Advancing Transfusion and
Cellular Therapies Worldwide

August 31, 2015

Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1613-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244

Re: CMS-1633-P – Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Proposed Rule

Dear Mr. Slavitt:

AABB appreciates the opportunity to comment on the proposed changes in the hospital outpatient prospective payment system (HOPPS) for 2016. AABB (formerly known as the American Association of Blood Banks) is a professional association dedicated to advancing transfusion medicine and cellular therapies. AABB's members include approximately 1,800 institutions, including hospital-based blood banks and laboratories, transfusion services and blood, cord blood and bone marrow collection facilities, as well as approximately 8,000 individuals involved in blood, bone marrow, cord blood and peripheral blood stem cell collection, processing, storage and infusion. This letter outlines our comments and concerns relating to the proposed payment rates for blood products, transfusion services and stem cell transplants.

Payments for Blood Products

AABB appreciates that CMS will continue to provide separate payments for blood products in the outpatient setting. These distinct payments recognize the important role blood and individual blood products play in caring for a wide range of patients. They also are needed to account for the increasing cost of blood products associated with critical blood safety measures provided by non-profit blood centers. **We urge CMS to maintain its policy of providing separate APC payments for blood products in 2016 and future years.**

8101 Glenbrook Road
Bethesda, MD 20814-2749
301.907.6977 MAIN
301.907.6895 FAX
www.aabb.org

However, AABB is extremely concerned about the proposed reductions in payments for individual blood products. CMS has proposed severe cuts for the vast majority of blood products. For example, the payment for leukocyte-reduced red blood cells (P9016) – by far the most frequently transfused product – would fall over 30% from $189 in 2015 to $131 in 2016.

The proposed blood product payment cuts would have a severe impact on hospital and blood center budgets and potentially threaten patient access to appropriate and available blood therapies. Non-profit blood centers across the country are already operating on extremely tight budgets, with a large percentage in the red, due, in part, to the positive trend in reductions in blood use and increased efforts by hospitals and hospital systems to cut costs. Blood centers and hospitals cannot absorb the drastic cuts CMS has proposed. Blood centers have already reduced capacity and operational expenses where appropriate. At the same time, new blood safety technologies, including pathogen-reduced platelets and plasma and enhanced bacterial testing, have recently been approved by the Food and Drug Administration (FDA). In addition, it is widely anticipated that FDA will approve a new blood screening test for Babesia – the most serious infectious risk in the US blood supply today, in the near future. If confronted with additional payment cuts, hospitals and blood centers could not afford to implement these safety advances and would be faced with making decisions that could adversely impact patient care.

Access to a safe and available blood supply is a national public health priority recognized by Congress and the Department of Health and Human Services (DHHS). On numerous occasions, DHHS' Advisory Committee on Blood Safety and Availability also has spoken to the need to ensure that reimbursement and funding are available to guarantee access to blood safety measures.[1] As hospitals and blood centers face increasing economic pressures, it remains critical that Medicare and other payers provide adequate payments for blood.

The proposed rule includes no explanation for these drastic cuts. To the contrary, CMS' own data indicate that, in general, the cost of blood products remained relatively stable from 2013 to 2014 (the years upon which the 2015 and 2016 payments are based). As illustrated in Table 1 below, CMS' proposed payments for the vast majority of blood products fall dramatically below their actual costs, as reflected in the agency's 2014 geometric mean cost data.[2]

[1] For example, in November 2010, the advisory committee identified as a priority the need to fully reimburse for the cost of blood safety measures. Similarly, in April 2009 the committee recommended that "when policy decisions are reached, there must be linkage of funding to ensure system-wide implementation of desired safety enhancements." http://www.hhs.gov/ash/bloodsafety/advisorycommittee/index.html

[2] AABB continues to believe that neither CMS' payment rates nor cost data adequately reflect hospitals' actual costs in providing blood products, including payments to blood centers as well as hospital overhead costs.

Table 1

HCPCS	Short Description	2013 Geometric Mean Unit Cost	2014 Geometric Mean Unit Cost	Final CY 2015 Payment Rate	Proposed CY 2016 Payment Rate
P9010	Whole blood for transfusion	$246.20	$231.51	$217.16	$166.85
P9011	Blood split unit	$140.90	$109.27	$130.40	$71.30
P9012	Cryoprecipitate each unit	$73.31	$66.44	$70.79	$47.31
P9016	RBC leukocytes reduced	$200.34	$199.64	$189.37	$131.12
P9017	Plasma 1 donor frz w/in 8 hr	$79.19	$78.23	$74.82	$50.88
P9019	Platelets, each unit	$126.92	$124.25	$115.31	$92.51
P9020	Platelet rich plasma unit	$151.39	$137.66	$135.88	$72.86
P9021	Red blood cells unit	$158.54	$155.03	$150.51	$99.65
P9022	Washed red blood cells unit	$339.84	$327.28	$320.19	$201.87
P9023	Frozen plasma, pooled, sd	$76.42	$84.67	$69.26	$70.91
P9031	Platelets leukocytes reduced	$118.92	$124.62	$112.08	$87.36
P9032	Platelets, irradiated	$177.25	$175.03	$168.57	$91.36
P9033	Platelets leukoreduced irrad	$171.69	$178.58	$162.19	$127.21
P9034	Platelets, pheresis	$440.86	$442.48	$419.39	$274.80
P9035	Platelet pheresis leukoreduced	$527.50	$526.92	$497.57	$349.38
P9036	Platelet pheresis irradiated	$599.93	$566.59	$569.29	$310.21
P9037	Platelet pheresis leukoreducedirrad	$711.74	$692.96	$674.16	$486.47
P9038	RBC irradiated	$216.04	$225.07	$207.77	$129.76
P9039	RBC deglycerolized	$495.54	$405.46	$463.79	$275.75
P9040	RBC leukoreduced irradiated	$294.65	$286.54	$275.36	$198.32
P9043	Plasma protein fract,5%,50ml	$206.93	$108.52	$23.04	$83.98
P9044	Cryoprecipitatereducedplasma	$86.74	$60.69	$78.53	$43.94
P9048	Plasmaprotein fract,5%,250ml	$33.87	$40.84	$33.62	$37.90
P9050	Granulocytes, pheresis unit	$1,935.67	$1,642.22	$1,836.96	$848.65
P9051	Blood, l/r, cmv-neg	$169.49	$243.25	$163.92	$180.44
P9052	Platelets, hla-m, l/r, unit	$790.83	$806.86	$704.09	$546.99
P9053	Plt, pher, l/r cmv-neg, irr	$697.21	$650.75	$658.23	$443.65
P9054	Blood, l/r, froz/degly/wash	$300.46	$339.40	$244.08	$239.96
P9055	Plt, aph/pher, l/r, cmv-neg	$465.07	$455.68	$393.94	$352.20
P9056	Blood, l/r, irradiated	$145.35	$143.58	$134.47	$110.13
P9057	RBC, frz/deg/wsh, l/r, irrad	$513.17	$232.74	$448.67	$150.97
P9058	RBC, l/r, cmv-neg, irrad	$290.44	$275.27	$274.67	$185.81
P9059	Plasma, frz between 8-24hour	$74.82	$79.82	$71.36	$54.42
P9060	Fr frz plasma donor retested	$63.27	$65.32	$58.80	$40.52

Furthermore, unlike in previous years, when the payment rates for blood products were uniformly a set percentage of their costs, there is wide variability in the relation between the cost data and the 2016 proposed payment rates. As illustrated in Table 2 below, in 2013 to 2015 (the years in which the geometric mean unit costs were available in the annual "Drugs blood brachy cost statistics" files), the blood APC payment rates always exceeded 96% and averaged 97.74%. In stark contrast, the proposed 2016 payment rates average only 67.94% of the 2014 geometric mean unit costs. For the highest volume product, leukocyte-reduced red blood cells (P9016), the percentage is only 65.68%.

Table 2
2013-2015 Final APC Payments as a Percentage of Geometric Mean Unit Costs

Year	Final APC Payment Rates as a % of Geometric Mean Unit Costs for Blood and Blood Products*	
	Average Across all Products	Range
2013	97.21%	97.18% - 97.22%
2014	99.65%	99.64% - 99.66%
2015	96.36%	96.33% - 96.37%

*Percentages derived from data in "Drugs blood brachy cost statistics" files from 2013-2015 OPPS final rules

Therefore, AABB respectfully urges CMS to reanalyze its data to recalculate its payment rates for blood products. In order to adequately compensate providers and ensure patient access to potentially life-saving therapies, **AABB asks that CMS revise the payment rates for individual blood products to align more with the 2014 geometric mean costs. Specifically, we recommend that the final APC payment rates for blood products be set at a level that is <u>at least</u> 97.74% of the 2014 geometric mean unit costs.**

For well over a decade, AABB and others in the transfusion medicine community have consistently commented to CMS that APC payment rates for blood products lag behind their actual costs and fail to account for safety advances in a timely manner. These payments typically are below the amounts hospitals pay blood centers for individual products and furthermore do not provide for additional hospital overhead costs. Therefore, AABB asks that CMS consider potential alternative methodologies for setting APC payment rates for blood products, seeking input from affected stakeholders. AABB would welcome the opportunity to work with CMS and other interested parties to determine the most appropriate payment methodology to allow for timely implementation of blood safety measures and availability of patient-appropriate blood products.

Payments for Transfusion-related Services

In addition, AABB is troubled by the proposed changes in policy and payment cuts for transfusion-related laboratory services. Transfusion medicine CPT codes (CPT codes 86850-86999), in most instances, cover patient-specific blood preparation services (such as crossmatching, typing and antigen screening) that are performed prior to an anticipated blood transfusion.

We remain concerned with CMS' assignment of APC 0345 (Level I Transfusion Laboratory Procedures) to conditional packaging. Although the services assigned to this APC frequently are provided in conjunction with a transfusion procedure, it is not uncommon for the services to be performed on blood units that ultimately are not transfused to the beneficiary. For example, these services may be performed several days prior to a surgical procedure as part of pre-operative evaluation, or as part of investigating adverse reactions to a prior transfusion event. In such instances, it is likely that the blood preparation service could be the only service reported on the claim, since the hospital would not be billing for a blood product or a transfusion procedure. **It is critical that separate payment for these services be available when the service is provided alone.**

Furthermore, AABB opposes CMS' proposal to assign APC 0346 (Level II Transfusion Laboratory Procedures) to conditional packaging. These services require more extensive resources and lead-time. It is not unusual to spend multiple days to obtain, prepare, and test products so that safe and timely transfusion is possible when needed – often for our most critically ill patients. The time, effort and costs are incurred by Transfusion Services based on the crossmatch order, even if the units are not transfused at the time.

The proposed cuts to payments for nearly all transfusion laboratory procedures are extreme, with several cuts approaching 60 percent or more. AABB fears that patient access to quality care may be threatened by these payment cuts coupled with increased bundling of services.

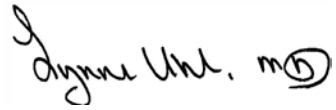
Payments for Stem Cell Transplants

Lastly, AABB remains concerned that the payment for allogeneic hematopoietic stem cell transplants is grossly inadequate, particularly when taking into account the actual costs associated with donor search and product acquisition. Transplant centers commonly expend $30,000 to $50,000 on donor cell acquisition alone, depending on the patient's tissue-type and the type of donor cell source. This figure does not include additional costs associated with providing the actual transplant or any markups. Transplant centers will not be able to afford providing hematopoietic cell transplants to Medicare patients in the outpatient setting, therefore jeopardizing patient access to this life-saving therapy.

Thus, AABB urges CMS to alter its methodology for reimbursing for HCT transplants, including paying separately for acquisition costs (as it does for organ transplantation).

Thank you again for the opportunity to offer these comments. If you have any questions or require additional information, please contact AABB director of public policy, Theresa Wiegmann at 301-215-6554 or theresa_w@aabb.org.

Sincerely,



Lynne Uhl, MD
President, AABB