December 2, 2019

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1717-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

**Re: Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (CMS-1717-FC)**

Dear Administrator Verma:

AABB, America's Blood Centers and the American Red Cross are pleased to submit comments to the Centers for Medicare & Medicaid Services (CMS) in response to the final rule with comment period updating the Medicare hospital outpatient payment system for 2020. In response to a request supported by our organizations, CMS established HCPCS code P9099, a miscellaneous code for blood components and products. While we appreciate that CMS created this code, the status indicator that CMS assigned to the code is quite problematic. Specifically, we are concerned that status indicator "E2," which CMS assigned to P9099, nullifies the intent of the new code since it precludes hospitals from being compensated for the costs of a blood component or product billed with HCPCS P9099.

As CMS acknowledges in the Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures, "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***. A miscellaneous code may be assigned by insurers for use during the period of time a request for a new code is being considered under the HCPCS review process…."[1] CMS explains that, "claims with miscellaneous codes are manually reviewed, the item or service being billed must be

[1] Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures, *available at* https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/2018-11-30-HCPCS-Level2-Coding-Procedure.pdf (last visited November 15, 2019) (emphasis added).

clearly described, and pricing information must be provided along with documentation to explain why the item or service is needed by the beneficiary."[2]

In contrast, the "E2" status indicator, which is intended for items, codes and services for which pricing information and claims data are not available, specifies Medicare non-payment when submitted on outpatient claims. In addition, when CMS first implemented status indicator "E2" in the CY 2017 final rule updating the Medicare hospital outpatient payment policies and rates, the Agency specified, "… we are assigning edit 13 to status indicator 'E2' items and services. ***This edit will result in a line item rejection. A line item rejection is when a line has reached a final disposition with no payment for a reason other than medical necessity under section 1862(a)(1) of the Act.***"[3]

Thus, assignment of the "E2" status indicator to P9099 is clearly inconsistent with the intended benefit of the new miscellaneous/NOC blood product code. The "E2" status indicator is problematic since (1) it will result in a line item rejection of the item billed with the code; (2) hospitals will experience frustration and increased administrative burden due to receiving a line item rejection; (3) hospitals may stop using P9099 when they realize the code results in a line item rejection; (4) some hospitals' billing software might not allow the code to be used since if a hospital tries to bill P9099, the code will be rejected; and (5) the pricing data submitted with the code will be lost by the Medicare program, and will not be able to be used for future rate setting purposes.

As CMS is aware, under the Medicare hospital outpatient prospective payment system, the Agency "makes separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered." CMS' longstanding methodology uses the most recently available hospital cost reports to set payment rates for blood and blood products.[4]

Thus, we respectfully request that, effective January 1, 2020, CMS revise the status indicator assigned to HCPCS P9099 to support the intent of miscellaneous codes by enabling immediate billing for newly approved blood products and technologies. In addition, we believe the status indicator assigned to the code should be aligned with CMS' reimbursement policy for blood and blood products by allowing for separate (i.e., not bundled) reimbursement for these new blood products and technologies, and facilitating the collection of pricing data, which can be used for future rate setting purposes.

AABB, America's Blood Centers and the American Red Cross believe that the miscellaneous code for blood components and products, if assigned to a different status

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[2] *Id.*
[3] 81 Fed. Reg. 79562, 79731 (Nov. 14, 2016).
[4] 84 Fed. Reg. 61142, 61154 – 61155 (Nov. 12, 2019)

indicator, has the potential to begin to address current challenges that result from delays between FDA's approval of a product or technology and CMS' establishment of a billing code for the same product or technology.

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,

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