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President

Kenneth Anderson, MD
Dana-Farber Cancer Institute
450 Brookline Avenue, Room M557
Boston, MA 02115-5450

phone 617-632-2144

fax 617-632-2140

kenneth_anderson@dfci.harvard.edu

President-Elect

Alexis Thompson, MD, MPH
Ann & Robert H. Lurie Children's Hospital of Chicago
225 E. Chicago Avenue
Box #30
Chicago, IL 60611

phone 312-227-4384

a-thompson@northwestern.edu

Vice President

Roy L. Silverstein, MD
Medical College of Wisconsin
Clinical Cancer Center
9200 W. Wisconsin Avenue
Milwaukee, WI 53226

phone 414-805-0815

rsilverstein@mcw.edu

Secretary

Robert A. Brodsky, MD
Johns Hopkins University
Ross Building, Room 1025
720 Rutland Avenue
Baltimore, MD 21205

phone 410-502-2546

brodsro@jhmi.edu

Treasurer

Susan Shurin, MD
222 Quince Street
Unit 2C
San Diego, CA 92103

phone 240-328-8542

sxs15@yahoo.com

Councillors

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John C. Byrd, MD
Mary Dinuer, MD, PhD
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Terry Gernsheimer, MD
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Martin Tallman, MD
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Executive Director

Martha Liggett, Esq.
mliggett@hematology.org

Seema Verma, MPH

Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

VIA E-MAIL macra-episode-based-cost-measures-info@acumenllc.com

Re: Episode-Based Cost Measure Development for the Quality Payment Program

Dear Ms. Verma:

I am writing on behalf of the American Society of Hematology (ASH) regarding the request for comments on the document entitled, *Episode-Based Cost Measure Development for the Quality Payment Program (QPP)*. As we work with our members to prepare to participate in the new QPP, we appreciate the opportunity to work with the Centers for Medicare and Medicaid Services (CMS) to ensure that the cost measures, episode groups, and associated episode triggers apply to the work performed by our members; and most importantly, accurately reflect the challenges of treating patients, many of whom have complex hematologic disorders.

ASH represents over 16,000 clinicians and scientists worldwide, who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists were pioneers in demonstrating the potential of treating various hematologic diseases; and we continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians who are providing care to patients in diverse settings including teaching and community hospitals, as well as private practices.

ASH greatly appreciated CMS' decision not to include the cost component in the scoring for the Merit-Based Incentive Payment System (MIPS) for 2017. We believe it is critical that the required risk adjustment, attribution methodologies, and episode measures should be finalized, and that the public should have an opportunity to comment on cost components, prior to their being used to calculate a physician's MIPS score. While we appreciate the work being done to address these issues, we remain concerned that these methodologies and measures will not be ready for 2018, specifically as they apply to the complex and rare hematological conditions that we treat. For our patients, addressing the cost of care requires having a complete understanding of the patient incorporating clinical risk data, which are not currently captured in routine billing coded data. Importantly, measures should normalize guideline adherence and meaningful outcomes to ensure that the patient is protected.

All physicians, regardless of specialty, must be meaningfully measured under the cost component, and physicians should have adequate time to understand how these tools work in practice, before such time as they impact physician reimbursement. ASH continues to urge CMS to provide physicians with an opportunity to review their cost scores based on at least one full year of performance using the new measures, before they impact a provider's MIPS composite score.

After reviewing the draft list of care episodes and episode groups, ASH believes that our members will be at an unfair disadvantage in 2018, based upon the progress to date to develop episode care and patient condition groups and codes. Our members treat patients with conditions such as acute leukemia, chronic lymphocytic leukemia, and myeloma, which cannot be adequately captured and measured by the list of episodes and groups currently available. We appreciate that hematologic disorders are a topic for a future clinical subcommittee. Until this group is formed and their work is completed, our members will be at a distinct disadvantage when being assessed on the 10 existing cost measures and additional measures under development.

Patients with malignant and non-malignant blood disorders represent diverse patient populations, whose cost of care assessment requires a carefully-nuanced analysis that extends far beyond what is feasible with coded billing data. For patients with acute leukemia, the cost per patient may vary by *orders of magnitude* based upon disease status (therapy-responsive vs. refractory to standard treatment modalities), genetic/molecular/genomic risk assessments, age, performance status, and the intent of treatment (curative vs. palliative). For patients with adverse-risk genetic and genomic features (such as the presence of duplications of the *FLT3* gene), blood/bone marrow stem cell transplant represents best practice. Those undergoing transplant represent a very high-cost population of patients, whose high-cost care results in better survival outcomes and represents high-value care. Unfortunately, the clinical risk data used in this clinical assessment cannot be gathered through CMS' standard data abstraction methods. This deficiency creates a paradox, since those institutions that offer the best therapeutic approach to this patient population are likely to be unfairly penalized when compared to other institutions which fail to follow best practice.

Similarly, patients with chronic lymphocytic leukemia with unmutated heavy chain genes or with deletions of chromosome 17 have much worse survival outcomes and higher care costs than those chronic lymphocytic leukemia patients without these abnormalities. These high risk patients may benefit from hematopoietic cell transplantation, which therefore represents best practice and incurs greater care costs. CMS's current data abstraction and cost assessment methods again fail to capture this level of differentiation.

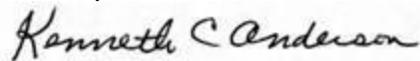
As specialists in internal medicine, hematologists may see a patient once in order to diagnose and recommend treatment, may take over care for long period of time in the event of a newly diagnosed disease such as leukemia, or may serve as a long-term primary care physician for patients with a lifelong blood disease such as sickle cell disease. Their level of influence on a given patient may differ substantially on the basis of that role, and this must be reflected accurately in episode groups, and ultimately in cost measures. Moreover, measuring the work of hematologists differs substantially from physicians whose work is procedure-based and easily broken into defined episodes. The type of cognitive work that is required by hematologists in making complex diagnoses or in serving as a primary physician for the patient for either the short or long term of their illness requires a more nuanced accounting of physician role and responsibility. CMS must take steps to ensure that they recognize these roles of caregivers for hematologic disorders when comparing cost of care.

The above described considerations are particularly critical for the cancer patients treated by our members. We appreciate that CMS recognizes that this patient population poses unique challenges to assess cost and resource use, particularly as it relates to cancer staging. Cancer and other complex hematological diseases will require CMS to carefully weigh the role of costs and risk stratification as these episode groups are developed. In an abstract presented at the 2016 ASH meeting, the impact of clinical risk upon cost of care was described for patients undergoing allogeneic transplant for acute leukemia. In this analysis, the patients' care costs rose based upon their age, disease status, performance status, intensity of transplant therapy, and the choice of transplant donor. These are data that are not routinely reflected in billing data, but reflect the complex decisions necessary to ensure that patients achieve the best survival outcomes. Without rigorous risk/cost adjustments, we risk incentivizing the under-treatment or suboptimal treatment of patients with advanced blood cancers.

While the agency requested comments on the best way to incorporate Part D drug costs into the episode groups, ASH is particularly concerned about how Part B drug costs will be incorporated. Our members rely on Part B drugs to treat patients, including those with cancer. There are a limited number of opportunities to substitute similarly effective, lower cost, alternative drugs for these patients without adverse health effects. The MIPS cost measures must be developed and implemented in a manner such that physicians are not penalized for prescribing higher-cost drugs which have lower toxicity and incremental benefit. Furthermore, a treatment regimen cannot be judged on the Part B drug cost alone, as many cancer patients require supportive care medications that may fall outside of Part B. ASH discourages CMS from constructing measures, episode groups, and triggers that would drive decisions about care based upon any data other than the best available medical evidence. We encourage you to consider this concern, as you are finalizing a risk-adjustment methodology.

Thank you for the opportunity to provide these comments. We welcome the opportunity to discuss these proposals, and others being considered, with you and your team. If you have any questions or require further clarification, please contact Leslie Brady, ASH Policy and Practice Manager at lbrady@hematology.org or 202-292-0264.

Sincerely,

A handwritten signature in black ink that reads "Kenneth C. Anderson". The signature is written in a cursive style with a clear, legible font.

Kenneth C. Anderson, MD
President