ACUMEN

MACRA Episode-Based Cost Measures:
Wave 4 Measure Development
Public Comment Summary Report

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1 OVERVIEW

1.1 Project Title

Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act of 2015 (MACRA) Episode-Based Cost Measures: Wave 4 Measure Development

1.2 Dates

The Call for Public Comment ran from December 16, 2020, to February 5, 2021.

1.3 Project Overview

The Centers for Medicare & Medicaid Services (CMS) has contracted with Acumen, LLC, to develop episode-based cost measures for potential use in the Merit-based Incentive Payment System (MIPS) to meet the requirements of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The contract name is "Physician Cost Measures and Patient Relationship Codes (PCMP)." The contract number is 75FCMC18D0015, Task Order 75FCMC19F0004. As part of its measure development process, Acumen gathers input from groups of stakeholders and experts, including this opportunity for interested parties to submit comments on the candidate episode groups for development in Wave 4.

This Call for Public Comment invited stakeholders to submit feedback on prioritizing episode-based cost measures to develop for the upcoming Wave 4 of episode-based cost measure development and to provide feedback on preliminary specifications for several measure areas. In Waves 1-3, Acumen obtained input on measure prioritization by convening experts in Clinical Subcommittees (CS). These CS were structured around a clinical area or a type of measure. During each Wave, we met with the CS in person for a one-day meeting to discuss and vote on preferred episode groups.

We understand that this past year is unlike previous Waves and has presented new challenges for the community, particularly front-line clinicians. We also received feedback during the August – September 2020 field testing for the Wave 3 measures expressing interest in more flexible participation options. As such, for Wave 4, we sought input on candidate episode groups through an extended public comment period that lasted over 7 weeks. This allowed for greater flexibility for specialty societies and professional associations to provide input and widened the range of stakeholders who could contribute feedback.

1.4 Information About the Comments Received

We solicited public comments and conducted education and outreach using the following methods:

- Posting a Call for Public Comment on the CMS Currently Accepting Comment webpage
- Hosting 2 office hours sessions for specialty societies to address questions
- Posting a presentation recording with additional information[1]
- Sending multiple email notifications to various relevant stakeholders and email lists (i.e., CMS listserv, Measures Management System listserv, Acumen general stakeholder mailing list, the PFAnetwork listserv,[2] and a targeted specialty society outreach list)

We received 36 comments via email and survey response.

- We received comments from 25 organizations and 8 individuals; 2 comments were from person and family stakeholders.
- The verbatim text of each submitted comment is presented in Appendix A: Public Comment Verbatim Report.

[1]CMS, "The MACRA Wave 4 Cost Measure Development Presentation," Quality Payment Program Webinar Library (January 2021), https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1302/MACRA%20Wave%204%20Cost%20Measure%20Development%20Slide%20Deck.pdf.

[2] The PFAnetwork listserv is an email list of Person and Family Advisors (PFAs) maintained by PFCCpartners.

2 STAKEHOLDER COMMENTS: FEEDBACK ON WAVE 4 CLINICAL AREAS

This section summarizes the feedback received on the Heart Failure (Section 2.1), Mental and Behavioral Health (Section 2.2), Therapy and Rehabilitation (Section 2.3), and Rheumatology/Arthritis (Section 2.4) clinical areas considered for measure development in Wave 4.

2.1 Heart Failure

This section summarizes the feedback and provides responses for comments received on the Heart Failure clinical area. The following subsections describe comments on patient heterogeneity, the different roles for clinicians of various specialties providing care, potential opportunities for improvement, preliminary trigger codes, indicators of quality, and potential Clinical Expert Workgroup composition.

2.1.1 Addressing Subtype and Severity

Multiple commenters suggested categorizing subtypes for a Heart Failure measure using (i) heart failure with preserved ejection fraction (HFpEF), or diastolic heart failure, and (ii) heart failure with reduced ejection fraction (HFrEF), or systolic heart failure. Commenters pointed out that treatment and diagnosis varied across the two subtypes, and noted that clinical guidelines are well developed for HFrEF, but HFpEF is often miscoded, particularly in the outpatient setting, which may pose challenges in accurately defining the subtype. One commenter also suggested another subtype, which includes heart failure with mid-range and recovered left ventricle ejection fraction (HFmEF). Alternatively, one commenter noted there are subtypes for ischemic vs. non-ischemic cardiomyopathy, which may be examined through International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis codes.

Commenters provided suggestions and recommendations for identifying patients with different subtypes of heart failure using Medicare claims data. Commenters noted that while heart failure is clinically defined based on the measurement of left ventricular ejection fraction (LVEF), the subtypes are defined in claims using systolic, diastolic acute, and chronic congestive heart failure codes. One commenter recommended using a limited set of ICD-10-CM diagnosis codes in the "I50 family" (i.e., I50.2 and sub-codes, I50.4 and sub-codes, I50.814, and I50.82). Another commenter suggested identifying systolic heart failure patients by the presence or interrogation of an automatic implantable cardioverter defibrillators (AICD).

Commenters also provided feedback on identifying severity through claims data. A few commenters suggested using the ejection fraction for severity, which could be identified through Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System

(HCPCS) codes (e.g., echocardiograms or other imaging) if only evaluating systolic heart failure. Another commenter suggested measuring severity by intensity of claim activity (e.g., frequent admissions or emergency department [ED] visits) to determine severity over time. This commenter mentioned that an intensive care unit stay, mechanical ventilation, and the use of a pulmonary artery catheter will identify severity during the inpatient admission. One commenter suggested severity could be identified if patients have a left ventricular assist device (LVAD), have received a transplant, or have elected the hospice benefit. Another commenter suggested using I50.4 and its sub-codes to identify severity, as these represent more advanced forms of heart failure and be used in risk adjustment.

A few commenters suggested that heart failure severity could be identified by the American College of Cardiology Foundation (ACCF) and the American Heart Association's (AHA) stages of Heart Failure and the New York Heart Association (NYHA) functional classification system. Despite these guidelines, commenters noted it would be challenging to identify and quantify the stages and severity levels in claims since these are subject to an individual clinician's evaluation of a patient.

Commenters shared thoughts on accounting for severity through risk adjustment. For systolic heart failure, one commenter recommended including risk adjustment variables for weight loss, physical activity level, blood pressure, renal function, potassium levels, and discharge medications (if an inpatient stay occurred). One commenter suggested adding risk adjustment variables for owning a scale, using telemedicine, dietary adherence, literacy level, and access to transportation. Commenters also suggested that the risk adjustment model capture social risk factors (SRF) like dual eligibility status, as well as the number and severity of comorbidities. A commenter recommended considering clinician performance in certain health care systems in risk adjustment as well (e.g., academic medical centers typically care for more complex, poor, and sick patients).

A few commenters recommended excluding the following patient populations to improve the clinical homogeneity of the overall patient population (i.e., patients with similar care trajectories and costs of care):

- Patients with LVAD
- Patients with heart transplants
- Patients with right heart failure
- Patients with heart failure due to valvular disease
- Patients receiving extracorporeal membrane oxygenation (ECMO)
- Patients in cardiac shock
- Patients who have a dual diagnosis of renal or liver failure

One commenter shared a recently published article about optimal heart failure treatment for patients with systolic heart failure and suggested that it would be a helpful resource for understanding this subtype, its severity, and treatments.[3]

Commenters asked for more clarity on the scope of the measure because of the potential heterogeneity in diagnosing and treating patients with heart failure across settings (e.g., outpatient versus inpatient), and suggested that opportunities for improvement could be focused in the outpatient setting. Commenters noted that goal-directed medical therapy (GDMT) may be more relevant in the outpatient setting, and this may unfairly penalize primary care providers treating patients in the inpatient setting. Other commenters were concerned about limiting the scope of the measure to chronic heart failure, and noted that an acute heart failure measure is an area where clinicians can directly influence care and improve patient outcomes.

A few commenters suggested limiting the scope of the measure to the set of ICD-10-CM codes in the I50 family to prevent capturing common "volume overload from inadequate dialysis," situations that are often miscoded as diastolic heart failure (i.e., I50.3 and sub-codes), since many patients with end-stage renal disease (ESRD) have diastolic dysfunction. Another commenter suggested excluding a mix of other heart failure codes and "high output failure" codes, like I50.8 and sub-codes, except I50.814 and I50.82, for a more homogeneous patient population, since this type of heart failure could be caused by underlying conditions (e.g., obesity, anemia).

Overall, the commenters were concerned about the potential for unintended consequences with a chronic Heart Failure measure due to heterogeneity and complexity of the patient population. Several commenters were concerned about addressing patient heterogeneity through claims data because current ICD-10-CM codes are not precise enough to accurately capture subtypes or severity levels. They also mentioned that heart failure has a multitude of underlying causes (e.g., hypertension for patients with diastolic heart failure) that are not defined by a single test and would yield different diagnoses and treatments. Another commenter also suggested using more than just Medicare claims data (e.g., clinical registry data).

2.1.2 Addressing Roles of Various Specialties

Many commenters acknowledged that many different types of clinicians provide care to patients with heart failure as part of the patient's care team, which includes cardiologists, ED clinicians, internists, hospitalists, nephrologists, palliative care nurses, physician assistants, and other primary care providers. Commenters stated that clinicians of different specialties have

[3] Committee Writing et al., "2021 Update to the 2017 Acc Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure with Reduced Ejection Fraction: A Report of the American College of Cardiology Solution Set Oversight Committee," J Am Coll Cardiol (Jan 4 2021). https://doi.org/10.1016/j.jacc.2020.11.022.

distinct roles in a patient's care. For example, a few commenters noted that patients who are referred to cardiologists are likely sicker than patients who are not referred to cardiologists. Another commenter mentioned that the cardiologists would make AICD referral decisions or prescribe newer medications, while primary care providers would likely manage symptoms. One commenter noted that diastolic heart failure patients are more likely to be managed by internists than patients with systolic heart failure. Another commenter noted that ED clinicians also provide care for heart failure exacerbations.

A few of the commenters noted that attribution of the measure will be challenging, since care is focused on team-based approaches. On this topic, one commenter noted that as clinicians implement team-based approaches, advanced practice providers (APPs) like physician assistants or nurse practitioners are engaging in more patient encounters that lead to overall better patient management. However, the commenter recommended excluding individual APPs in attribution because they could be attributed the full costs of care for the episode, when they were only responsible for part of the care. Alternatively, the commenter suggested benchmarking APPs within the appropriate cardiology specialty, in recognition of the specialty care they provide, instead of the primary care designation.

2.1.3 Opportunities for Improvement

A few commenters suggested that there may be improvements in follow-up care, selection of medications and treatments, and telehealth services. A person and family commenter suggested improving follow-up testing to measure patients' maintenance of fitness goals following a cardiac rehabilitation program. One commenter suggested improving upon the GDMT for patients with systolic heart failure, and a few commenters suggested delivering more services via telemedicine, given the recent COVID-19 pandemic as well as the opportunity to establish more consistent follow-up care in general.

2.1.4 Preliminary Trigger Codes

Comments in this section were mainly focused on addressing heterogeneity, instead of requesting specific modifications to the list of preliminary trigger codes. However, Section 2.1.1 contains specific codes for the relevant subtypes that could be used as preliminary triggers.

One commenter stated that the preliminary set of trigger codes isn't used frequently in practice. Another commenter noted that heart failure isn't defined by a single lab test, and while ICD-10-CM codes provide substantial granularity, coding practices in the outpatient setting are not appropriately or consistently applied when diagnosing patients. The commenter provided an example where a clinician treating a patient who received a previous heart failure diagnosis may actually have a peripheral edema from another cause (e.g., venous insufficiency) and will require different treatments and have different costs than a heart failure patient.

2.1.5 Quality Alignment for Assessing Value

A few commenters emphasized alignment of cost measures with existing quality measures to ensure that the quality of care is not negatively impacted by attempts to control cost. One commenter suggested that the following quality measures (for systolic heart failure patients) be considered for potential alignment with a Heart Failure cost measure:

- American College of Cardiology (ACC) Heart Failure Measure: Patient Self Care Education (from the Qualified Clinical Data Registry [QCDR])
- Merit-based Incentive Payment System (MIPS) #008 (NQF 0083): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)[4]
- MIPS #005 (NQF 0081): Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for LVSD[5]
- MIPS #236: Controlling High Blood Pressure[6]

One commenter noted that quality measures for the outpatient setting should also be considered for potential alignment, since most services are provided in this setting. However, the commenter cautioned that assessing patients mainly in the outpatient setting might result in admissions of more complex patients, leading to more readmissions.

A few commenters were concerned that holding clinicians accountable for a chronic heart failure episode could create perverse incentives, like avoiding necessary hospitalizations to improve their performance, or could penalize clinicians for appropriate hospitalizations, cardiac rehabilitation, and use of advanced therapies. One of the commenters also shared 2 studies on the Hospital Readmission Reduction Program (HRRP) and suggested that programs like these, which aim to reduce the rate of readmissions to hospitals, have led to increases in mortality.[7]

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[4] CMS, "Quality ID #8 (NQF 0083): Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)," Quality Payment Program (November 2020), https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2021_Measure_008_MIPSCQM.pdf.

[5] CMS, "Quality ID #5 (NQF 0081): Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)," Quality Payment Program (November 2019)," https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2020_Measure_005_MIPSCQM.pdf.

[6] CMS, "Quality ID #236: Controlling High Blood Pressure," Quality Payment Program (November 2020), https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2021_Measure_236_MIPSCQM.pdf.

[7] G. C. Fonarow, M. A. Konstam, and C. W. Yancy, "The Hospital Readmission Reduction Program Is Associated with Fewer Readmissions, More Deaths: Time to Reconsider," J Am Coll Cardiol 70, no. 15 (Oct 10 2017). https://doi.org/10.1016/j.jacc.2017.08.046.; A. Gupta et al., "Association of the Hospital Readmissions Reduction Program Implementation with Readmission and Mortality Outcomes in Heart Failure," JAMA Cardiol 3, no. 1 (Jan 1 2018). https://doi.org/10.1001/jamacardio.2017.4265.

A few commenters also suggested looking at quality indicators that aren't covered by the existing quality measures described above. The quality indicators provided by commenters are summarized below in the following categories:

- Chronic Condition Disease Management: A person and family commenter noted that important quality indicators like blood pressure or heart rhythm monitoring could be assessed through apps (e.g., Fitbit) to manage the chronic condition and improve quality of life. Another commenter suggested a few other important quality indicators, including care coordination, reducing disparities in care and outcomes for racial and ethnic minorities, palliative and end-of-life care, disease management programs, and safety measures.
- Medications: A commenter suggested evaluating the usage of other common heart failure medications used for HFrEF patients, including mineralocorticoid receptor antagonists (MRAs) and sodium/glucose cotransporter 2 (SGLT2) inhibitors.
- Mortality: A commenter noted that complications may occur following both good care (e.g., side effects from medications) and no care, which may lead to an increase in mortality. Therefore, the commenter suggested that mortality is an important balancing metric for a Heart Failure cost measure, as for any cost measure.

2.1.6 Clinician Expert Workgroup Composition

Commenters generally recommended that a heart failure-specific Clinician Expert Workgroup (hereafter referred to as workgroup) include various types of cardiologists, such as clinical/general, office and hospital-based, heart failure, advanced heart failure, interventional cardiac electrophysiology, transplant, cardiothoracic surgery. Commenters also recommended additional specialties for inclusion in the workgroup, which includes cardiac imaging specialists, internists, family medicine practitioners, cardiac rehabilitation specialists, pulmonologists, social workers, occupational therapists, ED clinicians, and geriatricians. Commenters also suggested including clinicians with experience with:

- Direct treatment of the condition in the outpatient setting
- Compensatory activities and energy conservation
- Treatment of acute exacerbations in the ED setting
- Medical coding knowledge relevant to the condition, including investigation on Advanced Alternative Payment Models using claims data

2.2 Mental and Behavioral Health

This section summarizes the feedback and provides responses for comments received on the Mental and Behavioral Health clinical area. The following subsections describe comments on which of the candidate episode groups to prioritize for development in Wave 4 (Major Depressive Disorder, Schizoaffective Disorder, Bipolar Disorder) to prioritize for development in Wave 4, patient heterogeneity, potential opportunities for improvement, preliminary trigger codes, indicators of quality, and potential Clinical Expert Workgroup composition in turn.

2.2.1 Episode Group Prioritization

Multiple commenters supported major depressive disorder (MDD) as a more feasible option for an episode-based cost measure in the Mental and Behavioral Health clinical area than other conditions. Commenters noted that MDD is a much more prevalent condition, and less often features "split care" across many settings, which can complicate attributing episodes of care to one provider. Commenters also cited well-established treatment efficacy for MDD and significant clinical and societal costs in the aggregate. On the other hand, one commenter noted that schizoaffective disorder and other mood disorders have more defined treatment paradigms that are measurable and reportable compared to MDD. To measure resource use associated with treatment of MDD, multiple commenters suggested using extended patient history to classify patients as having MDD and to identify hospitalizations, attempted suicide, and a history of debilitating chronic illness.

One commenter noted that bipolar and schizoaffective disorders usually require continuous, inter-episodic care in order to promote medication adherence and early intervention. Patients with schizoaffective disorder and bipolar disorder may also need additional inpatient services as part of the treatment pathway. The commenter noted that the benefits of these additional services can be hard to measure through claims data, such as suicide risk detection, reduced psychosocial impairment, and greater quality of life, while at the same time incurring higher costs due to inpatient or ED visits.

Finally, one commenter discussed differences in treatment patterns between MDD and severe instances of the other mental health conditions. Schizoaffective disorders feature chronic psychosis and psychosocial impairment, on top of episodes of mood fluctuation, which can result in common inpatient and ED visits. For patients with bipolar disorder, continuous care is required to monitor adherence, update medications, and therapy for the psychosocial impacts of the condition. It also commonly features inpatient and emergency room visits.

2.2.2 Addressing Severity

To account for severity of MDD, several commenters suggested accounting for the various etiologies of depressive symptoms in risk adjustment, in addition to typical risk-

adjustment variables like ICD-10 diagnosis codes or depression screening data, such as the Patient Health Questionnaire (PHQ-9). Multiple commenters suggested accounting for the presence of other psychiatric conditions, with one providing literature on the association of psychiatric comorbidities and additional mental health spending.[8, 9, 10] Commenters also raised using prior hospitalizations and ED visits in risk adjustment to account for severity. One commenter suggested accounting for cognitive decline or dementia as its own etiology for depression, while another suggested age, sex, race, dual eligibility in Medicare and Medicaid, and clinical severity as potential sub-groups. Additional suggestions included differentiating psychological stress and anxiety from MDD, and including patients with substance use disorders as a sub-group for MDD. Multiple commenters suggested including treatment-resistant depression (TRD) as a sub-group of the episode group.

Commenters provided differing perspectives on the evaluation of acute inpatient hospital stays. One commenter suggested including inpatient stays because they reflect the severity of the condition, be it MDD or a severe mental illness, and present a wide variability in cost. Another commenter suggested excluding inpatient stays, reasoning that patients often end up in the hospital for reasons other than the clinician's discretion, such as limited availability of Medicare-covered outpatient services, the timing of their admission, or the patient's inability to care for themselves.

2.2.3 Opportunities for Improvement

Commenters noted that variation in treatment patterns are may be due to important patient factors, such as physical and psychosocial comorbidities, life factors like childhood trauma, chronic illness, old age, or socioeconomic status, previous hospitalizations, and previous visit adherence, rather than clinician discretion.[11] Commenters noted that these features are

[8] R. Thom, D. A. Silbersweig, and R. J. Boland, "Major Depressive Disorder in Medical Illness: A Review of Assessment, Prevalence, and Treatment Options," Psychosom Med 81, no. 3 (Apr 2019). https://doi.org/10.1097/PSY.0000000000000678.

[9] M. A. Gupta and F. C. Simpson, "Obstructive Sleep Apnea and Psychiatric Disorders: A Systematic Review," J Clin Sleep Med 11, no. 2 (Jan 15 2015). https://doi.org/10.5664/jcsm.4466.

[10] G. E. Hunt et al., "Prevalence of Comorbid Substance Use in Major Depressive Disorder in Community and Clinical Settings, 1990-2019: Systematic Review and Meta-Analysis," J Affect Disord 266 (Apr 1 2020). https://doi.org/10.1016/j.jad.2020.01.141.

[11] F. Mols et al., "Depressive Symptoms Are a Risk Factor for All-Cause Mortality: Results from a Prospective Population-Based Study among 3,080 Cancer Survivors from the Profiles Registry," J Cancer Surviv 7, no. 3 (Sep 2013). https://doi.org/10.1007/s11764-013-0286-6; A. M. Lasserre et al., "Clinical and Course Characteristics of Depression and All-Cause Mortality: A Prospective Population-Based Study," J Affect Disord 189 (Jan 1 2016). https://doi.org/10.1016/j.jad.2015.09.010; F. C. van Krugten et al., "Indicators of Patients with Major Depressive Disorder in Need of Highly Specialized Care: A Systematic Review," PLoS One 12, no. 2 (2017). https://doi.org/10.1371/journal.pone.0171659; N. Moise et al., "Observational Study of the Differential Impact of Time-Varying Depressive Symptoms on All-Cause and Cause-Specific Mortality by Health Status in Community-Dwelling Adults: The Regards Study," BMJ Open 8, no. 1 (Jan 5 2018). https://doi.org/10.1136/bmjopen-2017-017385.

important to capture so that improved coordinated care that is more resource-intensive is not penalized.

2.2.4 Preliminary Trigger Codes

One commenter pointed out that Acumen's initial list of trigger codes in the public comment posting does not include any psychiatry CPT codes.[12] The commenter proposed that the absence of these codes would leave out a sizable number of episodes, citing that a large share of initial psychiatric evaluations are performed by psychologists or social workers who may be billing more specific psychiatry CPT/Healthcare Common Procedure Coding System (HCPCS) codes.

One commenter also suggested excluding non-conventional outpatient visits for mental health as trigger services (such as those occurring in nursing, assisted living, or home health settings), because these patients are significantly different from typical depression patients.

2.2.5 Quality Alignment for Assessing Value

One commenter suggested measuring the association with presence of goal concordant care, for example via an advance care plan, as a measure of quality to align with the cost measure.

2.2.6 Clinician Expert Workgroup Composition

Commenters generally recommended that the workgroup for any of the 3 candidate episode groups include psychiatrists, psychologists, and social workers. Commenters also recommended additional specialties for inclusion in the workgroup, including primary care clinicians, occupational therapists, ED clinicians, and geriatricians. Commenters also suggested that the workgroup include clinicians with experience with direct treatment of the condition, particularly in the outpatient setting, and treatment of acute exacerbations in the ED setting.

2.2.7 Other Concerns and Feedback

Commenters expressed some concerns about challenges that cost measures for mental health conditions may face regarding appropriate provider attribution. One commenter noted that patients receiving care for mental health conditions often receive care from multiple providers ("split treatment") across different settings. Care includes outpatient mental therapy (from a social worker or psychologist), inpatient treatment, including ED visits, psychopharmacology (from a psychiatrist), and inpatient and outpatient management of comorbid chronic medical

[12] CMS, "MACRA Episode-Based Cost Measures: Wave 4 Measure Development," CMS Currently Accepting Comments Page (December 2020), https://www.cms.gov/files/document/wave-4-measure-development-call-public-comment.pdf.; CMS, "Preliminary Specifications of Wave 4 Candidate Episode Groups workbook), CMS Currently Accepting Public Comments Page (December 2020), https://www.cms.gov/files/document/preliminary-specifications-wave-4-candidate-episode-groups-workbook.xlsx.

conditions (with the appropriate specialist). The commenter suggested that this fragmentation of care across settings may complicate the cost measure's capacity to measure resource use attributable to one clinician.

Commenters noted that some of the existing episode-based cost measure frameworks (i.e., the frameworks for acute inpatient medical condition measures and procedural measures) may be insufficient to capture the whole spectrum of care for chronic mental health conditions. One commenter noted that patients with depression or severe mental illnesses often receive care in multiple different settings, and another noted that primary care providers manage care for patients who live in areas with less availability of mental health services. One commenter also expressed concern about health equity and social determinants of health (SDOH), citing recent findings on the role of risk adjustment in perpetuating spending gaps between disadvantaged patients, particularly Black patients, and others.[13]

[13]Ziad Obermeyer et al., "Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations," Science 366 (2019-10-25 00:00:00 2019).

2.3 Therapy and Rehabilitation

This section summarizes the feedback and provides responses for comments received on the Therapy and Rehabilitation clinical area. The following subsections describe comments on which of the candidate episode groups (Low Back Pain, Low Back and Neck Pain) to prioritize for development in Wave 4, the new therapy framework, addressing the need for therapy, opportunities for improvement, preliminary trigger codes, potential Clinical Expert Workgroup composition in turn.

2.3.1 Episode Group Prioritization

All commenters suggested that low back pain and neck pain, if both developed as cost measures, should be developed as separate measures. A large majority of commenters recommended developing a measure for low back pain rather than neck pain because low back pain has more clear clinical guidelines and fewer etiological confounders. One commenter suggested developing more specific sub-groups for a neck pain measure, such as subsetting among shoulder, thoracic joint, sacroiliac joint, or other loci of pain. Many commenters opposed inclusion of low back pain and neck pain in the same measure because the conditions are sufficiently different.

Many commenters also emphasized the need to distinguish chronic and/or recurrent patients from acute care or first-time patients, as they present very different clinical and cost profiles. For example, chronic low back pain patients more often have underlying chronic conditions that require treatment extraneous to low back pain, receive opioid treatment, and receive care over longer periods of time. One commenter also advised including non-chronic versions of low back pain, because the differences between sub-acute, acute, and chronic low back pain are often subtle and not easily measured. The commenter also stated that private payers don't distinguish between these types of conditions, and flagged a study finding success in distinguishing between radiating and non-radiating pain to predict costs.[14]

2.3.2 Therapy Framework

Many commenters provided feedback on the potential triggering and attribution methodology. One commenter pointed out that patients may be repetitively referred to therapy due to a lack of understanding of chronic care management among healthcare team members, and suggested that MIPS measures should encourage team-oriented care.

One commenter provided feedback on the initial framework, stating that the clinician prescribing a service is often not in the same TIN as the clinician rendering the service, which

[14]Milliman, Inc., "Impact of Physical Therapist Services on Low Back Pain Episodes of Care," The Private Practice Section of the American Physical Therapy Association Webpage, (April 2018), https://ppsapta.org/userfiles/File/ImpactofPhysicalTherapistServicesonLowBackPainEOC.pdf.

may lead to confusion around attribution. Physiatrists often see the patient before referral to a specialist, for example. The commenter also noted that physical therapists can only treat patients without a prescription under Medicare for 30 days, so the triggering approach may miss referred care beyond that window.

One stakeholder shared specifications for a grouper developed by the Hospital of Special Surgery to measure the cost of care of back pain patients, which includes attribution for a wide range of specialties, including physical therapy, psychiatry, primary care, anesthesia, and orthopedic surgery, and which excludes patients with spinal deformities, inflammatory diseases, fracture/trauma, and pregnancy. Another commenter requested that attribution only apply to clinicians who are providing the service in question, rather than holding specialists accountable for downstream costs of a patient whose care they are not coordinating.

Many commenters provided input on potential sub-groups. Commenter supported sub-grouping approaches including chronic versus acute patients, separating patients requiring therapy due to trauma from patients with a different mode of onset, and stratifying among those who receive surgery, imaging, or injections versus those who don't. Other methods of sub-grouping were suggested by 1 or 2 commenters, such as by the socioeconomic status of the patient, or whether the care sought qualifies as recommended care. One commenter suggested sub-grouping among surgical categories, such as fusion, trauma, or one of the several inflammatory conditions. Another commenter suggested sub-grouping based on the Glassman et al. (2011) classification, which uses a functional diagnostic matrix to classify spinal conditions and provide more granular clinical guidelines, using the dimensions of symptoms, structural pathology, and compressive pathology to classify cases. [15]

One commenter suggested stratifying by the length of the episode of care, using cutoffs of 1, 4, and 12 weeks to classify low back pain, noting that simple diagnosis categories can complicate the administrative burden of measure implementation. One commenter suggested a 12-week cutoff to separate patients with acute versus chronic low back pain, while another commenter asked for clarity on how CMS will differentiate between chronic and acute low back pain.

Commenters also flagged predictors of cost that should be included in risk adjustment. Two commenters raised age, gender, severity of symptoms, and functional scores, such as the Oswestry Disability Index, or the Patient-Reported Outcomes Measurement Information System (PROMIS-10). One commenter suggested that the number of comorbidities should not be a risk adjustor, as it is in the CMS-HCC Model Version 24. Two commenters suggested excluding cancer patients, and several commenters advocated excluding all patients who enter treatment

[15]S. D. Glassman et al., "A Diagnostic Classification for Lumbar Spine Registry Development," Spine J 11, no. 12 (Dec 2011). https://doi.org/10.1016/j.spinee.2011.11.016.

due to injury. One commenter recommended excluding diagnoses related to spinal deformity, inflammatory conditions, and spine fractures or traumas, noting that they are excluded in clinical guidelines and may represent more complex and expensive cases. For services that should be excluded, one commenter suggested eliminating palliative care from the measure.

Some additional refinements to the measure framework were suggested. One commenter provided a list of CPT/HCPCS codes that should be included for attribution, and suggested a 90-day episode window rather than the original 180 days. One commenter noted that while referrals are common, as of 2005 the Medicare Benefit Policy Manual allows direct access to a physical therapist without referral. This may allow attribution without an evaluation and management (E&M) claim. One commenter suggested separating claims with a GP modifier from those without one, as a way of focusing the cost measure on physical therapy costs.

Two commenters noted that chiropractors aren't reimbursed by Medicare for the full scope of their care, raising concern about claims-based measurement of resource use. One commenter suggested introducing a bundled payments model to preserve Medicare beneficiaries' access to chiropractic care.

2.3.3 Opportunities for Improvement

Commenters listed many possible ways of measuring improvement in care. One commenter suggested that assigning downstream costs, such as support services, medications, imaging, surgery, clinician visits, and ER visits to the attributed clinician could create room for improvement through accountability for these costs. Another commenter said that attributing occupational therapists the measure may impede patient access.

One commenter pointed to a study showing evidence of early intervention, active care, and direct access to physical therapy all reducing downstream costs, and which has stimulated discussion among private payers about facilitating early access to physical therapy.[16]

Another commenter suggested that imaging compliance, improvement during initial treatment for another condition, orthopedic and neurologic consult rates, and comorbidities all be included because they influence musculoskeletal outcomes, and thus would signify improved care if properly administered.

Finally, one commenter suggested accounting for various patient features, such as activity level, work status, 3rd party litigation, health literacy, and downstream outcomes like functional ability and resource utilization, as a way of measuring downstream improvements in

[16] Milliman, Inc., "Impact of Physical Therapist Services on Low Back Pain Episodes of Care," The Private Practice Section of the American Physical Therapy Association Webpage, (April 2018), https://ppsapta.org/userfiles/File/ImpactofPhysicalTherapistServicesonLowBackPainEOC.pdf.

the patient's health. Activity level and recurrence were similarly flagged by one other commenter.

2.3.4 Preliminary Trigger Codes

Commenters provided input on the initial set of trigger codes shared in the posting that can be used to initiate a therapy episode. One commenter stated that the initial list of codes was extensive and well-researched, but was cautious of attempting to measure all costs associated with back pain through a therapy framework.

One commenter suggested vastly expanding the list of triggers to include acupuncture, chiropractic care, ED visits, injections, osteopathic manipulation, office consultations and visits, preventive visits, physical therapy evaluations, and manual therapy. Two commenters flagged other services that signal an episode of low back pain, such as spinal injections, electrical stimulation (e-stim), manual therapy, massage, or acupuncture. Another commenter provided a list of evaluation and re-evaluation codes to include.

One commenter also noted that physical therapists cannot bill E&M codes, suggesting instead that the triggering methodology should use an evaluation code and a confirming procedure or modality code.

2.3.5 Quality Alignment for Assessing Value

Commenters provided suggestions on quality indicators and measures related to low back pain. One commenter mentioned the RAND Corporation/University of California, Los Angeles (UCLA) Appropriateness Method and a set of American Board of Medical Specialties (ABMS) Maintenance of Certification Part IV quality improvement activities. The commenter also emphasized the need to shift the focus in quality measures away from orthopedic surgery and towards a more general approach, suggesting patient-reported outcome performance measures (PRO-PMs), the Oswestry Disability Index (ODI), or PROMIS-10.[17] Another commenter suggested the ODI as well, along with work status, pain outcomes, back pain beliefs, physical activity, and health care utilization as quality outcomes.

2.3.6 Clinician Expert Workgroup Composition

Commenters generally recommended that the workgroup for either of the candidate episode groups should include various types of therapists and related specialties, such as physical therapists, occupational therapists, chiropractors, physiatrists, and pain management clinicians. Commenters also recommended additional specialties for inclusion in the workgroup, which

[17] "PROMIS Global-10," Code Technology, accessed February 19, 2021, https://www.codetechnology.com/promis-global-10/.

includes neuro-radiologists, neurosurgeons, anesthesiologists, and geriatricians. Commenters also recommended including clinicians with experience with:

- Direct treatment of the condition, particularly in the outpatient setting
- Spinal manipulation or low back pain surgery
- Non-pharmacologic pain treatments
- General rehabilitation and compensatory activities
- Treating acute exacerbations in the emergency department
- Relevant coding knowledge, including for chiropractors
- Low back pain outcomes assessment
- Procedural and non-procedural treatment
- Pre- and post-procedural evaluation and treatment

2.3.7 Other Concerns and Feedback

Several commenters reiterated the multi-disciplinary aspect of care for low back pain. Two commenters emphasized the positive roles that occupational therapy and chiropractic care can play in multi-dimensional care. However, commenters noted that there may be barriers to including these specialties in the cost measure, stating that occupational therapists may have limited influence over costs and that chiropractors cannot bill Medicare for E&M, physical therapy, or physical medicine. Commenters noted that these barriers to Medicare reimbursement may reduce patient access to spinal manipulation treatment through out-of-pocket costs, even though the American College of Physicians recommend spinal manipulation as a first line treatment for low back pain patients. One commenter expressed interest in developing a broader episode-based cost measure not limited to therapy.

One commenter expressed concern about the draft trigger and attribution methodologies creating barriers to specialty referral and timely imaging services, especially for the treatment of cervical spondylotic myelopathy. One commenter noted that occupational therapists often receive very complex patients, whose history may not be reflected in just 1 or 2 trigger claims.

Commenters highlighted challenges in measuring costs precisely. One commenter said that reviewing claims in isolation may not provide enough information to define the patient's clinical path. Another commenter emphasized the importance of both the type of initial provider and of the timing of early treatment in the patient's resource use to downstream costs and recovery trajectory.

One commenter suggested that CMS extend cost measures to Part C, with the goal of harmonizing payer policies and standards of measurements across the industry, between Medicare and private insurers.

2.4 Rheumatology/Arthritis

This section summarizes the feedback and provides responses for comments received on the Rheumatology/Arthritis clinical area, which contained the candidate episode group of Rheumatoid Arthritis. The following subsections describe comments on patient heterogeneity, attribution and different roles for clinicians of various specialties, opportunities for improvement, preliminary trigger codes, indicators of quality, and potential Clinical Expert Workgroup composition in turn.

2.4.1 Addressing Severity

Commenters described many methods of characterizing severity of rheumatoid arthritis, including assessments and testing, presence of extra-articular manifestations, and other non-claims disease and functional status activity indices.

A commenter noted that the severity of rheumatoid arthritis can be identified through objective assessments and biomarker testing. The commenter pointed to a number of tests, including erythrocyte sedimentation rate, C-reactive protein (CRP), rheumatoid factor (RF), antibodies of cyclic citrullinated peptides (CCP), antibodies to mutated citrullinated vimentin (MCV), and other multi-biomarker tests designed for rheumatoid arthritis. Some of this information may be available in claims data (e.g., ICD-10 diagnoses for elevated levels).

One commenter recommended identifying disease severity directly through the presence of extra-articular manifestations (e.g., pulmonary, ocular) reported on claims that would indicate a patient has a more severe disease. Another commenter suggested looking for the presence of other comorbidities or services as a proxy for disease severity, such as coronary artery disease, lymphoma, lung disease, vasculitis, side effects from medications (e.g., corticosteroids), history of orthopedic surgery, laboratory imaging, and neurodiagnostic services. With either approach, commenters suggested risk adjusting or excluding these sub-populations, as they would likely account for a small number of patients who are clinically more complex and require different care needs than the rest of the patient population.

Commenters also suggested using disease and functional status activity indices to identify and address severity. Indices like the Routine Assessment of Patient Index Data 3 (RAPID3), Clinical Disease Activity Index (CDAI), and Simple Disease Activity Index (SDAI) use patient and provider reported outcomes which may be quantified into a score to categorize the disease severity. Commenters noted that these instruments are widely used among rheumatologists, but acknowledged they are not observable through claims data.

Commenters said that it would challenging to characterize disease severity based on the specialty of the treating clinician alone, because primary care clinicians may be managing a patient's rheumatoid arthritis in geographic areas with limited access to rheumatologist.

2.4.2 Addressing Attribution and Roles of Various Specialties

Many commenters said that primary care clinicians and rheumatologists are the main clinicians involved in care and have distinct roles with regards to diagnosis, symptom management, and treatment. Commenters also suggested that a rheumatoid arthritis episode should be attributed to clinicians that are most involved in the patient's care, which usually includes the 2 aforementioned specialties.

One patient and family commenter discussed the key role that their primary care clinician played in referring them to a rheumatologist for diagnosis, monitoring, testing, and treatment. Commenters emphasized the importance of referral to a rheumatologist as soon as symptoms are suspected to diagnose rheumatoid arthritis at an early stage and prevent further joint damage. Other commenters said that rheumatologists also manage the patient's symptoms and prescribe the latest medications and treatments. However, a few commenters suggested that a primary care clinician could co-manage the patient's rheumatoid arthritis in less severe cases or manage care if they are operating in a rural area without access to a rheumatologist.

While commenters generally identified rheumatologists and primary care clinicians as the main specialties involved in care, one commenter also noted that other specialists, like orthopedists, psychologists, neurologists, or pulmonologists could be involved in a patient's care, which may warrant attribution.

2.4.3 Opportunities for Improvement

Many commenters noted potential opportunities for improvement in selecting treatments (e.g., drug therapies) and preventing adverse effects and overuse of expensive biologics. Commenters also said that costs for rheumatoid arthritis are driven by the cost of medications, treatments, and prior therapies along with the disease duration.

One commenter suggested improving the selection of medications prescribed by rheumatologists by consulting American College of Radiology (ACR) guidelines for patients with mild to moderate Rheumatoid Arthritis. The guidelines recommend that a patient begin treatment with 12 weeks of disease-modifying antirheumatic drugs (DMARDs) prior to starting biologic therapy, with exceptions for patients with severe rheumatoid arthritis or those who cannot take the DMARDs. They also recommended that biologic naïve patients who fail DMARD therapy could begin treatment with a biosimilar drug, which has significantly lower costs.

Despite these guidelines, commenters also mentioned that rheumatologists may choose therapies based on various other factors, including affordability, financial incentives, insurance requirements (i.e., step-therapy, prior authorization), patient preferences, and previous experience or familiarity with the medication. For example, one commenter observed that

primary care clinicians seem to prescribe lower costing medications (e.g., methotrexate) than rheumatologists. Another commenter also recommended CMS discussion regarding a rheumatoid arthritis drug pricing model development.

Commenters also suggested improving the tools that may predict a patient's response to medications as a way to prevent adverse effects. They noted that current ACR guidelines exist as one tool to encourage treatment selection, but suggested the need for a more prescriptive approach. For example, commenters recognized that patients may have to go through a few trials, often "stepping through" classes of medications (e.g., tumor necrosis factor [TNF] inhibitors) before coverage is granted for a physician's preferred treatment, as one commenter discussed. Commenters suggested that lab tests or innovations in precision diagnostics may help rheumatologists better target treatments to improve early disease control and lower overall costs.

A few commenters also discussed reducing use of other treatments and services. To prevent overuse of biologics for patients who do not meet the appropriate criteria, one commenter suggested developing guidelines based on prior failure or complications from medications and therapies. Another commenter suggested improvements could be made to account for medication costs in the outpatient setting, infusion costs in all clinical settings, and SRFs. Another commenter suggested identifying the optimal frequency of lab monitoring to prevent overuse of advanced imaging.

A person and family commenter identified many opportunities for care improvement in areas, such as managing pain and symptoms like flare-ups, assessing mental and physical health statuses, assessing disease progression and severity, and evaluating medication effectiveness and side effects.

2.4.4 Preliminary Trigger Codes

One commenter suggested that the draft list of trigger codes in the supplemental workbook was too broad. The commenter suggested that rheumatologists and primary care clinicians may use a more restricted set of codes, and the draft codes could also be used by other clinicians (e.g., in surgical or rehabilitation services). They suggested that the rare complications codes such as rheumatoid arthritis with lung disease, vasculitis, and cardiac disease are potentially useful for tracking rare complications.

The commenter suggested removing M07 codes as they are related to other forms of inflammatory disease and removing M06.4 since it is nonspecific. While excluding broader codes could result in inability to capture orthopedic costs, the commenter reconciled that this would better focus the measure scope on outcomes and cost savings based on early management. The commenter said that managing longstanding rheumatoid arthritis may be complicated due to a patient's previous therapies, comorbidities, and prior drug therapies and complications.

2.4.5 Quality Alignment for Assessing Value

Commenters provided examples of existing quality measures and important quality indicators to assess alongside cost. One commenter mentioned existing quality measures endorsed by the National Quality Forum (NQF) for commonly used functional and activity status for rheumatoid arthritis. The commenter also mentioned a patient safety measure that the ACR recommends prior to starting medications, including tuberculosis and hepatitis testing. Another commenter noted that the Rheumatology/Arthritis clinical area would be a good candidate for the MIPS Value Pathways (MVPs) as a cost measure to assess alongside existing quality measures. A person and family commenter noted that consistent care by a clinician with expertise in treating rheumatoid arthritis is an important quality indicator, as this can result in fewer office visits, less medication experimentation, and better responses to flare ups, which lead to less severe symptoms and pain for the patient with improved outcomes.

2.4.6 Clinician Expert Workgroup Composition

Commenters generally recommended that a Rheumatoid Arthritis workgroup should include rheumatologists as well as geriatricians and occupational therapists. Other factors that commenters noted were that the workgroup should include clinicians with experience with:

- Direct treatment of the condition, particularly in the outpatient setting
- Participation in other measure development
- Rehabilitation and compensatory activities
- Relevant medical coding knowledge

One commenter recommended representation specific organizations and societies, naming the Coalition of State Rheumatology Organizations (CRSO), the Alliance for Transparent & Affordable Prescriptions (ATAP), and the ACR.

2.4.7 Other Concerns and Feedback

One commenter had questions and concerns about the triggering and attribution methodologies. The commenter asked if the general chronic condition framework considers all diagnoses on a claim (as opposed to just the first-listed diagnosis), noting that ophthalmologists may include rheumatoid arthritis as a secondary or tertiary diagnosis for during visits. The commenter expressed that ophthalmologists often care for patients with ophthalmic aspects secondary to rheumatoid disease (e.g., uveitis), but don't have input on the patients' general care and shouldn't be attributed the measure (e.g., by applying specialty exclusions like those for the Total Per Capita Cost measure). The commenter expressed concerns that ophthalmologists may bill E&M codes or other services that overlap with chronic condition measure framework attribution requirements and noted the importance of distinguishing ophthalmologists treating

only uveitis in patients from primary care clinicians or rheumatologists managing the rheumatoid arthritis.

One commenter suggested the scope of the measure should focus on early management of new rheumatoid arthritis patients. The commenter suggested using defined care paths centered on aggressive management with traditional oral medications to order to maximize early outcomes, which could be followed by newer agents, including biologics and others if the patient fails to improve under standard measures of disease activity or develops a complication to therapy that would require modifications to conventional therapy to drive further improvement.

One commenter was concerned with the cost of therapies, since they have varying prices and effectiveness, depending on the patient, and that the overall cost of drugs is generally not known by either prescribing physicians or patients. Additionally, the commenter noted that prescribing clinicians often do not have insight into the required co-insurance or costs, leading to adherence issues. The commenter suggested implementing guardrails that require clinicians to review the cost of options with patients before prescribing to improve shared decision-making, and proposed consideration of companion measures to assess availability of cost data at point-of-care. The commenter also recommended that CMS create reports modeled after hospital Program to Evaluate Payment Patterns Electronic Report (PEPPER) reports to improve usability and provide actionable information to clinicians treating patients, with rheumatoid arthritis-specific categories like the usage of conventional versus biologic agents, infusions, and imaging, as well as hospitalizations.

One commenter noted that there are no appropriate cost/resource measures for rheumatologists under the current cost measures used in Quality Payment Program (i.e., in MIPS and Advanced Alternative Payment Models).

One commenter noted that rheumatoid arthritis medications often span across both Medicare Parts B and D. As such, the commenter recommended that CMS implement a mechanism that could account for all pharmaceutical costs, similar to what has been discussed for certain Bundled Payments for Care Improvement (BPCI) models. The commenter noted that only including Part B costs could put physicians who administer Part B drugs at a significant disadvantage compared to those who order/prescribe drugs covered under Part D. The commenter was also concerned that the current methodology could create incentivizes to use Part D drugs instead of Part B.

3 STAKEHOLDER COMMENTS: FEEDBACK ON OTHER MEASURE CONCEPTS AND DEVELOPMENT FOR FUTURE WAVES

This section summarizes comments received on measures concepts that we may explore for future development. The sections below present feedback on cost measurement for non-patient facing clinicians, head and neck disease clinician, emergency room/emergency department (ED) clinicians, and oncologic care, as well as comments on the information gathering process for future Waves of development.

3.1 Cost Measures for Non-Patient Facing Clinicians

This section summarizes comments received on potential cost measure development for non-patient facing clinicians, such as clinicians specialized in anesthesia, pathology, and radiology. The following sub-sections include discussions on potential opportunities for improvement for these clinicians, the extent to which these clinicians can reasonably influence care, and potential episode duration.

3.1.1 Opportunity for Improvement

One commenter appreciated the public comment opportunity for potential development of cost measures centered on care provided by non-patient facing clinicians.

A commenter recommended exploring radiology cost measure concepts that link to existing quality measure topics, like breast cancer screening or incidental imaging findings. One commenter recommended a potential breast cancer screening cost measure for radiologists, as radiologists have the ability to influence care in this area. A commenter noted that there are well-established quality metrics that breast imaging clinicians use to audit the quality of their practice (e.g., cancer detection rate, recall rate, and true/false positive rates), which would act as a fair balance to a breast cancer screening cost measure if reintroduced into MIPS and which could potentially be a candidate for an MVP.

A commenter noted that incidental imaging findings would be a worthwhile concept to explore for cost measurement, as it may address prevention, unnecessary repeat testing, and evidence-based follow-up care. A commenter mentioned that an abdominal computed tomography (CT) incidental finding measure may begin with a CT scan, capture downstream management and referrals to specialists, and assess outcomes for whether a radiologist recommended follow up. A commenter noted that MIPS includes quality measures focused on incidental finding-appropriate recommendation, providing an opportunity for cost-quality alignment.

One commenter noted that radiologists may influence costs by communicating with ordering clinicians to ensure appropriateness of the study, or by avoiding practice standards that

commonly suggest the potential usefulness of a magnetic resonance imaging (MRI) tests. They noted that there are opportunities for improvement in imaging (such as volume, test type, patient queue duration) while noting that attribution would be challenging due to the parallel influence of the patient-facing clinician (e.g., ordering a study).

3.1.2 Reasonable Influence of Non-Patient Facing Clinicians

A commenter noted that cost measurement for pathologists would require a unique framework; however, the commenter has explored alternative mechanisms which did not yield significant variation in the costs of pathology services relative to other costs over which pathologists exercise less influence.

One commenter suggested that certified registered nurse anesthetists (CRNAs) may be assessed via cost measurement for their holistic pain management services that mitigate opioid use, improve patient outcomes, and reduce costly complications. The commenter also noted that pre-anesthetic evaluations and selection of appropriate anesthetic medication prevent complications. Another commenter noted that anesthetists may reasonably influence costs directly related to their intervention, airway injury for intubation, untreated hypothermia, and nerve injury for a peripheral block.

3.1.3 Episode Duration

One commenter recommended a one-year episode window for a potential breast cancer screening cost measure for radiologists, suggesting it may include screening mammography through cancer diagnosis or return to annual screenings.

One commenter noted that anesthesia-related complications generally occur within 24 to 72 hours of the procedure, suggesting an episode window for anesthesia should be appropriately long enough to reflect these complications. Another commenter noted that the episode duration for non-invasive anesthesia (e.g., 14 days) should be generally shorter than the episode duration for invasive anesthesia (e.g., 90 days).

3.2 Cost Measures for Head and Neck Disease Clinicians

This section summarizes the feedback and provides responses for comments received on potential cost measure development for head and neck disease clinicians, otolaryngologists, or ear, nose, and throat (ENT) clinicians. The sub-sections below describe comments that may inform potential candidate episode groups and describe other relevant concerns or feedback.

3.2.1 Scope for Candidate Episode Groups

Commenters recommended candidate episode groups covering chronic rhinosinusitis, oral cavity cancer, sensorineural hearing loss, allergic rhinitis, vocal cord paralysis, dizziness/imbalance, obstructive sleep apnea, nasal obstruction, and thyroid cancer. They recommended that these concepts can relate to development of MVPs over time.

A commenter expressed that the measure concepts that may be the most impactful in terms of prevalence and volume include chronic rhinosinusitis and allergic rhinitis, hearing loss, chronic otitis media (with and without surgery), sleep apnea, thyroid disease, and nasal obstruction. They noted these are most likely to identify performance gaps and help standardize care. They also asserted that concepts with wider variability in treatment patterns should yield larger performance gaps and potential cost savings. One commenter recommended prioritizing procedural cost measures, as they have a more definitive start and end.

3.2.2 Other Concerns and Feedback

One commenter noted that there are various challenges for ENT cost measurement, such as the difficulty in identifying "best care" consensus for certain conditions, but that there is existing literature on these various treatment paradigms, particularly for sinusitis. One commenter noted that measure concepts involving tumors are challenging to define episode duration, as tumors may recur indefinitely.

3.3 Cost Measures for Emergency Clinicians

This section summarizes the feedback and provides responses for comments received on potential cost measure development for emergency clinicians. The sub-sections below discuss feedback on the scope and definition of episode groups, attribution, episode duration, and other relevant concerns or feedback.

3.3.1 Scope and Definition of Candidate Episode Groups

One commenter recommended that the candidate episode groups should be focused on common acute undifferentiated conditions for which there is sufficient volume, episode cost variation, and admission rates of less than 90% at the national level; they noted that these might

include shortness of breath, chest pain, abdominal pain, syncope, and altered mental status. A commenter suggested focusing on conditions that complete the continuum of care for chronic condition and acute inpatient medical condition cost measures that are already developed.

One commenter recommended that a cost measure for ED care should focus on cases that result in discharge, noting that claims data could be used to trigger, attribute care to a provider, and assign services for care in the post-discharge period. The commenter suggested that assigned services may be determined based on the diagnosis in alignment with evidence-based literature. A commenter noted that an ED cost measure would improve ED clinicians' performance through the adoption of care coordination models, improved shared decision-making, and the use of telehealth services.

3.3.2 Attribution

One commenter recommended that episodes should be attributed to the clinician that submits the Medicare Part B claim for services. The commenter expressed that it is assumed this clinician makes the final determination of advisability of discharge and is most likely to be responsible for the patient's final assessment, discharge diagnosis, and participation in shared decision-making for needed care coordination. A commenter noted that attribution for current episode-based cost measures isn't yet designed to capture care for ED clinicians, and suggested studying the contributions of ED care to cost of episodes using claims data.

3.3.3 Episode Duration

One commenter advised that the episode window be informed by a review of claims data to identify the timeframes for the occurrences of readmissions, deaths, and return ED visits, and suggested that 7 to 11 days would be an appropriate window of time. Another commenter similarly suggested 7 to 10 days based on their review of Medicare claims data.

3.3.4 Other Concerns and Feedback

One commenter described an emergency medicine-specific alternative payment model, the Acute Unscheduled Care Model (AUCM), which is a bundled payment model where emergency physicians accept some financial risks for discharge decisions on certain episodes of acute unscheduled care. The model's initial episodes focus on abdominal pain, altered mental status, chest pain, and syncope. The model also emphasizes ensuring follow-up, minimizing redundant post-ED services, and avoiding post-ED discharge safety events.

3.4 Cost Measures for Oncology

This section summarizes the feedback and provides responses for comments received on potential cost measure development for oncology care, specifically related to coding challenges.

One commenter noted that administrative burden would be a challenge for identifying cancer staging. Another commenter mentioned that cancer stage specificity is essential to accurately assess quality or cost, noting that ICD-10-CM codes and International Classification of Diseases for Oncology (ICD-O) are insufficient for staging information. They noted that cancer stage information is typically recorded in clinical narrative text notes and other informal means of communication in electronic health records (EHRs). Also, they mentioned that CancerLinQ data contain adequate tumor, nodes, and metastases (TNM) values and American Joint Committee on Cancer (AJCC) stage, which are usually in EHR data but must be codified.[18] However, it was also noted that there are certain barriers to AJCC data, such as the data not reflecting the edition being used and the need for an expensive proprietary license.

A commenter elaborated that the American Society of Clinical Oncology developed HCPCS codes for specific staging combinations for specific quality measures; however, the commenter noted this doesn't provide a long-term solution to the issue, and recommended that existing Systematized Nomenclature of Medicine (SNOMED) data or AJCC staging data be incorporated into claims data or captured via a parallel or mapped code set. A commenter stated that oncologists may know the cancer stage with more granularity, whereas other clinicians may not be aware, and they suggested that a cost measure ensure that non-oncologists are not penalized for their involvement in care.

3.5 Information Gathering Process

This section summarizes the feedback and provides responses for comments received on the process by which we gather information from stakeholders regarding episode group prioritization for future Waves of development. This question was posed given the new public comment used to gather stakeholder input in the early stages of Wave 4 episode-based cost measure development, which was adopted to allow commenters more time and flexibility to provide input on episode group prioritization given current demands on the clinical community, particularly for front-line clinicians.

While there are benefits to this approach given the current climate, Acumen sought comment on preferences to return to a process based on convening Clinical Subcommittees (CS) for this stage in future Waves. Commenters were in favor of using the CS approach in future Waves of development.

[18] "About Us," ASCO CancerLinQ, accessed February 19, 2021, https://www.cancerlinq.org/.

3.6 Other General Feedback

This section summarizes the feedback and provides responses for comments received on the topics not directly aligned with the sections above.

One commenter asked whether Wave 4 development will be restricted to the frameworks that were described in the posting materials (i.e., chronic condition and therapy frameworks).

A commenter noted that a barrier for neurologists in value-based care models and programs is the lack of neurology-specific cost measures. They recommended prioritizing conditions like dementia, Alzheimer's disease, Parkinson's disease, and migraine, noting the type of care for these conditions represents substantial variation in the acute and long-term care settings with high associated costs related to patients and caregivers. They also noted that these conditions have well-defined diagnostic criteria, quality measures, and are often clearly delineated between primary care, specialists, and subspecialists.

One commenter recommended developing cost measures related to the most prevalent and costly diseases and conditions. A commenter recommended publishing granular data on specialty-specific participation and performance data for greater transparency on MIPS cost measures. They noted this type of data would help societies evaluate and conceptualize cost measures that share attribution for complex and comorbid conditions.

A commenter noted that episode-based cost measures are well suited for certain surgical procedures; however, most of medicine is about caring for people with multiple concurrent conditions. They recommended a system for episode-based cost measures that focuses beyond treatment of isolated conditions.

A commenter expressed support for the new MVP framework for MIPS, noting it will be a challenge for clinicians whose specialty is not reflected by existing cost measures.

Two commenters raised concerns about attribution for individual clinicians for cost and quality measures in the Quality Payment Program, noting it may not accurately represent the type of care delivered to patients. They suggested that attribution should factor important elements of value-based care such as care coordination, team-based care, and cost-sharing.

A commenter expressed support for developing a potential cost measure to address patients' unmet palliative care needs, such as pain, fatigue, anxiety, and spiritual distress.

4 OVERALL ANALYSIS AND RECOMMENDATIONS

4.1 Overall Analysis of Comments

We appreciate the engagement of stakeholders and person and family representatives with the Wave 4 clinical areas and candidates episode groups and areas for potential future development. We will consider all the feedback received during the public comment period, as it is key to our measure development approach. The rest of this section summarizes key findings from the public comments received for each clinical area along with our responses and next steps.

4.1.1 Heart Failure

Overview of Comments

- Commenters acknowledged the complexity of chronic heart failure and the heterogeneity within the heart failure patient population, which pose challenges for cost measure development. Commenters' concerns included coding limitations and associated challenges to identify heart failure subtypes and severity levels, accounting for underlying causes of heart failure, and potential unintended consequences with cost measurement.
- Commenters recommended limiting the measure scope using I50 diagnosis codes for systolic, diastolic acute, and chronic congestive heart failure. Some commenters suggesting a further-limited scope that excludes patients presenting with heart failure symptoms due to other underlying conditions, and others recommended excluding patients with distinct etiologies or more severe cases.
- Commenters also suggested potential ways to identify the severity of heart failure through proxies like imaging or testing to estimate the ejection fraction, additional care visits (e.g., hospitalizations, ED visits, intensive care unit stays), mechanical ventilation, and diagnosis codes for more advanced forms of heart failure.

Responses

- We appreciate the stakeholder engagement and feedback on targeted questions for the Heart Failure clinical area. We will consider all feedback received to inform discussions with CMS to finalize the episode groups for measure development in Wave 4. We recognize commenter feedback that patient heterogeneity is challenge for a potential Heart Failure cost measure, and will continue to seek input from the stakeholder community on addressing these challenges in the future.
- We also would like to provide more context on questions commenters raised about the chronic condition measure framework. First, we appreciate commenter feedback on factors to include in risk adjustment. Currently, risk adjustment for the chronic condition framework accounts for full and partial dual status as well as the number of comorbidities (i.e., HCC count), to ensure that the model is accounting for patient characteristics and comorbidities that may impact cost in ways that are outside of clinicians' reasonable influence. Second, we appreciate commenter feedback that acute care for heart failure is also an important area to evaluate. Even if heart failure costs are evaluated using a chronic condition measure type,

inpatient stays, like readmissions, are important complications of care to capture and could be captured through service assignment.

4.1.2 Mental and Behavioral Health

Overview of Comments

- Commenters strongly supported developing a cost measure for major depressive disorder (MDD) over bipolar disorder and schizoaffective disorder, and one commenter provided initial input on draft trigger codes.
- Commenters stated that severe mental illnesses are often treated across many settings, without consistent communication between providers, which may pose unique challenges in the ability for attributed clinicians to influence care.
- Commenters noted that attribution will have to account for the prevalence of referrals in mental health treatment.
- Commenters stated that shorter-term existing episode-based cost measure frameworks (i.e., the frameworks for acute inpatient medical condition measures and procedural measures) may be insufficient to capture the whole spectrum of care for chronic mental health conditions.
- Commenters recommended risk adjusting for items like history of hospitalizations, past trauma, recurrent episodes of depression, and associated chronic physical or psychosocial illnesses to account for severity, with one commenter calling attention to the potential need to explore how geographic variation in access to Medicare-covered treatments affects service utilization.
- A commenter suggested incorporating measures of quality to align with the cost measure.

Responses

- We appreciate the extensive feedback on measure development for the Mental and Behavioral Health clinical area. We will consider all feedback received to inform discussions with CMS to finalize the episode groups for measure development in Wave 4. We recognize commenter feedback that established episode-based cost measure frameworks that focus on shorter periods of observation (i.e., procedural and acute inpatient medical condition measures) may not be appropriate to evaluate care for chronic mental health conditions. We agree that it's important to capture the ongoing and team-based nature of care for patients with chronic mental health conditions, which we propose may be better evaluated instead by the chronic condition measure framework. We also acknowledge stakeholder comments about challenges in attribution and unique aspects of treatment for care of mental health conditions. We will continue to seek input from the stakeholder community during future measure development and refinement of measure specifications, including on topics raised in this comment period such as risk adjusting for patient history and treatment across settings, and we will iteratively test the measure specifications and monitor for unintended consequences. Additionally, we acknowledge that evaluating cost in absence of quality may not reflect nuanced care decisions, which commenters also discussed. The MIPS program ensures that clinicians are evaluated on costs alongside categories for appropriate quality measures, improvement activities, and promoting interoperability to provide a more complete picture of clinician performance.

4.1.3 Therapy and Rehabilitation

Overview of Comments

- Commenters supported developing a cost measure for low back pain only rather than low back and neck pain (or evaluating the 2 conditions separately), citing different spending profiles between the 2 conditions.
- Commenters recommended that attribution allow the possibility for attribution beyond physical therapists to include chiropractors, occupational therapists, surgical teams, and others.
- Commenters recommended accounting for severity by addressing factors like radiating versus non-radiating pain, trauma, injections, imaging, socioeconomic status, surgery, functional scores, and cancer.
- Commenters suggested that the framework rely on shorter periods of observation than in the draft framework (e.g., 90 days.)

Response

- We appreciate the detailed feedback that commenters submitted on measure development for the Therapy and Rehabilitation clinical area. We will consider all feedback received to inform discussions with CMS to finalize the episode groups for measure development in Wave 4. We will also continue to seek input from the stakeholder community during measure development and refinement of measure specifications.

4.1.4 Rheumatology/Arthritis

Overview of Comments

- Commenters supported developing a Rheumatoid Arthritis measure.
- Commenters recommended a measure scope focused on patients with new Rheumatoid Arthritis, using a set of defined care pathways and treatments.
- Commenters recommended accounting for biomarker testing (e.g., erythrocyte sedimentation rate, C-reactive protein, rheumatoid factor, antibodies of cyclic citrullinated peptides, antibodies to mutated citrullinated vimentin), previous drug therapies and complications, extra-articular manifestations, comorbidities, and disease duration to characterize disease severity.
- Commenters identified primary care clinicians and rheumatologists as the main clinicians involved in care, acknowledging that access to specialists (e.g., in rural areas) could be a potential challenge.
- Commenters supported including costs of drugs covered under Medicare Part D, noting that medication costs are a large component of costs of care for rheumatoid arthritis.

Response

- We appreciate the detailed feedback that commenters submitted on measure development for the Rheumatology/Arthritis clinical area. We will consider all feedback received to inform discussions with CMS to finalize the episode groups for measure development in Wave 4.

We will also continue to seek input from the stakeholder community during measure development and refinement of measure specifications.

- We would also like to take the opportunity to address commenters' questions that relate to the chronic condition measure framework. We appreciate stakeholder input about the importance of incorporating Part D prescription drug costs and also understand that stakeholders are concerned that Part D costs be fairly evaluated. During the national field testing period in Wave 3 of measure development, the chronic condition measures allowed for the inclusion of Part D drug costs and applied a standardization methodology to account for the variation in Part D drug prices. The standardization methodology allows calculation of Part D standardized amounts that reflect meaningful differences in provider resource use.[19]

4.1.5 Cost Measures for Non-Patient Facing Clinicians

Overview of Comments

- Commenters recommended a breast cancer screening cost measure for radiologists, citing the degree of influence radiologists may have over this measure, well-established quality metrics, and potential to be a candidate for a future MVP. The recommended window for a breast cancer screening measure was one year.
- Commenters mentioned that pathology may be more challenging for episode-based cost measures, while a cost measure for anesthesia clinicians (e.g., anesthesiologists, CRNAs) may be feasible with a relatively short window (e.g., less than 90 days).

Response

- We appreciate the feedback and engagement related to cost measurement for non-patient facing clinicians, including the specific examples of cost measures for radiology and related considerations, and are interesting in further exploring these areas in the future. We will consider all feedback received for future measure development.

4.1.6 Cost Measures for Head and Neck Disease Clinicians

Overview of Comments

- Commenters recommended candidate episode groups covering chronic rhinosinusitis, oral cavity cancer, sensorineural hearing loss, allergic rhinitis, vocal cord paralysis, dizziness/imbalance, obstructive sleep apnea, nasal obstruction, and thyroid cancer, noting that they may relate to MVP development over time. Some advocated for prioritizing concepts with more prevalence and impact, while others suggested procedural measures as they have a more clear start and end.
- Commenters also noted potential challenges for ENT cost measurement, including identifying the appropriate care standards and window for a measure that is known to have indefinite and reoccurring complications (e.g., tumors).

[19] CMS, "Part D Payment Standardization Methodology for 2020 Cost Measure Field Testing," MACRA Feedback Page (August 2020), https://www.cms.gov/files/document/macra-2020-cmft-part-d-standardization.pdf.

Response

- We appreciate the stakeholder feedback and engagement related to potential candidate episode groups and cost framework considerations for head and neck disease clinicians. We are interested in learning more about the various options as they relate to critical criteria (e.g., performance gap) and how they may fit into the future of MVPs. We will consider all feedback received for future measure development.

4.1.7 Cost Measures for Emergency Clinicians

Overview of Comments

- Regarding measure scope, some commenters recommended an ED cost measure to focus on cases that result in discharge, while others mentioned that we may try to connect an ED measure with the care evaluated by certain chronic condition or acute inpatient medical condition measures to evaluate the full continuum of care.
- Some scope examples could be for common acute undifferentiated conditions with sufficient volume, cost, and low national admission rates, such as shortness of breath, chest pain, abdominal pain, syncope, and altered mental status.
- Commenters suggested a short window of approximately 7 to 11 days.

Response

- We appreciate this feedback on a potential emergency care cost measure. We appreciate the comments on attribution and information on the AUCM and will continue to further explore these topics. We will consider all feedback received for future measure development.

4.1.8 Cost Measures for Oncology

Overview of Comments

- Commenters raised that ICD-10 and ICD-O coding is insufficient for cancer staging information.
- Commenters noted that more granular information is available in EHRs and in AJCC data, though these sources present barriers to access. HCPCS codes for specific staging combinations are available from ASCO, but commenters noted this doesn't provide a long-term solution to the issue of coding challenges, and recommended that existing SNOMED or AJCC staging data be incorporated into claims data or captured via a parallel or mapped code set.

Response

- We appreciate these comments that provide valuable insights into the various sources and barriers for granular cancer staging information. We recognize that access to the more granular cancer staging data presents some challenges that we may continue exploring and discussing. We are also interested in learning more about the ASCO approach of using HCPCS codes as proxies for cancer staging. We will consider all feedback received for future measure development.

4.1.9 Information Gathering Process

Overview of Comments

- Commenters recommended revisiting the CS approach for future Waves.

Response

- We appreciate the support for the CS approach and will assess the tradeoffs between this approach and the current public comment approach for future Waves of measure development.

4.1.10 Other Feedback

Overview of Comments

- Commenters suggested measure development to evaluate overall palliative care needs and neurology-specific conditions (dementia, Alzheimer's disease, Parkinson's disease, migraine).
- Commenters suggested prioritizing cost measures by most prevalent and costly conditions, recommended publishing more granular specialty-specific participation and performance data for greater transparency and actionability for MIPS cost measures, and suggested revisiting the application of individual clinician attribution within the broader Quality Payment Program.
- Commenters noted that the MVP framework will be challenging for clinicians whose specialty isn't reflected by existing cost measures. Some emphasized the need to evaluate cost of care more broadly beyond just the piecemeal treatment of conditions in isolation.

Response

- We appreciate this feedback on potential episode-based cost measure development for additional clinical areas, which can be revisited further as potential areas for future measure development. We also appreciate the recommendations on criteria to prioritize and will continue to discuss these criteria with CMS when determining areas for development.
- We value the broader comments on the Quality Payment Program and MVPs as a whole and will share this feedback with CMS.

5 APPENDIX A: PUBLIC COMMENT VERBATIM REPORT

This appendix contains the verbatim texts of the comments received. The information is provided in a list format and presented in order of the comment number, or assigned identification number for the comment. The list presents the name, affiliated organization, and date of submission (date of receipt of the comment via email or survey submission). The submitter name for each comment is the name of the person who signed the letter or filled out the survey. For some comment submissions, the person who signed the comment letter is not the same as the person who submitted the comment nor the same as the contact person provided in the comment.

Please note that the verbatim text has been edited to improve the readability of this report. We omitted letter template details (e.g., company logo), email signatures, and sensitive personally identifiable information. Also, respondents' complete survey responses were concatenated together without the questions intact.

5.1 List of Verbatim Comments

5.1.1 Comment Number 1

- **Date:** 01/11/20
- **Submitter Name, Credentials, and Organization:** Connie M. Lewis, MAN, ACNP-BC, NP-C, CHFN, FHFSA, American Association of Heart Failure Nurses
- **Comment Text:** HFrEF and HFpEF would be a way to identify. Keep in mind that we only have guidelines for HFrEF. Not every HFpEF is treated the same eg. if hypertension is the cause, control hypertension. HFpEF from amyloidosis is very different for diagnosis and treatment. HF patients are usually admitted for congestion, however, not always. Sometimes the issue is hypovolemia, hypotension, worsening renal function, or arrhythmias. Treatment strategies differ. The DC follow up care should reflect stability and GDMT as indicated. For HF admissions, if Wave 4 only looked at HFrEF with congestion, then patients could be risk stratified by weight loss, activity, BP, renal function, potassium, and DC medications. NYHA class could be used, it is not always documented. ICD-10 codes may be useful if clinical markers and consultations are identified, eg LVEF 20% with hypotension, LVAD/transplant consultation, or Hospice/Palliative care consultation. The primary provider may be a PCP, HF MD/NP/PA, other cardiologist. Eg., some EP cardiologist keep their HF patients, others refer to HF MD/NP/PA. Same with general cardiologist, they will keep their HF patients until they become more complex. HF providers manage HF, the patient may also be seen by multiple specialist for other co-morbidities, eg. CAD, renal disease, arrhythmia. A newly diagnosed patient may have more follow up visits, with and without HF medication titration, and test than a chronic stable patient. As HF progresses the patient requires more follow up. Risk adjustment may help. Telehealth is important for management. We have seen the success since COVID-19. Reimbursement for telehealth. We need to improve GDMT in the HFrEF patients. Many of the trigger codes are not used routinely. If they were, we could

improve subgroup analysis and treatment. The ACC has published new quality measures for HF, most are for HFrEF.

5.1.2 Comment Number 2

- **Date:** 01/13/21
- **Submitter Name, Credentials, and Organization:** Rachel Groman, MPH, Heart Health Strategies
- **Comment Text:** For the Wave 4 public comment period and associated materials, I was wondering if you could clarify whether TEPs that are eventually assembled to develop Wave 4 measures will have to adhere to the specific measure frameworks described in the appendix of the attached document. For example, will the Chronic Heart Failure measure need to rely on a one-year episode window and the trigger and attribution logic described in the appendix or will the TEP have the flexibility to decide what parameters are most appropriate? Thanks.

5.1.3 Comment Number 3

- **Date:** 01/14/21
- **Submitter Name, Credentials, and Organization:** Rebecca Yowell, American Psychiatric Association
- **Comment Text:** I had a quick question about the preliminary specs (Preliminary Specifications of Wave 4 Candidate Episode Groups workbook (XLSX)) I was taking a quick look at the CPT codes and they don't include any of the CPT codes from the Psychiatry section of CPT such as the initial evaluation codes (90791, 90792) and the psychotherapy codes (908xx series). If these are trigger codes it doesn't factor in several of the primary behavioral health services and would exclude psychologists and social workers from the measure for the most part since the only codes on the list they could bill are related to ABA services (which is billed by a small subset of folks).

  Was this intentional? If so, what was the rationale?

5.1.4 Comment Number 4

- **Date:** 01/16/21
- **Submitter Name, Credentials, and Organization:** Connie Lewis, MSN, ACNP-BC, NP-C, CCRN, CHFN, FHSA, American Association of Heart Failure Nurses
- **Comment Text:** I have previously submitted my comments and the 2021 Update to the "2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure treatment: Answers to 10 Pivotal Issues About Heart Failure with Reduced ejection Fraction" was just released as article in press. I strongly feel that reading this manuscript with assist the group in understanding the complexity of HF and could add valuable guidance in the measures.[20]

[20] Committee Writing et al., "2021 Update to the 2017 Acc Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure with Reduced Ejection Fraction: A Report of the American College of Cardiology Solution Set Oversight Committee," J Am Coll Cardiol (Jan 4 2021). https://doi.org/10.1016/j.jacc.2020.11.022.

5.1.5 Comment Number 5

- **Date:** 01/16/21
- **Submitter Name, Credentials, and Organization:** Janice N. Lambert, Patient and Family Advisory Council for Comagine Health, PFAnetwork
- **Comment Text:** I was fortunate that a primary care doctor suspected the possibility of rheumatoid arthritis and recommended the testing to confirm the condition. Otherwise I would have gone undiagnosed much longer, causing more joint damage, thus greater severity and pain. I was referred to a rheumatologist for treatment and monitoring of my condition. I believe this specialist is necessary to navigate available treatments and medications to keep my symptoms under control. I don't believe a general practitioner has the time or expertise to address all of the possibilities in medication and treatment that are available for rheumatoid arthritis patients today. Some patients must try several treatment protocols to find one that helps. I don't understand all of the coding practices necessary to comply with Medicare billing practices but I do know I have proven confidence in the ability of my rheumatologist to know the disease is progressing and what can be done to control the progression and severity. Measuring incidents of pain, progression of joint damage, number and severity of flare ups, ability of patient to continue to perform daily and preferred activities, effectiveness and side effects of current medications, general state of physical and mental health. I believe one of the most critical obstacles is the price of the medications that have now been proven to successfully stop or greatly slow the symptoms (joint damage) of rheumatoid arthritis. Even with Medicare, I must pay about $7,000 per year for the biologic medication that has enabled me to resume almost normal physical activity. Many people cannot afford to pay for these drugs. A second problem is access to the specialist who is current on the best treatments and medications available to help each patient - one treatment does not fit all. Consistent care by a provider competent in treating rheumatoid arthritis can result in fewer office visits, less medication experimentation, better responses to flare ups, etc. resulting in less severe symptoms and pain for the patient who is then better able to care for him/herself and be more independent.

5.1.6 Comment Number 6

- **Date:** 01/20/21
- **Submitter Name, Credentials, and Organization:** O Tousey Wilson, PFAnetwork
- **Comment Text:** I would like to see the use of personal apps in managing long term care of CHF patients. It would seem to me that fit Bit data along with blood pressure, weight scale, and heart rhythm monitoring could allow closer automated management of people. Allowing earlier and more successful interventions yielding superior quality of life. The cardiac rehab is a great program but wouldn't a follow up visit testing the patients maintenance of fitness gains be a valuable tool in assessing the various programs?

5.1.7 Comment Number 7

- **Date:** 01/26/21
- **Submitter Name, Credentials, and Organization:** Kara Gainer, JD, American Physical Therapy Association

- **Comment Text:** On behalf of the American Physical Therapy Association, we appreciate the opportunity to offer comments on which episode-based cost measures to develop for the upcoming Wave 4 of measure development. Please find our detailed comments below.

  4.3 Therapy and Rehabilitation
  CMS states in its call for comment on wave 4 measure development: "The Therapy and Rehabilitation clinical area would represent the new measure framework we are exploring for Wave 4, focusing on the care and treatment provided by physical therapists and related specialties for broad conditions such as Low Back Pain or both Low Back and Neck Pain. This is a framework that is ripe for development, as it may build from the chronic condition framework to capture the care provided by therapists. Low back and neck pain are also common conditions that are impactful for patients, and a measure for these conditions would address the variation in treatment (e.g., duration/frequency, medication use- particularly opioids, use of higher cost interventions like imaging). A broad topic such as Low Back Pain would also be a strong candidate for a MVP, as it is a common condition with applicable MIPS quality measures. Additionally, we have received input suggesting the development of a Low Back Pain measure from our TEP and other stakeholders, noting the need for cost measurement centered on the care provided by therapists participating in MIPS."

  Response: Based on the statement above, APTA seeks clarification from CMS:
  - "Low back and neck pain": Would this include patients who are being treated for *both* low back pain and neck pain? Is the intent that the measure framework would focus on physical therapists who are treating low back and neck pain concurrently?
  - "Chronic condition framework": Does CMS view low back pain as a chronic condition, and if so, how will patients with acute pain versus chronic pain be differentiated?

  Question 1: We identified 2 concepts for this clinical area, which includes Low Back Pain or an alternative approach for both Low Back and Neck Pain. Given the criteria for measure prioritization and the essential features of cost measures described above, which of the options would be preferable for the first therapy episode-based cost measure, and why? Are there additional concepts that would be valuable to explore within this clinical area? For a cost measure focused on the ongoing treatment and care for these conditions, what are some areas of opportunity for improvement a measure may be able to capture regarding care and potential mitigation of complications?
  Response: If CMS intends to adopt only one therapy episode-based cost measure, then APTA recommends that the agency adopt a low back pain episode-based cost measure. If CMS adopts two therapy episode-based cost measures, then we recommend that CMS adopt a low back pain episode- based cost measure and an independent neck pain episode-based cost measure. CMS must not pursue the low back and neck pain "alternative" approach. The complexity of two diagnoses that may or may not be related creates a significant challenge in clinical practice. To address variation in treatment techniques, it is important to focus on a single condition for which there are clinical practice guidelines and less confounding variables. Integrating two clinical practice guidelines simultaneously should not be the first step in a new measure framework. CMS should consider a concurrent back and neck pain episode-based cost measure only after it establishes independent low back pain and neck pain episode-based cost measures.

APTA Academy of Orthopaedic Physical Therapy has developed clinical practice guidelines on both neck pain and low back pain:

- Neck pain
- Low back pain (currently undergoing revisions)

As it relates to cost measures, APTA recommends a focus on physical therapy costs (care provided and billed with a GP modifier) ***in addition to*** the downstream impact on the utilization of pain medications, imaging, surgical intervention, physician visits, emergency room visits, and support services such as transportation and home health aides.

Question 2: Based on the draft approach described in the "Appendix_Framework" tab of the Preliminary Specifications of Wave 4 Candidate Episode Groups workbook, which refinements would you recommend? What are types of services to use as indication of ongoing therapy management and care?

Response: APTA requests clarification on what a related specialty would be. APTA's recommendation would be that claims with the GP modifier be evaluated separately from any other billing specialty. Physical therapists do not bill evaluation and management codes. In addition, a physical therapist does not bill a subsequent therapy evaluation code in a single episode of care. Moreover, depending on the length of the therapy episode, a re-evaluation code may or may not be billed. The triggering claim should be an evaluation code and the confirming claim should include a procedure or modality code. Further, 180 days would represent a very long episode for physical therapy. We urge CMS to consider a shorter episode window; for instance, from date of trigger claim to 90 days thereafter. The CPT codes should include:

Evaluation/Re-Evaluation Codes

97161, low complexity physical therapy evaluation
97162, moderate complexity physical therapy evaluation
97163, high complexity physical therapy evaluation
97164, physical therapy re-evaluation

Procedure Codes/Modalities

97010 Hot or cold pack
97012 Mechanical traction
97035 Ultrasound
97110 Therapeutic exercise
97112 Neuromuscular reeducation
97113 Aquatic therapy with exercise
97116 Gait training therapy
97124 Massage therapy
97140 Manual therapy
97150 Group therapeutic procedures
97350 Therapeutic activity
97535 Self-care management training
97750 Physical performance test/measure
G0283, 97032 Electrical stimulation

Question 3: Based on the draft triggering approach, how should a therapy cost measure address the variation across patients for the need of therapy regarding Low Back Pain or for Low Back and Neck Pain (e.g., patients with chronic pain versus patients with a recent spinal surgery)? Some options include sub-grouping, risk adjusting, or excluding. Similarly, what recommendations do you have for how a measure may address patients with radicular syndrome/pain or arthritis?
Response: APTA recommends sub-grouping of the low back pain population. Population sub-groups could be based on duration of symptoms (i.e., acute, chronic/persistent), surgical/nonsurgical and, if surgical date of surgery, presence or absence of radicular symptoms, comorbidities, and diagnoses.

Question 4: Are there any other concerns that may be present with assessing the care for patients with these conditions? If so, what are some potential approaches to address these concerns for a cost measure?
Response: While there is a low back clinical practice guideline (as noted above), in practice, there is considerable variation in treatment. Reviewing and tracking claims in isolation may not be adequate to determine the actual procedures represented by the CPT codes billed during the treatment episode. For instance, there should be a way to distinguish between claims that include active interventions, including manual therapy (CPT 97140) versus those that include passive modalities. Additionally, a physical therapist cost measure should be based upon care delivered only by a physical therapist (or physical therapist assistant under the supervision of a physical therapist). Other providers that bill the CPT codes that are used to trigger a low back pain and/or neck pain episode of care should be excluded, or their data segregated. We also support risk adjustment.

5.1.8 Comment Number 8

- **Date:** 01/29/21
- **Submitter Name, Credentials, and Organization:** Devika Nair, MD MSCI, Vanderbilt University Medical Center
- **Comment Text:** Major depressive disorder should achieve priority, given its prevalence, independent associations with mortality through biologic and behavioral mechanisms, and its increased incidence during COVID (due to social isolation, etc.). Additional concepts that would be worth exploring are: Psychological Stress (distinct from Major Depressive disorder), and Anxiety. Additional opportunities for improving any measure related to mental and/or behavioral health would be contextualizing these symptoms in the setting of chronic disease management (such as chronic kidney disease, malignancy, dementia) and life impacts. Patients do not live in a vacuum, and it's the life impact associated with these diseases that is the goal of assessing and addressing them. I would be interested in helping with these transformative efforts. include whether associated with suicidal or homicidal ideation/action, include whether associated with anxious mood/anxious features, include whether associated with cognitive decline or dementia. See my notes above re: contextualizing these symptoms in the setting of comorbidity burden. association with hospitalizations, associations with visit adherence and engagement in health behaviors, association with timeliness of making other healthcare divisions such as dialysis decisions or advance care planning. association with presence of goal concordant care (via an advance

care plan, as an example). yes - id be happy to provide input in the following areas: kidney disease, diabetes, hypertension, psychosocial/behavioral issues, geriatrics, palliative care.

5.1.9 Comment Number 9

- **Date:** 01/30/21
- **Submitter Name, Credentials, and Organization:** Jennifer Bracey, MD, Society of General Internal Medicine
- **Comment Text:** I'm still a bit unclear: would this measure be for outpatient CHF or for inpatient? I think the two are very different beasts with different quality measures. An example of why this is important is that goal directed medical therapy may be more relevant in the outpatient setting--for example, hydralazine/imdur may be held inpatient to give room in the blood pressure to tolerate IV diuresis, etc. thus it would look from the chart that the patient is not receiving GDMT when, in fact, they were as an outpatient. If inpatient, the primary care provider should not be penalized for an example such as above. HFpEF v. HFrEF, diastolic heart failure v. systolic heart failure, preserved v. reduced ejection fraction are all different codes physicians input that reflect the same principle. AICD presence/interrogation via claims data may help indicated systolic heart failure. Symptomatic (NYHA classification) v. analytical/number-based (if discussing systolic heart failure then could categorize severity based upon ejection fraction). If discussing systolic, I almost prefer the latter approach as we have all seen that 1) symptomatology can be quite subjective or appear phenotypically different despite EF's as well 2) symptomatology can be confounded by the presence of another diagnosis (such as COPD, interstitial lung disease, pulmonary HTN, etc.). Not sure if this belongs under severity categorization but I would be way of using "volume overload" in claims data as this could create heterogeneity by capturing renal disease or liver disease. They do play different roles. 1) the patient may be able to access one or the other more frequently (thus one may be monitoring symptoms, weight gain more frequently) 2) the cardiologist would make all AICD referral decisions 3) partially depending on #1 above, medication management could be mucked around by the other (for example, the cardiologist should not be penalized if the primary care doctor makes a change or vice versa: not sure how we could adjust for that). See answers to #9 above. I think that risk adjustment plays a HUGE role in this measure: owning a scale at home, sophistication to use telemedicine, dietary adherence, literacy level, transportation to appointments, etc.). Heart failure seems ripe for telemedicine if a scale is provided to a patient by a clinic. My answer to #7 may have gotten at this. I would tend to avoid "volume overload" for stated reasons v. adjust for this by excluding dual diagnoses of renal failure or liver failure. #9 and 10 above.

  For (A) there are certainly opportunities for cost in imaging (how much imaging is ordered, how long it takes a hospital to get a patient in queue for, say, MRI). However attribution may be tough as the radiologist simply reads the film whereas it is up to the patient-facing clinician to order the study or up to the hospital re: efficiency of obtaining imaging which affect length of stay. (A) is certainly interesting to consider. I would defer this discussion to someone more familiar (i.e. an anesthesiologist or a surgeon) It's interesting that "forcing" a timeline on a hospital could cause them to be improve cost (finding a disease at end-stage v. earlier) and quality (same example)... I defer this to an ENT and others

  At the top of my head: an oncologist more intimately knows the stage whereas others (a hospital medicine team, for example) may not know the staging especially when a patient

chooses oncology care with one healthcare entity as opposed to the site of inpatient hospitalization or primary care. Thus I would be careful that non-oncologists are not penalized for not knowing the stage (have to wait on outside hospital records especially if a weekend, etc.)

I think this would be fascinating but probably should hear what you mean by this. I missed the two webinars.

5.1.10 Comment Number 10

- **Date:** 02/02/21
- **Submitter Name, Credentials, and Organization:** Paul Heidenreich, MD, MS, VA Palo Alto Health Care System
- **Comment Text:** The accuracy of EF group (reduced vs. Preserved) by ICD10 codes is unclear though likely improving. It was only moderate when I examined this about 5 years ago in the VA health care system. Ischemic vs. Non-ischemic may be a useful separation that can be done with ICD10 codes. Those with LVAD and transplant are so different that they should be there own separate groups or excluded. The intensity of claim activity (frequent admissions, ED visits for HF) is likely the best way to determine severity over time. ICU stay, mech ventilation, use of pulm.artery catheter will identify severity during admission. This will vary substantially based on preference of the physicians. Preserved LVEF patients more likely to be managed by internal medicine than reduced LVEF patients. Difficult to say when an episode starts and stops for a chronic disease like HF. I would examine longer time periods. Another issue is that higher quality care is likely to be more expensive. A new diagnosis of HF with reduced EF requires a large number of visits to get the person on quadruple life prolonging medical therapy and possibly insert a life prolonging device (ICD/CRT). It will be much less expensive (and worse quality of care) to just give a diuretic and say come back in 6 months. No additional feedback. It is unclear how much HF care is inefficient/unnecessary. Complications are likely to occur with good care (side effects from meds) compared to no care (that will increase risk of death). Thus, mortality must be a balancing metric to any cost metric. Mortality, hospitalization, use of BB, ace/arb/anti, mra and SGLT2 inhibitors in HF with reduced LVEF.

5.1.11 Comment Number 11

- **Date:** 02/02/21
- **Submitter Name, Credentials, and Organization:** Devika Nair, MD, MSCI, Vanderbilt University Medical Center
- **Comment Text:** I'm a nephrologist and physician scientist at Vanderbilt who conducts research specific to the serious illness needs of older adults with kidney disease, and I have experience with psychometrics and measure development. I have previously participated in MACRA workgroups.

  I was wondering if there was interest or impetus to develop a measure to assess patients' unmet palliative care needs as a whole (pain, spiritual/existential distress, fatigue, death anxiety, value clarification, etc.). These needs are prevalent yet unassessed and unaddressed in many of my patients, and I know this applies to many adults living with other chronic

conditions as well.

5.1.12 Comment Number 12

- **Date:** 02/03/21
- **Submitter Name, Credentials, and Organization:** David Glasser, MD
- **Comment Text:** Thank you for the opportunity to comment on Wave 4 measures. I do have a question and concern about the trigger diagnoses for the rheumatoid arthritis measure.

  Ophthalmologists often care for patients with uveitis secondary to rheumatoid disease. While we manage the ophthalmic aspects of the disease, we do not have input into these patients' general care and should not be included in this measure. However, we may include RA as a secondary or tertiary diagnosis code when billing for visits to manage their uveitis.

  My question: will only the firs- listed diagnosis on the claim form trigger this measure?

  My concern: if not, and if ophthalmologists (and other specialists that manage complications of RA but not the underlying disease itself) are not specifically excluded, the measure will be inappropriately applied to providers that have no significant control over the cost of care.

  Thank you for the detailed reply. The two checks in attribution methodology that you describe are not sufficient to distinguish between ophthalmologists treating only uveitis in RA patients and primary care physicians or rheumatologists managing the RA.

  Ophthalmologists often use E/M codes. They are not restricted to use by primary care providers, nor are they indicative of primary care services. This led to multiple cases of misattribution under the TPCC measure, and led CMS to exclude a number of specialties from that measure.

  An ophthalmologist who treats two different patients with RA and uveitis requiring prescriptions during the reporting period and the 1 year look-back period would be attributed cases despite treating only the uveitis. Many ophthalmologists would meet this criterion.

  This could result in RA patients with uveitis, who typically require an inexpensive course of topical steroids and 3-5 follow-up office visits over a relatively short time interval to be seen by an ophthalmologist more often than their primary care physician for E/M office visits during the reporting period. It is not unusual for these RA patients to be on an expensive biologic prescribed by the primary care physician, while the ophthalmologist's steroid prescription and office visits are an insignificant component of the cost of their care.

  Nor is the ophthalmologist central to the management of the underlying RA, which is typically performed by the primary care physician or a rheumatologist. While a uveitis episode may indicate a flare of RA activity requiring an adjustment in systemic medication, it is the primary care physician or rheumatologist that manages that systemic medication.

  Since ophthalmologists do not manage the underlying RA, it would seem prudent to exclude them from the measure based on taxonomy codes, similar to the exclusion of several

specialists from the TPCC measure.

5.1.13 Comment Number 13

- **Date:** 02/03/21
- **Submitter Name, Credentials, and Organization:** Aamir Siddiqui, MD, American Society of Plastic Surgeons
- **Comment Text:** they need to apply their evidence based guidelines to the process and communicate with the patient facing clinicians. specifically for anesthesia, it should be related to their direct intervention, airway injury for intubation, untreated hypothermia, nerve injury for a peripheral block. non-invasive 14 days. invasive 90 days. ENT covers a very broad spectrum sleep, hearing, sinus, oralpharnyx, peds, cosmetic. you need an idex case for each subgroup. procedures, because it should have a definitive start and stop. tumors can recurrence so lifelong monitoring, biopsying, imaging. no end point. based on predetermined algorithms. transfer and admissions should meet a criteria. no opinion. all tests ordered in the ED all consults attributed to the ED doc. no opinion. drawback is administrative burden. yes subcommittees.

5.1.14 Comment Number 14

- **Date:** 02/04/21
- **Submitter Name, Credentials, and Organization:** Aimee Cegelka, The American Geriatrics Society
- **Comment Text:** The American Geriatrics Society is a not-for-profit organization of over 6,000 health professionals devoted to improving the health, independence and quality of life of all older people. We very much appreciate this opportunity to provide feedback on a topic that is particularly important to our members. We shared your call for comments with member experts on episode-based cost measures and our comments are outlined below.

  General Comments
  While we have provided feedback on the specific criteria of some of the episodes listed below, we are concerned about the overall direction of episode-based accountability measures for physicians.

  Episodes can be useful for certain surgical procedures that address a single medical issue, have an obvious accountable physician, and a definable onset and ending. Yet most of medicine and virtually all of geriatrics is in caring for whole persons who have multiple concurrent conditions. It is unfair and misleading to disassociate any one clinical condition from the others, as the entirety of the patient's problems and their treatment must be considered when treating the patient. Properly treating the patient's rheumatoid arthritis, for instance, means considering also the effects of any one treatment on the patient's other issues, problems and conditions. The current episode-based cost measures incentivize physicians to treat isolated problems. We need a system that looks at treating the whole-person, not their specific diseases. Such a system may look at the panel of patients being cared for by a practice, the socio-demographics of the patients, their disease burden and their quality outcomes. Each physician (or practice) then becomes their own "episode" of care.

Another issue of concern is the attribution of care to a single physician. Medicine is increasingly a team sport. The best of us are adept at maintaining long term the channels of communication and collaboration among consultants, therapists, specialists, social workers, community agencies, food delivery services, and many others who are engaged in caring for the patient. This is hard work, yet it is devalued in a system that seeks accountability for disease-specific, time-limited episodes of care. For geriatricians, the TPCC measure (total per capita cost) is the best currently available approach for attributing patients, but refinements or alternatives to this approach are still needed.

Comments on the Following Clinical Areas for Wave 4

Heart Failure

1. Heart failure is a heterogeneous syndrome, with a multitude of underlying causes, not defined by a single laboratory test or feature. ICD-10 provides substantial granularity, but the precision of coding practice (especially in the outpatient setting) is not good. It will be necessary to exclude certain etiologies (e.g. heart failure due to valvular disease, right heart failure) in order to create a reasonably homogeneous population for comparison.)
2. Most heart failure treatment involves medication. Cardiologists are more likely to prescribe newer medications, but it is not clear that this difference relates to differences in severity rather specialty. In general, patients who are referred to cardiologists will tend to be sicker than those who are not. Some treatments will reflect greater severity of disease, e.g., the use of ventricular assist devices, infusion of inotropic agents, transplantation, but these treatments apply only to the very most severe cases and are not useful for stratification for the population of HF patients.
3. We believe the population of patients treated by cardiologists are likely sicker, but the roles are similar for the vast majority of patients.
4. Anecdotally the accuracy of clinical diagnosis in the outpatient setting is a matter of concern. Overdiagnosis is a problem; every physician has seen patients with a prior erroneous diagnosis of HF who in fact have peripheral edema from another cause (e.g., venous insufficiency) but not heart failure. The course and costs of such patients will be very different from those who have heart failure. Unlike diabetes, which is precisely defined by laboratory parameters, HF diagnosis can be quite variable.
5. Like other chronic diseases, HF does not produce regular consistent costs over time. Instead there can be long periods of relative stability punctuated by episodes of high cost, e.g., hospitalizations. Thus, like other chronic diseases, the evaluation of HF costs are highly subject to timing effects. Longer evaluation periods will mitigate this to an extent but also may reduce the utility of the information.
6. Risk adjustment in this context will suffer from small numbers. When applied to large numbers as in its use for health plans, the performance of risk adjusters improves as random variation is reduced.

Rheumatoid Arthritis

Costs for the care of RA patients are driven by the cost of medication and the costs of surgical treatments. I think most primary care doctors will prescribe methotrexate (low cost) but I suspect not biologics (expensive). There may be financial incentives for rheumatologists to prescribe one drug over another for non-clinical reasons, e.g. the

physician my benefit financially by administering a drug given IV in the doctor's office instead of prescribing an oral medication taken by the patient at home. We don't know enough to comment on the use of surgical treatments, however, patients are not often hospitalized for non-surgical treatment of rheumatoid arthritis.

Additional Topics for Future Waves
Cost measures for non-patient facing clinicians
Radiologists could influence costs in several ways.
1. They could communicate with the ordering clinician to ensure that the study ordered is the optimal approach to the clinical problem. This would require radiologist-initiated communication. This does not happen.
2. They could reduce/avoid the common CYA practice of including in their report a statement like "an MRI might be useful in further defining the problem"

In general, both of these issues involve potentially avoidable costs because of additional studies being performed.

5.1.15 Comment Number 15

- **Date:** 02/04/21
- **Submitter Name, Credentials, and Organization:** Joseph Hornyak, MD PhD, American Academy of Physical Medicine and Rehabilitation
- **Comment Text:** On behalf of the more than 9,000 physiatrists of the American Academy of Physical Medicine and Rehabilitation (AAPM&R), we appreciate the opportunity to submit comments in response to the MACRA Episode-Based Cost Measures: Wave 4 Measure Development. AAPM&R is the national medical specialty organization representing physicians who are specialists in physical medicine and rehabilitation (PM&R). 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. Physiatrists utilize cutting-edge as well as time-tested treatments to maximize function and quality of life. AAPM&R has actively participated in several earlier waves of measure development through comment opportunities and participation on clinical subcommittees. Below, we have outlined our comments regarding the Therapy and Rehabilitation clinical area framework.

  The call for public comment notes that the February 2020 TEP and other stakeholders have identified "the need for cost measurement centered on the care provided by therapists participating in MIPS." While we recognize and value the role of therapists in the treatment of low back pain, physical therapy is only one element of the treatment of this condition. Physical Therapy is often part of a more extensive low back pain care plan typically directed by a physiatrist or other physician and including other specialties such as nursing and behavioral health. Services provided to low back pain patients can include encounters with various providers and interventions such as imaging, injections, prescriptions and/or surgeries. Narrowing this measure to physical therapy alone would result in an extremely narrow view of the costs associated with this condition.

  As previously mentioned, physiatrists are often responsible for the creation and

implementation of comprehensive care plans for patients with low back pain. Our members can offer key insights into the development of a measure in this clinical area. ***We strongly encourage the inclusion of PM&R in any next steps for the development of a low back pain cost measure.***

Response to Question 1

AAPM&R recommends the Wave 4 Therapy and Rehabilitation measure focus solely on low back pain because of its prevalence. Combining low back pain and neck pain into a single cost measure could add too many confounding variables. We do recognize neck pain as a key area for further exploration. Additional areas for exploration in this space include knee pain, hip pain, and shoulder pain.

Response to Question 3

AAPM&R recognizes the complexities of building a cost measure for low back pain due to the degree of variability in patient presentation and experience. We recommend consideration of separate acute and chronic low back pain measures, defining acute as duration of under 12 weeks from initial diagnosis and chronic as 12 weeks or more in duration. We strongly encourage risk adjustment for this measure, and we would recommend that it be done via age, gender, severity of pain and functional outcome scores. AAPM&R's clinical data registry uses PROMIS-29 to calculate functional outcome for all low back pain patient. Pairing cost data with patient reported outcome measures will help determine efficacy of the episode of care. Additional subgrouping of patients could include:

- Surgical patients vs. nonsurgical patients
- Imaging vs. non-imaging
- Traumatic vs. non-traumatic
- Injection vs. non-injection

We discourage use of the quantity of comorbidities as a risk adjustment strategy.

5.1.16 Comment Number 16

- **Date:** 02/04/21
- **Submitter Name, Credentials, and Organization:** Athena Poppas, MD, FACC, American College of Cardiology
- **Comment Text:** The American College of Cardiology (ACC) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed development of episode-based cost measures for potential use in the Merit-Based Incentive Payment System (MIPS). The ACC envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its more than 52,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world renowned JACC Journals,

operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions. For more, visit acc.org.

The ACC continues to support the development of new cost measures that more accurately hold clinicians accountable for the costs of care that are reasonably under their control. The College has dedicated our commitment to this effort through the nomination of members to the CMS/Acumen measure development workgroups focused on cardiovascular cost measures. The College is aware that there has been longstanding interest in measuring the cost of care for chronic conditions, specifically heart failure, which continues to be a high-cost patient population.

Despite this interest, the ACC strongly urges CMS to reconsider the feasibility of creating an accurate, condition-based cost measure for heart failure. The College is concerned that due to the complexity and heterogeneity of this patient population, any cost measure for heart failure has the potential to create unintended consequences; it still remains a challenge to correlate increases in quality to the reductions in the cost of care. In response to the opportunity to provide feedback on the target areas, clinical episodes, and other considerations as provided in the Call for Public Comment for Wave 4 of MACRA Episode-Based Cost Measures, the ACC will focus on the clinical area of Heart Failure (HF). Our responses to the primary and general questions for the development of a cost measure for this clinical area are located below.

Categorizing Subtypes of Heart Failure

Unlike an acute coronary syndrome, heart failure is a progressive disease, and it will be difficult, based on any set of claims data or staging system, to adequately locate patients on their trajectory of the disease. Clinically, heart failure is generally classified based on the measurement of left ventricular ejection fraction (LVEF). This includes heart failure with preserved ejection fraction (HFpEF), heart failure with reduced ejection fraction (HFrEF), or heart failure with mid-range and recovered LVEF (HFmEF). However, these terms are generally not used with respect to administrative claims. Currently, coders frequently use codes for systolic, diastolic acute and chronic Congestive Heart Failure (CHF).

ACC recommends that categorization of heart failure should be linked only to a limited set of the ICD-10 code I50 family; by limiting to this set the College also recognizes that this may lead to lower patient volumes attributed. However, limiting to these codes would capture true cases of heart failure and eliminate patients such as those with end-stage renal disease who present with signs of heart failure, but it is not the underlying condition. These codes could include:

- I50.2 and its subcodes, which capture all forms of systolic dysfunction
- I50.4 and its subcodes, which capture all forms of combined systolic and diastolic dysfunction
- I50.814 — right ventricular failure due to left ventricular failure
- I50.82 —biventricular failure

Furthermore, the following codes should be considered for exclusion for the reasons stated according to each category. The College is greatly concerned that attribution of these patients to a heart failure measure may result in unintended consequences that penalize clinicians for treating patients where heart failure is an underlying condition, or patient populations where there are no strong evidence-based measures to ensure quality outcomes.

- I50.3 and subcodes. This is the family of exclusively diastolic heart failure codes. o There are no outcomes data on optimal care for diastolic dysfunction.
    - Exclusion of this category would remove the very common "volume overload from inadequate dialysis" situation often miscoded as diastolic heart failure, as most end stage renal disease patients have diastolic dysfunction.
- I50.8 and subcodes, except I50.814 and I50.82 as above. This is the family of "other heart failure" codes.
    - This is a mixture of codes. It may not be desirable to assess performance for "high output failure".

Even with the above recommendations, the ACC continues to emphasize the difficulty of creating a cost measure for chronic heart failure, as demonstrated alone through the coding structure which illustrates the heterogeneity of this population.

Categorizing Levels of Severity

Categorizing levels of severity becomes more difficult when relying only on existing billing and coding data. The College continues to underscore the importance of exploring how to incorporate data on social determinants of health to assess their impact on patient cost and quality outcomes. Dual eligibility status could be one such method, but further methodologies must be developed.

The College provides some suggestions for identifying claims and services that can be used to define disease severity. The College emphasizes that even this approach is imperfect, as many of these may serve as proxies for measuring severity, but each individual patient will have his or her own comorbidities and characteristics.

- I50.4 subcodes, I50.814, and I50.82 each represent more advanced forms of HF and could be used in risk-adjustment for quality and cost.
- Extracorporeal membrane oxygenation (ECMO)/Cardiogenic Shock episodes and all patients with Left Ventricular Assist Devices (LVAD) or Transplants should be excluded.
- Numerous guidelines and recommendations exist surrounding the diagnosis and treatment of heart failure. Taken together, the 2013 ACCF/AHA Guideline for the Management of Heart Failure documents that both the ACCF/AHA stages of Heart Failure (relevant to both individuals and populations) and the New York Heart Association (NYHA) functional classification system could provide the necessary information to describe the severity of the condition, though extraction of some of this data from claims may be difficult.

Attribution

The ACC believes that attribution of care for a complex longitudinal condition such as heart failure to a single clinician under MIPS will have inherent flaws. Attribution remains a challenge when care crosses a continuum of time and patients see a variety of providers in multiple settings. In addition, some health outcomes are not directly attributable to the care provided by a clinician.

The ACC has several recommendations to improve definitions of accountability and minimize negative consequences. First and foremost, attribution methods should be clear as it is important to ensure an accurate relationship is described between a patient and a clinician. The correct provider should be held responsible for the patient's outcomes and costs. For the heart failure population, hospitalizations are often the driving cost and it may be difficult to attribute this cost to a single clinician or group as the care team may span across multiple groups and settings of care.

Additionally, the ACC encourages CMS to explore the utilization of other data sources, such as clinical registry data, and analytic techniques to support more accurate attribution and ensure that evidence supports the assignment of responsibility. CMS must also provide clinicians with the claims data behind their cost episodes so they can fully understand and act on manageable costs. This would require greater transparency and access to data from CMS. This would ultimately provide the much-needed information for providers to make meaningful differences in the costs of care. With the increase in team-based care, it becomes important to determine the appropriate proportions of care and outcomes across all members of the care team.

Cardiologists, primary care physicians, physician assistants, advanced practice nurses, and other specialties make up the care team for a chronic heart failure patient. As more clinicians implement team-based approaches, advanced practice providers (APPs) are engaging in more patient encounters that lead to better patient management. Because of this, the ACC recommends excluding APP encounters in the attribution process, as there is the potential for individual APPs to be attributed full costs of care for the episode. If APP encounters must be included, then they need to be benchmarked to the appropriate cardiology specialty and not default to primary care attribution.

Quality Alignment

The ACC strongly recommends the alignment of cost measures with quality measures to ensure that the quality of care is not negatively impacted by attempts to control cost. Much of heart failure patient care occurs in the outpatient setting and as such, measures of care in this setting remain appropriate and deserve consideration for alignment. One caution is that since many patients are seen on an outpatient basis, this may also result in admissions of more complex patients, and thus may increase readmissions. Any cost measure must avoid penalizing clinicians for medically necessary admissions of complex patient cases.

At a minimum, the ACC recommends the following quality measures for consideration to align with any cost measure for chronic heart failure:

- QCDR measure ACCPIN3: Heart failure: Patient Self Care Education

- CMS #008: Beta Blocker use for LV dysfunction
- CMS #005: ACEi/ARB/ARNI use for LV dysfunction
- CMS #236: Controlling high blood pressure

Quality of life, care coordination, reducing disparities in care and outcomes for racial and ethnic minorities, palliative and end-of-life care, patient education, disease management programs and safety measures should also be tied to heart failure as these are important considerations for chronic disease management.

Other Concerns

Even with the recommendations provided, creating an accurate and actionable cost measure for chronic heart failure is a daunting task. The College strongly encourages the Agency to carefully weigh the unintended risks of such a measure in the MIPS program on patient outcomes and clinician performance before moving forward with measure development. The development and implementation of quality measures that strive to improve patient outcomes for the heart failure population should be prioritized over the development of a potentially flawed cost measure.

The ACC also emphasizes the impact of health inequities, patient clinical complexity, and social determinants of health on differences in average costs, particularly with this patient population. Clinicians at certain types of health care systems, such as academic medical centers, typically care for populations of patients who tend to be sicker, poorer, and more complex than patients treated elsewhere; this measure may place these clinicians at a disadvantage. Disease progression is variable as well among patients and is often impacted by factors outside of the clinician's control, including for heart failure patients. Major challenges in care remain for patients with chronic CHF and the opportunities for unintended consequences abound, including attribution issues, risk stratification, identification of accurate triggers across the inpatient and outpatient settings, and overlap with other conditions such as Coronary Artery Disease, Atrial Fibrillation, and Valvular Heart Disease.

In light of these comments, CMS should reconsider whether the development of a chronic heart failure measure will incentivize better care for patients. The ACC recommends exploration of measures that promote actions leading to better care for patients and do not inadvertently penalize clinicians for actions such as appropriate hospitalizations, referral to cardiac rehabilitation, and the use of advanced therapies that may add to short-term cost but contribute greatly to improved outcomes and quality of life in the long-term.

The ACC looks forward to ongoing discussion and collaboration with CMS to support the ability for clinicians to focus on the delivery of high-quality patient care under an evolving value-based payment environment. We appreciate the Agency's consideration of the comments presented in this letter.

5.1.17 Comment Number 17

- **Date:** 02/04/21

- **Submitter Name, Credentials, and Organization:** Madelaine A. Feldman, MD Michael C. Schweitz, MD, Coalition of State Rheumatology Organizations
- **Comment Text:** The Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist.

  Today, we write to share feedback on the development of episode-based cost measures in the Rheumatoid Arthritis (RA) clinical area as part of the MACRA Episode-Based Cost Measures (Wave 4) Call for Comments.

  Broad Comments
  According to Acumen, the RA clinical area would focus on a chronic condition measure that would apply to rheumatologists and primary care clinicians that manage care for patients with the condition. Acumen notes that RA is a priority given its prevalence in Medicare, as well as potential opportunities for improvement due to variations in treatment and management options (e.g., drug therapies), monitoring, and adverse effects. CSRO agrees. As we've noted in prior comments to the Centers for Medicare and Medicaid Services (CMS) on its Quality Payment Program (QPP), there are no appropriate cost/resource measures for rheumatologists under the current cost measures used in the QPP programs (i.e., the Merit-Based Incentive Payment System (MIPS) and Advance Alternative Payment Models (AAPMs)).

  Of note, Acumen highlights a potential improvement opportunity associated with variations in treatment, with a focus on available drug therapies. First and foremost, we note that RA medication options span across Parts B (medical) and Part D (pharmacy). To date, CMS has yet to implement a mechanism that could account for all pharmaceutical costs when evaluating physician resource use, although this has been discussed in the context of certain Bundled Payments for Care Improvement (BPCI) models (e.g., Inflammatory Bowel Disease, or IBD). Our understanding is that CMS faces challenges including Part D costs in resource use measurement, which 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. CMS has previously noted that use of the Hierarchical Condition Categories (HCC) model may account for some conditions that require Part B drugs and are therefore more costly, but we contend that it does not distinguish between the appropriateness of Part D drugs versus Part B drugs and unduly punishes physicians who ultimately determine that Part B drugs are most appropriate for their patient. Under the current MIPS cost measures, the 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. We are concerned the RA measure in development will face the same challenges and concerns.

  Whether the solution is to remove Part B drug costs or to incorporate Part D drug costs, the most important thing is that episode-based cost measures do not have an adverse impact on practice patterns and do not discourage treatments that best meet the needs of the patient.

Response to Key Questions

Question 1: What are ways to account for different severity levels for Rheumatoid Arthritis? Are there considerations like the specialty of the attributed clinician (e.g., internal medicine versus rheumatology) that may help inform different severity levels? We may use techniques like risk adjusting or sub-grouping for services that are indicative of various levels of severity. Are there certain types of services or diagnoses available via claims that may be useful in identifying various levels of severity?

To account for different severity levels in RA patients, rheumatologists use disease activity indices (subjective) and blood-based testing (objective). Commonly used disease activity indices include the Routine Assessment of Patient Index Data 3 (RAPID3), Clinical Disease Activity Index (CDAI) for RA, and Simple Disease Activity Index (SDAI) for RA. These patient reported outcome tools are frequently used alongside objective assessments and biomarker testing, such as erythrocyte sedimentation (sed) rate, C-reactive protein (CRP), rheumatoid factor (RF), antibodies of cyclic citrullinated peptides (CCP), antibodies to mutated citrullinated vimentin (MCV), and other multi-biomarker tests designed for RA. Together, these tools help rheumatologists better direct treatment and are usually proportional to the aggressiveness of the treatment needed.

Regarding certain types of services or diagnoses available via claims that may be useful in identifying various levels of severity, we suggest considering the presence of comorbidities, such as premature coronary artery disease (CAD), lymphoma, interstitial lung disease, vasculitis, and side effects from medications (e.g., corticosteroids), as well as consultations with other specialties, a history of orthopedic surgery, and certain other laboratory, imaging and neurodiagnostic services.

Question 2: Are there any concerns regarding the attribution of Rheumatoid Arthritis episodes to clinicians from certain specialties (e.g., internal medicine versus rheumatology)? For reference, chronic condition measure attribution for clinicians includes the requirement that the clinician within the attributed clinician group must bill at least 30% of "primary care" evaluation and management (E&M) codes with a relevant chronic condition diagnosis and/or chronic condition-related Current Procedural Terminology/Healthcare Common Procedure Coding System (CPT/HCPCS) codes for related services with a relevant chronic condition diagnosis on Part B Physician/Supplier claim lines during the episode (along with other requirements).

Regarding attribution, rheumatologists have the requisite expertise to accurately and appropriately diagnose, treat, and manage the care of RA patients. When primary care providers misdiagnose these conditions, or refer these patients for intervention by a rheumatologist too late, disease progression is heightened and more difficult to control; costs to the Medicare program and beneficiaries are increased; and, beneficiary outcomes and quality of life are diminished until control is regained, if at all. All patients suspected of RA should see a rheumatologist; less severe cases are occasionally managed by primary care providers with input from rheumatologists.

Question 3: For a cost measure focused on the ongoing treatment and care for Rheumatoid Arthritis, what are some areas for opportunity for improvement a measure

may be able to capture regarding care and potential mitigation of complications?

There are several opportunities to improve care and mitigate complications in RA. First and foremost is ensuring patients suspected of or diagnosed with RA should have a consultative visit with a rheumatologist and initiative treatment as soon as possible to mitigate long term complications and disability. Primary care providers have less expertise in the diagnosis, treatment and management of RA, and should not be routinely relied upon.

Another opportunity is ensuring rheumatologists are mindful of American College of Rheumatology (ACR) guidelines, which suggests that newly diagnosed RA patients with mild to moderate disease are given 12 weeks of disease-modifying antirheumatic drugs (DMARDs) prior to starting biologic therapy. There should be exceptions for patients who can't take DMARDs or have highly active disease requiring more aggressive treatment. This would improve quality of care by decreasing side effects of combining medications and decrease cost of giving expensive drugs, unless indicated, early in RA disease. Related, another potential opportunity is for biologic naïve patients that fail DMARD therapy to start treatment with a biosimilar drug, which have significantly lower costs.

Finally, a key opportunity is using tools that predict response to medications. While patients suffering from RA have benefited greatly from pharmaceutical innovations, it can take a few "trials" to find the drug option that is best suited based on the patient's clinical circumstances and characteristics. Of note, the current RA guidelines from the ACR are not prescriptive; rather, they serve as a tool and encourage treatment recommendations to be made through shared decision-making processes, accounting for patients' values, preferences, and comorbidities. Anticipated innovations in precision diagnostics, including those that identify individuals with a molecular signature of inadequate response to certain drug therapies, may enable rheumatologists to better target treatments with the goal of early disease control, which translates into improved outcomes with lower overall costs.

Question 4: Are there any other concerns that may be present with assessing the chronic care for patients with Rheumatoid Arthritis? If so, what are some potential approaches to address these concerns for a cost measure?

As noted above, we continue to have concerns about perceived limitations that have prevented CMS from including both Part B and Part D drugs in its cost and resource use measurement, which CMS has discussed in the context of its Total Per Capita Costs and Medicare Spending Per Beneficiary cost measures, and other episode-of-care models. If the RA episode-based cost measure only accounts for Part B drug costs, it will inadvertently penalize physicians who prescribe them. Consequently, it may drive physicians toward prescribing more Part D drugs to lower drug spending attributable to them, which may not be in the best interest of patients clinically or monetarily.

We maintain that cost and resource use measurement should not bias treatment decisions, nor penalize them for delivering clinically appropriate care in the best interest of their patients. Again, whether the solution is to remove Part B drug costs or to incorporate Part D drug costs, the most important thing is that episode-based cost measures do not have an adverse impact on practice patterns and do not discourage treatments that best meet the needs of the

patient.

5.1.18 Comment Number 18

- **Date:** 02/04/21
- **Submitter Name, Credentials, and Organization:** Loveleen Singh, MPH, College of American Pathologists
- **Comment Text:** The College of American Pathologists (CAP) appreciates the opportunity to offer comments on the Merit-based Incentive Payment System (MIPS) episode-based cost measure development for future waves. The CAP is a national medical specialty society representing 18,000 physicians who practice anatomic and/or clinical pathology. CAP members practice their specialty in clinical laboratories, academic medical centers, research laboratories, community hospitals and federal and state health facilities. Specifically, the CAP would like to provide feedback on possible future cost measures for non-patient facing clinicians, including pathologists.

  The CAP believes that MIPS episode-based cost measures for pathologists and other non-patient facing physicians will require a unique mechanism. To address this issue, the CAP previously sought to identify an alternative mechanism for calculating the value-based modifier or VBM (the predecessor to the cost category of MIPS) for pathologists in conjunction with our efforts to identify potentially relevant episodes of care that could be used in the calculation. However our analysis, in conjunction with consultation services from Avalere Health, of potential episodes of care that encompass pathology services did not show significant variation in the cost of pathology services relative to other costs over which pathologists exert little control.

  In addition, the CAP's analysis has shown that costs directly attributable to pathology services do not represent a large portion of episode spend and pathologists are not responsible for much of the total cost of care. However, pathology diagnosis and other laboratory testing managed by pathologists directly influence the clinical decision making of other specialties and could influence downstream cost. The challenge is that the cost of the pathology services themselves is both relatively invariant and substantially smaller than the effect of pathologists' interventions on downstream cost avoidance.

  While the CAP's past efforts at identifying pathology-based episodes have been unsuccessful, we look forward to working closely with CMS to establish alternative and appropriate ways of measuring pathologists' contributions to resource use for the purposes of MIPS. We thank you for the opportunity to provide input and for your consideration of our remarks.

5.1.19 Comment Number 19

- **Date:** 02/04/21
- **Submitter Name, Credentials, and Organization:** Kelly Golob
- **Comment Text:** Low back and Neck Pain would be preferable because they often occur simultaneously. Including treatment and management of low back and neck pain by Chiropractors is important to get the most comprehensive data possible. CPT codes for

Chiropractic Manipulation should be considered as part of ongoing therapy management and care (98940, 98941, 98942). Chiropractors are not reimbursed under medicare for any other codes, so omitting these manipulation codes would not capture a large percentage of medicare beneficiaries receiving treatment for low back and neck pain. Chiropractors are not eligible for reimbursement in medicare for E/M codes or other physical medicine and physical therapy codes that are within their scope of practice. In particular, the cost burden to medicare patients for the initial examination visit is a huge barrier that restricts many medicare patients with low back pain from accessing spinal manipulation which is a recommended first line treatment for spinal pain by the American College of Physicians most recent non-pharmacological pain treatment guidelines.

5.1.20 Comment Number 20

- **Date:** 02/04/21
- **Submitter Name, Credentials, and Organization:** Morgan Young
- **Comment Text:** -Trigger and define an episode would probably work best, although cases could be made for assigning costs to the episode. I don't have the epidemiologic or economic background to make strong assertions on that. -Recurrence of episodes over a time period would be valuable, as low back/neck pain both have a regular recurrence and substantial cost avoidance could be assessed by reduction in the frequency of episodes. -Downstream costs are critical to assess: imaging, injections, surgery, medical visits - care that extends outside of the rehab treatment, but has major impacts on total spend. Disability payments, if going to SSDI. Trigger codes look very thorough. E/M code tab - add 98940, 98941, 98942. Chiropractors treat significant amounts of spinal pain and should be included in the analysis. Unfortunately, Medicare does not reimburse them for their full scope of practice, so treatment patterns analyzed by billing practices will be skewed by payment policy. Subgrouping is important, due to the wide range of diagnoses present in triggering events. Traumatic rupture of disc does not have same natural history as segmental dysfunction. It may be prudent to subgroup by injury category, or exclude fracture/traumatic injury. Stratifying by chronic disease condition versus acute condition. These should not be all lumped for a total case cost average. I would hesitate to combine multiple areas of the spine into one analysis. They have quite different causes, profiles and even age risk factors. Neck and low back should be investigated separately. Imaging guidelines, guideline concordant treatment approaches, combined therapy of exercise, rehab, manipulation, education vs single interventions. Opioid prevention, surgical prevention. QoL adjustment for chronic condition. Work or home care participation. Initial provider type seen may impact outcome and costs. Early versus late initiation of conservative care, including chiropractic or physical therapy can change recovery trajectory. I hope that you will consider chiropractic as a "related specialty area" as they primarily treat spine episodes, despite inequity in CMS payment policy that is counter to their scope of practice in all 50 states. This is an opportunity to look at their impact, especially if an episode of care were created with a bundled payment, thus sidestepping reimbursement issues that artificially impose practice limitations and hinder care of the patient. Imaging compliance, orthopedic and neurologic consult rates, duration/frequency, home care compliance, comorbid factors and if these were improved/addressed during treatment for primary condition (smoking, obesity, diabetic control, hypertension, etc). All of these impact MSK outcomes and should be addressed

during visits. Extensive and well researched. May present scope creep in how you analyze impact of therapy across such diverse conditions. Quality of care is also measurable by how many non-LBP/NP comorbidities are addressed and referred out for care. Holistic treatment of the health of the individual, rather than siloed MSK care. Use of outcome measures, regular vitals and data for management of other conditions. Health and behavior attributes. Referral coordination

5.1.21 Comment Number 21

- **Date:** 02/05/21
- **Submitter Name, Credentials, and Organization:** Alex Limanni, MD, American College of Rheumatology
- **Comment Text:** Currently rheumatologists use disease activity and functional status assessments routinely in the office to assess severity and report these as quality measures these measures include both provider and patient reported measures currently. Clinician specialty will be challenging to use to indicate clinical disease severity and may worsen existing disparities in access to care and treatment. Claims indicating extra-articular disease in rheumatoid arthritis can identify patients with severe disease, but will underestimate disease severity in the population overall since these are rare occurrences in RA. Risk adjusting and sub-grouping could be useful in some cases but it is more likely that excluding certain types of complications in RA would be helpful because of their complexity and rarity. Ideally the patient's complete care team, including their primary care provider and rheumatologist and possibly their orthopedist, psychologist, neurologist, pulmonologist or other specialists involved in their care, would be attributed to incentivize coordinated care and communication. Again, limited access to rheumatologists among disadvantaged populations may complicate attribution so as to avoid worsening existing disparities in access and outcome. A cost measure should consider medication costs including outpatient medications and infusion medication costs in all clinical settings. A cost measure will likely need to be stratified by social risk to avoid worsening disparities. In RA, disease duration and prior therapy are critical reasons for current costs and outcomes. Probably the best use of a cost measure in RA might be to help reduce overuse of expensive biological and other drugs in patients who don't meet criteria for them and increase their use among disadvantaged populations who have less access to specialists and medications in general. A cost measure will want to consider all outpatient and infusion medication costs and will likely need to be stratified by social risk to avoid worsening disparities. Likewise the appropriateness of use of these advanced medications should be based on prior failure of initial early therapies for RA or complications and contraindication of said early drugs. I am concerned about the applications of cost measures in patients with complicated, longstanding and chronically severe RA as well as some patients with infrequent end-organ disease (e.g. interstitial lung disease, etc.). In that light, I think the best cost measure would be found in patients with new rheumatoid arthritis where we believe the opportunity to reduce cost and morbidity of the disease would be greatest. This would incentivize early diagnosis and referral to rheumatologists. I want to emphasize that a cost measure should be focused on early management of new RA patients using defined care paths centered around aggressive management with traditional oral medications in order to maximize early outcomes barring contraindications. These can then be followed by newer agents including the biological

drugs and others if the patient fails to improve using standard measures of disease activity or develops a complication to therapy or contraindication requiring switching or adding to conventional therapy to drive further improvement. I believe the list is too broad for our purposes since rheumatologists and presumably primary care doctors use a more restricted group of codes. I doubt that most of the other codes are used infrequently and probably used by surgical and rehabilitation services. The rare complications codes such as RA with lung disease, vasculitis, cardiac disease are useful possibly for tracking rare complications. The quality measures we report use a more restricted set codes I can provide. I would definitely delete M07 codes as they are related to another form of inflammatory arthritis, inflammatory bowel disease and M06.4 since it is a nonspecific code somehow placed under the RA codes, I can forward the codes we use to trigger measurement in our quality measures. Excluding many of the other codes will probably result in losing orthopedic costs, etc. and I understand that you might want to see those costs but at I believe that the measure should be directed at best outcomes and cost savings based on aggressive early management of this disease. Managing costs in established longstanding RA will be extremely complicated by previous therapies, comorbidity, and prior drug therapies and their complications. Currently we have NQF endorsed measures for rheumatoid arthritis disease activity and functional status. Each "recommends" the use of one of several commonly used DA and FS measurements. The ACR also recommends measures of patient safety including Tb testing and Hepatitis testing prior to starting certain medications. I can provide specifications if needed. In general I think this is reasonable depending on the frequency that multiple physician specialties will interact during a particular episode

5.1.22 Comment Number 22

- **Date:** 02/05/21
- **Submitter Name, Credentials, and Organization:** Rachel Groman, MPH, American Association of Neurological Surgeons/Congress of Neurological Surgeons
- **Comment Text:** Triggers and attributions may incentivize inappropriate withholding of specialty referral or timely diagnostic imaging. This is a particular concern in regards to recognition and treatment of cervical spondylotic myelopathy. We are also concerned about lumping LBP and neck pain into one cost measure since the pathway of conservative management may look very different, particularly depending on diagnostic accuracy (myelopathy vs neurogenic claudication).

5.1.23 Comment Number 23

- **Date:** 02/05/21
- **Submitter Name, Credentials, and Organization:** William T. Thorwarth, Jr., MD, FACR, American College of Radiology
- **Comment Text:** The American College of Radiology (ACR), representing more than 40,000 diagnostic radiologists, radiation oncologists, medical physicists, interventional radiologists, and nuclear medicine physicians, appreciates the opportunity to submit comments for consideration regarding measure concepts and development for future MACRA episode-based cost measures.

  The ACR supports Acumen's approach for a transparent and stakeholder-informed process in

developing cost measures for non-patient facing clinicians and welcomes discussions on how to approach episode-based measurement. The current cost measures within Merit-based Incentives Payment System (MIPS) are not typically attributed to radiology groups because the current measures structure often assess imaging costs but not radiological care. Care provided by radiologists does not usually fit into a traditional episode framework, and there is no existing measurement of care coordination between radiology teams and other specialties. Given these challenges, we emphasize that Acumen must consider opportunities for developing cost measures that link to existing quality measure topics, such as breast cancer screening and incidental imaging findings.

The ACR suggests developing a breast cancer screening episode-based measure encompassing screening mammography through cancer diagnosis or return to annual screening. This episode is almost entirely under the radiologist's direct control, making it easily attributable to a radiology group. The episode cost window for this measure would span one year.

Additionally, there are well-established quality metrics that breast imaging physicians use to audit the quality of their practice. Previously included in MIPS as Qualified Clinical Data Registry (QCDR) measures, cancer detection rate, recall rate, and true/false positive rates would be a fair balance to a breast cancer screening (BCS) cost measure. The ACR would advocate reintroducing these to MIPS, linked to a BCS cost measure. This suite of measures, including a cost measure, could provide a comprehensive view on the quality and efficiency of diagnostic care in this area to the benefit of patients and could potentially be a candidate for a CMS' MIPS Value Pathway (MVP).

Management and care coordination of imaging incidental findings, incorporating both prevention of unnecessary or repeat testing and assurance that evidence-based follow-up recommendations are completed, are concepts worthwhile to explore as cost measures for radiology. Across an incidental finding episode, prevention of low-value follow-up testing, or a "null event" may be assessed as part of the full episode, similar to a low back pain episode-based cost measure for orthopedics, where surgery was avoided and costs attributed would be limited to evaluation and management codes. For example, an abdominal CT incidental-finding episode may begin with the CT exam, carry through any downstream management or referrals to specialists, and compare costs of the episode when radiologist recommendations stated "no follow-up necessary" to cases where radiologist guidance was not explicit. Overdiagnosis of benign incidental findings places patients at risk for anxiety and unnecessary harm from diagnostic procedures and treatment. A standardized approach to managing incidental findings is desirable to reduce practice variation, decrease costs, limit the potential for harm from unnecessary therapies (biopsies or surgeries) and alleviate unnecessary patient and physician anxiety. Additionally, MIPS quality measures focused on incidental finding-appropriate recommendations currently exist, providing an opportunity for balance with cost measure(s) for this concept.

As previously stated, a significant challenge that radiologists confront is a lack of opportunity to be recognized for care coordination and the inability to be rewarded for team-based care led by radiologists. We hope that the potential areas of future cost measure development that we have outlined may increase radiologists' opportunities to participate in value-based care.

The ACR looks forward to continued conversations with Acumen and CMS on current and future cost measure development.

5.1.24 Comment Number 24

- **Date:** 02/05/21
- **Submitter Name, Credentials, and Organization:** James C. Stevens, MD, FAAN, American Academy of Neurology
- **Comment Text:** On behalf of the more than 36,000 neurologists and clinical neuroscience professionals, the American Academy of Neurology (AAN) appreciates the opportunity to provide comments regarding Acumen's episode-based cost measure development process for its Wave 4 cost measure concepts. While we are disappointed to see that neurological conditions were considered but not prioritized for development in this cycle, the AAN looks forward to collaborating on future development of cost measures that can be attributed to neurologists and address neurological conditions.

  The AAN is committed to engaging in value-based care programs that promote improved health outcomes at lower cost while meaningfully attributing and measuring clinicians on quality and cost performance. We are concerned by the continued dearth of neurology specific cost measures and the subsequent barriers this imposes on our membership to participate in value-based care models and programs that rely on the availability of relevant specialty and condition specific cost measures.

  The AAN is disappointed to see that Acumen has decided not to prioritize the episode group focused on mental and behavioral health conditions such as dementia, Alzheimer's disease, Parkinson's disease, and migraine in the Wave 4 measure development. The burden of care for these neurological conditions is substantial, with varying but significant costs in the acute and long-term care settings and with high associated downstream societal costs related to patients and their caregivers. We believe that not prioritizing the development of cost measures related to these conditions is a missed opportunity, especially given the well-defined diagnostic criteria, quality measures and often clearly delineated care between primary care, specialists, and subspecialists for many neurological diagnoses.

  The AAN believes a fundamental flaw of many cost measures, and some quality measures currently used in the Quality Payment Program, is their attribution to an individual provider or group. This attribution methodology does not accurately represent the reality of care delivered to patients, especially for complex diseases and conditions that neurologists treat. This extends to concepts that have been prioritized for Wave 4 development, including heart failure, psychiatric disorders, and low back pain, which will involve several providers during the inpatient and outpatient components of care. The commitment to attribute one provider or TIN to an entire episode of care conflicts with other tenets of value-based care programs that require and reward care coordination, team-based care, and cost sharing. The isolation of individual diagnoses and attribution to one clinician or TIN tends to miss the totality of the patient.

  The AAN believes it is appropriate to start with development of cost measures related to the

most prevalent and costly diseases and conditions and our concerns about attribution apply to each of the concepts under consideration. We detail our comments on the priority topics for Wave 4 cost measure development below.

Mental and Behavioral Health

To accurately capture an episode of care related to the conditions Acumen is considering in this category – Major Depressive Disorder, Schizoaffective Disorder, or Bipolar Disorder – it is critical to include the acute hospitalization episode group. The inpatient episode reflects the severity of the condition and is an area of clinical care with wide variability, ripe for measurement. However, we recommend Acumen consider additional measures of severity beyond hospitalizations and referral to psychiatry when crafting a measure in this topic area, as a large proportion of patients with mental diagnoses are cared for through primary care for several reasons including, lack of access to psychiatrists due to location (e.g., rural patients) or insurance status (e.g., psychiatrists that do not see Medicare or Medicaid patients). These are realities that must be addressed during the development process to appropriately measure and attribute costs related to these conditions. Additionally, Schizophrenia, Schizoaffective disorder or other specific mood disorders have more defined treatment paradigms that are measurable and reportable compared to broader diagnoses such as Major Depressive Disorder that would likely require more specific diagnostic criteria that is not consistently found in claims data.

Therapy and Rehabilitation

The AAN supports the development of a cost measure related to Low Back Pain and believes it is an area where best practices can have important clinical implications in both the short and long terms and where costs can be modulated. However, while the condition is common, its root causes are broad and variable which will make it difficult once again to attribute to an individual clinician. Our general concerns related to attribution, previously stated, apply to this concept as well. In low back pain cases, at minimum there is likely a referring/diagnosing clinician, pain specialist or proceduralists who may do extensive interventions, and a physical therapist. The AAN hopes that Acumen will carefully evaluate how best to delineate attribution for this broad, but important condition that often involves multiple clinicians.

Heart Failure

The AAN notes that the proposed heart failure measure concept seems to exclude the acute hospitalization group, and only suggests procedural and chronic care options. This seems ill advised as inpatient treatment can lead to variability in quality and outcomes including critical complications and is an area of focus that can be easily modulated by clinicians and hospital groups. There are several clinicians that play a role in care for patients with heart failure that should be considered during cost measure development for this concept including primary care, emergency medicine, hospitalists, nephrology, invasive and non-invasive cardiology, and palliative care. Acumen must clearly and appropriately reflect the shared nature of care for complex conditions in its attribution methodology for measures involving different clinicians and specialties. Such attribution methodology could serve as a model and be applied to other complex conditions, including neurological conditions in future waves of cost measure development.

To date, very little data has been made available on episode-based cost measures available in the Quality Payment Program. This lack of transparency makes it difficult for stakeholders including specialty societies to advocate and engage in cost measure development. Acumen should make more granular data, including specialty specific participation and performance data, publicly available for all cost measures. This would help stakeholders glean a better understanding of performance and attribution and allow for more representative ways of conceptualizing cost measures that share attribution for complex and comorbid conditions.

The AAN is interested to see how these cost measures will be incorporated into the forthcoming Quality Payment Program (QPP) MIPS Value Pathway (MVP) performance framework. While the AAN is generally supportive of the new MVP framework, we are concerned that specialties with few or no cost measures developed from the Acumen-led process will be disadvantaged as they will be less likely to participate in MVPs that appropriately attribute clinicians. We look forward to engaging with Acumen in the development of cost measures related to neurological conditions in the future. Thank you for the opportunity to share the AAN's comments on Acumen's Wave 4 Cost measure development cycle and we look forward to continued engagement moving forward.

5.1.25 Comment Number 25

- **Date:** 02/05/21
- **Submitter Name, Credentials, and Organization:** Nancy M. Albert, PhD, RN, CCNS, CHFN, CCRN, NE-BC, FAHA, FCCM, FHFSA, FAAN, Heart Failure Society of America
- **Comment Text:** On behalf of the Heart Failure Society of America (HFSA), I am writing to provide input on the Centers for Medicare and Medicaid Services (CMS) proposed development of Wave 4 episode-based cost measures for potential use under the Merit-Based Incentive Payment System (MIPS).

  HFSA is a multidisciplinary organization working to improve and expand heart failure care through collaboration, education, research, innovation, and advocacy. The vision of the HFSA is to significantly reduce the burden of heart failure.

  HFSA supports CMS' efforts to incentivize higher value care. As part of that process, we appreciate the need to evaluate and hold clinicians accountable for costs so long as measures are accurate, meaningful and actionable, and evaluated in the context of quality outcomes.

  HFSA actively engaged with CMS in earlier discussions regarding cost measure prioritization and highlighted the challenges of measuring the cost of a heart failure episode. As CMS again considers heart failure as a focus for Wave 4 cost measure development, we would like to reiterate our concerns about accurately capturing, attributing, and measuring costs associated with this chronic care episode.

  In alignment with our colleagues at the American College of Cardiology (ACC), we strongly urge CMS to reconsider the feasibility of creating an accurate, condition-based cost measure for heart failure. HFSA shares the concerns expressed in ACC's comment letter, including the potential for unintended consequences due to the complexity and heterogeneity of this patient population, the difficulty in attribution of what is commonly team-based care to an

individual clinician, and ongoing challenges related to correlating increases in quality to reductions in the cost of care. In addition to the concerns outlined in ACC's letter, we wish to further emphasize the following challenges related to capturing and measuring the cost of a heart failure episode:

- Defining the parameters and cost drivers of a chronic heart failure episode is much more complex than for a cardiac procedure, which was the focus of previously developed cost measures. Cardiac procedures are less likely to be associated with comorbidities and are much more easily attributable to a clinician primarily responsible for treating the patient. Chronic heart failure, on the other hand, is a very diverse disease. Claims data, alone, cannot accurately capture this population. Current risk adjustment methodologies cannot sufficiently account for the number and severity of comorbidities and other social determinants impacting this population. We are also concerned that attribution will be very challenging since many clinician types contribute to a patient's care (e.g., primary care provider, cardiologist, nephrologist, etc.).
- Unlike an acute coronary syndrome, heart failure is also a progressive disease, which requires continually adjusting for the location of the patient on their trajectory of the disease.
- As noted above, holding individual clinicians accountable for the cost of a chronic heart failure episode could create perverse incentives to keep costs down by avoiding necessary hospitalizations. Several published studies have shown that programs that aim to systematically reduce hospitalizations, such as the Hospital Readmission Reduction Program (HRRP), also result in a significant increase in mortality.[21, 22]
- There are currently insufficient quality incentives to offset the potentially detrimental impact of cost savings.
- Care pathways that have been shown to improve outcomes for heart failure patients, such as cardiac rehabilitation, are not covered by insurance and are often not accessible to many patients (e.g., lack of transportation), which will distort attempts to measure cost and overall value.
- In general, this type of measure is not appropriate for individual clinician level accountability and would be more appropriate for facility or system level measurement.

The HFSA thanks CMS and Acumen for the opportunity to be a part of this process and for considering its ongoing feedback. We look forward to continuing to work with the Agency as it identifies additional priority areas and works on the development of episode-based cost measures."

5.1.26 Comment Number 26

- **Date:** 02/05/21

[21] Fonarow, G. C., Konstam, M. A., & Yancy, C. W. (2017). The Hospital Readmission Reduction Program Is Associated With Fewer Readmissions, More Deaths: Time to Reconsider. *Journal of the American College of Cardiology*, *70*(15), 1931–1934. https://doi.org/10.1016/j.jacc.2017.08.046

[22] Gupta A, Allen LA, Bhatt DL, et al. Association of the hospital readmissions reduction program implementation with readmission and mortality outcomes in heart failure. *JAMA Cardiol*. 2018;3(1):44-53. doi:10.1001/jamacardio.2017.4265

- **Submitter Name, Credentials, and Organization:** Jean Brereton, MBA, American Academy of Otolaryngology-Head and Neck Surgery
- **Comment Text:** Thank you for the opportunity to provide comments regarding the upcoming Wave 4 and future waves for cost measure development. Below are our responses to the questions posed for future cost measure development for Otolaryngology-Head and Neck Surgery as outlined in the Wave 4 – Call for Public Comment.

  A. What clinically coherent candidate episode groups for head and neck disease care would you recommend as cost measure concepts? Some options we looked into include Sinusitis, Sinus Surgery, and Hearing Loss. What episode-based cost measures may help capture a broader set of ENT clinicians?

  We feel that this question should be divided into near-term and long-term opportunities. As we develop cost measures for both MIPS and MVP usage, we will be trying to include enough breadth so that all of our members will be able to feel comfortable being evaluated in areas that they practice. We would work on cost measures related to our initial MVP candidates first and then expand those clinical areas as we developed additional MVP candidates.

  Our initial candidates for cost measures would include Chronic Rhinosinusitis w/wo polyps, Oral Cavity Cancer, Sensorineural Hearing Loss and Allergic Rhinitis. Subsequent to that, we have interest in developing cost measures related to Vocal Cord Paralysis, Dizziness/Imbalance, Obstructive Sleep Apnea, Nasal Obstruction, Thyroid cancer and others as requested by our sub- specialty physicians.

  B. Based on the types of conditions treated or procedures performed by otolaryngologists, would episode-based cost measures around procedures or around chronic condition care be more impactful to capture performance gaps among ENT clinicians, and why?

  Otolaryngology treats a wide range of conditions ranging from hearing and balance disorders, sinus and allergy, voice and swallowing, head and neck cancer including thyroid and parathyroid disease, pediatric disease, facial plastic and reconstructive surgery and skin cancer. The most impactful areas would revolve around prevalence and volume. These would include some of the subjects mentioned above, particularly Chronic Rhinosinusitis and Allergic Rhinitis, Hearing Loss and Chronic Otitis Media (with and without surgery), Obstructive Sleep Apnea, Thyroid disease and Nasal Obstruction.

  The above-mentioned conditions would be the most likely to identify performance gaps and help standardize care in these areas. This would include the performance measures as well as the cost measures. We feel standardizing the performance measures first would then lead to more predictable cost of care and increase the value of the cost measures. The wider the variability in treatment patterns that exist, the more gaps will likely be identified and present opportunities for cost savings.

  C. **Are there any challenges with assessing the care for head and neck disease conditions or procedures? If so, what are some potential approaches to address these concerns for**

a cost measure?

There are significant challenges incumbent in putting together cost measures related to the above-mentioned disease processes and procedures. These include variability in care regimens that are associated with cost of care differences, the identification of all aspects of cost for episode-based and condition-based care is difficult and time-consuming and the lack of consensus as to what is "best care" for certain conditions all make this a difficult process. This is amplified by the difficulty in obtaining true costs that the AAO-HNS and other specialties are faced with. We were participants with the American College of Surgeons and Brandeis University in a pilot project to determine episode-based costs for thyroid, parathyroid and chronic rhinosinusitis. That project was quite expensive and took a great deal of time to complete. There is currently a significant amount of otolaryngology literature in cost comparative studies between various treatment paradigms for more common disease, particularly sinusitis. If that data is acceptable by CMS for developing cost measures, it would greatly simplify the development process and move things forward much more rapidly. For example, the following manuscript based on a Chronic Rhinosinusitis study utilizing the Truven claims database.[23]

We appreciate the opportunity to provide these comments and look forward to an opportunity to discuss cost measure development for Otolaryngology-Head and Neck Surgery.

5.1.27 Comment Number 27

- **Date:** 02/05/21
- **Submitter Name, Credentials, and Organization:** Mark S. Rosenberg, DO, MBA, FACEP, American College of Emergency Physicians
- **Comment Text:** On behalf of our 40,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to provide feedback to Acumen on the development of episode-based cost measures in "Wave 4." As emergency physicians, we provide acute, unscheduled care to patients with a broad range of healthcare conditions. Therefore, we first want to provide brief comments on a couple of topics being considered in Wave 4 before moving to emergency medicine-specific comments.

  4.1 Heart Failure: Question 3: We aim to capture care provided by clinicians for the chronic management of Heart Failure. Are there different roles in providing care that we should consider (e.g., do internal medicine and cardiology specialists play distinct roles)? ACEP notes that emergency physicians working in the emergency department (ED) play a distinct role in providing care for exacerbations of heart failure in the target conditions. It is not unusual in mild cases for patients to be evaluated and treated for an entire exacerbation in the ED or ED observation unit. The consideration of measuring these mini-episodes for the management of acute exacerbations that is attributed to an emergency physician might be a valuable undertaking in any efforts to improve the overall care for patients with chronic heart failure.

[23] Denneny JC 3rd, Cyr DD, Witsell DL, Brereton J, Schulz K. A pathway to value-based care of chronic rhinosinusitis using a claims database. Laryngoscope Investig Otolaryngol. 2018 Dec 28;4(1):193-206. doi: 10.1002/lio2.232. PMID: 30828639; PMCID: PMC6383304.

4.2 Mental and Behavioral Health: Question 3: Are there any other concerns that may be present with assessing the chronic care for patients with these conditions? If so, what are some potential approaches to address these concerns for a cost measure? The disposition of patients to the ED who present for new onset or previously diagnosed mental and behavioral health conditions is complex and not always driven by clinical condition but availability of inpatient mental health services, availability of community mental health services, or local models for allocating inpatient treatment for those without insurance. This results not only in difficulty at a macro level but may be dependent on time of day or day of the week when they receive initial care. In some cases, medical admissions may occur that are due not to the management of the underlying mental or behavioral health diagnosis but to the inability of a patient to care for themselves for a diagnosis that would normally be treated in the outpatient setting. It may be unlikely that administrative data alone will provide adequate data to address these variations nor to be amenable to current risk-adjustment models. One approach to these scenarios would be to exclude certain acute care or inpatient episodes from the cost measure.

5.1 Cross-Cutting Questions for All Wave 4 Candidate Episode Groups

Question 3: Quality alignment for assessing value—We solicit comments regarding alignment of quality of care with cost measures as well as comments on any indicators of quality that would be valuable to assess alongside the cost performance for the candidate episode groups.

The current episodes that are triggered by an inpatient admission do not capture the quality of care that occurs in the ED and in many cases is the determinant of the clinical outcome for conditions as an acute myocardial infarction, gastrointestinal bleed, congestive heart failure, or acute abdominal conditions requiring surgery. Current methods for attribution are not designed to attribute quality or cost to the ED care. ACEP recommends using administrative claims data to study the contribution of this care to the cost of an episode.

5.3.3 Cost Measures for Emergency Room Clinicians

Before addressing specific questions, ACEP would first like to request that Acumen change the reference to “emergency room,” to “emergency department,” as that is the more appropriate term.

We want to highlight ACEP’s ongoing work to evaluate the cost of emergency care. We have long understood that our health care system is moving away from fee-for-service towards more value-based care, where our work as clinicians will be evaluated based on both the quality and cost of care we provide. In order to help put emergency physicians in the driver’s seat to help manage this transition to value, ACEP developed the first emergency medicine-specific alternative payment model (APM), the Acute Unscheduled Care Model (AUCM).

Structured as a bundled payment model, the AUCM would improve quality and reduce costs by allowing emergency physicians to accept some financial risk for the decisions they make around discharges for certain episodes of acute unscheduled care. Initial episodes focus on patients with the following symptoms: abdominal pain, altered mental status, chest pain, and

syncope. The AUCM would enhance the ability of emergency physicians to reduce inpatient admissions, and observation stays when appropriate through processes that support care coordination. Emergency physicians would become members of the continuum of care as the model focuses on ensuring follow-up, minimizing redundant post-ED services, and avoiding post-ED discharge safety events that lead to follow-up ED visits or inpatient admissions.

ACEP submitted the AUCM proposal to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) for consideration. We presented the AUCM proposal before the PTAC on September 6, 2018. The PTAC recommended the AUCM to the HHS Secretary for full implementation. The AUCM met all ten of the established criteria, and the PTAC gave one of the criteria ("Scope") a "Deserves Priority Consideration" designation since the PTAC felt that the model filled an enormous gap in terms of available APMs to emergency physicians and groups.

They did recognize the need for the development of cost measures to support the model. The PTAC submitted its report to the Secretary in October 2018. The HHS Secretary responded to the PTAC's recommendation in September 2019, requesting the "the CMS Innovation Center… assess how key mechanisms of action in this model could operate as a component in a larger model dedicated to improving population health."

We are still waiting for CMMI to act on the Secretary's request, and we look forward to working with the Center to improve emergency patient care through the implementation of the model.

Question A: How can a measure on emergency room care appropriately address the result of the visit (e.g., release to community versus transfer to hospital)? How should cases where the emergency room visit leads to an inpatient admission (or transfer to another facility for follow-up care) be handled by an emergency room episode group?

Our work on the AUCM shapes our understanding of how we should be attributing the cost of episodes of acute unscheduled care to ED clinicians. Most of the current cost measures focus on episodes of care for those patients admitted to the inpatient setting or observation status. However, we believe that, going forward, we should be creating cost measures specific for ED care that results in discharge. Administrative data could be utilized to assign a trigger code, attribute the care to one professional, and to group that care with claims that occur in a post-discharge period of accountability that is determined by the diagnosis/undifferentiated condition that is alignment with evidence-based literature. In ACEP's review of administrative data of visits by Medicare FFS beneficiaries, this period is most likely 7-10 days. These episodes would allow for the creation of cost measures that meet the "Criteria for Measure Prioritization" outlined in section 3.1 of the Acumen document and be aligned with the "Essential Features of Cost Measures" outlined in section 3.2. We would highlight the opportunity for such cost measures to improve ED clinicians' performance through the adoption of care coordination models, better shared decision-making, and use of telehealth services.

Question B: What would be clinically coherent scopes for candidate episode groups for

emergency room care (e.g., visits for shortness of breath, chest pain, wounds)? Clinically coherent scopes should include those for which there is sufficient volume, sufficient variations in episode costs, and admission rates of less than 90 percent (at the national level) for acute undifferentiated conditions frequently evaluated in the ED. In the Medicare population these might include shortness of breath, chest pain, abdominal pain, syncope, and altered mental status. Consideration might be given to those conditions that would be complete the continuum of care between outpatient chronic care and inpatient care for clinical conditions for which measures have been developed.

Question C: Based on the type of care provided in the emergency room setting, how should individual clinicians and clinician groups be attributed episodes?

With respect to attribution, in the AUCM, the episode is attributed to the physician/practitioner who submits the Medicare Part B Claim for services. It is assumed that this will be the physician who makes the final determination of advisability of discharge and is most likely to be responsible for a final assessment of the patient, determining the discharge diagnosis, participating in shared decision-making and the hand off to the next provider as well as determining care coordination needs.

Question D: In terms of episode window, what are suitable timeframes that can assess care, treatment, and subsequent outcomes that may be reasonably influenced by attributed emergency room clinicians?

The episode window should be determined by a review of Medicare administrative data to identify the time frame in which re-admissions, death and return to ED care occur. Studies in the medical literature have defined these for a number of conditions. In general, a time frame from 7-11 days would be appropriate and end at the submission of the first claim for an evaluation and management service by a primary care or specialty practitioner.

We appreciate the opportunity to share our comments.

5.1.28 Comment Number 28

- **Date:** 02/05/21
- **Submitter Name, Credentials, and Organization:** Jerry Conway, Scipher Medicine
- **Comment Text:** Scipher Medicine appreciates the opportunity to provide feedback in response to the Call for Comments on MACRA Episode-Based Cost Measures (Wave 4). Our feedback focuses on the development of episode-based cost measures in the Rheumatoid Arthritis (RA) clinical area, which we agree is a priority area for measure development and a good candidate for a MIPS Value Pathway (MVP), and primarily addresses Questions 3 and 4.

  For background, Scipher Medicine was formed in 2015 by Drs. Joseph Loscalzo, Chief of Medicine at Brigham and Women's Hospital and professor at Harvard Medical School, and Laszlo Barabasi, Director of the Center for Complex Network Research at Northeastern University. Dr. Barabasi built the map of human disease biology that explains how protein-to-protein interactions govern disease development, progression and treatment. Following a decade of extensive research, the map has grown to include physically proven protein-to-protein interactions from more than 90% of human proteins, creating a breakthrough network model of underlying biological processes regulating disease. Using this network medicine platform, our company has developed a series of technologies and tools to better diagnose

and treat patients with complex healthy conditions, including autoimmune diseases such as RA and other urgent health challenges such as COVID-19.

Therapeutic Options for RA Treatment

Despite the plethora of treatment options, clinicians face significant challenges in establishing a plan of care for their RA patients. The American College of Rheumatology (ACR) guidelines recommend that clinicians employ a try and fail approach to medication therapy starting with conventional synthetic disease modifying antirheumatic drugs (csDMARDs) (e.g., methotrexate), followed by biologic originator DMARDs (boDMARDs) (e.g., tumor necrosis factor inhibitors (TNFi)) and or targeted synthetic DMARDs (tsDMARDs) (e.g., Janus Kinase Inhibitors (JAKinibs)). The guidelines do not prioritize one class of targeted therapy (boDMARDs or tsDMARDs) over another due to a lack of clear evidence. The guidelines, however, underscore the need for patients to be controlled, and in the void of a science-based approach, a try and fail approach is better than no action.

"The recommendation [ACR recommendation for patients with Established RA #4] is strong despite moderate to very low quality of evidence because for a patient failing DMARD monotherapy, clinical experience and indirect evidence support the benefits of adding these treatment options, and recommending no treatment is not an option."[24]

In general, each DMARD category includes various drug classes and medication options with some covered by Medicare as a medical benefit (Part B), and others as a pharmacy benefit (Part D).

Among the boDMARDs are the world's best-selling class of drugs: tumor necrosis factor inhibitors (TNFi). Around 90% of RA patients are prescribed a TNFi as a first-line targeted treatment – however, 70% of patients do not respond adequately to the TNFi class of drugs. As explained below, our technology can accurately predict a patient's inadequate response to TNFi's from a one-time, routine blood test.

Using Evidence-Based Data to Influence Episodes of Care in RA

Despite the guidelines, choosing the right therapy can be complicated and may rely on factors such as clinician experience with the medication, patient preference, affordability, and payer requirements (e.g., step-therapy, prior authorization, etc.). Without data to guide their decisions, rheumatologists have no means of understanding the likelihood of a patient's response to a drug before starting treatment. This can result in increased disease progression, wasted drug spend for the healthcare system, increased emergency department visits, inpatient hospitalizations, surgeries, and adverse events. In addition to these problems, patients may experience increased pain from ineffective treatment. Therefore, payers have regularly identified TNFi overuse, drug spend and the cost of the aforementioned complications as one of their greatest challenges.

[24] Singh J et al, 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis, Arthritis Rheumatol. 2016 Jan;68(1):1-26. doi: 10.1002/art.39480. Epub 2015 Nov 6. https://onlinelibrary.wiley.com/doi/full/10.1002/art.39480

Furthermore, the lack of a science-based approach to RA treatment selection has also opened the door for step-therapy requirements. Patients are often required to step through the class of TNFi options, sometimes more than once, before coverage is granted for the physician's preferred treatment selection. The barrier of step-therapy can negatively impact the RA patient's journey, including a possible increase in their disease progression. Step-therapy has been such a major challenge for patients that it has been addressed by legislation. Recently, Texas Senate Bill 680 was signed into law, limiting the use of step therapy.[25]

Using its network medicine platform, Scipher Medicine developed PrismRA®. PrismRA is a laboratory-developed test that identifies individuals with a molecular signature of inadequate response to all TNFi therapies. This enables clinicians to use objective scientific data to guide therapeutic decision-making and give their patients the best chance of achieving treatment targets. Improving the efficacy of first-line targeted therapies can help avoid the physical and monetary cost associated with uncontrolled RA. Most critically, it can save patients months of time and pain spent cycling through ineffective drug treatments.
Thank you for the opportunity to share feedback on the development of RA-focused episode-based cost measures for use in MACRA and as a foundation for MVPs. We urge you to consider the above information and our technology in the context of your efforts.

5.1.29 Comment Number 29

- **Date:** 02/05/21
- **Submitter Name, Credentials, and Organization:** Monica Wright, MHA, CPC, CPMA, CPCO, American Occupational Therapy Association, Inc.
- **Comment Text:** 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 under the Quality Payment Program (QPP). AOTA appreciates the opportunity to comment on the Acumen Wave 4 Cost Measures.

  Occupational Therapy's Role in Chronic Pain

  Occupational therapy practitioners are poised to play a key role in chronic pain management. Occupational therapy evaluation and treatment takes into account the cognitive-perceptual, environmental-behavioral, and psychological factors that influence chronic pain, in addition to the physical factors. This approach allows the occupational therapy practitioner to address

[25] Arthritis Foundation, Victory in Texas- Legislation Limits Step Therapy, http://blog.arthritis.org/advocacy/texas-step-therapy-win/#:~:text=On%20May%2023%2C%20Governor%20Greg,this%20is%20a%20major%20victory!

not just function and activities of daily living, but their biobehavioral causes as well.[26]

Occupational therapy's role in non-pharmacological pain management, including for low back and neck pain, is found in many evidence-based rehabilitation programs around the country, including the Veteran's Administration, the Mayo Clinic Pain Rehabilitation Center and the University of Pittsburgh Medical Center interdisciplinary chronic pain management program. Occupational therapy practitioners are qualified to address the physical, cognitive, and psychosocial components of pain management treatment.[27] Occupational therapy practitioners are able to address rehabilitation while accounting for each patient's ability, or inability, to participate in desired everyday activities and the effect of pain on their activities – the role of occupational therapy comes into focus when dealing with the multi-dimensional aspects of pain.

Occupational therapy treatment helps patients to prioritize activities and learn safe modifications and adaptations for daily tasks while completing a more comprehensive rehabilitation program that lowers the risk of experiencing exacerbations or relapses.

Research indicates that an integrated multidisciplinary approach that includes occupational therapy for spinal conditions is cost-effective and improves patient outcomes. For example, back school programs are highly effective in preventing back injuries and increasing functional engagement in daily life activities.[28]

Therapy and Rehabilitation

AOTA appreciates Acumen's decision to create a cost measure centered on the care provided by therapists participating in the Merit Based Incentive Program (MIPS). We understand that developing cost measures will make the creation of therapy-specific MIPS Value Pathways (MVPs) much easier.

AOTA supports creating a measure for both neck pain and low back pain together, provided the measure can be separated out for either condition. In other words, Acumen should allow for measurement of Low Back Pain or Neck Pain separately, in addition to Low Back Pain and Neck Pain for the same patient, so both conditions do not have to be present for a patient to be attributed to the measure.

Low Back Pain

Low back pain is a broad diagnosis that covers a range of acute and chronic conditions, each of which can vary greatly in cost. An acute surgical patient may be straightforward and low cost, while a chronic patient may have higher costs. AOTA has concerns as occupational

[26] Driscoll, Megan, and Nancy Baker. "Breaking the Cycle: Occupational Therapy's Role in Chronic Pain Management." Accessed February 1, 2021. https://www.aota.org/Publications-News/otp/Archive/2016/10-24-16-change-of-pace/chronic-pain-management.aspx.
[27] American Occupational Therapy Association. "New Occupational Therapy Evaluation Coding Overview." Accessed February 5, 2021. https://www.aota.org/-/media/Corporate/Files/Advocacy/Reimb/Coding/final%20version%2010%20page%20article.pdf
[28] Kjeken, I., Bø, I., Rønningen, A., Spada, C., Mowinckel, P., Hagen, K. B., & Dagfinrud, H. (2013). A three-week multidisciplinary in-patient rehabilitation programme had positive long-term effects in patients with ankylosing spondylitis: randomized controlled trial. Journal of rehabilitation medicine, 45(3), 260-267. https://doi.org/10.2340/16501977-1078

therapy practitioners often receive referrals for low back pain in complex, chronic cases. These patients may have had multiple previous treatments and present with additional comorbidities. These patients will inherently cost more than patients with an acute injury, referred perhaps for an initial treatment plan of physical therapy.

Occupational therapy can make an impact for patients with both acute and chronic low back pain by providing alternative strategies for daily living. This includes training in body mechanics, compensatory strategies, and other skills to allow meaningful participation in important like activities. However, if occupational therapy ends up being an upstream cost, or if the higher costs associated with these patients becomes attributable to the occupational therapy practitioner, it may impact patient access.

Due to the wide range of care being provided to patients and the differing nature of clinical management of these patients, it would be helpful to develop clinical care pathways and guidelines for treatment (thereby reducing unnecessary referrals to surgeons and inappropriate utilization of imaging studies specifically MRI's). AOTA has recommended two (2) occupational therapists to submit applications to serve on the Acumen technical expert panel to develop these cost measures. We urge Acumen to consider accepting an occupational therapist to inform the work of this panel as integral to Medicare Therapy/Rehabilitation needs. They will be able to provide detailed feedback on measure development issues, including but not limited to triggering events, CPT and ICD-10 coding concerns, and episode windows.

Thank you for the opportunity to comment on the Acumen Wave 4 Cost Measures. AOTA looks forward to a continuing dialogue with Acumen on measures that affect the ability of occupational therapy practitioners to provide quality, cost effective outpatient therapy services to Medicare beneficiaries.

5.1.30 Comment Number 30

- **Date:** 02/05/21
- **Submitter Name, Credentials, and Organization:** Mike Horsfield, PT, MBA, Private Practice Section of the American Physical Therapy Association
- **Comment Text:** On behalf of the almost 4,000 members of the Private Practice Section (PPS) of the 100,000-member American Physical Therapy Association, I write to provide feedback on proposed MACRA Episode-Based Cost Measure 4.3: Therapy and Rehabilitation.

  PPS is an organization of physical therapists in private practice who use their expertise to restore function, improve mobility, relieve pain, and prevent or limit permanent physical disabilities in patients with injury or disease. The rehabilitative and habilitative care they provide restores, maintains, and promotes overall fitness and health to a range of patient types. Representing physical therapists who are also independent small business owners, PPS encourages and supports policies that enable our members to focus on providing high-quality, cost-effective, and clinically appropriate outpatient physical therapy. Our members are proud of the quality of care they provide, and deeply appreciate CMS's inclusion of a proposed cost measure focused on physical therapy as part of its WAVE 4 efforts.

The Milliman Study

Initially, we hope to highlight for CMS work that PPS has conducted to date related to the physical therapy contribution to total cost of care. PPS recognized years ago that musculoskeletal rehabilitation was being targeted under alternative payment methodologies, including bundled payments, for musculoskeletal episodes of care and wanted to contribute to the effort. PPS has shared the results of a commissioned study, "Impact of Physical Therapist Services on Low Back Pain Episodes of Care," (the Milliman study) with private payers across the country and PPS leaders have endeavored to educate PPS members about its conclusions through various educational venues. These venues include multiple presentations available to PPS members that can be used to both educate themselves and advocate with payers to restructure their payment policies to encourage better health outcomes at lower cost by allowing for early access to physical therapy or direct access.

What the Milliman study shows is that starting physical therapy early results in lower overall costs. Major data points for the study are reflected below, and the entire study is available at https://ppsapta.org/userfiles/File/ImpactofPhysicalTherapistServicesonLowBackPainEOC.pdf

Again, the conclusions of the Milliman study illustrate three main points: First, if a physician chooses to refer a patient to a physical therapist, referrals sent early - in the first 14 days - result in lower costs and less use of invasive/higher cost procedures. Second, when accessing physical therapy for low back pain, direct access to physical therapy is the lowest cost method and results in less use of invasive/higher cost procedures. Third, clinical care of patients with recommended/active care results in lower cost and quicker outcomes than with passive care.

Application to Medicare Advantage

Beyond our focus on the Milliman study, PPS also appreciates the opportunity to express our desire for CMS to apply eventual cost measures like the one proposed in measure 4.3 to extend beyond traditional Medicare (Part B) and also be applied in Medicare Advantage (Part C, or MA). Government is at its best when it sets broad-based rules and standards for industry to work within. Including MA plans in the group of payers that will implement cost measures will help to create industry-wide standards that decrease administrative burden and the chaos at the practice level caused by multiple value-based schemes established by disparate payers. Physical therapists in private practice would benefit from uniformity in payer policies. Greater uniformity will also ultimately help improve patient care.

MA is important to patients and to physical therapists, and enrollment in the program is growing quickly.1 In addition, MA enrollment is highly concentrated within a handful of large insurers.2 In certain counties, MA plans account for more than 60% of Medicare enrollment.3 The actions of large insurers can have a large impact on small and large physical therapy practices and the variability they can create in value-based care systems can help or hurt a practice and its patients. The growth in MA enrollment is only poised to accelerate, and including these plans in the cost measure regime will have important smoothing effects for patient care.

Questions Posed by CMS

Initially, we wish to thank you and express our delight and enthusiasm that CMS is considering the development of a physical therapy-specific measure. Physical therapists in private practice have much to offer the health system by decreasing total cost of care while keeping quality of care high - and perhaps higher than with common surgical interventions. Focus on low back pain in particular seems wise as it is widespread within the Medicare population. Fundamentally, from the physical therapist in private practice perspective, treatment for low back pain as a whole seems reasonable and may include less surgical interventions than an extremity-related group.

The remainder of our comment response focuses on the specific questions posed by CMS as part of its presentation of Wave 4 proposed cost measure 4.3, language for which is reproduced below:

4.3 Therapy and Rehabilitation.

The Therapy and Rehabilitation clinical area would represent the new measure framework we are exploring for Wave 4, focusing on the care and treatment provided by physical therapists and related specialties for broad conditions such as Low Back Pain or both Low Back and Neck Pain. This is a framework that is ripe for development, as it may build from the chronic condition framework to capture the care provided by therapists. Low back and neck pain are also common conditions that are impactful for patients, and a measure for these conditions would address the variation in treatment techniques (e.g., duration/frequency, use of higher cost interventions like imaging). A broad topic such as Low Back Pain would also be a strong candidate for a MVP, as it is a broad and common condition with applicable MIPS quality measures. Additionally, we have received input suggesting the development of a Low Back Pain measure from our TEP and other stakeholders, noting the need for cost measurement centered on the care provided by therapists participating in MIPS.

Question 1: We identified 2 concepts for this clinical area, which includes Low Back Pain or an alternative approach for both Low Back and Neck Pain. Given the criteria for measure prioritization and the essential features of cost measures described above, which of the options would be preferable for the first therapy episode-based cost measure, and why? Are there additional concepts that would be valuable to explore within this clinical area? For a cost measure focused on the ongoing treatment and care for these conditions, what are some areas of opportunity for improvement a measure may be able to capture regarding care and potential mitigation of complications?

Question 1 Answer from PPS: Care for patients with low back pain and care for patients with neck pain is not similar enough to justify a unified cost measure for both conditions. Low back pain and neck pain arise from different conditions and are treated in different ways, and often by different specialists. As it is much more prevalent and treatment standards for low back pain are widely known and implemented by physical therapists across the country, we would urge CMS to consider focusing on low back pain for this cost measure. While the population that could be included in the cost measure would be larger if both conditions are included, it is also clear that physical therapists work with occupational therapists to treat neck pain and thus attribution can become less clear. We recognize that there are strategic considerations in regards to overall Medicare spending as to why CMS may wish to choose a larger population that includes both neck pain and low back pain, but are convinced that clinical care for both conditions is different enough to warrant a focus on

low back pain alone.

Physical therapists commonly utilize several tools that are helpful in ensuring patients with low back pain start with the appropriate provider, incorporate comorbidities commonly associated with low back pain into the prognosis and measure the effectiveness of the care delivered. We welcome the conversation on how we can best utilize the current standards of care to deliver higher valued care to Medicare patients.

With this in mind, there are important nuances to even the low back pain population that may or may not be reflected in the documentation associated with the condition. For instance, CMS has stated that the "framework … is ripe for development, as it may build from the chronic condition framework to capture the care provided by therapists." We are uncertain if the intent of this statement is thus for patients to be included only if they experience low back pain as a chronic condition. We are concerned that limiting the cost measure to only those with low back pain experienced as a chronic condition could further limit the number of patients involved, and thus the impact of the measure. In addition, we are uncertain how this further separation be accomplished under the rubric of the cost measure. Would the beneficiary be included only if their beneficiary's Evidence of Coverage (EOC) is explicit about this division? If so how is chronicity" defined by the measure and the EOC?

In the private sector, the majority of pricing models do not effectively address chronicity. They are often based only on the episode of care without chronic vs acute sub-categories. We would be very interested to work with Acumen and CMS to identify cost indicators that help define the contours and associated elements of chronicity (such as the use of opioids, repetitive imaging, or Electromyography) but we are unaware of a case rate model for these categories that has effectively and efficiently included these aspects of care. We raise this issue with some concern as CMS's adoption of specific aspects or definitions of chronicity may drive care in negative ways. CMS is such an important force in the US health system that its decisions in this area could move the rest of the health insurance system in ways that could be detrimental to physical therapy practice and patient care. Nevertheless, we stand ready to work with Acumen and CMS to explore the contours of chronicity as we value transparency and hope to make any eventual cost measure as impactful as possible. We note the excellent CMS resources available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/Methods_Overview.pdf which may help Acumen consider the chronicity question.

One other possible approach would be to create three categories to address chronicity. Acute could be defined as 1 to 4 weeks, subacute as 4 to 12 weeks and chronic as greater than 12 weeks. It is important to note that there is a growing body of clinical literature supporting the reality that patients with chronic pain are too often treated with opioids even if the comorbidities of depression, anxiety, PTSD, or substance use disorder are present.

If CMS/Acumen decides to disregard our recommendation and includes neck pain in the measure, the measure could benefit from a similar division. CMS/Acumen could consider a category for neck/shoulder, neck/thoracic or low back hip/Sacroiliac Joint Dysfunction which commonly occur together.

Functionally, we recognize that categorization of diagnoses complicates the administrative burden of measure implementation, and also that important information may not be adequately reflected in the data available to measure developers. In a perfect world, we believe that lumbar and cervical and non-surgical/surgical would also be important indicators to improve the accuracy of the measure, but also recognize that further divisions may serve to limit the impact of the measure on total cost of care or increase the administrative burden experienced by practicing physical therapists in implementing it. In working on the Milliman study, PPS and Milliman came to an agreement that it was beneficial to keep the granularity of their data's categorization (in particular, radiating and non-radiating). We hope that in our future work on the cost measure with CMS and Acumen that additional information will be presented that would help us understand why the population for the cost measure may be limited to those seeking care for chronic low back pain versus the spectrum of patient presentations.

Question 2: Based on the draft approach described in the "Appendix_Framework" tab of the Preliminary Specifications of Wave 4 Candidate Episode Groups workbook, which refinements would you recommend? What are types of services to use as indication of ongoing therapy management and care?

Question 2 Answer from PPS: In regards to "types of services to use as an indication of ongoing therapy management and care," we believe that referring to CPT codes would be fairly straightforward. Thus, in the instance of using E&M code reporting to trigger an episode, the use of CPT codes 97161-97163 would trigger an episode for physical therapy. We are uncertain if CMS/Acumen may also be proposing to use a "DC indicator" to end the EOC as well, as the way CMS/Acumen is defining the episode seems to be from the physician lens. We note that every state now allows some degree of direct access to physical therapists. In addition, as of 2005, the Medicare Benefit Policy Manual (Publication 100-02) states that Medicare beneficiaries may seek physical therapy services without seeing a physician or obtaining a referral as long as the state's practice act allows for such access and the requirements for the required certification of the plan of care are met. This reality also impacts the way that a patient's care can be "attribute(d) to a clinician," and would urge CMS and Acumen to consider how such attribution can be defined to include care provided by physical therapists.

Finally, in regards to Question 2, we urge CMS and Acumen to consider our experience with the Milliman Study. During our work with Milliman, we chose to include an indicator for 'recommended' vs. 'non-recommended' care. The proposed categorization for Measure 4.3 may be beneficial, but in our work with Milliman, we found value in changing initial recommendations by including manual therapy as a recommended intervention. Fundamentally, it would be important to exclude palliative care from the cost model.

Question 3: Based on the draft triggering approach, how should a therapy cost measure address the variation across patients for the need of therapy regarding Low Back Pain or for Low Back and Neck Pain (e.g., patients with chronic pain versus patients with a recent spinal surgery)? Some options include sub-grouping, risk adjusting, or excluding. Similarly, what recommendations do you have for how a measure may address patients with radicular syndrome/pain or arthritis?

Question 3 Answer from PPS: In response to this question, we urge CMS/Acumen to pay close attention to our experience with the Milliman Study. The Milliman model is helpful in highlighting the decreased cost of early intervention for low back pain and realizing down-stream savings. In addition, one pilot from ATI Physical Therapy has shown that while utilization of PT increases due to early intervention and direct access, overall costs per patient were lower. We are hopeful that any eventual cost measure will support and incentivize patients to pursue PT direct access with no utilization management barriers, as these barriers are becoming increasingly common in private practice physical therapy.

In addition, PPS supports surgical subcategories for low back such as fusion, ORIF for trauma and other more complicated diagnosis combinations such as Low back pain with stenosis, spondylolisthesis, SI instability, severe RA, OA, and osteoporosis. We are working with the APTA orthopedics section to confirm their most common categories and look forward to sharing the results of our findings.

Question 4: Are there any other concerns that may be present with assessing the care for patients with these conditions? If so, what are some potential approaches to address these concerns for a cost measure?

Question 4 Answer from PPS: Initially, one concern would be the limitation of the current episode-based cost measure reflecting treatment of chronic low back pain. Additionally, by tying a cost measure to a chronic population, there may be difficulty in isolating the physical therapy component from overall pricing as there are significant interdisciplinary inflections that occur when managing this population. Finally, the inclusion of models of trauma-informed care noted above will be important to consider as the measure moves forward through the approval and implementation process.

Conclusion
We appreciate the opportunity to comment.

5.1.31 Comment Number 31

- **Date:** 02/05/21
- **Submitter Name, Credentials, and Organization:** Catherine Maclean, MD, PhD, Hospital for Special Surgery
- **Comment Text:** On behalf of the Hospital for Special Surgery (HSS), a musculoskeletal specialty hospital in New York, NY, we appreciate the opportunity to provide feedback on development of cost measures in the upcoming cycle of episode-based cost measure development ("Wave 4") for the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Quality Payment Program (QPP).

  HSS is encouraged by the attention that the Centers for Medicare & Medicaid Services (CMS) has placed on important chronic conditions for musculoskeletal care, particularly in prioritizing low back and neck care and rheumatoid arthritis.

  Low back pain is a common condition that impacts up to 80% of the US population in their

lifetime and a common source of health utilization.[29] Guidelines exist recommending conservative treatment options such as physical therapy and avoiding the use of imaging without a trial of conservative therapy. However, patients still undergo a heterogeneity of treatment patterns and spinal conditions account for the 3rd largest source of spending.[30, 31]

HSS is the only academic medical center to specialize in the treatment of musculoskeletal care with the largest volume of musculoskeletal patients in the country. The HSS Center for the Advancement of Value in Musculoskeletal Care has spent the last 3 years focused on understanding and measuring both the quality of care and utilization patterns associated with low back pain. This has included the development of care pathways and standards using the RAND/UCLA Appropriateness method, developing ABMS Maintenance of Certification Part IV quality improvement activities on treating low back pain for primary care physicians, and developing groupers for measuring cost and utilization associated with the treatment of low back pain.

HSS believes that low back pain should be a priority as an episode-based cost measure, distinct from neck pain.

Clinical care guidelines from specialty societies such as the North American Spine Society, Academy of Orthopaedic Physical Therapy, American Academy of Family Physicians, and American College of Physicians are specific to the treatment of low back pain. Similar guidelines do not exist around neck pain. Utilization patterns will also differ in the evaluation and management of low back pain compared to neck pain. Cost measures should allow a comparison of a clinically coherent set of medical services for a specific condition.

HSS has developed a clinical episode grouper to allow for greater comparison of new onsite low back pain based on expert review and in adherence to clinical guidelines, such as those from the North American Spine Society. Using the inclusion and exclusion criteria from these guidelines can help ensure that opportunity for improvement is driven by evidence-based guidelines and allow for a greater understanding of unwarranted variation in the treatment of back pain. It also allows for treatment to be more consistently tied to existing quality measures for low back pain in the QPP, including patient-reported outcome performance measures (PRO-PMs) and facilitate the creation of MIPS Value Pathways (MVPs).

The HSS clinical episode grouper would not prohibit the comparison of other clinicians, and would apply across the wide spectrum of specialties that care for patients with low back pain, including physical therapists, physiatrists, primary care physicians, anesthesia pain management specialists, and orthopedic surgeons.

[29] Maher C, Underwood M, Buchbinder R. Non-specific low back pain. Lancet. 2017;389(10070):736-747. doi:10.1016/S0140-6736(16)30970-9

[30] Dieleman JL, Baral R, Birger M, et al. US spending on personal health care and public health, 1996-2013. *JAMA*. 2016;316(24):2627-2646. doi:10.1001/jama.2016.16885

[31] Ivanova JI, Birnbaum HG, Schiller M, Kantor E, Johnstone BM, Swindle RW. Real-world practice patterns, health-care utilization, and costs in patients with low back pain: the long road to guideline-concordant care. *Spine J*. 2011;11(7):622-632. doi:10.1016/j.spinee.2011.03.017

The HSS clinical episode grouper begins by defining diagnoses and specific professional claims where low back pain is first diagnosed. Patients with a diagnosis of low back pain in the prior year, prior spinal surgery, or diagnoses with spinal deformity, inflammatory disease, fracture/trauma, or pregnancy would be excluded.

Inpatient, outpatient, professional services, and drugs that are used in the treatment of low back pain are specified to ensure only costs and resources that can be attributed to low back pain utilization are measured and that clinicians are not adversely affected should a patient seek care for separate and distinct conditions.

Utilizing the Truven MarketScan Commercial Database from 2012-2015, with a base population of 85,301,642 members, the HSS clinical episode grouper identified 1,839,556 members meeting the definition of new onset low back pain. Average low back pain related costs for every patient with low back pain was $1,264.7 (SD = $5,158.3), showing that despite a more specific definition, there was still significant variation in utilization across multiple categories.

In comparing the trigger definitions from the HSS clinical episode grouper to the preliminary specifications from CMS, fails to exclude diagnoses related to spinal deformity, inflammatory conditions, and spinal fracture/trauma, all of which are typically exclusions in clinical guidelines. Clinicians who see patients with these diagnoses would be adversely affected and unfairly compared to patients with non-specific low back pain when compared on utilization and cost.

Trigger codes associated with professional services also fail to include a large variety of professional services where low back pain can first be diagnosed, including acupuncture, chiropractic manipulative treatment, ED visits, injections, osteopathic manipulative treatment, office consultations, office visits, preventive visits, PT evaluations, and some therapeutic procedures and manual therapies. Failure to include the wide range of measure may exclude a significant number of Medicare beneficiaries with the condition.

Furthermore, the trigger codes may limit applicability to physical therapists (PTs), and important discipline for the effective treatment of low back pain. Although PT's are licensed to treat without a prescription this is often limited to a period of 30 days. Most PT's will only see a patient after the patient has seen a physician or advanced practitioner (NP/PA) who can provide a suitable diagnosis code and prescription. The triggering approach described does not seem to account for this and may not capture all patients who are receiving ongoing therapy and care. By only looking at the TIN that includes a PT evaluation, the measure may miss initial evaluation and follow up. HSS believes CMS should include other trigger events such as a non-rehab evaluation and follow up to determine a chronic care episode. The usual order of chronic management would start look like this: a clinician/NP/PA evaluation/initial visit assigning a diagnosis of low back pain, followed by a PT evaluation with the same diagnosis code, followed by multiple PT visits for a period of time with the same diagnosis

codes, followed by a clinician/PA/NP assessment or follow-up typically within 30 days with the same diagnosis codes, ending with the end of treatment or a further cycle of physical therapy.

The TIN trigger may also not capture if the prescriber for physical therapy is not in the same TIN as the physical therapist. NPI may be a difficult attribution source especially if patients see multiple different PTs under the same TIN umbrella.

Attached you will find the specifications that HSS has developed including the logic for how the clinical episode grouper was defined to allow for fairer comparability while still helping clinicians identify opportunities for improvement.

Finally, the majority of low back pain related quality measures are oriented towards orthopedic surgeons, tracking pain or functional status following an orthopedic procedure. Further investment and integration of measures should allow for a greater diversity of clinicians to report on meaningful measures, specifically PRO-PMs, using non-proprietary instruments, such as the Oswestry Disability Index or PROMIS-10. Doing so would allow for the creation of MIPS value pathways that would be meaningful to all clinicians treating low back pain, rather than just surgeons.

Rheumatoid Arthritis is an important condition. The HSS Division of Rheumatology is acknowledged as one of the most respected in the US for diagnosing and treating systemic autoimmune disease, including work on advancing medical knowledge and discovery to achieve the best outcomes for patients.

Accounting for severity levels is important in comparing costs for treating Rheumatoid Arthritis (RA). The 'severity' RA can be characterized by disease activity which may be quantified by a number of validated scores such as the 'Disease Activity Score' (DAS) or the 'Chronic Disease Activity Index' (CDAI). Instruments endorsed by the American College of Rheumatology can be found here. While there is no single standard, it would be possible to define broad categories (e.g. high, medium, low) across instruments. A larger measure challenge, especially if the intent is to use disease severity as a risk adjustor is that these measures are not routinely collected. Furthermore, all of these instruments rely upon clinical data elements that are not available in claims data.

Disease severity can also be characterized in terms of extraarticular disease. For example, a patient with ocular or pulmonary manifestations would be considered to have more severe disease. However, this is the minority of patients. Diagnoses that indicate extra-articular disease are most helpful in helping identify varying levels of severity that could be applied to risk-adjustment or sub-grouping of services.

In geographic areas plentiful with rheumatologists, one might expect that more severe cases are treated by rheumatologists. However, there are many geographic areas with few/no

rheumatologists where PCPs would manage RA. Additionally, there are PCPs who as a matter of course manage RA. In terms of measuring either quality or cost, the rules should apply equally across clinicians who treat RA, regardless of specialty.

Attribution of the cost measure to be to whichever physician is managing the bulk of the RA care. However, consideration should be given to clinicians who co-manage RA patients. For example, a PCP in a rural area who co-manages RA patients with a rheumatologist. This is a desirable practice model of collaborative, integrated care that is good for patients in coordinating treatment. Care should be taken to avoid measurement/payment models that discourage this.

Areas for opportunity in the ongoing treatment and care of patients include the optimal frequency of lab monitoring. While the ACR details recommendations in its guidelines, these are generally expert opinion-based. Detailing the relationship between utilization frequency and complications could guide recommendations for optimal timing, leading to fewer complications and/or less testing with associated cost savings. Unnecessary utilization of advanced imaging is also a major cost driver for RA. Capturing this in feedback reports associated with overall cost measures would help to identify opportunities for improvement.

Several concerns should be noted on assessing the cost of chronic care for patients with RA. The first includes the cost of therapy paired with the fact that many different therapies with varying price tags are effective based on each patient's unique circumstances. The overall cost of drugs is generally not known by either prescribing physicians or patients. Patients generally have insight into the required co-insurance, but prescribing clinicians often do not, leading to adherence issues. Part of the problem is that it's hard to find the information. It is not readily available at the point of care. A measure that required physicians to review the cost of different therapeutic options with patients before prescribing would drive valuable shared decision-making conversations about the cost of drugs. A patient may prefer to take a less expensive drug and use their annual savings towards other discretionary purposes such as tuition for a family member or a vacation. For pharmaceutical benefit managers (PBM), it would be interesting to construct a companion measures that assess whether the PBMs make cost data available to clinicians and patients at the point of care.

In terms improving usability and giving clinicians/groups actionable information related to the measure, reports modeled after the PEPPR reports that CMS provides to hospitals would be useful. In such an RA report, categories including conventional v biologic agents; use of infusions; imaging; and hospitalization would be useful.

HSS would welcome the opportunity to contribute to the development of the cost measure process through clinician participation in clinical subcommittees and would be happy to meet with CMS to share more details on the HSS clinical episode grouper.

5.1.32 Comment Number 32

- **Date:** 02/05/21

- **Submitter Name, Credentials, and Organization:** Rebecca Yowell, American Psychiatric Association
- **Comment Text:** General comment: Your request for public comment has stimulated a productive discussion on potential options for measure specifications that could be used to assess episode of care costs for common, chronic psychiatric disorders. We have serious concerns that if not done properly, a measure could generate data that are not easily interpretable to identify target areas for improvement and/or worsen health disparities (https://pubmed.ncbi.nlm.nih.gov/31649194/). These concerns are particularly timely as there is increasing need for mental health care especially among our most vulnerable populations during the COVID-19 pandemic. We thus recommend working collaboratively with CMS and Acumen (CMS/Acumen) to develop an Episode-Based Cost Measure (EBCM) that would yield meaningful data by identifying areas for improvement that are mutable and policy relevant. The conundrum is the historical approach to the development of EBCMs does not fit with the clinical characteristics and course of common chronic psychiatric conditions or how psychiatric care is usually delivered. Assumptions for inpatient procedure-oriented care with follow-up outpatient care by the same physician are often not met. Thus, it is premature to select a specific condition for a cost measure without greater attention to revising substantially the current methodology. The suggested episodes have problems similar to those identified with the psychosis/related conditions EBCM developed previously. It is hard to conceptualize any of these in terms of a disease "episode," particularly in the context of psychiatric practice; none are comparable to discrete procedure based "episodes" (e.g., hip replacement, cholecystectomy). In addition, given the attribution problem, it is meaningless to hold psychiatrists responsible for the cost of care across different psychiatric treatment settings. The fragmentation of the mental health system has led to more and more psychiatrists providing care in a single setting (i.e., inpatient or outpatient). In many instances, patients receive care from multiple providers (split treatment) during inpatient and outpatient care. Further, psychiatric care is often team based, especially for the management of chronic psychiatric disorders that often have comorbid chronic medical conditions. It is thus difficult to hold one individual responsible across settings and across providers outside of a single system of care. If you must move forward, then the least problematic area, depending on how you develop specifications for the measure, would be Major Depressive Disorder (MDD). It is a common disorder with well-established treatment efficacy that has costly and negative outcomes both clinically and societally. Concerns to consider with this population include the following: MDD patients who see psychiatrists may have some degree of treatment resistance or subsyndromal symptoms. Many patients will require ongoing pharmacotherapy and psychotherapy to mitigate risks of relapse or significant impairment. Even when an individual with MDD exhibits response or remission of current symptoms, it can be difficult to define a discrete "episode" endpoint, particularly because we know that patients who have had recurrent MDD need ongoing treatment to prevent symptom recurrence and provide early intervention if symptoms do return. In addition, there are relatively high rates of comorbid disorders, such as substance use. CMS/Acumen should examine not only the primary psychiatric diagnoses but also other coded diagnoses, if feasible. For example, we anticipate that diagnoses such as suicide attempts or substance use disorders might also be documented among some individuals with a primary diagnosis of MDD whereas other individuals may have a different primary diagnosis but have MDD documented in another diagnosis data field. Further, many

individuals who will receive an MDD diagnosis in the pandemic era may technically meet MDD criteria, yet there is likely to be significant heterogeneity in symptoms and contributors (e.g., isolation, loneliness, grief, stress of political/social justice strife) across individuals and in comparison to pre-pandemic MDD patients. Thus, capacity should be built into the specifications to stratify by pre-and post-COVID-19 pandemic onset with matching calendar weeks or months. For claims data, approaches to create proxies of clinical severity include modifiers in the ICD-10 code, past year psychiatric hospitalization, prior ED visits for primary psychiatric diagnosis, prior contact with services for any suicide attempt, suicidal ideation, intentional self-harm, comorbid psychiatric diagnoses. If depression screening scale data is available, as from PHQ-9 data elements, the number of symptoms or their frequency can be used to gauge severity. Subgroups: Age, sex, race/ethnicity, and clinical severity. In addition to these subgroups, consideration should be given to stratification by dual eligibility (Medicare/Medicaid) status vs. Medicare-only coverage as a possible approach to assessing disparities within the measure, since dual eligible patients (Medicare/Medicaid) are at especially high risk and also have limited options for care. It is important to ensure that providers who do accept both types of payment will not be disproportionately penalized by any cost measure. Social determinants of health are another important component to consider. We understand that it is not possible to adequately correct for or stratify for the multiplicity of social determinants of health. If these are meant to apply to patients insured by CMS (whether related to age, disability status, and/or poverty), those individuals are much more likely to have increased severity/complexity from all of these factors. As was mentioned previously, we do not want to increase health disparities through the implementation of a cost measure. A population of patients with MDD will include individuals suffering from treatment resistant depression (TRD) for whom providing good care may require more intensive services that lead to higher costs during the episode of care. An episode of care cost measure may also not capture the potential cost savings of reducing emergency department (ED) and inpatient hospitalization if the time period for the measure is relatively brief and restricted to costs captured by billing data. Conversely, higher use of ED visits and inpatient care during an episode of care may also signal more responsive care because detection of risk for suicide is greater among persons who receive continuous outpatient psychiatric care. Further, Medicare data is unlikely to identify other factors that would offset the cost of high-quality depression treatment, such as improved work-place productivity and employment. Cost measures also require careful evaluation of their capacity to identify disparities in care and potential unintended consequences, such as worsening of access to and quality of care if a psychiatrist is held responsible for the additional costs of caring for the most vulnerable populations. We also have significant concerns about the ability of an EBCM to identify/ascribe responsibility for the cost of care. A quick review of publicly available Medicare claims data for 2017 shows that of the three groups of mental health professionals (psychiatrists, psychologists, and social workers) the majority of Medicare patients seen for an initial evaluation were seen by psychologists with non-physician mental health professionals (psychologists and social workers) evaluating almost twice the total number of new evaluations as psychiatrists. In some instances, care is provided by one clinician, whereas in other instances care is split across clinician types with psychiatrists or primary care physicians managing psychopharmacology and psychologists and social workers providing psychotherapies. Provision of care can also be split across settings, with inpatient psychiatrists managing care in the hospital and another clinician

(psychiatrist, psychologist, social worker, or PCP) or community-based program managing care in the outpatient setting. In most instances, particularly those reporting under MIPS, the individual clinicians are not part of a system of care but rather are independent from one another. Consequently, an outpatient psychiatrist will typically have minimal influence over the delivery or costs of evidence-based therapy by a social worker or psychologist on a community-based mental health clinic team. This model of care delivery in mental health is quite different from care delivery in other specialties, in which the physician is more often ordering or making referrals to other services or non-physician clinicians, and thus has greater accountability for and control of resulting costs. Such distinctions in the organization of mental health care delivery are essential to consider in constructing MIPS related measures, including cost measures. Individuals with schizoaffective disorder have mood episodes and fluctuations in mood, but these are typically superimposed on relatively chronic symptoms of psychosis with substantial residual psychosocial impairment that requires ongoing rather than episodic treatment. Many individuals with bipolar disorder and schizoaffective disorder need emergency department or inpatient care in the course of their illness, raising many of the same challenges as with the previously proposed inpatient psychosis measure. Although patients with bipolar disorder can have discrete manic or depressive episodes, they also have frequent residual depressive symptoms between episodes that can lead to substantial impairment. Ongoing chronic/inter-episode care is needed to promote adherence, monitor medications, intervene early in the event of relapse, and engage in therapy to deal with the psychosocial impacts of having bipolar disorder. Many individuals with bipolar disorder and schizoaffective disorder need emergency department or inpatient care in the course of their illness, raising many of the same challenges as with the previously proposed inpatient psychosis measure. We are happy to review and assist in future refinement of the trigger codes. In terms of the CPT codes that would signify eligibility for this measure, we would recommend a careful review of the available codes and their implications for an EBCM of this type. In particular, psychiatry specific codes, including those for psychotherapy, may be important to include whereas codes for settings of care other than conventional outpatient practice (e.g. home visits, assisted living facility, and nursing facility) may warrant exclusion.

5.1.33 Comment Number 33

- **Date:** 02/05/21
- **Submitter Name, Credentials, and Organization:** Angela Kennedy, DC, MBA, American Society of Clinical Oncology
- **Comment Text:** Cancer stage is one of the most important prognostic and treatment decisions in most cancer subtypes. Without the specificity of cancer stage, it is near impossible to accurately assess quality or cost measures that include specific therapies, costs, or outcomes. The ICD-10 is insufficient for staging and International Classification of Diseases for Oncology (ICD-O) is a topography and morphology coding system (in other words, a coded nomenclature), not a system for coding stage or extent of disease. ICD-O has no relationship to the TNM classifications of the International Union Against Cancer (UICC) or the American Joint Committee on Cancer (AJCC). The AJCC specifies criteria for staging each cancer type based on tumor characteristics (T), lymph node involvement (N), and tumor metastasis (M) known as the TNM staging system. Information related to cancer stage is

typically recorded in clinical narrative text notes and other informal means of communication in the Electronic Health Record (EHR) and not captured in discrete data elements nor is there specific coding for stage in administrative claims. In the ASCO big data platform, CancerLinQ, adequate TNM values and AJCC stage are usually in the EHR data, but are then needed to be codified to SNOMED. Issues with AJCC include: multiple editions that may include modifications to TNM categories; the clinical data does not reflect which edition is being used; and AJCC TNM terminology is proprietary, requiring a very expensive license, which is a barrier to broader use. Finally, its staging is very granular and there is pathologic and clinical staging that are not fully defined by a code system like ICD-10. To help address some of these issues, ASCO has recently developed HCPCS codes for specific staging combinations for specific quality measures. For example, HCPCS Level II – G9832: AJCC stage at breast cancer diagnosis = I (Ia or Ib) and T-stage at breast cancer diagnosis does not equal = T1, T1a, T1b. However, this does not provide a long-term solution to a complex issue. In order for staging to be captured in claims, existing SNOMED or AJCC staging would need to be incorporated into the data captured in claims or a parallel/mapped code set would need to be developed by CMS or work with a standards body to capture this information in claims.

5.1.34 Comment Number 34

- **Date:** 02/05/21
- **Submitter Name, Credentials, and Organization:** Matthew J. Smith, MD, MHL, North American Spine Society
- **Comment Text:** Low back pain. Although there are many commonalities between LBP and NP, there are also many differences in specific pathology and demographics. For an initial iteration, we recommend minimizing heterogeneity. • Activity level as measured by weekly minutes of moderate to vigorous physical activity accelerometer (personal device). Work status. Presence of 3rd party litigation. Presence of surgical red flags. Presence of psychological "yellow" flags. Health literacy regarding LBP. • Decrease downstream health care utilization including imaging, ER visits, injections and surgeries. Improved physical activity. Improved health literacy. Episodes of LBP often begin differently or without PT visits. Services can include modalities such as heat/ice/e-stim/interferenial, therapeutic exercise and manual treatments. Treatment from other providers including massage, acupuncture, chiropractors physicians and surgeons may indicate ongoing management of LBP. sub groups based on diagnosis (consider Glassman classification), exclusion of LBP due to cancer or infection, risk adjusting by comorbidities and socioeconomic factors. Patients may be repetitively referred to therapy due to a lack of understanding of chronic care management among healthcare team members. Role of self-management, risk of reliance on an external locus of control for behavior change and detriments of medicalization are not uniformly understood or messaged by care team of LBP patients. Perhaps as cost measure evolves into MVP, it could be used as a nidus of collaboration for accountable, team-based care by disparate stakeholders. Avoid creating penalties for having patient assessed by MD/DO. This could create medical risk and provide barrier for beneficiary to receive relief from symptoms. While cost control across team members may be reasonable, the ability of LBP healthcare providers to function as a team should be strengthened rather than hampered. Foster an environment where options for the non-anatomic components of LBP can be

helped. Many believe that medical technology has a limited role in correcting a physiological cause of LBP. Yet, patients cycle through allopathic disciplines looking for help and accumulating charges. Where will the LBP patients go if not to PT? How can LBP patients learn a ubiquitous message about the correct management of their condition? Engagement in physical wellness. Health literacy of LBP. Functional measures such as ODI, FOTO, work status, numeric pain scale. Changes in healthcare utilization. Changes in back pain beliefs. Changes in levels of physical activity.

5.1.35 Comment Number 35

- **Date:** 02/05/21
- **Submitter Name, Credentials, and Organization:** Lorraine Jordan, PhD, CRNA, CAE, FAAN, American Association of Nurse Anesthetists
- **Comment Text:** CRNAs are pain management experts who are uniquely qualified to help patients with complications associated with opioid use after surgery. CRNAs offer patients holistic pain management services that reduce or eliminate the need for opioids post-surgery through ERAS© protocols, CRNAs reduce the needs for opioids, improve patient outcomes, reduces the length of hospital stays and reduces costs. In addition, thorough preanesthetic evaluations will assist CRNAs in preventing complications and/or adverse events resulting from incomplete or inappropriate patient evaluations. Finally, the selection of appropriate anesthetic medication will help to reduce complications resulting from a patient's adverse reaction to the drug. Complications that arise from anesthesia generally occur within 24 to 72 hours 24- 72 hours of the procedure depending on the type of anesthetic used. An episode window that is appropriately long and which reasonably reflects when these anesthesia complications occur, would benefit and support CRNAs and other anesthesia providers participating in the MIPS program

5.1.36 Comment Number 36

- **Date:** 02/05/21
- **Submitter Name, Credentials, and Organization:** Edward Mariano, MD, MAS
- **Comment Text**: I am familiar with the EBCM methodology having worked on two measures that are currently in effect. I do not understand why this proposed EBCM is limited to therapy interventions. I would suggest chronic low back pain as a chronic disease measure and consider care and interventions more broadly.