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American Red Cross

September 26, 2019

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

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Proposed Rule (CMS–1717–P)

Dear Administrator Verma:

AABB, America's Blood Centers and the American Red Cross welcome the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) in response to the proposed rule related to the hospital outpatient prospective payment system (OPPS) published in the Federal Register on August 9, 2019. Collectively, our organizations represent the nation's blood collection establishments, transfusion services, and transfusion medicine professionals. Our comments focus on CMS' proposals related to the laboratory date of service (DOS) policy as well as reimbursement for blood products.

We urge CMS to finalize the proposal to exclude from the laboratory DOS policy exception blood banks and blood centers and to clarify that all molecular testing performed by blood banks and blood centers is excluded from the policy exception.

Our organizations strongly support CMS' proposal to exclude blood banks and blood centers from the laboratory DOS policy exception at 42 C.F.R. 414.510(b)(5). We believe that excluding blood banks and blood centers from the laboratory DOS policy exception will ensure that Medicare beneficiaries continue to have timely access to important, specialized molecular tests performed by these entities.

We concur with CMS' reasoning that blood banks and blood centers typically perform molecular testing to identify the most compatible blood product for a patient, which enables hospitals to prevent adverse conditions associated with blood transfusions. Examples of molecular testing performed by blood banks and blood centers include red blood cell genotyping (HCPCS codes 81403and 0001U) and platelet antigen genotyping (HCPCS code 81105). We strongly believe that hospitals should be permitted to continue billing and receiving payment for

such testing performed to support safe blood transfusions. Blood centers and blood banks performing the tests should be allowed to continue seeking payment from the hospital.

We recommend that CMS revise the proposed definition of "blood bank and blood center" to "an entity whose primary function is the performance or responsibility for the performance of, the collection, processing, testing, storage and/or distribution of blood or blood components intended for transfusion and transplantation." CMS' proposed definition - "an entity whose primary function is the collection, storage and dissemination of blood products" - omits "processing" and "testing" which are two critical, unique functions performed by blood centers. Our revised definition clearly defines the role of blood banks and blood centers, distinguishes these entities from other types of laboratories and is consistent with the definition used by AABB, which accredits the activities conducted by blood centers and blood banks.

In addition, we urge CMS to clarify that all molecular testing performed by blood banks and blood centers, such as molecular testing for red blood cells, white blood cells and platelets, is excluded from the laboratory DOS policy exception. Most blood centers do not currently bill Medicare as laboratories and lack the infrastructure, resources and expertise in their Finance/Billing departments to engage in direct third-party billing for laboratory services. In general, they do not currently obtain information, such as patients' insurance information, discharge information, or ICD-10 code(s), which would be necessary for determining if the hospital or the blood center should bill for testing. Blood centers are facing significant financial challenges and do not have the resources to absorb potential burdens resulting from the applicability of the laboratory DOS policy exception.[1] Thus, requiring blood centers to comply with the laboratory DOS policy exception would create considerable burdens and has the potential to cause delays and jeopardize Medicare beneficiaries' access to care. We believe that requiring hospitals to identify which molecular tests performed by blood centers are subject to the DOS policy exception would create an undue burden on Medicare beneficiaries.

Finally, we do not believe that CMS should determine the applicability of the DOS policy exception for tests performed by blood banks and blood centers based on the ordering physician's determination of whether the results of a molecular test are intended to guide the treatment provided during a hospital outpatient encounter. We believe that this requirement has the potential to create new burdens and lead to delays in the ordering and the downstream testing of samples. Additionally, it has the potential to create confusion among blood centers and blood banks and hospitals regarding which entity is responsible for billing Medicare, and this confusion has the potential to result in erroneous billing. Therefore, we do not believe that ordering physicians (whether the patient's physician or the transfusion service medical director) should determine the applicability of the date of service policy exception for molecular testing performed at blood banks and blood centers.

In summary, our organizations strongly support CMS' proposal to exclude from the laboratory DOS policy exception blood banks and blood centers and request that CMS clarify

[1] Klein HG, Hrouda JC and Epstein JS. Crisis in the Sustainability of the U.S. Blood System. *New England Journal of Medicine* volume 377 #15, 2017 pp1485-1488

that all molecular testing performed by blood banks and blood centers is excluded from the policy exception.

The proposed reimbursement rate for pathogen reduced platelets (P9073) is erroneous. We ask that CMS continue to crosswalk P9073 to P9037 (leukoreduced, irradiated apheresis platelets) for 2020 and 2021 to help ensure that pathogen reduced platelets remain accessible to Medicare beneficiaries.

CMS' proposed rate for pathogen reduced platelets (P9073) for 2020 is based on flawed data and has resulted in a payment rate far too low. Unfortunately, the 2017 claims data for pathogen reduced platelets from four high-volume hospitals, which collectively submitted a substantial portion of the OPPS claims for pathogen reduced platelet units, was erroneous. CMS recognized in the 2019 OPPS final rule that "there indeed may have been confusion about billing that has led to aberrancies in the data we have available for ratesetting."[2] As a result, for 2019, CMS continued to crosswalk P9073 to the code for leukoreduced, irradiated apheresis platelets (P9037), acknowledging that P9037 was the closest proxy to the expected payment rate for pathogen reduced platelets.

CMS proposed to establish the 2020 payment rate for pathogen reduced platelets using 2018 claims data. Since the 2017 erroneous claims data was not identified until late in 2018, the same mistake that was in the 2017 data is reflected in the 2018 claims data. In addition, since pathogen inactivation is a relatively new technology, the volume of claims for 2018 remains relatively low. It is our understanding that Medicare reported 4,687 pathogen reduced platelet units billed under the OPPS in 2018, which is higher than the number of units reported in 2017 and reflects the adoption of a new technology.

Approximately 30 percent of the 2018 OPPS claims for pathogen reduced platelet units reported a cost for each unit that was at least $100 below their reported cost for leukoreduced, irradiated apheresis platelets (P9037). As we explained in our comments responding to the 2019 OPPS proposed rule, this disparity is noteworthy since pathogen reduced platelets (P9073) are produced using a different, novel, more costly technology than leukoreduced, irradiated apheresis platelets (P9037). Thus, we believe that similar to the 2017 claims data, the 2018 claims data includes billing errors that have resulted in an artificially low payment rates for P9073. The proposed payment rate P9073 for 2020 is $600.87, which is substantially lower than $659.54, the proposed payment rate for P9037. We believe that there may have been some progress towards more accurate billing practices; the 2020 proposed payment rates for P9073 ($600.87) and P9037 ($659.54) are more closely aligned than the 2019 proposed payment rates for the same codes. However, the 2018 claims data and the disparate proposed payment rates highlight that erroneous billing practices likely persist.

Absent adequate reimbursement, hospitals may be reluctant to adopt new technologies that offer significant patient benefit, such as pathogen reduced platelets. We believe that the proposed reimbursement rate for pathogen reduced platelets is based on flawed data and could negatively impact the availability and implementation of this new safety technology. A two-year crosswalk is necessary because it is too late to correct the 2019 data, which will be used to

[2] 83 Fed. Reg. 58818, 58834 (Nov. 21, 2018).

calculate the payment rate for CY 2021. **Therefore, AABB, America's Blood Centers and the American Red Cross urge CMS to continue cross-walking P9073 to P9037 through 2020 and 2021**.

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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).

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