August 15, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue SW
Washington, DC 20201
Attention: CMS-1656-P

cc: Patrick Conway, Deputy Administrator for Innovation & Quality, CMS Chief Medical Officer
Sean Cavanaugh, Deputy Administrator & Director, Center for Medicare
Carol Blackford, Acting Director, Hospital and Ambulatory Policy Group
Lawrence Wilson, Director, Chronic Care Policy Group
Steve Phurrough, Medical Officer, CMS

RE: Medicare Program: Hospital Outpatient Prospective Payment Policy Changes and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates [CMS-1656-P]

Administrator Slavitt:

On behalf of the National Marrow Donor Program (NMDP)/Be The Match® and the American Society for Blood and Marrow Transplantation (ASBMT), we want to thank you for providing us with the opportunity to comment on the Proposed Rule entitled "Medicare Program: Hospital Outpatient Prospective Payment Policy Changes and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates".

For the thousands of people diagnosed every year with life-threatening blood cancers like leukemia and lymphoma, a cure exists. During the past 25 years Be The Match®, operated by the National Marrow Donor Program® (NMDP), has managed the largest and most diverse marrow registry in the world through a competed contract overseen by the Health Resources and Services Administration (HRSA). Each year the Congress appropriates funds to operate this program, the C.W. Bill Young Cell Transplantation Program (Program). Since the mid-1980s, the Congress has reauthorized the Program with virtually unanimous support. As the steward of this critical federal public health program, we work to identify and eliminate barriers that face those patients in need of one of these life-saving transplants. In addition to being a core component of our contracts with the HRSA, assisting with third-party payer matters is a function of the Office of Patient Advocacy as outlined by the Congress in the statute authorizing the Program.

The American Society for Blood and Marrow Transplantation (ASBMT) is an international professional membership association of more than 2,000 physicians, investigators and other healthcare professionals promoting blood and marrow transplantation and cellular therapy research, education, scholarly publication and clinical standards. From its beginning, ASBMT activities have focused on fostering research and development of transplantation both as a science and a therapy; conducting and coordinating analyses for effective regulation of autologous and allogeneic transplantation; sponsoring publications and meetings for the exchange of scientific and clinical information; providing recommendations and guidelines about

the role of transplantation as a therapeutic approach for reimbursement by third-party insurers; and encouraging physicians and ancillary health care personnel to enter the field of blood and marrow transportation. ASBMT is committed to ensuring access to all patients who need hematopoietic cell transplants.

Together, the NMDP and ASBMT represent the interests of more than 2,000 transplant physicians, nearly 200 transplant programs, 13.6 million registered individuals willing to donate and over 300,000 transplant patients.

We sincerely thank the Centers for Medicare & Medicaid Services (CMS) for your attention to outpatient payment of hematopoietic cell transplantation (HCT) in the Proposed Rule, particularly since this is still a low volume service but one that we believe will grow over time. Therefore, it is important to establish appropriate payment now while the volumes are still low. Additionally, we support CMS' proposed change of creating a Comprehensive APC for allogeneic HCT as we believe this is a more appropriate way to set the outpatient payment rate. As CMS works to finalize the Proposed Rule, we ask that the Agency make the following revisions so that hospitals can be more appropriately reimbursed for this life-saving procedure when deemed appropriate by the clinical team to be provided in the outpatient setting:

I. Utilize correctly coded claims to establish the payment rate for C-APC 5244

Our analysis of the proposed C-APC 5244 (Level 4 Blood Product Exchange and Related Services) shows that CMS calculated the payment rate of $15,267 for CY 2017 using all 40 claims with CPT code 38240 (Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor) without an evaluation of whether all 40 claims were accurately coded per CMS' billing guidance. We understand CMS does not and cannot conduct such an evaluation as a routine part of its rate-setting process given this would be time-consuming and not always simple to determine if claims are correctly reported. However, we believe in instances when a clear determination of correct claims can be made, as can be in this case, then it should.

This is especially important when the total claim volume is low and a few miscoded claims can significantly impact the overall rate-setting process. Furthermore, CMS has provided specific billing guidance on requirements for a correct claim for allogeneic HCT. Therefore, CMS can easily discern correctly billed allogeneic HCT outpatient accounts. Allogeneic HCT, by definition, requires the use of donor cells which CMS instructs transplanting providers report on claims in a particular manner. Per the Medicare Claims Processing Manual (90.3.3.A. Billing for Allogeneic Cell Transplants: Definition of Acquisition Charges for Allogeneic Stem Cell Transplants) and CY 2016 OPPS Final Rule (CMS-1633-F)[1], hospitals must report all services with revenue code 0819 that are required to acquire stem cells from a donor, including services such as:

- National Marrow Donor Program fees, if applicable, for stem cells from an unrelated donor;
- Tissue typing of donor and recipient ;
- Donor evaluation;
- Physician pre-admission/ pre-procedure donor evaluation services;
- Costs associated with harvesting procedure;

[1] https://www.gpo.gov/fdsys/pkg/FR-2015-11-13/pdf/2015-27943.pdf

- Post-operative/post-procedure evaluation of the donor; and
- Preparation and processing of stem cells on the recipient's outpatient claim under[2]

CMS issued the above billing clarification in March 2009 and our organizations have extensively educated transplant center colleagues about this language. Furthermore, an evaluation of inpatient claims shows a significant improvement in providers reporting in conjunction with the claims processing manual language. As the vast majority of allogeneic HPC procedures are provided in the inpatient setting, it makes sense that providers have improved their coding and billing practices in that setting. Unfortunately the same cannot yet be said for the outpatient setting. This is likely because very few HCT procedures are performed at present on Medicare outpatients. Additionally, it is unusual to ask providers to hold charges over time and since this is unique to allogeneic HCT and not something billing staff come across daily, it is likely most are not well accustomed in holding these charges and then reporting all donor related charges using revenue code 0819 in the manner outlined by CMS on the recipient's transplant claim. This, along with the fact, that outpatient HCT is still relatively new explains why staff find reporting these charges challenging and why charges are often missed, incomplete, or incorrectly reported to CMS.

As such, we sincerely ask that CMS re-calculate the payment rate for proposed C-APC 5244 using only the subset of claims from its database that have both CPT code 38240 <u>and</u> revenue code 0819 present so that the payment rate for the newly proposed C-APC accounts for both the procedural service as well as the donor search and cell acquisition charges as defined per CMS' billing guidance above. Claims with CPT code 38240 but without revenue code 0819 should not be used for rate-setting calculations for C-APC 5244 as these claims are missing donor acquisition charges central to the provision of allogeneic HCT and are hence incorrectly reported claims. Using correctly coded claims, those with both CPT code 38240 and revenue code 0819, will result in a payment rate that more accurately reflects the cost of providing HCT to Medicare beneficiaries. Our analysis indicates that this would mean that 26 claims out of 40 would be used in the rate-setting process.

While 26 claims may seem to be "too few" claims for rate-setting, we know the agency has in the past used far fewer claims for rate-setting and we believe the volume of claims is less critical than the accuracy of the claims used and therefore strongly support CMS' use of correctly coded claims for setting the rate for C-APC 5244.

The table below shows our analysis of CY 2015 CPT 38240 claims.

Table 1: Analysis of claims with CPT code 38240

	Geometric Mean
CPT Code 38240 (all claims)	$15.989.23
CPT Code 38240 with Revenue Code 0819 (26 Claims)	$29,093.03

[2] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c03.pdf

II. Ensure that cost center line 112.50 is incorporated into the calculation of inpatient rate-setting as well as the proposed outpatient rate-setting

The Proposed Rule creates a new standard cost center 112.50, cost center code 11250 and a dedicated cost center line 112.50 to record acquisition costs associated with allogeneic HCT. We applaud CMS in taking this step to isolate HCT expense so that future rate setting can be improved as hospitals adopt this new cost center. As CMS knows, cost reporting based on total expense and revenue impact both the inpatient and outpatient prospective payment rate setting process. We are therefore concerned that CMS did not propose or finalize a companion notice in the FY 2017 IPPS Final Rule. Perhaps the agency does not need to do this through rule making and can instead address it through manual guidance or discuss it in the final CY 2017 OPPS Final Rule but in any case, if a new standard cost center 112.50 is created we believe it must be utilized for both inpatient and outpatient acquisition cost reporting. Therefore, we support the creation of this cost center as long as CMS clarifies through rule making, sub-regulatory guidance and/or cost reporting instructions that this cost center is applicable for inpatient and outpatient reporting since standard cost reporting principles will continue to apply with this newly proposed cost center.

Furthermore, we have some additional concerns regarding this cost center's treatment if finalized. In the CY 2016 IPPS Final Rule (CMS-1632-F)[3], CMS stated, *"line 112…are excluded from the calculation of CCRSs and the IPPS relative weights. Consequently, any costs related to charges billed under revenue code 0819 that are reported on line 112 would not be captured in the MS-DRG relative weight calculations*."

Given CMS' statement above, we seek clarification on whether this exclusion will apply to the new proposed cost center 112.50. Our understanding of cost reporting principles is that total expense is reported in a cost center regardless of the care setting (i.e., inpatient versus outpatient status) and are concerned that the use of the new proposed cost report line will result in errors in rate-setting for C-APC 5244 if the underlying cost-to-charge ratios are not accurate because the expense and revenue in cost center 112.50 has not been applied uniformly to all patients, both inpatient and outpatient, pursuant to correct cost reporting principles.

Furthermore, we want to ensure that the new cost center 112.50 will be used in IPPS and the MS-DRG relative weight calculations. We do not believe that differential treatment between inpatients and outpatients was the intent of the Proposed Rule and ask that CMS *confirm that expense listed on the proposed cost center line 112.50 will be expense for both inpatients and outpatients and that the resulting information will be included in future inpatient prospective payment rate-setting calculations as well as C-APC calculations*.

III. Ensure that revenue code 0815 is approved for both inpatient and outpatient claims

Similar to our request that CMS clarify that cost center 112.50 be used for acquisition expense of all patients, both inpatients and outpatients, we would like confirmation that the newly proposed revenue code 0815 that providers would use to report their acquisition charges would also be the required revenue code on inpatient claims rather than 0819. We believe this is

[3] https://www.gpo.gov/fdsys/pkg/FR-2015-08-17/pdf/2015-19049.pdf

CMS' intent if 0815 is finalized, but believe the agency must release instructions that are absolutely clear to ensure the earliest adoption and provide the best opportunity for providers to accurately and consistently report donor acquisition charges on their inpatient and outpatient claims so CMS can associate these charges with total acquisition expense reported with cost center 112.50. Our organizations will work to share the new reporting information with our transplant center partners once finalized.

IV. Ensuring that all donor acquisition expense is captured in cost center 112.50

The NMDP and ASMBT wish to ensure accuracy in reporting acquisition expense and revenue and understand that this information is used in the development of the IPPS national cost-to-charge ratio (CCR) calculations. We understand that only with the combination of accurate cost reports and accurate claims, will CMS be able to improve the relative weights for allogeneic HCT payment under each of the respective payment systems.

As we have commented to CMS in the past, allogeneic HCT encompasses two type of donors – those donors harvested by a provider other than the transplanting provider where NMDP invoices the transplanting provider and secondly, donors whose marrow or cells are harvested directly by the transplanting provider. In the former instance, it will be very straightforward for providers to record the NMDP invoice cost in the new 112.50 cost center and to report the revenue using revenue code 0815 if finalized on the transplant recipient's claim. This involves holding the donor related charges until time of transplant, but the NMDP invoice is recorded in the transplanting provider's accounting system as expense and also as revenue under the 112.50 cost center. This results in an accurate match of expense and revenue for cost-to-charge calculations.

For those donors harvested by the transplanting providers where there is no NMDP invoice, CMS has also instructed providers to accumulate the donor charges from the harvested donor claims and report these under revenue code 0819 (soon to be 0815) on the recipient's claim. When the accumulated charges are posted on the recipient's claim, it results in revenue posting again under the 112.50 cost center. However, there are no instructions of how the provider is supposed to either reclassify its expense from the departments which performed the harvesting services or estimate expense. The original revenue and expense for the harvested donor services remain in the individual ancillary departments such as the laboratory.

Without clear instructions from CMS on the reclassification of expense and revenue .on the second type of donor harvested directly by the transplanting provider, when CMS receives information in cost center 112.50, the expense will represent only the expense for those donors invoiced to the provider by NMDP, but the revenue as reported through billed charges (0819 today and soon to be 0815) will represent the NMDP donor charges plus the charges for donors directly harvested by the provider. The expenses associated with these donors remains in the respective routine and ancillary departments without being correctly reclassified to the 112.50 acquisition cost center. Therefore, we are concerned that without a methodology and clear instructions from CMS about how to re-assign expense into 112.50 from the ancillary departments, the resulting CCRs will be incorrect and understated as they are today and will not result in the type of improved rate setting CMS intends with its proposals.

Therefore, the NMDP and ASBMT wish to collaborate with CMS on the best method to resolve this issue so that clear cost reporting instructions are released to providers. One way for CMS

to get more information would be for providers to report their direct NMDP invoice cost for those donors on the recipient's claim under the remarks field locator 80 or as a value code and amount. With this approach CMS would be able to isolate the cases/claims that represent unrelated allogeneic cases for which the transplant center receives an NMDP invoice vs. those cases where the transplant center harvests donors internally. This would enable CMS to understand the volume and cost differences of different types of allogeneic HCT patients which can further facilitate analysis and the development of more accurate payment rates over time.

The NMDP and ASBMT would be pleased to work with CMS to resolve any questions in regards to the proposed changes to outpatient HCT. Furthermore, please know that we intend to continue to educate our members to adopt these changes and report both expense and revenue as accurately and completely as possible to CMS. Please contact Stephanie Farnia, NMDP Payer Policy Director, sfarnia@nmdp.org (763)-406-8669, if you have additional questions.

Sincerely,

AMERICAN SOCIETY FOR BLOOD & MARROW TRANSPLANTATION

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NATIONAL MARROW DONOR PROGRAM/BE THE MATCH

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