Ms. Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-5522-FC  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244  

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

Dear Ms. Verma:  

The American Society of Hematology (ASH) is pleased to offer comments on the final rule with comment period implementing the Medicare Access and CHIP Reauthorization Act (MACRA) (CMS-5522-FC).  

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 through bone marrow transplantation, and we continue to be innovators in the fields of 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 appreciates the many changes that were made to the new Quality Payment Program (QPP) in the final rule. The Society thanks the Centers for Medicare and Medicaid Services (CMS) for continuing to work to ensure that small and rural practices are able to meet the requirements of the QPP. ASH is supportive of the finalized proposal to increase the low volume threshold for eligible clinicians to exclude those with either a Medicare expenditure of $90,000 or less in Medicare Part B payments or 200 or fewer Medicare Part B beneficiaries. ASH also applauds the agencies’ willingness to continue to provide a level of flexibility to clinicians participating in the QPP and supports CMS finalizing the performance threshold at 15 points for the 2018 performance year and finalizing the proposal to provide additional flexibility through multiple submission mechanisms, which will be implemented for the 2019 performance year.  

The Society offers our comments on the provisions outlined below.  

Cost Performance Category  
ASH supported the proposal to maintain the weight of zero for the cost category for the second year of the program and was disappointed to see CMS finalize the weight at 10 percent for the 2018 performance year. 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. Hematologists treat patients with rare yet costly diseases and disorders. ASH members report scoring high on quality but also high on cost on Quality and Resource Use Reports (QRURs). Data shared with ASH from one institution participating in the Oncology Care Model shows that of 67 beneficiaries with
acute leukemia, only 24 were 20 percent or more under the target price; of 226 beneficiaries with chronic leukemia, only 85 were 20 percent or more under the target price; of 132 beneficiaries with myelodysplastic syndrome, only 58 were 20 percent or more under the target price; of 315 beneficiaries with multiple myeloma, only 119 were 20 percent or more under the target price; and of 448 beneficiaries with non-Hodgkin’s lymphoma, only 116 were 20 percent or more under the target price. The Society would be happy to meet with you to discuss these data.

These data are not a result of low quality care but rather an indication of the high cost of care for these patients. It shows why CMS must develop metrics that account for the complexity and cost of the care required by the patients treated by our members and other physicians who treat patients with other rare or high cost illnesses. For this reason, ASH cannot support the agency’s policy of weighting this category at 10 percent for the 2018 performance period and urges you to down weight this category until more work is done to ensure the measures of cost allow all physicians an equal opportunity to succeed.

**All-Payer Combination Option**

ASH supports the finalized proposal to allow eligible clinicians to participate in All-Payer Advanced Alternative Payment Model (APM) arrangements beginning in the 2019 performance period. The All-Payer Combination Option allows eligible clinicians to become Qualified Practitioners (QPs) through participation in a combination of Advanced APMs with Medicare and Other Payer Advanced APMs.

The Society views sickle cell disease (SCD) as an area ripe for the development of an innovative delivery and payment model and believes a Medicaid model would be most appropriate. Patients with sickle cell disease are high utilizers of health care services, frequenting the emergency department (ED) and routinely being admitted for inpatient hospital stays. The majority of these patients are covered by Medicare or Medicaid, or are dual-eligible. Unfortunately, there is little published data on SCD beneficiaries, but estimates from the Centers for Disease Control and Prevention show that about 50 – 60 percent of SCD patients (50,000 – 60,000) nationwide are on Medicaid, while there are about 20,000 SCD patients on Medicare. Few providers are able to specialize in SCD because of low reimbursement rates for Medicaid, in addition to a lack of education on how to treat the disease. ASH has launched a multifaceted "Call to Action" on SCD including educational efforts to educate and train hematologists and others on how to best treat this disease; however, the devastating physical burden of the disease, in addition to the dearth of providers, leaves this population with few options at this time. CMS’ approval of All-Payer Advanced APM arrangements brings us closer to developing a delivery and payment model for clinicians treating patients with SCD. We look forward to working with the agency to develop an innovative model of care to improve outcomes and the health of these patients.

**Inclusion of Part B Drugs**

ASH would also like to take this opportunity to express concern with the inclusion of Part B drugs in the application of penalties and bonuses under the Merit-based Incentive Payment System (MIPS). Unlike the bonuses and penalties assessed under the legacy quality reporting programs (the Physician Quality Reporting System, the Value-Based Modifier, and Meaningful Use), those in MIPS will be calculated based on all of a physician’s Part B payments, including those for Part B drug payments. The language in the MACRA statute does not exclude these drugs from the calculation. Many specialty physicians, including hematologists, 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. A recent analysis by Avalere shows that specialty physicians will be disproportionately impacted by inclusion of Part B drugs in the calculation for MIPS payment adjustments because these specialists bill for more Part B drugs than their counterparts in primary-care focused specialties. Additionally, members of both the US House of Representatives
and the US Senate sent letters to CMS in October 2017 asking the agency to exclude separately payable Part B drugs from the application of the MIPS adjustments.

ASH urges CMS to address this policy administratively and exclude the cost of Part B drugs from the calculation for the payment adjustment under MIPS.

**Physician-Focused Payment Model Technical Advisory Committee**

In the final rule, CMS decided to maintain the current definition of a Physician-Focused Payment Model (PFPM) to include only payment arrangements with Medicare as a payer, rather than expanding the definition to include Medicaid. As all-payer arrangements become available, ASH urges CMS to expand PTAC’s review process to include Medicaid.

Additionally, the Society supports the recent discussions within the health care community around allowing the Physician-Focused Payment Model Technical Advisory Committee (PTAC) to provide technical assistance to physicians and organizations creating and submitting ideas for new APMs. The rules and requirements for creating and qualifying as an Advanced APM are convoluted and confusing. While physicians play a vital role in this process, they do not have the expertise or the time to develop the technical aspect of these models. At a recent House Energy & Commerce Committee hearing, PTAC Chair and Vice Chair, Jeff Bailet and Elizabeth Mitchell, cited lack of technical assistance as one of three barriers to transforming care and payment. Specifically, they stated that “most physicians have experience changing care delivery but have not been trained in the development of incentives, payment models or risk management.” Additionally, they highlighted that small rural practices are especially lacking in the resources needed to afford technical support, and consequently to meaningfully participate in APMs.\(^1\)

Currently, PTAC is not authorized to provide technical assistance, and we hope this can change. The Society was recently one of dozens of signees on a letter led by the American Medical Association (AMA), which called on Congress to help make statutory changes to the Medicare Access and CHIP Reauthorization Act (MACRA), including urging Congress to authorize the PTAC to provide technical assistance to developers of APMs.

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 Suzanne Leous, ASH Chief Policy Officer at sleous@hematology.org or 202-292-0258, or Leslie Brady, ASH Policy and Practice Manager at lbrady@hematology.org or 202-292-0264.

Sincerely,

Alexis Thompson, MD, MPH
President

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