September 13, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1772-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; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; (CMS-1772-P)

Dear Ms. Brooks-LaSure:

The Association for the Advancement of Blood & Biotherapies, America's Blood Centers and the American Red Cross appreciate the opportunity to submit comments in response to Centers for Medicare & Medicaid Services' (CMS) Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems proposed rule for calendar year 2023. Collectively, our organizations represent the nation's blood collection establishments, transfusion services, and transfusion medicine professionals.

Our organizations appreciate that CMS established Healthcare Common Procedure Coding System (HCPCS) code P9099 to enable providers to report the use of unclassified blood products. As a result of the unique nature of the blood supply, we recognize the challenge faced by CMS in identifying the appropriate status indicator for this code. We thank CMS for their continuing work to identify the appropriate payment methodology as evidenced by the proposal to increase the payment rate of $7.79 to $56.58 for HCPCS code P9099.[1] Unfortunately, this payment rate does not represent the cost of commonly used existing products and is insufficient to cover the expected costs of innovative new products. Additionally, this level of payment is likely to create a financial barrier for providers offering new and innovative blood products to Medicare beneficiaries.

We propose that CMS adopt one of two alternative solutions: (1) change the status indicator assigned to HCPCS code P9099 (blood not otherwise classified [NOC]) to "F" to authorize A/B MACs to pay hospitals on the basis of reasonable cost; or (2) assign Q-codes to new blood products and adopt an expedited review of coding and payment policies for novel blood products.

[1] The previous rate of $7.79 was based on a HCPCS code that has not been used for over a decade, whereas the current proposal is based on a rarely ordered product, the fifth lowest cost blood product.

HCPCS P9099 Code Status Indicator Change to "F" (Payment at Reasonable Cost)

We are concerned that Medicare beneficiaries may not have access to innovative blood products due to the disparity between the reported costs billed to P9099 and CMS' proposed payment rate. According to the CMS CY 2023 NPRM Drug Blood and Brachy Costs Statistics data file, in CY 2021, a total of 87 blood product units were billed to HCPCS code P9099 and unit costs ranged from $263.50 to $796.95 with an arithmetic mean of $430.03 and a geometric mean unit cost of $419.48. The lowest cost blood product billed to code P9099 was more than $200 over CMS' proposed payment rate for P9099. Additionally, the geometric mean unit cost for all 87 units billed to code P9099 was over $360 higher than the proposed payment rate. This suggests that the current blood products billed using P9099 have costs that are much higher than the $56.58 proposed payment rate, and are similar to the costs of red blood cells and apheresis platelet products utilized in outpatient hospital settings. CMS can ensure that hospitals are adequately compensated for providing Medicare beneficiaries with new and innovative blood products by reimbursing P9099 on a reasonable cost basis.

Additionally, payment based on reasonable cost would not create a greater incentive for overutilization than the existing individual HCPCS blood product codes. The OPPS is not currently designed to create meaningful cost management incentives for blood products, injectable drugs, or biologicals assigned product-specific APCs that are separately paid based on ASP or claims-based cost data (blood products).

Assign HCPCS Q-codes for Novel Blood Products

As an alternative to changing the HCPCS Code P9099 status indicator to "F", our organizations ask that CMS expedite the review process for establishing codes and payment rates for newly approved blood products. Similar to drugs and biologics, CMS should review the HCPCS applications for novel blood products quarterly, which would allow for more frequent and timely updates. CMS should assign novel blood products temporary Q-codes, which should be effective the next quarter. These temporary Q-codes should be cross-walked to the most appropriate established code and would provide hospitals with the ability to bill for new blood products that do not yet have a permanent code or are awaiting assignment to a permanent P-code. CMS should assign the new blood products a permanent P-code as soon as possible.

We appreciate that CMS established HCPCS code P9099 in recognition of the fact that there must be some mechanism by which new blood products can be billed. Our organizations believe that reimbursement should adequately reflect the adoption and implementation of innovative blood products and be in line with the policy the U.S. Department of Health and Human Services outlined in Adequacy of the National Blood Supply: Report to Congress 2020. "The payment system for blood components needs to encourage public and private investments and enhance necessary improvements in safety. This must include the costs of innovation for implementing new mandated regulatory requirements for safety, for developing improved blood components, and for utilizing new blood therapies." Additionally, we continue to urge CMS to work with manufacturers and the blood community to educate providers on how to bill for new blood products and to expeditiously establish new billing codes and provide separate payments for these blood products and services in the hospital outpatient setting.

Thank you for the opportunity to provide comments on the proposed rule. If you have any questions, please contact Susan Leppke (301-547-3962, sleppke@aabb.org) Diane Calmus (202-654-2988, dcalmus@americasblood.org) or Liz Marcus (202-303-7980, liz.marcus@redcross.org).

Sincerely,

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