



September 24, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-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-1695-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) that was published in the Federal Register on July 31, 2018. Collectively, our organizations represent the nation's blood collection establishments, transfusion services, and transfusion medicine professionals.

Our comments focus on the following areas:

1. The proposed reimbursement rate for pathogen reduced platelets;
2. The applicability of recent changes to the "14-day rule" to certain services and tests performed by blood centers;
3. Payment policies related to stem cell transplants;
4. Policies for chimeric antigen receptor T- cell (CAR-T) therapy; and
5. Proposed policies for certain services furnished in off-campus provider-based hospital departments.

- 1. The proposed reimbursement rate for pathogen reduced platelets (P9073) is erroneous. We ask that CMS crosswalk P9073 to P9037 (leukoreduced, irradiated apheresis platelets) for 2019 and 2020 to help ensure that pathogen reduced platelets remain accessible to Medicare beneficiaries.**

CMS' proposed rate for pathogen reduced platelets (P9073) for 2019 is based on flawed data and has resulted in a payment rate far too low. CMS proposed to establish the 2019 payment rate for pathogen reduced platelets using 2017 claims data. Few claims were submitted for

pathogen reduced platelets in 2017, which is not surprising given that pathogen inactivation is a newly-introduced technology. Unfortunately, claims data from four high-volume hospitals appear to be erroneous. These hospitals collectively submitted 1,267 of the 2,772 total OPPS claims for pathogen reduced platelet units in 2017, resulting in CMS establishing an incorrect and artificially low reimbursement rate for pathogen reduced platelets for 2019.

These four hospitals, which submitted approximately 46 percent of the OPPS claims for pathogen reduced platelet units in 2017, reported a cost for each unit that was at least \$100 below their reported cost for leukoreduced, irradiated apheresis platelets (P9037). This disparity is noteworthy since pathogen reduced platelets (P9073) are produced using a different, novel, more costly technology than leukoreduced, irradiated apheresis platelets (P9037). As a result of these likely billing errors, the proposed 2019 payment rate for P9073 is \$445.68, which is substantially lower than \$623.47, the proposed payment rate for P9037. We believe that resolution of these errors will result in a payment rate for pathogen reduced platelets (P9073) higher than leukoreduced, irradiated platelets (P9037). CMS acknowledged that P9037 was the closest proxy to the expected payment rate for pathogen reduced platelets by crosswalking P9073 to P9037 for OPPS rate-setting purposes until now.

Hospitals have already billed CMS for pathogen reduced platelets for most of 2018, and therefore the errors in the claims submitted in 2017 are most likely also going to carry forward into the claims submitted in 2018, which would be used to calculate the 2020 reimbursement rates. 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. **Therefore, AABB, America's Blood Centers and the American Red Cross urge CMS to continue cross-walking P9073 to P9037 through at least 2019 and 2020.**

2. AABB, America's Blood Centers and the American Red Cross request that CMS clarify the applicability of recent changes to the "14-day rule" (42 CFR 414.510) to certain services and tests performed by blood centers.

Our organizations understand that under the 14-day rule that was finalized in the 2018 hospital outpatient payment rule, laboratories performing molecular pathology tests and certain advanced diagnostic laboratory tests (ADLTs) will be required to bill Medicare for the tests. In contrast, hospitals will no longer be permitted to bill Medicare for these tests when they are performed by outside laboratories. CMS recognized challenges associated with the implementation of the 14-day rule when the Agency announced that it will exercise enforcement discretion until January 2, 2019. Additionally, we appreciate that CMS recently issued a document entitled, "Frequently Asked Questions: Revised Laboratory Date of Service Exception Policy," to clarify certain aspects of the policy.

America's non-profit blood centers provide the nation's blood supply. Blood centers are not Medicare providers, are not privy to identifiable health information, and do not have the infrastructure in place to bill Medicare or other payors. Requiring blood centers to assume the

administrative task of billing Medicare for testing to identify appropriate blood units for specific patients is not feasible or appropriate under the current payment structure.

AABB, America's Blood Centers and the American Red Cross are concerned that CMS' clarifying documents do not address the potential impact of the 14-day rule on certain services and tests performed by blood centers, such as red blood cell phenotyping (HCPCS Code 81403), HPA-typing (HCPCS Codes 81105 – 81112) and red blood cell genotyping (HCPCS Code 0001U), which are included on the list of laboratory codes subject to the 14-day rule.

We request that CMS confirm that blood-center testing is exempt from the revisions to 42 CFR 414.510 ("14-day rule"), and to clarify that hospitals are permitted to bill for these tests under the OPFS. We believe that excluding these tests from the 14-day rule would be in keeping with the intent of Section 100.2 of Chapter 16 the Medicare Claims Processing Manual, which states that "tests primarily associated with the provision of blood products" are not considered by Medicare to be clinical laboratory services:

Some CPT codes in the 80000 series are not clinical laboratory tests and are therefore never subject to [clinical laboratory] fee schedule limitations. Some of these codes are exempted because they are not clinical laboratory services. They include codes for procedures, services, blood products and auto-transfusions. They include codes such as whole blood, various red blood cell products, platelets, plasma, and cryoprecipitate. Other codes for tests primarily associated with the provision of blood products are also not considered to be clinical tests. Such tests identify various characteristics of blood products, but are not diagnostic in nature. These include various blood cross matching techniques. If they are covered, Medicare pays exclusion codes under the MPFS, reasonable charges, reasonable costs, or OPFS as applicable.¹

3. AABB, America's Blood Centers and the American Red Cross encourage CMS to adopt policies that promote accurate, appropriate payments for stem cell transplants.

A. Comprehensive APC (C-APC) for Autologous Stem Cell Transplant.

We support the C-APC for allogeneic stem cell transplant, which CMS introduced in CY 2017, and we believe CMS should pursue a similar strategy for autologous stem cell transplant. A C-APC for autologous stem cell transplant would improve the accuracy of reimbursement and is appropriate since the primary procedure is often furnished on the same date of service as other ancillary, supportive and adjunctive services. For 2019, CMS was only able to use 14 single procedure claims out of 379 total claims to set the APC payment rate for autologous stem cell transplant (CPT code 38241). If CMS uses all claims associated with autologous stem cell transplant, it will improve the accuracy of the reimbursement rate for this important service.

¹ CMS. Medicare Claims Processing Manual, Chapter 16 – Laboratory Services, Section 100.2 – Laboratory Tests Never Subject to the Fee Schedule. Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf>. Emphasis added.

B. Recalculation of Reimbursement Rate for Allogeneic Transplantation of Hematopoietic Progenitor Cells (C-APC 5244)

AABB, America's Blood Centers and the American Red Cross believe that CMS' proposed 2019 payment rate for allogeneic transplantation of hematopoietic progenitor cells (C-APC 5244) is flawed due to potential errors in the rate-setting process. We are concerned that CMS unintentionally left out important packaged costs from the rate-setting calculation, including donor search and cell acquisition costs that were historically reported with revenue code 0819, but which are now reported with the newly released revenue code 0815. Although this revenue code requires a HCPCS code, HCPCS codes are not typically reported and many payers, including CMS, do not edit for it. For the development of the C-APC 5244 payment rate, CMS included all line items of revenue code 0819 irrespective of the presence of a HCPCS code on that line. We believe that CMS should apply the same reasoning to revenue code 0815.

Revenue code 0815 was released for use in 2017, and therefore it appears for the first time in claims used to set reimbursement rates for 2019. CMS intended to ensure that the allogeneic C-APC payment rate reflects donor search and acquisition costs when the agency established C-APC 5244 and the edit requiring the presence of revenue code 0815 when CPT code 38240 is billed on outpatient claims. While CMS used all 36 single procedure claims for setting the payment rate, the agency only used the revenue code 0815 line item from the 19 claims that had both revenue code 0815 and a HCPCS code report (typically 38204). We encourage CMS to add revenue code 0815 to its packaged revenue code list as a technical rate-setting correction, and to recompute the payment rate for C-APC 5244 for CY 2019 using all claims with revenue code 0815. We believe that this will result in a more accurate payment rate that is reflective of all donor search and cell acquisition costs.

If CMS intends to require hospitals to report a HCPCS code with revenue code 0815, we encourage CMS to release detailed instructions to providers and establish a claims edit for the future. If this is the case, we recommend that CMS specify that HCPCS code 38240 is the appropriate code to report.

C. Cost Reporting Instructions for Cost Report Line 0077

Although CMS established cost center 77 to capture donor search and cell acquisition costs as of January 1, 2017, the Agency has not yet provided any manual instruction to hospitals regarding how to correctly aggregate donor search and cell acquisition costs to this cost center. It is relatively easy to identify donor expense for unrelated donor cells, which are generally a purchased service and individual invoices for these services are sent to the hospital. Alternatively, providers work up related donors (i.e., siblings or other family members) in-house, and do not have guidance on how costs should be reclassified from individual departments that treat related donors (i.e., lab, clinics, etc.) and then aggregated in cost center 77.

While section 231.11.1 of Chapter 4 of the *Medicare Claims Processing Manual* includes information on donor search and cell acquisition charges, there are not specific instructions regarding how a hospital should reclassify to cost center 77 the expense associated with related donor services from the departments that treat related donors. The revenue for these services are typically posted to each individual donor's patient account under typical department revenue

codes (e.g., 300 for lab) and held, due to CMS' instructions that they be billed under revenue code 0815 on the recipient's transplant claim. The original related donor charges on individual donor patient accounts can be used by the hospitals at cost reporting. By applying the respective department's Cost-to-Charge-Ratios (CCRs) to the donor charges by department, the resulting calculated expense can be reclassified from those departments to cost center 77. The revenue billed under the departments should be removed, as this was posted on recipient's accounts under revenue code 0815.

We encourage CMS to issue detailed instructions to providers and the Medicare Administrative Contractors so the expenses in cost center 77 will be complete and accurate for both related and unrelated donors. Within these instructions, we believe CMS should specify that "physician pre-procedure donor evaluation services" should not be reported as facility costs on the hospital claim or the hospital's cost report in center 77. Rather, these physician pre-procedure donor evaluation services should be billed in real-time rather than being held until the transplant recipient's claim.

D. Donor Search and Cell Acquisition Payment Policy

Current Medicare payment policy for stem cell transplant does not adequately cover the costs hospitals incur when providing transplants in either the inpatient or outpatient settings. One significant problem is that CMS includes the cost of the cell acquisition in the MS-DRG and C-APC. We ask that CMS align its transplant policies and reimburse acquisition costs outside of the MS-DRG and C-APC payments.

4. AABB, America's Blood Centers and the American Red Cross encourage CMS to change the status indicators for the new codes established for Chimeric Antigen Receptor T – Cell (CAR-T) Therapy.

We support the HOP Panel's recommendation to change the status indicators for the new Category III CAR-T CPT codes (0537T-0540T) from "B" to "S," and to cross-walk these codes to the stem cell transplant APCs. While CAR-T is not stem cell transplant, we believe that the assignment of these services to these APCs would be consistent with CMS' decision to assign CAR-T therapy to autologous stem cell transplant MS-DRG 016 in the FY 2019 Medicare hospital inpatient prospective payment system (IPPS) final rule.

We also support the request made by public presenters at the May 2018 HCPCS meeting to remove clinical services from the definition of the CAR-T product Q-codes, Q2040, and Q2041, so that the codes' descriptions reflect only the drug. This will allow providers to accurately report services furnished to patients and will ensure that CMS receives accurate data. We believe status indicator "S" for separately payable procedures is appropriate, since these codes represent new services. By assigning a payable status indicator, CMS will enable hospitals to bill and be paid appropriately for the services they provide during each step of the CAR-T process, regardless of when or where the service is rendered.

5. **AABB, America’s Blood Centers and the American Red Cross request that CMS not finalize its proposals to (1) expand the site-neutral payment policy to certain outpatient services furnished in off-campus provider-based hospital departments; or (2) to reduce the reimbursement rate for clinic visits (G0463) provided in off-campus provider-based departments.**

AABB, America’s Blood Centers and the American Red Cross request that CMS rescind its proposals to expand the site-neutral payment policy to new clinical families of services furnished in off-campus provider-based hospital departments (PBDs) that were previously excepted from the site-neutral payment policy. CMS’ proposal would apply to blood product exchange (including transfusion, apheresis and stem cell procedures, covered by APCs 5241-5244), pathology (APCs 5671 – 5674), and diagnostic/screening test and related procedures (APCs 5721-5724; 5731-5735; 5741-5743).

We are concerned that CMS’ proposal could result in inadequate payment rates for services furnished in off-campus PBDs. For instance, although most transfusion services are furnished at a hospital’s main campuses due to the proximity to the blood bank and the needs of the patients, if services are furnished in an off-campus PBD, the cost of the services may be higher due to costs associated with transporting blood. Despite this increased cost, CMS’ proposed policy would reduce payment for services furnished in off-campus PBDs.

Similarly, we do not believe that CMS should finalize its proposal to reduce the reimbursement rate for clinic visit services (G0463) provided in off-campus PBDs. CMS justified a payment reduction of 60 percent based on needing to control “unnecessary volume increases.” However, CMS did not assess whether changes may be due to factors such as changing patient demographics, clinical needs, technological innovations or other variables. We believe this significant payment cut is premature.

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If you have any questions, please contact Leah Stone, Director, Public Policy and Advocacy, AABB (301-215-6554, lmstone@aabb.org), Kate Fry, Chief Executive Officer, America’s Blood Centers (202-654-2911, kfry@americasblood.org) or Liz Marcus, Director, Hospital Sales and Marketing, American Red Cross (202-303-7980, liz.marcus@redcross.org).

Sincerely,

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