and left heart catheterization are procedures that serve primarily as *diagnostic* tools and as a result are not intrinsically therapeutic. These episode group costs are dependent on the underlying medical conditions which may either be acute or chronic. For example, atrial septal defect, acute congestive heart failure (CHF), advanced diagnosis of shortness of breath, valve disease or pulmonary arterial hypertension could each lead to right heart catheterization. Each of these underlying diagnoses would likely be associated with highly variable outcomes and costs of care. It is the condition and underlying disease processes that will drive the costs of these episode groups not the procedure involved.

Ventricular Tachycardia (VT) Ablation and Coronary Thrombectomy

The ACC recommends removing ventricular tachycardia (VT) ablation and coronary thrombectomy from the list. There is *no clear cost driver* for VT ablation. Instead, co-existing heart disease will drive the costs and outcomes for this episode group. Coronary thrombectomy is not considered to be a separate procedure in Medicare coding and reimbursement policies and

is almost always performed as a component of PCI. Consequently, it does not define a unique group of patients.

Acute Medical Conditions

Cardiac Arrhythmia & Conduction Disorders

While some episode groups under this category may be appropriate, some are too broad, encompassing multiple conditions with marked variability in disease types and severity reflecting a wide range of costs within the group. The appropriate variance of costs within this episode group will make it extremely challenging to construct a baseline cost for it. The cardiac arrhythmia and conduction disorders episode group encompasses patient populations who may present with any of six different conditions

- Atrial fibrillation
- Atrial flutter and atrial tachycardia
- Bradyarrhythmia and conduction disturbance
- Supraventricular tachycardia
- Ventricular fibrillation and cardiac arrest
- Ventricular Tachycardia

Heart Failure and Shock

The ACC suggests that CMS consider separating heart failure and shock into two distinct episode groups as there are many cases in which heart failure is not associated with shock. It should be noted that there are multiple causes of shock and non-cardiogenic shock can exist in patients with widely differing comorbidities. Additionally, there are also coding issues inherent with this patient population, making it difficult to ensure that valid data is available to identify the appropriate services and associated conditions that would be included in an episode.

Acute Myocardial Infarction, Discharged Alive

The ACC recommends separating the AMI, Discharged Alive episode group into two separate groups defined as (1) Acute ST Elevation Myocardial Infarction (STEMI) with a type I classification and (2) Non-ST Elevation Myocardial Infarction (NSTEMI) with a type I classification. STEMI and NSTEMI patient populations are clinically distinct from each other and are treated differently. Replacing this heterogeneous episode group, AMI, with these groups representing more closely defined populations will reflect this clinical distinction. AMI is not a single defined entity. Substantial work over the past few decades has been done to achieve more clarity surrounding the most current (third) universal definition for AMI. In prior comments on the proposed rule, ACC explained this definition in detail.

Current hospital codes differentiate between STEMI and NSTEMI patients, yet do not necessarily capture the full distinction between MI types nor do they ensure that patients meet all elements of the AMI definition. Consequently, what is coded as AMI often only meets the definition in part and may be limited to abnormal biomarkers that can be detected without an acute occlusion of a coronary artery. A relatively typical example is interpreting changes in troponin levels as an AMI without considering other clinical indicators. This example was so commonplace that it drove the need for ACCF Expert Consensus Document on Practical Clinical

Considerations in the Interpretation of Troponin Elevations authored by experts representing the ACC and cardiovascular subspecialty societies. As a result, aligning coding with clinical reality will be necessary for establishing clinical homogeneity in the AMI model. This concern has been widely cited in the literature. **The ACC supports the proposal put forth in the March ICD-10 Coordination and Maintenance Committee Meeting for revisions of current codes and development of new codes for the classification of types of MI.** These codes are expected to be released in October 2017. The proposal includes a new subcategory code, 121.A1, referring to Type 2 MI due to demand ischemia or secondary to ischemic balance. Additionally, the proposal includes creating a new code for type 3, 4 and 5 AMIs, 121.9, which restores a WHO code that had previously been removed. **These new ICD-10 codes for the classification of types of MI better capture the nuances, reflecting specificity for distinguishing between type 1 and other types of MI.**

Acute Myocardial Infarction, Expired

The ACC recommends removing the Acute Myocardial Infarction, Expired from the list of episode groups. While there may be opportunity for savings, in practice, this episode group may be complicated to implement due to varying times of death during the patient's course and factors outside of the clinician's control such as the desires of patients and their families. CMS excludes this under the Advancing Care Coordination for Episode Payment Models, recognizing that there is a limited ability for hospitals and clinicians to seek cost efficiencies for a patient whose outcome is death from AMI. Moving forward, CMS should ensure alignment of the AMI episode group (which ACC is recommending splitting into STEMI and NSTEMI as stated above) with the episode payment model for AMI to minimize burden on clinicians.

Chest Pain

The ACC recommends removing the Chest Pain episode group. Chest pain is a symptom, yet is reflected as an episode group. There are widely varying etiologies of and underlying conditions associated with this symptom. For example, coronary artery disease may manifest as multiple symptoms including but not limited to chest pain while aortic dissection and pulmonary embolus, two very different conditions, may also present with chest pain. There are well known coding challenges with the MS-DRGs associated with chest pain (311 and 312) because it may be linked to multiple etiologies, with appropriately varying work-ups and costs ranging from those that are brief and inexpensive to those that are more lengthy and costly. In circumstances where a clear etiology can be identified, patients with chest pain would ultimately fall in an underlying condition-based episode group such as STEMI, pulmonary embolus, pericardial effusion, esophageal spasm etc. or a procedure-based episode. If, however, a clear etiology cannot be determined, this will present significant challenges in creating an episode group for this symptom.

Syncope & Collapse

For similar reasons to those stated above for chest pain, the ACC recommends removal of the Syncope & Collapse episode. Underlying causes range from benign vaso-vagal syncope to that associated with hypertrophic cardiomyopathy or valvular aortic stenosis. In circumstances

where a clear etiology can be identified, patients with syncope and collapse would ultimately fall in an underlying condition-based episode group.

Peripheral Vascular Disorders

The ACC recommends removal of the Peripheral Vascular Disorders episode group. This episode group will be challenging to implement because of the heterogeneity of patient presentation and the large number of appropriate diagnostic and therapeutic approaches that can be taken by clinicians. Additionally, outcomes and costs are frequently significantly affected by common comorbidities such as diabetes and coronary artery disease.

Request for Clarification

Atrial Fibrillation/Flutter (Acute) is not presented as an episode group for public comment. The ACC recognizes that there is an existing acute exacerbation episode identified in CMS' Supplemental CMS Episode Groups Posting released in 2016. The ACC seeks clarification from CMS and its contractors as to whether this episode is open for comment, not open for comment, or is not intended for implementation under the QPP.

Chronic Conditions

Coronary Artery Disease

CMS should not implement this episode until further development. Coronary Artery Disease is too broad a diagnosis at least until more experience is gained with episode groups. Patient groups should at least initially be narrowed to those with an acute event such as STEMI or a procedure, such as PCI. Moreover, there is potential to game the system.

Heart Failure

Heart failure will be challenging to implement due to the heterogeneity of the patient population. Causes of chronic heart failure vary widely ranging from those associated with severely reduced ejection fraction due to multiple myocardial infarctions to those with preserved ejection fraction and/or restrictive or hypertrophic cardiomyopathies. The ACC recommends CMS and its contractors work through the details and refinement of this episode group with the Heart Rhythm Society and the Heart Failure Society of America. Additionally, we would note that few heart failure bundled payments for care improvement (BPCI) programs managed to earn savings.

Additional Considerations for Chronic Condition Episode Groups

In response to CMS requesting comment on methods to incorporate disease severity or staging information to improve meaningful comparison of cost and quality of care furnished to patients, ACC recommends considering using functional class and/or disease severity. For example, NYHA functional class can be used for heart failure and disease severity (mild, moderate and severe) can be used for valve disease. Standardized definitions for these classifications are widely used and addressed in the ACC/AHA guidelines.

In response to CMS requesting comment on options for constructing episode groups for chronic conditions, the ACC recommends grouping chronic conditions by disease etiology

and type rather than treatment. There is often overlap of treatment methods such as medications for different conditions. For example, beta blockers are used for both for heart failure and atrial fibrillation. However, each condition does have specific performance measures to evaluate quality and it is of utmost importance to ensure those measures are reasonable for the condition. Adjusting for comorbidities will be critical.

Comments on Cost Measurement Development Framework

The College supports the six key aspects of cost measurement as identified via stakeholder feedback mentioned in the document provided. They are the basis for the comments which address each of the components of the cost measurement development framework.

Defining an Episode Group

As illustrated in the comments above, the ACC agrees that there must be a balance between clinical similarity in complexity, cost, and patient outcomes, and the ability to collect a sufficient number of cases in order to achieve statistically valid measurement for cardiovascular episode groups.

Assigning Items, Services and Their Respective Expenditures to Episode Groups

In terms of the second component, assigning items, services and their respective expenditures to episode groups, Medicare’s definition of unrelated services is relatively untested. Practical approaches must be taken to ensure appropriate assignment of items and services including. CMS and its contractors must monitor for unintended consequences such as possible overlapping of episode groups as stated earlier.

Attributing Groups to Clinicians

In terms of the third component, attributing groups to clinicians, the ACC continues to support team-based care. For episode groups occurring in the inpatient care setting, it will be particularly difficult to attribute care to a single clinician; rather it may be more appropriate to attribute care to the entire care team. The ACC and cardiovascular subspecialty societies have worked hard to foster a team approach in cardiology as all members on the team involved in patient care have a role to play. Attribution of categories to the whole team should help raise the bar for the whole group. If the categories are attributed to an individual team member, the concern for unintended consequences, such as patient selection resulting in higher risk patients losing out, cannot be overstated. In addition, this may foster competition among group members, rather than promoting the team effort. “Peer pressure” to improve performance of individual members can be highly effective, if under-performers want to continue to be part of the care team. Roles of individual team members in contributing to overall patient care must be clear and may differ depending on the patient’s situation or circumstance. For example, the primary care physician’s role would differ from that of cardiologists. The role of general cardiologists would differ from interventional cardiologist and electrophysiologists. Ultimately, these roles would differ from that of ancillary physicians involved. For patients with advanced heart failure, the cardiologists may provide the patient’s medical home whereas for milder forms of heart failure, that role might remain with the primary care physician. There are multiple levels of attribution that must be worked through.

Attribution is likely to be one of the most challenging components of this framework and CMS and its contractors must spend time working with stakeholders to understand and communicate the details of how attribution will be handled. Historically, the attribution used in QRUR has been fraught with issues. Subgroups and the forthcoming patient encounter codes and modifiers may assist with narrowing down which members of the care team are most directly associated with each patient.

Risk Adjusting Groups

In terms of the fourth component, risk adjusting groups, the College strongly supports risk stratification based on social determinants of health including socioeconomic and educational status in addition to risk adjusting for patient co-morbidities. The ACC recommends deferring to the work done by the National Quality Forum in socioeconomic status risk adjustment. In response to CMS requesting comment on possible unintended consequences of using cost measures in MIPS and steps to avoid disadvantaging clinicians who assume the care of complex patients such as by applying episodes for comparison of complex patients, unintended consequences could include selection of less complex patients to artificially lower costs or reducing access to patients who may be at higher risk to reduced medical adherence due to lower socioeconomic status or education level. Acknowledging and accounting for the socioeconomic status of patients is critical to minimizing unintended consequences. Additionally, keeping the coding and documentation elements as simple as possible will be helpful. Ensuring that physicians can code out co-morbidities and account for the severity of their patients' illness needs to be simplified.

Aligning Cost with Quality

In terms of the fifth component, aligning cost with quality, while the ACC recognizes that CMS and its contractors plan to provide further guidance in the near future on aligning cost with quality, the document provided does not include sufficient detail as to how quality will be incorporated. This is a priority for the College. The ACC recommends aligning episode group cost with quality measures in a manner that is transparent and clearly evident to providers and the public. One of the most critical components of the framework is appropriately aligning cost with quality. Appropriate performance measures represent a clear way to track certain aspects of episode groups that are clinically meaningful. In addition, CMS should support specialty societies in the development of patient outcome measures and appropriate use measures to ensure that no patient is harmed by the underutilization of services in an attempt to control costs. Aligning quality measures ensures that the quality of care does not diminish as clinicians seek ways to find efficiencies in cost.

CMS should work with specialty societies to identify quality measures that best align with each episode group. Measures selected must be meaningful yet not administratively burdensome and consistent with ACC's principles of public reporting of physician quality data including attribution to the accountable entity and scientific validity. At a minimum, CMS should use those measures approved for MIPS quality reporting, including non-MIPS quality measures reported through qualified clinical data registries (QCDRs). This will reduce the administrative burden of requiring clinicians to select from a new list of measures. In response to CMS requesting comment on methods to align quality of care considerations with cost measures, ACC recommends using performance measures developed by the ACC,

American Heart Association and the cardiovascular subspecialty societies to align quality of care with cost. Adherence to measures in a cost-conscious manner should also concomitantly improve quality and patient outcomes. As stated above, CMS should also consider how the data contained in clinical data registries can be used to align quality, cost, and outcomes measurement. This would require partnership between CMS and specialty societies to match claims data to the valuable longitudinal clinical data in these registries.¹

Quality measures associated with episode groups should be released at the same time and integrated seamlessly within MIPS. Implementation of quality measures in episode groups that are in any way different from measures used elsewhere in federal programs would add unneeded complexity to the system and would be counterproductive in terms of supporting meaningful comparisons among providers participating in the various programs.

MIPS participants must be given clear direction as to whether certain quality measures would be mandatory to report if they are attributed to a particular episode. CMS could consider an approach where rather than apply every cost episode group to a clinician or group, the clinician/group selects a limited number of the most relevant episodes based on patient population and then reports those quality measures aligned with those cost measures. This could avoid a problem where clinicians are measured on cost episodes but are reporting no relevant quality measures. There are no shortcuts when it comes to measuring quality and an approach that is based on “starting simple” and strengthening measures later cannot be supported since the cost measures have the potential for placing patients at risk and need to be appropriately balanced with performance measures from the outset.

In response to CMS requesting comment on each elements of the cost measurement development framework and whether there are additional elements to consider in developing cost measures from episode groups. Quality can be measured by utilizing up to date performance measures that are already available to us and for which we have performance data. For example, measures for atrial fibrillation were recently updated to extend beyond anticoagulation. It would be appropriate, when indicated to begin measuring quality of care provided to patients with atrial fibrillation by first assessing patient adherence to anticoagulation, particularly since data demonstrate a wide gap in this area and that have a clear impact on patient outcomes. This is an example of a circumstance in which the accountability with respect to the outcome is shared by clinician and patient².

Closing Remarks

The accurate and appropriate measurement of cost for physician performance continues to be an ongoing challenge. The ACC welcomes the opportunity to continue working with CMS and its contractors on the development of episode groups and cost measures for use under the QPP. The College has many practicing cardiologists and cardiovascular practice administrators willing to dedicate time to this effort. Incorporating their perspectives throughout the development and implementation of episode groups will help CMS to ensure that these measures work under a real-world application and do not unintentionally penalize clinicians or more importantly, do not affect patient’s access to care.

The College respectfully requests that as we continue to provide CMS and its contractors with insight, that communication remains open and transparent. In order for our members to provide

the most informed comments, and aid the development of these episode groups in a timely manner, the College must understand how CMS and its contractors are applying our comments to ongoing work.

1 J Am Coll Cardiol 2008; 51:1993-2001

2 J Am Coll Cardiol 2014;64:2133-45

COMMENT 69 OF 69

Date: 5/5/2017

Commenter Name, Professional Title, and Organizational Affiliation: Andrea P. Thau, President, American Optometric Association

Text of Comment:⁸

The American Optometric Association (AOA) appreciates the opportunity to provide these comments to the Centers for Medicare and Medicaid Services (CMS) as the agency continues its work to develop episode-based cost measures for the Quality Payment Program. The AOA represents 33,000 doctors of optometry and optometry students. The AOA is the voice of the nation's family eye doctors and the leading authority on eye health, vision care, and patient safety issues. Doctors of optometry serve patients in nearly 6,500 communities across the country, and in 3,500 of those communities are the only eye doctors. With this knowledge and perspective, we believe the recommendations and considerations below may improve the CMS efforts to develop and define episode groups for the purpose of cost analysis and comparisons.

We understand that CMS has selected cataract surgery as an area of focus for a procedure based episode group based on the high volume of cataract surgeries performed annually. Using the procedure based approach is appropriate. The initial diagnosis of cataract is most frequently made by a doctor of optometry or ophthalmologist. The patient's decision to proceed with cataract surgery to decrease disability involves consultation with a doctor of optometry and/or ophthalmologist. As the "Routine Cataract Removal with Intraocular Lens (IOL) Implantation" episode group has been classified by CMS as a procedural episode group based on the reporting of a CPT code, rather than a diagnosis code, it is appropriate to use the trigger code CPT 66984 (Removal Of Cataract With Insertion Of Lens) to start the beginning of these episodes of care. To begin the episode with the initial diagnosis of cataract would likely pull into the episode procedures and costs that may be unrelated to the diagnosis of cataract, so proceeding with the CPT trigger code is more appropriate in this case.

While CMS has indicated that the billing of CPT 66984 triggers the routine cataract removal episode, no date for the closing of the episode is provided. For the acute inpatient medical condition episodes, CMS notes a 90-day period would be used. For the chronic condition episodes, a 12 month period will be utilized. For this procedure based episode, the episode should be no longer than 90 days, which is the global period for the procedure.

⁸ This commenter submitted a comment after the close of the public comment period on April 24, 2017. The comment has been included in this report for completeness.

As CMS moves forward in assessing cataract surgery care costs, it is critical for CMS to consider the various players who work to provide care for patients having cataract removal surgery. For these patients, doctors of optometry and ophthalmologists may work together as a team to provide complete preoperative, intraoperative, and postoperative care to meet the patient's needs. For the “Routine Cataract Removal with Intraocular Lens (IOL) Implantation” episode group, CMS may want to explore the possibility of creating episode sub-groups for the cataract episodes for which co-management of a patient occurs. This would allow CMS to better evaluate and compare cases for which cataract patients are co-managed by two physicians and for those cases for which there is no co-management.

The AOA is also very interested in the diabetes episode group and ensuring that the episode is appropriately defined. Doctors of optometry perform the majority of comprehensive, dilated eye examinations for people with diabetes in the United States and are well versed in the treatment and management of diabetic eye disease. The AOA supports the inclusion of the diabetes ICD-10 codes E083-E08.351; E08.359; E08.36 and E08.39. These codes are all related to diabetes and the eye. Diabetes is the leading cause of vision loss for Americans under the age of 74, and doctors of optometry are dedicated to early diagnosis and timely treatment to prevent diabetes related blindness. In addition, doctors of optometry are committed to educating their patients about ways of preventing and minimizing eye complications caused by diabetes, and routinely work with other health care professionals-including primary care physicians, endocrinologists, podiatrists, dental professionals, pharmacists and specialty eye surgeons to ensure patients receive the highest quality care, maintain good vision, and live healthy lives. The inclusion of these diagnosis codes on the trigger code list for the diabetes episode is critical.

Thank you for the opportunity to provide these comments.