September 24, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-P
7500 Security Boulevard
Baltimore, MD 21244

SUBMITTED ELECTRONICALLY VIA http://www.regulations.gov

Re: Medicare Program; Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model (CMS-1695-P)

Dear Administrator Verma:

The American Society of Hematology (ASH) is pleased to offer comments on the proposed rule outlining revisions to the Hospital Outpatient Prospective Payment System. We appreciate the opportunity to provide these comments to the Centers for Medicare and Medicaid Services (CMS) on the provisions impacting our members.

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 offers comments on the issues outlined below, which are of particular importance to the Society’s members:

1. Request for an Autologous Transplant Comprehensive APC (C-APC)
2. Status Indicators and APC Assignments for Chimeric Antigen Receptor T-Cell (CAR-T) Therapy Category III CPT Codes
3. Request for Information on a Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

Request for an Autologous Transplant Comprehensive APC (C-APC)

ASH appreciated the introduction of a C-APC for allogeneic stem cell transplant in CY
2017 and believes a similar strategy should be pursued for autologous transplant, which is used frequently to treat blood cancers, such as leukemia or lymphoma. Since the inception of C-APCs, CMS has requested input on additional types of services and significant procedures that would lend themselves well to a C-APC, due to the existence of a primary procedure that is provided on the same date of service as other ancillary, supportive, and adjunctive services. This is indeed the case with autologous stem cell transplant since other separately payable procedures, as well as packaged items and services including supplies and laboratory tests, are typically provided on the same day allowing it to fit well within the CMS C-APC paradigm. By creating a new autologous transplantation C-APC, CMS would further its own goal of having larger bundles of services while simultaneously improving its overall rate-setting process by being able to use all autologous claims for rate-setting.

As CMS studies the claims data, it will see that the services associated with autologous stem cell transplant (such as laboratory tests) are typically provided on the same day as the transplant service. By using all of the claims associated with autologous stem cell transplant, CMS will gain a more complete picture of the services associated with transplant, better understand the overall cost, and be able to more appropriately reimburse hospitals for this important and life-saving service. The Society strongly encourages CMS to create a C-APC for autologous stem cell transplant as an interim final decision for CY 2019.

**Status Indicators and APC Assignments for Chimeric Antigen Receptor T-Cell (CAR-T) Therapy Category III CPT Codes**

ASH supports the recommendation by the CMS Advisory Panel on Hospital Outpatient Payment to change the status indicators for the new Category III CAR-T CPT codes from “B” to “S,” and cross-walk these codes to the stem cell transplant APCs. While CAR-T is NOT stem cell transplant, we recognize that, in the absence of coded claims data, CMS has to make the best assignment based on clinical and resource homogeneity. We believe that the assignment of these services to these APCs resembles CMS’ decision to assign CAR-T therapy to autologous stem cell transplant MS-DRG 016.

The Society also supports CMS’ outpatient policy staff working closely with the agency’s HCPCS Coding Department to adopt the recommendations made by many of the public presenters, including ASH staff, at the May 2018 HCPCS meeting about the CAR-T product Q-codes, Q2040, and Q2041. ASH requests that CMS remove clinical services from the definition of the CAR-T product Q-codes so that the codes’ descriptions reflect only the product. This will allow hospitals and health systems to accurately report the services when they are provided to patients and also ensure that CMS receives accurate data.

We believe status indicator “S” for separately payable procedures is appropriate, since these are codes representing new services. By assigning a payable status indicator, CMS will enable hospitals to bill and be paid appropriately for the services they provide during each step of the CAR-T process, regardless of when or where the service is rendered. Streamlining the coding and billing of new services and instructing providers on how to code and bill correctly is critical in order for providers to be paid appropriately both today and in the future.

**Request for Information on a Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model**
The proposed rule includes a request for information (RFI) seeking public comment on developing a model program to test private market strategies to accelerate the move to a value-based system building on CMS’ Competitive Acquisition Program (CAP). CMS is seeking input on how a program could be structured for high-cost therapies, which would include value-based pricing strategies. In the recently released Inpatient Prospective Payment System Final Rule, the RFI in this rule was referenced as a way to develop a strategy on CAR-T therapy payment. The Society is acutely aware that CAR-T therapy is costly, with the current products priced at $373,000 and $475,000, and understands and supports efforts to control costs in the Medicare program. However, after discussions with ASH members, the Society feels strongly that a CAP model is not appropriate for CAR-T therapy payment for the following reasons:

First, CAR-T therapy is an evolving area of medicine. With over 400 clinical trials in process, additional products are expected on the market as soon as 2019. The currently approved therapies are individualized as described above, but clinical trials are underway to develop allogeneic universal or “off-the-shelf” CAR T-cells. It is inappropriate to use a CAP model at this time when we do not yet know what other products will be approved, when, and if they will continue to be personalized or universal.

Secondly, the CAP model as described in the proposed rule is specific to the Part B setting and therefore, is not site-neutral. The vast majority of CAR-T patients receive the therapy in the inpatient setting. Even if these individuals receive the transfusion in the outpatient setting, a significant percentage will be admitted to the inpatient setting within 24-72 hours due to severe adverse events, and thereby, transforming the outpatient administration claims to inpatient claims. The Society is concerned about the financial incentivization to shift CAR-T patients to the outpatient setting that has been created by the current inpatient payment structure. Financial incentivization to a specific care setting for a new technology could result in hasty site of care transitions that may not be in the best clinical interests of the beneficiaries needing treatment or the financial well-being of the Medicare program. ASH’s response to the proposed IPPS rule included a site-neutral payment solution to cover the product cost with a pass-through payment. We recognize that CMS was not prepared to do that at this time; however, we encourage CMS to develop a value-based framework that is site-neutral.

Lastly, any value-based payment model must also account for the cost of care and the CAP only accounts for the cost of the therapy. It is common for individuals receiving CAR T-cell therapy to experience adverse events. These adverse events are usually manageable but do increase the cost of this treatment as patients are typically required to be admitted as inpatients, often in the intensive care unit, until these side effects are resolved.

ASH urges CMS not to implement a CAP model for CAR-T therapy for the reasons stated above. Furthermore, the Society believes practitioners and CMS’ experiences with this therapy are so limited at this point that it is premature to create any value-based purchasing program for this treatment. We welcome the opportunity to work with CMS as more products come to market and we gain additional experience to develop a value-based purchasing program that best meets the needs of patients and providers.

Thank you for the opportunity to provide comments on the proposed rule outlining revisions to the Hospital Outpatient Prospective Payment System for 2019. We welcome the opportunity to discuss these proposals, and other 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 202-296-0264.

Sincerely,

Alexis Thompson, MD, MPH
President