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Administrator, Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-5522-P

200 Independence Avenue, SW

Washington, DC 20201

Re: Medicare Program; CY 2018 Updates to the Quality Payment Program (CMS-5522-P)

Dear Administrator Verma:

The American Society of Hematology (ASH) is pleased to offer comments on the proposed rule for Year 2 of Medicare's Quality Payment Program (QPP).

ASH represents over 17,000 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 is extremely supportive of the agency's efforts to respond to stakeholder concerns about the QPP program and place a priority on improving outcomes and reducing burdens on clinicians, allowing them to focus on patient care. The proposals for Year 2 of the program, including the adjustments made to accommodate small practices, the efforts to reduce administrative burden, and continuing to allow the use of 2014 Edition Certified Electronic Health Record Technology (CEHRT), are critical to reducing burden, but we believe there is further room for improvement and offer comments on portions of the rule that we believe require further refinement:

1. Low-Volume Threshold
2. MIPS Submission Mechanisms
3. Cost Performance Category
4. Complex Patient Bonus
5. Quality Performance Category – Facility-Based Measurement
6. Quality Performance Category – Topped Out Measures
7. Continuing Medical Education as an Improvement Activity

Low-Volume Threshold

ASH supports the increase of the low-volume threshold to exclude individual eligible clinicians or groups that have Medicare Part B allowed charges less than or equal to

\$90,000 or that provide care for 200 or fewer Part B-enrolled Medicare beneficiaries. Our Society had previously expressed concern about the ability of small private practices, including those in rural areas to be able to succeed in the QPP, and this increase of the low-volume threshold will exempt a greater percentage of small practices.

MIPS Submission Mechanisms

CMS is proposing to allow multiple submission mechanisms, as necessary, to meet the requirements of the quality, improvement activities, or advancing care information performance categories for CY 2018. ASH thanks CMS for their efforts to create more flexibility for reporting and increasing the ability for a clinician to receive the maximum number of points available. The Society encourages CMS to continue to look for ways to increase flexibility with the QPP. We believe that the best way to ensure participating clinicians can meet the requirements of each performance category is to increase the number of meaningful measures available. ASH hopes to work with CMS to ensure that all our members have meaningful measures on which to report.

Cost Performance Category

CMS is proposing to weight the cost performance category at zero percent for the 2020 payment year in MIPS. The agency notes that by reweighting the cost performance category to zero in performance period 2018, there will be a sharp increase in the cost performance category weight to 30 percent in performance period 2019 and therefore, is seeking comments on maintaining the previously-finalized cost performance category weight of 10 percent for the 2018 performance period. ASH feels strongly that until the required risk adjustment, attribution methodologies, and episode measures are finalized, clinicians should not be scored on the cost performance category and consequently, ASH supports the proposal to maintain the weight of zero for the cost category for the second year of the program.

All physicians, regardless of specialty should have adequate time to understand how the cost component 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.

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, for example, 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 bone marrow 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 significant problem since tertiary care centers and providers who offer this expensive, high quality, personalized medical care are likely to be unfairly penalized when compared to those caring for patients with less complicated diagnoses who require less expensive care.

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.

One of the measures included in the cost performance category is the Medicare Spending per Beneficiary (MSPB) measure. As it stands, an episode will be attributed to the MIPS eligible clinician with the plurality of Medicare Part B charges. CMS is not proposing any changes to the attribution methods for this measure. Clinicians must be attributed at least 35 cases to be scored on this measure. The Society suggests that CMS also adjust for intensity and take into account complex patients receiving personalized medicine.

Our members feel strongly that using claims to measure cost performance does not fully capture all aspects of providing high quality care at low cost, especially for many hematologic diseases, most of which are considered rare. As it stands, hematologists are at an unfair disadvantage under the cost performance category. Before this category counts towards a clinician's final score, CMS must finalize the required risk adjustment, attribution methodologies, and ensure that there are adequate episode measures for all specialties, including hematology.

Complex Patient Bonus

CMS is proposing to add a complex patient bonus to the final score for the 2020 MIPS payment year for clinicians that submit data for at least one performance category. CMS will calculate an average Hierarchical Condition Category (HCC) risk score, using the model for Medicare Advantage risk adjustment, for each MIPS eligible clinician or group, and use that average HCC risk score as the complex patient bonus. The Society believes that a complex patient bonus has the potential to address some of our concerns above that using claims to measure cost performance does not fully capture all aspects of providing high quality care at low cost.

ASH would like to work with CMS to ensure that this bonus works for all patient populations. For example, a very fit Medicare beneficiary without any other chronic conditions may require much more expensive therapy, while an older and unfit Medicare beneficiary with multiple chronic conditions (diabetes, renal failure, vascular disease) may only receive supportive care or outpatient chemotherapy (decitabine or azacytidine). The same can also occur in chronic lymphocytic leukemia (CLL), myeloma, or lymphoma, where a high HCC score selects patients who would get less expensive care and a low HCC score selects for patients who are fit and likely to get more complex care.

ASH would be happy to work with CMS to further study the best way to apply such a bonus to patients with hematologic malignancies and consider other options for scoring complexity. The Society feels that the cost performance category should not be implemented until this is addressed.

Quality Performance Category – Facility-Based Measurement

CMS is proposing to implement a facility-based scoring option on a limited basis in the 2018 performance year. The agency proposes for the 2020 MIPS payment year to include all the measures adopted for the FY2019 Hospital Value Based Purchasing (VBP) Program on the MIPS list of quality measures and cost measures. A clinician is eligible for facility-based measurement under

MIPS if they are determined to be facility-based as an individual if he/she furnishes 75 percent or more of his/her covered professional services in sites of service identified by the place of service (POS) codes used in the HIPAA standard transaction as an inpatient hospital (POS code 21) or an emergency room (POS code 23).

As stated previously, a major concern of ASH is the lack of meaningful measures available to our members. There are currently only four hematology specific measures included in the program, and most hematologists will not be able to apply all four to their practice. Therefore, including the option for a clinician to report on facility-based measures would likely benefit institution or academic based practices and ASH supports this proposal. However, this does not address the problem of a lack of meaningful measures and CMS must recognize the fact that specialists, especially those treating highly complex but orphan diseases, are facing the same obstacle to meaningful participation.

Quality Performance Category – Topped Out Measures

ASH understands CMS' concerns about the disproportionate impact topped out measures may have on a clinician's score and supports the agency's efforts to include meaningful measures that continue to accurately reflect a clinician's improvement or regression in their practice. As proposed, this methodology stands to benefit providers in large institutions whose groups have many applicable measures and easily substitute new measures for those that are deemed to be topped out. However, ASH urges CMS to consider this proposal's impact on solo practitioners and small practices, particularly those in specialties with few applicable measures like hematology. This is another situation where the lack of meaningful hematology measures may undermine our members ability to succeed in MIPS, and we urge CMS to work with ASH and other specialties in a similar position to expand the meaningful measures available to our members. We urge CMS to consider if there are alternative, applicable measures for those identified as topped out before removing them from the measures set.

Continuing Medical Education as an Improvement Activity

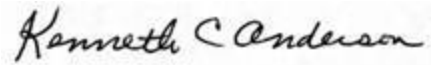
CMS proposes to recognize quality improvement-practice improvement (QI-PI) continuing medical education (CME) as an improvement activity within the Merit-Based Incentive Payment System (MIPS). Specifically, the proposed rule recommends that "completion of an accredited performance improving medical education program" be added under the list of Improvement Activities under MIPS in the QPP. ASH is supportive of this inclusion. CMS' decision marks an important step in ensuring that provider education is appropriately recognized as a critical tool in promoting better cost and performance outcomes and the Society strongly supports this decision.

CME is essential in advancing strategic outcomes while also providing flexibility to providers. With thousands of in-person and online courses offered across the country, physicians have access to a diverse range of educational materials that can reinforce existing best practices and help the healthcare industry adapt to the latest trends. These results are replicated in academic studies, suggesting that CME is essential in the process of lifelong learning and performance improvement that can have a significant, beneficial impact on patient outcomes.

In order to best accomplish the goals of the QPP, we encourage CMS to include in the final rule this provision that would ensure physicians are rewarded for their participation in accredited CME activities that involve the assessment of patient outcomes or care quality.

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