August 29, 2014

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS–1613–P: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: Appeals Process for Overpayments Associated With Submitted Data

Dear Administrator Tavenner:

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 "Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: Appeals Process for Overpayments Associated With Submitted Data" (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 stem cell transplants (SCTs) by establishing adequate reimbursement when these transplants are provided in an outpatient setting.

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.

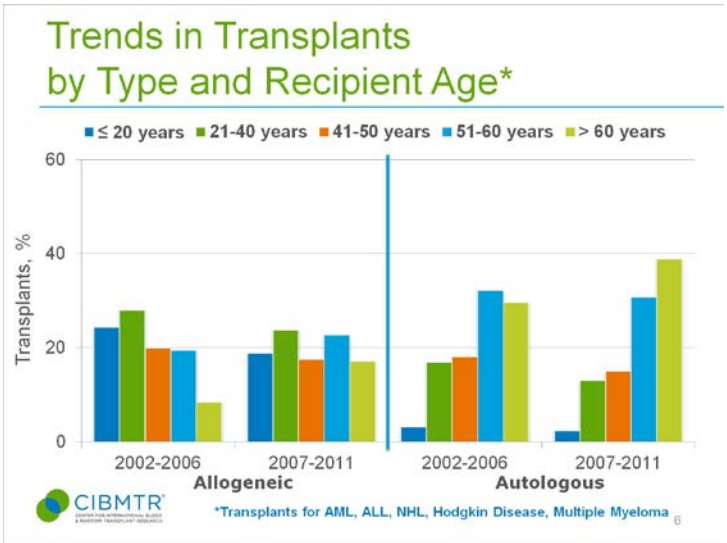
The American Society for Blood and Marrow Transplantation is an international professional membership association of more than 2,000 physicians, investigators and other healthcare professionals promoting blood and marrow transplantation and cellular therapy research, education, scholarly publication and clinical standards. From its beginning, ASBMT activities have focused on (1) fostering research and development of transplantation both as a science and a therapy; (2) responding to and representing multiple medical and scientific disciplines involved in blood and marrow transplantation; (3) defining commonly accepted medical practice and developing standards of medical care for autologous and allogeneic transplants that can be used as guidelines for transplant centers and for professional training in blood and marrow transplantation; (4) conducting and coordinating analyses for effective regulation of autologous and allogeneic transplantation; (5) sponsoring publications and meetings for the exchange of scientific and clinical information; (6) sponsorship of voluntary accreditation programs for transplant centers; (7) providing recommendations and guidelines about the role of transplantation as a therapeutic approach for reimbursement by third-party insurers; and (8) encouraging physicians and ancillary health care personnel to enter the field of blood and marrow transportation and assisting them with mentoring, research funding, an annual training course, editorial

awards, travel grants and other similar programs. ASBMT is committed to ensuring access to all patients who need adult stem cell transplants.

I. CMS Should Protect Access for Beneficiaries Who Need a Live-Saving Adult Stem Cell Transplant.

Advances in medical science now allow individuals over the age of 65 to benefit from life-saving adult stem cell transplants (SCT). 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. The results have been positive. Outcomes data clearly demonstrate that SCT is as effective a treatment for individuals who are 65 and older as it is for younger patients.

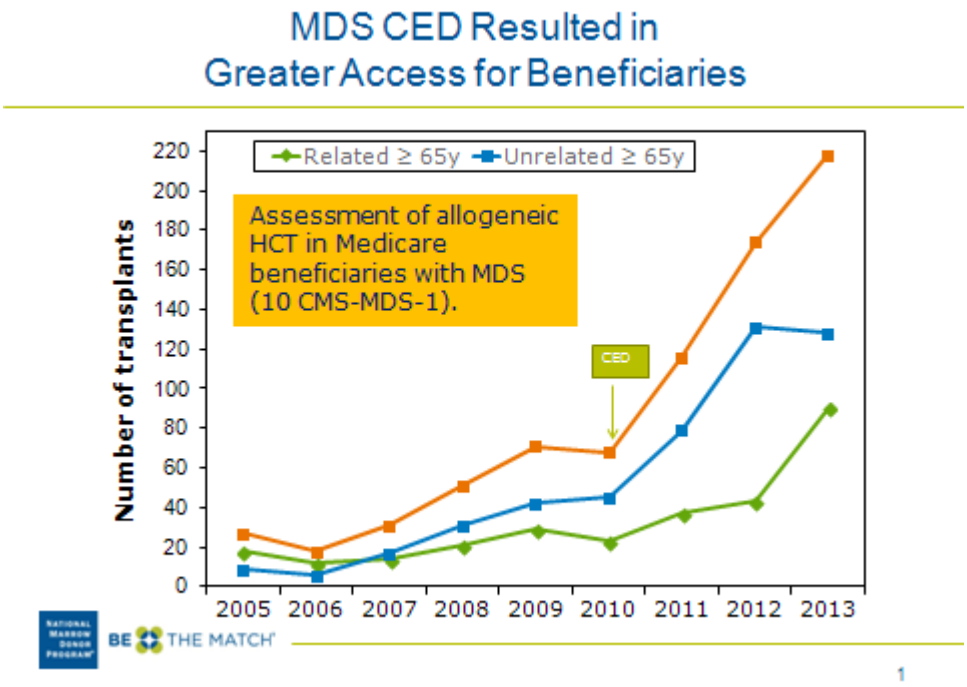
Between 2010 and today, the rate of SCT in the over 65 population has increased substantially, though the absolute numbers are still comparatively low (FY13 data, n= approximately 3500 per year, autologous and allogeneic, inpatient and outpatient combined).



Patients who do not have access to transplant will likely face expensive, futile alternative treatments. There are no potentially curative alternatives for Medicare beneficiaries eligible for SCT. If access is limited, the mortality rate is extremely high.

The Medicare program has recognized this advance and now covers SCTs for certain types of conditions, including Myelodysplastic Syndromes (MDS). The growth in SCT for MDS in the Medicare population since

the CED began indicates the financial and policy barriers that are preventing clinical access, shown in the chart below.



However, these results are only a part of the solution in assuring access to beneficiaries. Reimbursement policies also need to be in place for patients to have access to these types of transplants. In our work with transplant centers trying to provide SCT to Medicare beneficiaries, it has become clear that the current reimbursement amounts create a significant barrier to beneficiaries in need of a bone marrow or cord blood transplant. Reimbursement rates in both the inpatient and outpatient settings are significantly below the actual cost of delivering these life-saving procedures. At the same time, there are a growing number of Medicare beneficiaries in need of SCT. 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, programs have reported anecdotal average losses of tens of thousands of dollars per patient. This fact is not surprising given that Medicare continues to pay separately for allogeneic transplantation procedures under APC 0111 (Blood Product Exchange) and APC 0112 (Apheresis and Stem Cell Procedures), with proposed rule geometric mean costs of approximately $1,127 and $3,064, respectively. Additionally, the current reimbursement mechanism does not treat donor search and acquisition costs in the same manner as it does solid organ acquisition costs.

These losses are threatening the continued existence of such programs as hospital administrators question the financial ability to continuing to offer transplant to Medicare beneficiaries. Patients who do not have access to transplant will likely face expensive, futile alternative treatment. In most cases, the lack of a transplant will result in death.

We appreciate that the Agency would like additional data before adjustment of the reimbursement rates. However, as have discussed, the lack of experience with coding these type of transplants means that very few hospitals have completed the cost reports appropriate. The NMDP and ASBMT are already four years into an educational initiative to try to help hospitals better understand the appropriate way to code SCTs when they are medically appropriate. Even so, it will take several years before the data sets are sufficiently robust to support

a revision to the payment rates. Because we believe it is critical that CMS begin addressing the reimbursement problem to protect access to these transplants for beneficiaries, we offer a set of suggestions in Section II to try to establish an appropriate reimbursement methodology while additional data can be collected.

II. The NMDP and ASBMT Strongly Encourage CMS To Improve the Accuracy of the Data Being Reported on SCT and To Reconsider Applying Comprehensive APCs (C-APCs) for SCTs that Occur in the Outpatient Setting.

The NMDP and ASBMT appreciate CMS's ongoing review of the rate-setting methodology current being applied to SCT in the outpatient setting. However, we remain concerned about the current reimbursement rates for SCT because they threaten beneficiaries' access to bone marrow and cord blood transplants, as described above. 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.

A. We Recommend that CMS Reconsider Establishing C-APCs for SCT To Establish the Appropriate Methodology for Determining Reimbursement Rates.

While we appreciate the Agency's interest in continuing to monitor the impact of payment rates for SCT, as well as the volume of outpatient allogeneic transplant services, we remain concerned that the number of transplants in the hospital outpatient department setting will decrease if payment rates are not set closer to the actual cost of providing these services. As the steward of the national registry, one of our obligations is to reduce barriers to transplants. Thus, we would like to continue working with CMS to develop a comprehensive solution for this problem.

We understand that donor search and acquisition costs for SCT are considered packaged within the hospital outpatient department setting, which is why we continue to urge CMS to establish comprehensive APCs (C-APCs). Using the C-APC methodology would parallel the methodology used in the inpatient rate-setting system. Under the inpatient prospective payment system, CMS allows the donor search and acquisition costs to be package into the transplant procedure and become part of the data utilized in the rate-setting process for the Medicare Severity – Diagnosis Related Group (MS-DRG). We ask for methodological equity in the outpatient setting.

The current APC rate-setting methodology's reliance on single procedure claims often precludes these packaged charges from being reflected in the APC payment rates. As it stands today, any improvement providers make in their coding, billing, or charge capture processes and reporting of SCT claims will more than likely <u>not</u> be used by CMS in its rate-setting due to the single vs. multiple procedure claims issue. In fact, claims that are correctly coded *from a clinical standpoint* will almost certainly be multiple procedure claims, as there are many billed services that occur in support of and ancillary to the main SCT procedure. The 2015 CPT Cost Statistics file provided with the proposed rule supports our concern – only 8 of the 60 transplant claims filed were able to be sorted as single claims, and <u>none</u> of these were utilized in the rate-setting process. The only two codes utilized were apheresis and photopheresis, neither of which is similar in clinical complexity or resource use to transplantation. This is typical of the data files from recent years. The geometric means of 38240 and 38241 below reflect the issue of concern, in that they are not clinically correct claims capturing the full resource consumption of SCT.

APC 0112 - Apheresis and Stem Cell Procedures
APC GMEAN DATE 06/03/14 CATEGORY 18.00 67.00 1.00 OFFLINE?
GMEAN COST (TOTAL) = $3,037.67

HCPCS		SI	DESCRIPTION	--TOTGMN---	--FREQ--	PCT	TOT.FREQ.
0264T	NJ11	S	Im bl mrw cel ther xcl hrvst	$0.00	0		0
0265T	NJ11	S	Im bl mrw cel ther hrvst onl	$0.00	0		0
0342T	NI14	S	Thxp apheresis w/hdl delip	$0.00	0		0
38240		S	Transplt allo hct/donor	$720.72	8		60
36515		S	Apheresis adsorp/reinfuse	$1,041.55	42		90
38241	CP8	S	Transplt autol hct/donor	$1,330.26	12		283
*36516		S	Apheresis selective	$2,130.90	1264	13	1352
*36522		S	Photopheresis	$3,241.22	7906	85	9482
0263T	NJ11	S	Im bl mrw cel ther cmpl	$3,267.69	2		4
38232	NI12	S	Bone marrow harvest autolog	$3,281.66	7		44
38230	CP8	S	Bone marrow harvest allogen	$3,935.11	4		18
					9245		11333
				TOTALS:			

It is for this reason that our organizations ask CMS to reconsider our recommendation to create C-APC, or alternate methodology, for these services. We fully understand that moving these services to a C-APC will not result in an improved reimbursement rate currently, but a corrected methodology would allow for the possible of reimbursement to move into alignment with true cost over time. Thus, this methodology coupled with additional guidance from the Agency and educational efforts by the NMDP and ASBMT would establish the correct framework for addressing the problem in a data-driven manner.

Establishing C-APCs for SCT services would also align the payment policy with the Agency's efforts to establish more comprehensive payment bundles and packaging. It would also allow all billing detail from future claims to be fully captured by the rate-setting process. Moreover, the structure of C-APCs, in which all reported outpatient claims data would be used to determine future reimbursement rates, would be highly motivating to hospital outpatient departments attempting to improve the reporting of their actual costs to report accurately and completely each and every time. Most importantly, it would create a solid foundation for ensuring continued beneficiary access to these services.

B. We encourage CMS to Revise the Way Cost Information about SCT Is Provided To Improve the Accuracy of the Data.

We also 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 three 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 SCT claims. This would be defined by the presence of an outpatient allogeneic CPT procedure code.

Third, we suggest that CMS describe clearly in the preamble to the final rule that it is incumbent on hospitals to report the donor charges with their claims. We believe the additional emphasize in a final rule could help our efforts to educate hospitals about the importance of providing accurate cost data about donor charges to allow the Agency to appropriately monitor the costs of SCTs, as well as to potential adjust 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 60 cases per year in the outpatient setting is a very small volume service in comparison with most Medicare services for beneficiaries. However, these 60 individuals greatly benefited from receiving a transplant. In addition, these 60 transplants were able to avoid the resource-intensive inpatient setting. 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,

NATIONAL MARROW DONOR PROGRAM – Be The Match

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