November 20, 2017

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

RE: Center for Medicare and Medicaid Innovation Request for Information

Dear Administrator Verma:

I am writing on behalf of the American Society of Hematology (ASH) regarding the Request for Information (RFI) for the Centers for Medicare and Medicaid Services (CMS) Innovation Center.

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 is pleased to see that through this RFI, the Innovation Center is seeking feedback on a new direction to promote patient-centered care and the testing of market-driven reforms that empower beneficiaries as consumers, provide price transparency, increase choices and competition to drive quality, reduce costs, and improve outcomes. ASH appreciates the opportunity to offer the following comments:

**Guiding Principles**

ASH recommends that specialty societies be among the public stakeholders that participate in partnerships and collaborations with the Center for Medicare and Medicaid Innovation (CMMI), as one of CMMI's guiding principles regarding “transparent model design and evaluation.” Many specialty physicians, including hematologists, treat patients with rare and costly disorders and diseases. As the Innovation Center continues to develop new models, it is imperative that specialty societies are involved. ASH recommends that efforts on approving alternative payment models include rare diseases, in order to ensure that care is improved for everyone, not just those with more common diseases. Individuals with rare diseases, such as sickle cell disease (SCD), often face more and greater complications, such as severe pain, stroke, acute chest syndrome, organ damage, and in some cases premature death.
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. Furthermore, 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 is focused on 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. As previously indicated in this letter, ASH sees SCD as an area of need for the development of an innovate payment and delivery model and is especially pleased to see that one of the eight areas of focus for the Innovation Center is on state-based and local innovation, including Medicaid-focused models. The Society believes that this type of model would be most appropriate for SCD and is eager to work with the Innovation Center to move this forward.

Also, it is important that the Innovation Center engage with providers when developing risk adjustment and patient attribution standards for all payment models. The outcomes and costs associated with treating patients with rare diseases should not be evaluated under the same methodologies as more common conditions in both the non-Medicare and Medicare populations, because these patients often require complex, expensive treatments by multiple providers. ASH looks forward to working with you to ensure that new models of care not only promote the best outcomes for these patients, but also assures that the risk structure of these models reflects the realities of delivering care.

**Potential Models**

*Expanded Opportunities for Participation in Advanced APMs*

CMS is seeking comments on ways to increase opportunities for eligible clinicians to participate in Advanced APMs and achieve threshold levels of participation to become Qualifying Participants (QPs). To do this, the Society strongly recommends that CMS recognize areas of physician expertise and patient need that are not represented by existing APMs. This includes hematologic diseases and disorders in coagulation, as well as severe hemoglobinopathies, such as sickle cell disease and thalassemia. ASH would be pleased to work with the Innovation Center to help develop a model or models that would fit for one or more of these diseases or disorders.

Furthermore, the Society encourages the Innovation Center to develop models that hold physicians accountable for factors they can change, such as hospital readmissions, rather than those they cannot, such as the cost of drugs. Our members who participate in the Oncology Care Model (OCM) struggle with this issue. To potentially succeed in the Oncology Care Model, physicians could cut costs by providing less effective, but also less expensive treatments, rather than higher quality therapies that may be more expensive. Physicians, however, want to provide good, evidence-based, high quality care, which in some cases may be more expensive. Unfortunately, by doing so under the OCM, they will get penalized for providing this more expensive, but more appropriate, care. As more specialty care models are developed, this issue must be addressed.
Physician Specialty Models

While ASH supports the development of innovative payment and delivery models, the Society cautions against creating models that silo care, and we urge the Innovation Center to consider mechanisms that facilitate the identification and connection of specialty societies that would benefit from collaboration. As the RFI indicates “one potential option may be to include specialty physician management of a defined population of beneficiaries with complex or chronic medical conditions, including multiple chronic conditions.” This description is similar to that of a Patient Centered Medical Home, of the Medical Home Model. This model of comprehensive, team-based care is appropriate for patients with sickle cell disease; however, this model would also fit well with many other chronic, complex conditions.

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 Advanced Alternative Payment Models (APMs). The rules and requirements for creating and qualifying as an Advanced APM are convoluted and confusing. While physicians are a vital voice 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 most likely lacking in the resources needed to afford technical support, and consequently to meaningfully participate in APMs. 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.

Prescription Drug Models

ASH has strong concerns about the overall cost of medical care and in particular the cost of drugs. Every day, hematologists encounter situations in which patients with medical insurance are having difficulty paying for expensive drugs. Given continuing advances in the identification and targeted treatment of particular blood cancers, there is usually little or no choice in the selection of chemotherapeutic agents for most conditions, many times leaving the provider with no option other than to prescribe expensive, but clinically vital treatments. Accordingly, ASH supports the testing of new models for prescription drug payment. In the development of such a model, the Society encourages CMS to explore the incorporation of risk-sharing agreements, clinical decision support tools, and value-based purchasing arrangements.

However, ASH reminds CMS that innovative payment models do not always work for every specialty across the board. For example, while episode bundles work well in clinical areas in which there is little deviation from a common practice, they would not work well for some hematologic conditions, where innovation has been rapid, and often comes in the form of new, expensive drugs or the combination of new drugs. For example, last year, the U.S. Food and Drug Administration (FDA) approved daratumumab in combination with bortezomib and dexamethasone or with lenalidomide and dexamethasone for patients with relapsed or refractory multiple myeloma. Additionally, FDA has approved several other stand-alone and combination therapies for
blood disorders in the past year. The cost of these new therapies, alone or in combination, can drive up costs significantly, and physicians should not be penalized or dis-incentivized for offering their patients state-of-the-art therapy in new payment models. Rather, payment models must incentivize physicians to provide the right treatment(s) at the right time. ASH welcomes the opportunity to work with the Innovation Center as models in this space are considered.

Program Integrity
The RFI states that “CMS is seeking comment on ways that CMS may reduce fraud, waste, and abuse and improve program integrity.” ASH continues to be concerned about the issue of reducing the administrative burdens on physicians; we appreciate that especially in the last year the Administration has made regulatory relief a priority. ASH is a member of the Cognitive Care Alliance, which urges revision of the current medical documentation guidelines for Medicare’s evaluation and management (E/M) codes. This offers an opportunity for CMS to provide an immediate and substantial reduction of administrative burden for all practicing physicians.

The guidelines for E/M documentation were last updated in 1997, before the widespread adoption of electronic health records (EHRs). The conventional auditing tools used for patient EHR design were originally developed to distinguish between the work intensity levels for the E/M service codes. EHRs evolved to become electronic versions of the paper based office notes of the 1990s, with enhancements specifically designed to fulfill auditing requirements. In order to optimize billing, software institutionalized the various information categories used for chart audit.

Unfortunately, EHR documentation has not kept pace with the intricacies of rare diseases, the comorbidities often associated with them, and the unprecedented pace of new treatment modalities. We would be pleased to work with CMS to devise nuanced E/M codes to more accurately capture the work involved in the complex management of hematologic patients.

Physician and provider interaction studies have consistently shown that EHRs have led to a decline in physician satisfaction, time with patients, and patient satisfaction, as well as increases in burnout. Current EHRs are often filled with extraneous information that does not accurately describe the care of the patient or provide a meaningful summary of clinical thinking.

Existing E/M documentation expectations fail to capture the cognitively intense work of services delivered by hematologists and other cognitive physicians. The linear nature of the current coding/auditing mandate means that “elements” (inputs and outputs) count once, if they count at all. There is no accounting for the interactivity of elements and the complexity that emerges as elements accumulate. Additionally, there is no recognition of the clinical expertise achieved with years of training and experience that creates the ability to instantly recognize a pattern and make a diagnosis of enormous clinical value in a matter of moments.

ASH is concerned about the profound deficiencies of the E/M codes as well as the associated documentation requirements. These codes do not accurately define discrete levels of cognitive service, do not capture the broad range of services, and undervalue the critical role that complexity and physician-patient interaction demand in ensuring the safe provision of high quality healthcare services to patients.

We believe that improving the documentation expectations for E/M services must be linked to correcting the legacy deficiencies in both definition and valuation of these services. There has been
no adjustment in the definitions and only incremental changes in their valuations, since the development of the Resource Based Relative Value Scale (RBRVS), despite the increasingly complex and interacting medications and health care conditions presented by Medicare beneficiaries. There is demonstrably more work involved than 25 years ago due to the intense E/M services delivered by our members. Despite their best efforts, CMS has not been able to address this issue. While the agency has failed to act, we are concerned about a potential for a significant workforce shortage in hematology because of the burnout, low work satisfaction, and the undervaluation of the services our members provide.

Addressing the unnecessary administrative burden created by the existing E/M documentation guidelines offers an opportunity to substantially improve the face-to-face experience of care, from both patient and physician perspectives. Revising and improving the documentation expectations allows the existing service codes to be reworked in ways that match the current content of E/M service delivery. ASH believes that this process should begin with the development of a representative knowledge-base that will then lead to a better definition of the discrete levels of E/M services. We urge CMS to conduct the research necessary to redefine and revalue cognitive E/M services, as we believe that this will not only improve the accuracy and precision of the fee schedule, but will also reduce the burden on cognitive physicians. ASH would be pleased to assist with this effort.

Thank you for the opportunity to provide feedback. We welcome the opportunity to discuss these comments and others being considered with you and your team. If you have any questions or require further clarification, please contact Suzanne Leous, ASH Director of Government Relations and Practice 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,

Kenneth C. Anderson, MD
President