Advancing Transfusion and Cellular Therapies Worldwide

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American Red Cross

October 1, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1736-P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted Electronically Via http://www.regulations.gov

RE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned Hospitals (CMS–1736–P)

Dear Administrator Verma:

AABB, America's Blood Centers and the American Red Cross appreciate the opportunity to submit comments in response to the Centers for Medicare & Medicaid Services' (CMS) Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems proposed rule for calendar year 2021. Collectively, our organizations represent the nation's blood collection establishments, transfusion services, and transfusion medicine professionals. Our comments focus on CMS' proposal to revise the status indicator assigned to the miscellaneous Healthcare Common Procedure Coding System (HCPCS) code P9099 (Blood component or product not otherwise classified).

Our organizations appreciate that CMS established HCPCS code P9099 to enable providers to report unclassified blood products. As recognized by CMS, "the importance of miscellaneous codes is that they allow suppliers to begin billing immediately for a service or item as soon as it is allowed to be marketed by the Food and Drug Administration (FDA), even though there is no distinct code that describes the service or item."[1] Consistent with this acknowledgment, CMS recognizes in the proposed rule concerns shared by our organizations the status indicator initially assigned to P9099 – "E2" (Not payable by Medicare when submitted on an outpatient claim) – would be problematic since hospitals would not receive payment when they use unclassified blood products and claim lines billed with P9099 would be rejected by Medicare, thereby preventing providers from tracking the utilization of unclassified blood products.

AABB, America's Blood Centers and the American Red Cross support CMS' proposal to assign P9099 a status indicator of "N," which would allow providers to report the cost of unclassified

[1] Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures. Nov. 29, 2018. Accessed 12/6/2018 at: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf.

blood products. As a result, unlike other blood products, the cost of unclassified blood products would be packaged into their affiliated primary medical procedure. While we support this temporary approach to enable immediate billing of new items and services, we request that CMS work with manufacturers and the blood community to expeditiously establish new billing codes and provide separate payments for these blood products and services in the hospital outpatient setting. These distinct payments recognize the important role blood and individual blood products play in caring for a wide range of patients and are needed to account for the increasing cost of critical blood safety measures provided by blood centers.

In contrast, we do not believe that CMS should set a payment rate for P9099 at the rate of the lowest cost blood product (P9043 (Infusion, plasma protein fraction (human), 5 percent, 50 ml), which has a proposed payment rate for 2021 of $8.02 per unit. This de minimis payment rate could have the unintended effect of discouraging the adoption and implementation of new items and services, which would be contrary to the intent of establishing a miscellaneous code.

Finally, we request that CMS continue to work with manufacturers and the blood community to establish timely reimbursement pathways for new technologies. For example, in September 2019, FDA issued a final guidance, "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion." [2] The final guidance offers options to achieve enhanced safety of platelets for transfusion. The additional costs associated with some of the methods of compliance with this guidance are already addressed through existing OPPS payment policies. In May 2020, FDA provided clearance for bacterial detection by large volume delayed sampling (LVDS). Our organizations look forward to working with CMS to ensure that reimbursement pathways exist for all blood products and tests that are necessary as a result of FDA guidances.

If you have any questions, please contact Leah Stone (301-215-6554, lmstone@aabb.org), Diane Calmus (202-654-2988, dcalmus@americasblood.org) or Liz Marcus (202-303-7980, liz.marcus@redcross.org).

Sincerely,

Debra BenAvram
Chief Executive Officer
AABB

Kate Fry
Chief Executive Officer
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J. Chris Hrouda
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[2] Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bacterial-risk-control-strategies-blood-collection-establishments-and-transfusion-services-enhance. Accessed September 22, 2020.