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Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (CMS-1678-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 and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs for 2018.

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 looks forward to working closely with the Centers for Medicare and Medicaid Services (CMS) as the agency implements this proposed rule and offers the following comments which focus on areas of particular importance to our members:

1. 340B Drug Pricing
2. Packing of Low Cost Drug Administration Services
3. Bone Marrow Transplants – Hematopoietic Cell Harvesting

340B Drug Pricing

CMS is proposing to reduce payments for separately payable drugs and biologicals acquired under the 340B program from the current payment rate of average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. CMS is seeking comments on whether certain hospitals (rural, sole community, or PPS-exempt cancer hospitals) or certain types of drugs, such as blood clotting factors, should be excluded from the reduced payment.

The 340B program provides covered entities access to discounts on outpatient drugs and

was created to help certain safety-net providers stretch federal resources in order to better serve low-income, uninsured and medically vulnerable patients. As an organization of physicians and scientists who care for desperately ill patients, including those with blood cancers such as leukemia, lymphoma, and myeloma, as well as those with non-malignant conditions such as hemophilia, sickle cell disease, thalassemia, thrombophilia, and various anemias, ASH is supportive of efforts to ensure patients have access to safe and effective hematologic drugs. High drug prices continue to be a major issue facing patients with hematologic conditions and ASH continues to identify and advocate for ways to limit patient out-of-pocket expenses.

Given the 340B program's focus on low-income patients, it is imperative to ensure that an across the board 22.5 percent reduction in reimbursement does not create barriers for patients to access drugs if providers are unable to cover their actual acquisition costs. And, while this policy alters the relative disparity between payments for some hospital outpatient departments (HOPDs) and physician practices, it still does not address the persistent challenges physician practices face in obtaining payment that covers acquisition costs. ASH has strong concerns with this proposal and the Society urges CMS to first and foremost consider the patient and to not take action that could create barriers to access to care.

CMS does give consideration to certain exemptions that would have a direct impact on patients with hematologic diseases and disorders, both malignant and non-malignant. Therefore, if this proposal goes through, we think exemptions should be made for rural, sole community, and PPS-exempt cancer hospitals as well as blood clotting factor.

Treatments for a number of blood diseases and disorders, including chemotherapy agents and treatments for hemophilia known as clotting factor therapies are extremely expensive. The cost of many of these treatments can exceed \$10,000 a month, resulting in extremely high and unmanageable out-of-pocket costs for many patients. Reducing reimbursement for drugs acquired under the 340B program would have a significant impact on access to care for cancer patients receiving treatment at rural and cancer hospitals that are currently 340B covered entities.

Hemophilia is a rare disorder affecting less than 20,000 individuals in the US. The care for the majority of these patients is provided at a small number of hospitals (around 135) that have Hemophilia Treatment Centers (HTCs). HTCs receive federal grants from the Maternal and Child Health Bureau and are eligible to participate in the 340B drug discount program as grantees. The HTCs significantly rely on the savings from drugs purchased under the 340B program to provide life-saving blood clotting factors to the patients they serve, which frequently cost more than \$200,000 a year for a patient with the severe form of the disease. Studies have shown that HTCs have a significant effect on reducing mortality in patients with hemophilia.

Again, the Society urges CMS to not take action that could create barriers to access to care. For the reasons stated above, ASH supports the exemptions for rural, sole community, and PPS-exempt cancer hospitals as well as blood clotting factor, and is happy to work with CMS to address the challenges faced by physician practices and HOPD's when reimbursement does not cover drug acquisition costs.

Packaging of Low Cost Drug Administration Services

In the proposed rule for CY2018, CMS proposes to conditionally package low-cost drug administration services when they are performed with another service. CMS proposes to package

Level 1 and Level 2 Drug Administration (APCs 5691 and 5692, respectively), except for selected add-on HCPCS codes and preventive service codes within these APCs. The agency states that it believes this proposal will foster a more consistent approach to packaging and “promote equitable payment between the physician office and the hospital outpatient department.”

ASH disagrees that CMS’ proposal to package low-cost drug administration services will promote equitable payment between the physician office and hospital outpatient department given that all drugs and drug administration services are separately paid for in the physician office setting. In the proposed rule, CMS states its belief that hospitals can receive separate payment for clinic visits and drug administration services, and that physicians are not allowed to receive payment for an office visit when a drug administration service is provided.

However, CMS’ own National Correct Coding Initiative (NCCI) edit manual clearly states that physicians are allowed to report and be paid for both a drug administration service and an office visit (except for the lowest-level office visit represented by CPT code 99211) during the same encounter. This is allowed if the office visit is medically necessary, significant, and separately identifiable. In addition, we note that all drugs are separately paid in the physician office setting. For these reasons, we fail to see how CMS’ proposal to package low-cost drug administration services could ever result in equitable payment. In fact, all it will do is to increase the payment differential that already exists between the two settings.

Additionally, ASH disagrees with CMS’ assertion that low-cost drug administration services are similar to other low-cost ancillary services that CMS traditionally packages. We also do not agree that these services are “adjunctive, supportive, or dependent to” a primary procedure in the way other ancillary services are. Instead, we strongly believe that low-cost drug administration services, like all drug administration services, are separate and distinct and should continue to receive separate payment.

Again, we can look to CMS’ NCCI edit manual, which contains hundreds upon hundreds of code pairs involving the very same low cost HCPCS drug administration codes that CMS now proposes to conditionally package. These NCCI code pairs identify services that are related such that they typically cannot be billed together during the same encounter. In some cases the services can never be billed together; in others, a modifier must be used when they are billed together to alert CMS that this is clinically appropriate. Hence, CMS’ own coding initiative already addresses packaging of drug administration services when they are supportive, dependent or adjunctive to another primary service. ASH believes that, even when low-cost drug administration services are provided with other services, they represent a separate and distinct service that should remain separately payable. It is unnecessary for CMS to introduce another element of non-payment through the OPPS concept of packaging.

Furthermore, given the fact that so many drugs are already packaged under the OPPS, including a large number of oncology drugs, we do not support the proposal to add another layer of packaging that would impact drug administration services. Such a change should only be made after CMS conducts an in-depth analysis of the impact this “packaging on top of packaging” would have on drug administration and other APCs. We strongly believe that massive distortions are likely to occur if CMS proceeds with its proposal.

Lastly, the combination of CMS’ proposal and existing CPT facility coding hierarchy rules are likely to result in some low-cost chemotherapy drug administration services being packaged into services

such as hydration or therapeutic infusion. This would create significantly distorted payment rates. We cannot imagine any circumstance under which CMS would package a chemotherapy injection and a packaged chemotherapy drug into hydration—yet that is exactly what will occur if CMS finalizes this proposal.

ASH urges CMS to abandon its proposal to package low cost drug administration services; the Society recommends that the agency continue to pay separately for them.

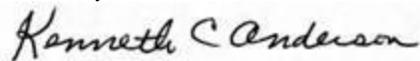
Bone Marrow Transplants – Hematopoietic Cell Harvesting

ASH appreciates CMS' attention to outpatient payment of Hematopoietic stem cell transplantation (HSCT) in the CY 2018 OPSS proposed rule and the CY 2017 OPSS Final Rule. In the proposed rule, we noticed that CMS shifted the CPT code 38205 status indicator from "B" to "S". While we support CMS' efforts to promote consistency in reporting donor search and cell acquisition costs, we request that CPT code 38205 remain assigned to status indicator "B," as it has been since 2010, instead of the proposed shift to status indicator "S".

CPT code 38205 describes blood-derived hematopoietic progenitor cell harvesting for transplantation and represents the donor acquisition cost for an allogeneic hematopoietic cell transplant. CMS billing guidance instructs that all services provided to the donor must be held and reported through revenue code 0815 (previously 0819) on the recipient's transplant claim. As recommended by this year's Advisory Panel on Hospital Outpatient Payment (HOP), maintaining status indicator "B" provides indication that CPT code 38205 cannot be reimbursed separately and avoids the potential for erroneous and inappropriate billing to a donor. Additionally, we encourage CMS to look at the entire series of donor-related CPT codes to ensure consistency with billing guidance.

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 questions or require further clarification, please contact Leslie Brady, ASH Policy and Practice Manager, at lbrady@hematology.org or 202-292-0264.

Sincerely,



Kenneth C. Anderson
President