August 25, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201
**Attention: CMS-1633-P**

***Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals under the Hospital Inpatient Prospective Payment System [CMS-1633-P]***

Dear 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 and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals under the Hospital Inpatient Prospective Payment System" (Proposed Rule).

As described in more detail below, we strongly urge the Centers for Medicare and Medicaid Services (CMS) to protect beneficiary access to bone marrow and cord blood transplants, also known as hematopoietic cell transplants (HCTs) by establishing adequate reimbursement when these transplants are provided in an outpatient setting. As the Agency looks more toward providing access to precision medicine for beneficiaries, it would be short-sighted to compromise access to one of the earliest types of treatment that is tailored to the individual at the genetic level.

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 the 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 Health Services and Resources Administration (HRSA), assisting with third party payor matters is a function of the Office of Patient Advocacy as outlined by the Congress in the statute authorizing the C.W. Bill Young Cell Transplantation Program.[1]

The American Society for Blood and Marrow Transplantation 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

[1] 42 U.S.C. §274k(h)(2)(D).

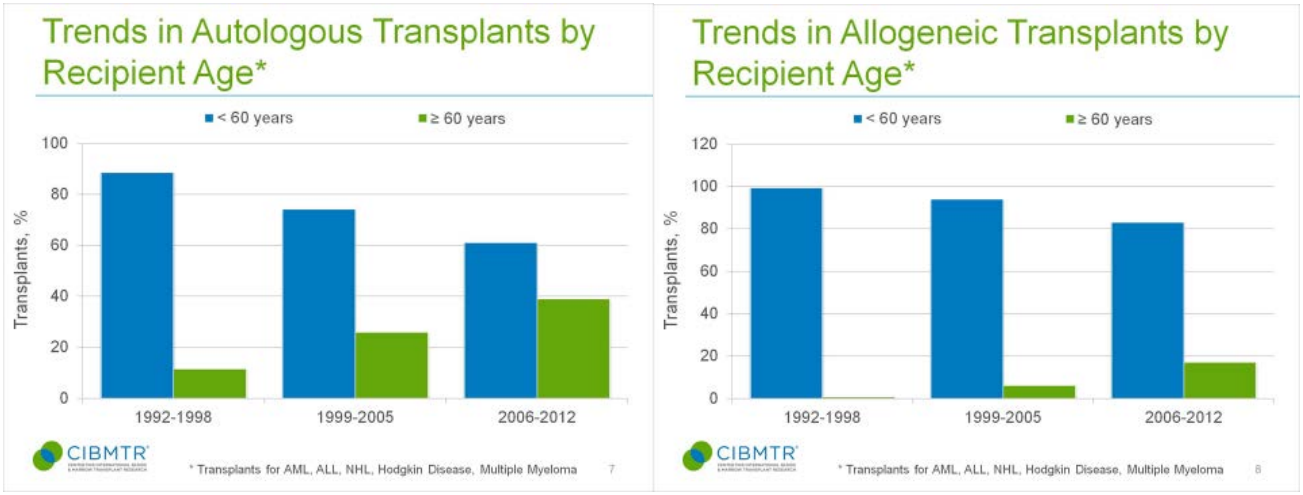
of autologous and allogeneic transplantation; sponsoring publications and meetings for the exchange of scientific and clinical information; providing recommendations and guidelines about the role of transplantation as a therapeutic approach for reimbursement by third-party insurers; and encouraging physicians 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, 12.5 million registered donors and over 300,000 transplant patients.

## I. Beneficiary Access to an Outpatient Hematopoietic Cell Transplant Is in Jeopardy Due to Inadequate Reimbursement

Advances in medical science now allow individuals over the age of 65 to benefit from life-saving hematopoietic cell transplants (HCT). The most critical change in the treatment protocol has been related to making the process less toxic for the patient. These developments have allowed physicians to perform these transplants in an older population and in some cases in the less costly outpatient setting. The results have been positive. Outcomes data clearly demonstrate that HCT is as effective a treatment for individuals who are 65 and older as it is for younger patients.

The rate of HCT in the over 65 population has increased substantially since 2010, though the absolute numbers are still comparatively low – approximately 1,000 allogeneic transplants annually in the Medicare beneficiary population. As described in detail below, the ability of hospitals to support these transplants without clear reimbursement rules is diminishing and it seems highly unlikely that those patients who medically need a HCT transplant will be able to receive one unless the policies are modified.




Patients who do not have access to transplant will face expensive and likely futile alternative treatments. There are no potentially curative alternatives for Medicare beneficiaries eligible for HCT. If access is limited, the mortality rate is extremely high. To provide beneficiaries with access to this important treatment, in both the inpatient and outpatient settings, Medicare should provide appropriate reimbursement. Given the substantial federal investment in maintaining the national registry, it is important to ensure that all Americans, including Medicare beneficiaries, can have access to the transplants facilitated through the federal public health program.

In our work with transplant centers trying to provide HCT to Medicare beneficiaries, it has become clear that current Medicare reimbursement is inadequate and is beginning to create a significant barrier to beneficiaries in need of a bone marrow or cord blood transplant. **This applies to reimbursement rates in both the inpatient and outpatient settings; neither rate is sufficient to cover the cost of the cells required to provide an allogeneic unrelated transplant. We recognize that Medicare does not intend to cover 100% of the cost of procedures, but current payment rates are significantly below even a portion of the actual cost of delivering these procedures.** At the same time, there are a growing number of Medicare beneficiaries in need of HCT. Together, these facts are creating a situation in which transplant programs are being forced to make difficult decisions about the care they provide.

On both the inpatient and outpatient side, transplant hospitals have reported average losses of tens of thousands of dollars per patient. **In the OPPS setting, Medicare has currently proposed assignment of these procedures to APC 5281, with a proposed payment of $3,045.31.** This rate does not begin to cover the cost of an outpatient unrelated HCT. The cost to identify a donor and procure unrelated donor cells is approximately $30,000-$60,000 depending on the patient's individual genetics and the type of cell sources available. This dollar range reflects a true picture of the provider's cost just for the cells, without any markup cost, and does not reflect the rest of the cost involved in providing the actual procedure. We encourage CMS to understand that unrelated cell acquisition costs are ***site neutral*** and do not increase or decrease because the transplant happens in the outpatient vs. inpatient setting. Patients and donors are matched on the basis of human leukocyte antigens (HLA) and the level of matching required for successful HCT exceeds that needed in solid organ transplant. In addition, patient racial and ethnic background impacts the likelihood of finding a closely matched donor.

The lack of cost-based reimbursement for donor identification and cell acquisition remains a major concern primarily because CMS' existing rate-setting process under both the OPPS and IPPS is unable to appropriately account for cell acquisition cost (approximately $30,000-$50,000) as evidenced by the APC and MS-DRG rates. The lack of appropriate reimbursement is likely to create a disparity in access to care for HCT between Medicare beneficiaries and the commercially insured population over time and that is of great concern to the NMDP and ASBMT.

In the FY2016 Final IPPS rule, CMS states that a "MAC will not make separate payment for these acquisition services because hospitals may bill and receive payment only for services provided to a Medicare beneficiary who is the recipient of the stem cell transplant and whose illness is being treated with the stem cell transplant" [FY2016 Final IPPS rule, CMS-1632-F, pp 105-106]. This statement seems to imply that CMS is unable to provide reimbursement for cell acquisition purposes because the cells are being harvested from another live individual (the donor) who is not a Medicare beneficiary, whereas acquisition of solid organs for transplantation are provided from recently deceased individuals, through an organ procurement organization. However, CMS does provide separate payment for the acquisition of kidneys for use in solid organ transplantation. The National Kidney Foundation reports that 5,535 of the 17,105 kidney donations (32.3%) in 2014 came from living donors[2], many of which would be used on Medicare beneficiaries. CMS does not reimburse differently for transplants utilizing live donor organs. The NMDP acts similarly to an Organ Procurement Organization (OPO) for solid organs as it facilitates the anonymous transfer of cells from the donor to the recipient required to carry out an unrelated HCT procedure.

[2] https://www.kidney.org/news/newsroom/factsheets/Organ-Donation-and-Transplantation-Stats

The financial losses incurred to treat Medicare HCT patients are threatening the viability and stability of transplant programs and may result in programs closing, resulting in possible access to care issues for Medicare beneficiaries. As previously stated, patients who do not have access to transplant will face expensive, likely futile alternative treatment options. In most cases, the lack of a transplant will result in death.

The NMDP and ASBMT have partnered to provide robust educational resources to transplant programs over the last four years. These resources include webinars, in-person education sessions, and written materials, all focused on helping them to be compliant with Medicare coding and billing guidance and to help them understand the overall APC and MS-DRG rate-setting processes so they report their charges completely and accurately. The reporting accuracy of transplant programs has increased significantly in this time period. While additional improvement can still be made by transplant centers, CMS should recognize that no matter how complete and accurate their reporting is, reimbursement rates will remain inadequate given several issues we have observed in CMS' rate-setting methodology in both the outpatient and inpatient settings. These are issues we've raised with the agency previously and ones that we continue to believe are critical to resolve.

We urge CMS to address the methodological issues outlined below in order to generate improved reimbursement for HCT and to protect and expand access to these transplants for its beneficiaries. We raise questions and offer suggestions below.

## II. We Encourage CMS To Examine Its Estimation of Cost from Provider Claims and Implement Processes to Improve the Accuracy of Provider Reported Data

The NMDP and ASBMT appreciate CMS's ongoing review of the rate-setting methodology currently being applied to HCT in both the inpatient and outpatient settings. We sincerely appreciate CMS' HCT discussion in the FY 2016 IPPS Final Rule which now clearly instructs providers to report their HCT donor related costs using cost report lines 62 or 63. CMS now shows that it maps revenue code 0819 to the blood and blood products cost center group of 6200 and 6300 (only for charges associated with MS-DRG 014) and we believe this information will be helpful to providers. However, we have a concern based on our review of the OPPS revenue code to cost center crosswalk, which shows revenue code 0819 mapping to cost center 8600 for "other organ acquisition". This is the primary and sole cost center mapped to this revenue code, which raises the question of why CMS would use a different methodology for estimating HCT donor related search and acquisition costs included in MS-DRG 014 vs. those included in outpatient transplant within proposed APC 5281. We do not believe CMS intends for such a methodological difference and encourage the agency to streamline its revenue code to cost center cross-walk between the OPPS and IPPS for this revenue code, as well as others where a mismatch appears.

While we appreciate CMS' discussion and clarification in the FY 2016 IPPS Final Rule that HCT donor costs are to be reported under either 6200 or 6300 and matched with HCT revenue billed under 0819, we wonder if it would be more appropriate over the long term for CMS to create a dedicated cost report line for the collection of these costs as they are significant and typically much higher than the lower cost blood and blood product costs. To comingle these costs with other lower cost blood and blood products or labs can result in charge compression. CMS has worked hard to address the issue of charge compression for other items and services and we believe a similar approach should be taken for HCT. **The NMDP and ASBMT request CMS create a separate, dedicated cost center line for HCT, similar to how it established this for Implantable Devices, MRI, CT Scan, and Cardiac Catheterizations.**

**Along with this, we believe it would likely be useful for CMS to work with the NUBC to release a new, dedicated, revenue code for providers to use when reporting their HCT donor search and cell acquisition charges.** We would be happy to work with CMS on this request as we believe a dedicated

revenue code along with a dedicated cost report line will help eliminate any confusion that may exist today on how to appropriately report charges and costs. Once a dedicated cost report line is available, all HCT transplant providers can be instructed to use it. Within a few years, CMS will have better data to work with to understand HCT donor search and cell acquisition costs, which are a significant part of the overall transplant procedure cost, especially in the outpatient setting. We would then expect CMS to use this data to inform its future rate-setting processes with the ultimate goal of fair and consistent payment for donor search and cell acquisition costs under both the OPPS and the IPPS.

### A. We Recommend Separate and Site-Neutral Reimbursement for Acquisition Costs

Addressing search and procurement costs is essential to protecting beneficiary access. The process of finding a matching adult volunteer donor or a cord blood unit is not simple. Once a patient and physician determine that the patient requires a bone marrow transplant and that there is no potential donor in the patient's family, the search for a potential volunteer donor begins. Seventy percent of patients do not have a match in their family and must search the Be The Match Registry to find an unrelated donor or cord blood unit. The patient's physician requests a search of the Be The Match Registry and then reviews the results. The preliminary search results will show a list of potential donors and cord blood units that are predicted to be a HLA match for the patient. Additional testing is needed to find out which of the potential donors or cord blood units are truly suitable for the patient. The next step is to begin a formal search of the registry. The goal of the formal search is to find out whether potential donors or cord blood units listed on the preliminary search results are truly suitable matches for the patient. This search is an agreement between the patient and the transplant center which allows the center to contact potential donors and have lab tests done on behalf of the patient. An average of 4-7[3] potential donors, both related and unrelated, are tested at this stage. The vast majority of commercial insurers separately reimburse transplant hospitals for the cost of these tests. Currently, Medicare does not.

With these test results in hand, the patient's physician will identify the best donor or cord blood unit for the patient. The transplant center will retest the identified donor or cord blood unit to confirm the match. The donor will also have more blood tests and a physical examination to ensure that they do not have an infection or a disease that could be passed onto the patient through the transplant. These tests also make sure that cell donation is safe for the donor. The vast majority of commercial insurers cover the cost of these tests and make separate payments as costs are incurred. Currently, Medicare bundles them with the DRG or APC payment.

The transplant physician will determine whether to ask for marrow to be extracted through a surgical procedure or for peripheral blood stem cells (PBSC) will be collected through apheresis. This decision is made based on the disease and condition of the patient, as well as the donor. If cord blood is the best cell source option, a sample of the cord blood will be tested to confirm that it matches the patient. Screening for infectious diseases and other medical problems is done before the cord blood units are stored.

Next, the transplant center and the donor center will work together to schedule a donation date. The date depends on the patient's health and when the patient will be ready for transplant. On the scheduled date, the marrow or blood cells are collected. A trained volunteer or professional courier from Be The Match will bring the new cells to the transplant center as quickly as possible but within 48 hours. If cord blood is chosen for the transplant, the transplant center will ask for the cord blood unit to be shipped. Cord blood is stored frozen and

[3] The number of donors tested depends on an individual patient's Human Leukocyte Antigen (HLA) typing. For more information, please see: www.bethematch.org/Transplant-Basics

can be delivered to the transplant center within 24 hours. Be The Match will arrange the shipment of the cord blood to the patient's transplant center.

The average cost for search and procurement is $30,000-$60,000. HRSA reviews the costs associated with these services and has agreed to the rates charged to the transplant centers. Transplant centers are not able to shoulder these upfront costs without cost reimbursement, especially when the MS-DRG and APC rates are set at amounts below the cost of providing services to these patients beyond the search and procurement costs.

Thus, just as CMS does for living kidney donors and corneal tissue, as well as solid organs, CMS should recognize the search and procurement costs associated with HCT transplant. We continue to believe that the Agency has sufficient authority to act without additional Congressional action, as described in the attached memorandum. We also understand that the Agency has concerns about exercising this authority. Given these concerns and the unique role of the government in overseeing HCT transplants, we encourage you to meet with us to discuss these concerns more specifically and try to find ways to protect access to beneficiaries by making sure that the reimbursement rates cover the search and procurement costs associated with providing transplant.

The number of transplants provided annually in the outpatient setting is low – 66 allogeneic and 319 autologous in CY14. Transplant centers would like to consider the development of outpatient allogeneic transplant programs but have been unable to move forward due to inadequate reimbursement in this setting. CMS states that the acquisition costs are packaged into APC payment rates. However, as stated in previous comments, the complexity of an HCT procedure makes it unlikely for CMS to have usable single procedure or pseudo-single procedure claims for the rate-setting process. The CY2014 data identified 11 of the 66 HCT claims as single procedure claims, and we strongly believe these are miscoded or incorrectly reported claims. Even with the known cost reporting and claims processing issues, the geometric mean cost for CPT code 38240 is $6,106.54, almost twice the APC geometric mean of $3,217.20.

The average true cost to a transplant program for just the identification of a donor source and acquisition of cells is between $30,000-$60,000, as stated previously. This cost is clearly not reflected in the APC payment rate in any meaningful manner. We believe this is primarily due to CMS' single vs. multiple procedure claims issue but may also be due to the fact that CMS uses the hospital's department specific CCR for other organ acquisition (revenue code 819 per the OPPS revenue code to cost-center crosswalk is mapped to cost center 8600) to reduce charges reported with revenue code 0819 to costs. This is problematic since most hospitals still struggle with understanding CMS' rate-setting methodology and/or applying a mark-up such that CMS can compute a cost that matches their own. This again reinforces the need for CMS to better isolate the actual costs associated with donor source and cell acquisition.

We ask that CMS develop a reasonable cost basis solution for HCT that mimics the acquisition cost procedures for solid organ transplantation, as this would be the simplest solution for the agency and for providers and would help preserve and expand access to HCT. If this is not done, then at a minimum CMS must find a way to incorporate the donor search and cell acquisition charges reported through revenue code 819 into the overall outpatient transplant APC rate. CMS could do this by creating a Composite APC whereby it looks for the allogenic transplant CPT code and a revenue code 0819 and creates an appropriate rate or CMS could study applying the Comprehensive APC concept to HCT. CMS should create payment parity for the donor search and cell acquisition component of HCT between the inpatient and outpatient settings.

**B. We Encourage CMS to Assess Methods That Would Improve Data Accuracy.**

We appreciate the Agency's efforts to improve billing guidance, but urge CMS to continue to emphasize to hospital outpatient departments the importance of providing accurate data so that CMS has the information it needs to assess the payment rates on an ongoing basis. Ideally, we would ask that the agency continue to review ways to reimburse separately for donor search and acquisition costs, as it does for solid organ transplant. Alternatively, we encourage CMS to take some additional steps that would improve the quality and accuracy of the data it receives.

First, CMS could require transplant centers to submit their actual cost information on the UB-04s for both allogeneic related and unrelated transplant patients. This would be similar to how it collects cost information for devices replaced at full or partial cost and then use this information for donor search and acquisition costs in the rate-setting process.

Second, CMS could instruct providers to report their actual cost on the revenue code 0819 claim line item so that CMS can apply a default cost-to-charge ratio of 1.0 for outpatient allogeneic HCT claims. This would be defined by the presence of an outpatient allogeneic CPT procedure code and would at least allow CMS to reimburse providers appropriately in the outpatient setting for their donor search and cell acquisition costs which is not being done today.

Third, as stated previously, we believe CMS would be able to collect much more accurate and complete data on donor search and cell acquisition costs if it creates a dedicated cost report line for the collection of these costs and instructs providers to use it rather than asking providers to report these costs in line 62 or 63. Along with this, CMS should request the NUBC to release a new, dedicated, revenue code for providers to use when reporting their HCT donor search and cell acquisition charges.

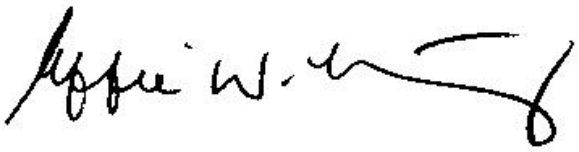
Finally, we suggest that CMS describe clearly in the preamble to the final rule that it is incumbent on hospitals to report all of their donor search and cell acquisition charges on the recipient's transplant claim. We believe the additional emphasize in a final rule as well as more discussion in the claims processing manual would help our continued efforts to educate hospitals about the importance of providing accurate and complete cost data about donor search and cell acquisition charges to allow CMS to appropriately monitor the costs of HCTs, as well as to create more accurate payment rates in the future.

## III. Conclusion

The NMDP and ASBMT are ready to support additional data studies to assess any remaining potential alternate methodologies for capturing hospital acquisition costs and would be pleased to work with the agency. We acknowledge that 66 cases per year in the outpatient setting is a very small volume service in comparison with most Medicare services for beneficiaries. However, these individuals greatly benefited from receiving a transplant. In addition, these 66 transplants were able to avoid the resource-intensive inpatient setting which helps reduce costs for the Medicare program. Improved reimbursement methodology and the potential to be reimbursed for true costs in the future would further encourage growth in the utilization of outpatient transplantation. We appreciate that CMS will continue to monitor the issue. Please do not hesitate to contact Stephanie Farnia with the NMDP at (612) 884-8640 sfarnia@nmdp.org if you have additional questions.

Sincerely,

**AMERICAN SOCIETY FOR BLOOD & MARROW TRANSPLANTATION**



Effie W. Petersdorf, MD
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**NATIONAL MARROW DONOR PROGRAM / BE THE MATCH**

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