August 21, 2017

Administrator Seema Verma
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
CMS-1677-P 4; Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850
(Submitted electronically via Regulations.gov)

Re: Quality Payment Program - CMS–5522–P

Administrator Verma:

The American Society for Blood and Marrow Transplantation (ASBMT) is an international professional membership association of more than 2,200 physicians, scientists and other healthcare professionals promoting blood and marrow transplantation and cellular therapy research, education, scholarly publication and clinical standards. ASBMT is dedicated to improving the application and success of blood and marrow transplantation and ensuring access to all patients who need hematopoietic cell transplants.

Blood and marrow transplantation has several pseudonyms, including bone marrow transplantation, stem cell transplantation, cord blood transplantation, peripheral blood stem cell transplantation and hematopoietic cell transplantation. For purposes of simplification and scientific comprehensiveness, we will utilize hematopoietic cell transplantation (HCT) for the remainder of this document.

Hematopoietic cell transplantation is a medical sub-specialty comprised of physicians with Board Certifications in Internal Medicine, Medical Oncology, Pediatrics, Hematology and/or Immunology. Despite common misconceptions, HCT physicians are not surgeons and the introduction of hematopoietic cells into patients is performed via infusion, not open incision or other surgical procedures. HCT is a procedure that involves the infusion of either autologous (self) or allogeneic (donor) hematopoietic stem (progenitor) cells into a patient to reconstitute the patient’s immune system as part of a larger treatment course for three primary clinical purposes: 1) treatment of malignancy, 2) replacement or modulation of an absent or poorly functioning
hematopoietic immune system, 3) treatment of certain genetic diseases.\textsuperscript{1} CMS recognized the unique role and qualifications of HCT physicians by designating a unique code for Hematopoietic Cell Transplant and Cell Therapy (HCTCT) physicians in November 2016.\textsuperscript{2}

\textit{HCT Utilization in the United States}

By Federal mandate, the Center for International Blood & Marrow Transplant Research (CIBMTR) records data on each of the allogeneic HCTs performed within the United States each year. In 2015, the most recent verified data year, approximately 8,000 Allogeneic HCTs and 14,000 Autologous HCTs were performed on patients in the United States.\textsuperscript{3} Of these, approximately 50\% were performed in individuals 60 years of age or older. There has been substantial growth in the number of transplants performed in older individuals in the last 20 years due to advancements in preparative regimens and the ability to manage common age-associated co-morbidities.

\textbf{Comments on Quality Payment Program Year 2 Proposed Rule}

ASBMT appreciates the opportunity to comment on several areas of concern in regard to the Quality Payment Program (QPP) Year 2 Proposed Rule. Our member clinicians work primarily in large academic medical centers, specialty cancer hospitals or other stand-alone cancer focused institutions and many will be participating in the Advanced APM track through the Oncology Care Model. The commentary we provide in this letter is relevant to our members planning to participate in QPP via MIPS.

\textit{Implementation Timeline and Weighting}

ASBMT appreciates CMS’ demonstrated flexibility and acknowledgement of the complexities of implementation that is demonstrated in the Year 2 proposals, including raising the low-volume threshold and retaining a cost weight of 0\%. We support these modifications.

\textit{Quality Topped Out Measures}

We understand CMS’s rationale for eliminating ‘topped out’ measures after three years through the rule making process. We ask that CMS review topped out measures being considered for

\textsuperscript{1} National Institutes of Health, National Cancer Institute \texttt{Hematopoietic Cell Transplantation Summary}

\textsuperscript{2} CMS \texttt{MLN Matters MM957}

elimination in the context of possible alternatives for subspecialties before proposing removal. If a subspecialty area has a limited number of relevant options for reporting, it will be problematic to find another clinically meaningful measure to replace the one being removed. If CMS chooses to eliminate measures from specialty areas with limited options, we ask that CMS give more than one year’s notice so that the relevant societies may work together to develop new valid, meaningful and reliable measures.

Calculation of Cost-Based Measures

To achieve accuracy in cost comparisons and outcomes, CMS needs to have access to detailed information about the patient population, such as disease sub-type and stage, modifiers indicative of disease status and comprehensive coding of all comorbidities affecting care, outcomes and costs. Current provider and coder practices do not reflect this need and CMS should develop programs encouraging providers and facilities to improve the accuracy of coding together. Additionally, CMS should consider utilizing codes that can be linked to the social determinants of health in order to gain a clearer picture of the patient encounter. There are codes available in ICD-10 that may be useful in understanding these elements, including compliance with medications or medical care or stress due to family dynamics. To assist with promotion of documenting these social determinants and other sensitive information, including mental health diagnoses, it would be useful for CMS to allow providers to maintain restricted sections of the chart for providers to document such problems so that this information may be confidentially shared with other providers during times of care transitions. CMS could also consider asking for the ICD-10 Coordination and Maintenance Committee to develop coding to capture other issues of care complexity – such as lack of a care giver, home located at an extended distance from hospital and inability to afford medications.

Episode of care cost calculations have largely been focused on surgical procedure episodes; additional work is needed when evaluating acute care and chronic illnesses. Chronic medical diseases, acute medical disease and/or acute exacerbations of chronic disease have much more heterogeneity of costs than standard surgical procedures due to the disease severity differences and the interactions of the episode-driving illness with other co-morbidities. ASBMT understands MACRA statutorily requires CMS to compare providers caring for chronic and acute medical diseases without procedures. To minimize the distortions of extreme variance and low numbers, ASBMT requests CMS use the mean plus 1 standard deviation for the financial baseline unit for comparison, rather than just the mean, for physician providers of chronic disease management and acute medical disease care.
Acuity Adjustment

ASBMT acknowledges that CMS recognizes the need for medical acuity adjustment in doing cost comparison of care providers. We ask that CMS pay special attention to the application of the HCC system developed for Medicare Advantage beneficiary payments. Cancer staging and molecular phenotyping are the drivers of medical oncology treatment decisions and care costs, but are not captured in ICD-10 coding and therefore are not being used in the complexity calculations. As part of monitoring QPP’s ability to assess patient severity, CMS could work to implement new coding where needed and have frequent procedural reviews of factors requiring changes in acuity adjustment for medical disease. Without accurate adjustment, access challenges could arise for the sickest beneficiaries as increasingly levels of Medicare reimbursement are tied to provider outcomes and some providers may feel the need to screen accordingly.

In November of 2016, ASBMT was notified by CMS ASBMT’s request for separate specialty designation for our physicians was approved; physicians performing transplant and cell therapy services were to be designated as Hematopoietic Cellular Transplantation and Cellular Therapy physicians (HCTCT) rather than be considered as Hematology or Hematology-Oncology physicians. CMS approved this request because HCTCT physicians have demonstrated higher and different resource utilization than Hematology and Hematology-Oncology physicians in claims database analyses. This designation will be available for providers to utilize in FY2018 and we ask that CMS consider having HCTCT physicians not be mapped to HCC acuity designations for Hematology (1.95) or Hematology-Oncology (1.92), but be coded instead as Critical Care Physicians (2.06) until enough data exists to create a specific acuity attribution for HCT clinicians. The acuity level and nursing needs of HCTCT inpatients meet Medicare criteria for critical care beds; patient resource consumption is as great as intensive care patients.

Specialty Designation of Non-Physician Care Providers

Many ASBMT members are nurse practitioners and physician assistants who play crucial roles in their care teams. Advanced Practice Providers (APPs) are not able to claim specialty designation status in the Medicare claims data in the same way that our member physicians will be able to in the upcoming fiscal year, but they will be evaluated for their costs of care through the MIPS system. APPs working in the transplant field may be adversely judged against similar degreed providers who provider care for lower complexity patient populations that utilize fewer
resources. ASBMT urges CMS to consider attaching specialty designation to activities of physician assistants and nurse practitioners practicing on their own license. ASBMT is appreciative of allowing performance analysis at the team level by using a common tax identification (TIN) as an alternative to comparisons using NPI numbers. In HCT, our physician members work in team formats with set periods of time as the lead inpatient physician – patients may experience 2 or more physician lead ‘shifts’ during their transplant stay. ASBMT views this use of group identifiers as consistent with Congressional intent to promote team based care delivered by appropriate level providers.

Qualified Clinical Data Registry
Since 1972, the Center for International Blood and Marrow Transplant Research (CIBMTR) has continuously captured hematopoietic cellular transplant outcomes, both from the United States and internationally. CIBMTR’s focus on data collection has resulted in over 1,000 peer reviewed outcomes publications that have improved outcomes for the past 4 decades. CIBMTR has data collection and measurement insights that would likely be useful to CMS and other disciplines. We appreciated CMS’s efforts in the first QPP annual rule to allow clinical data registries that collect center-specific data to act as qualified clinical data outcomes registries (QCDR) through collection of data of a specialty group of doctors practicing under a common TIN. Current program requirements are still problematic for CIBMTR to qualify as a QCDR. We would propose that ASBMT and CIBMTR meet with CMS to share capabilities and concerns with the current program requirements.

Contact Information and Resources for CMS

The ASBMT greatly appreciates the opportunity to review the Agency’s proposal in regard to the Quality Payment Program. ASBMT peer-elected leaders, member clinicians and policy staff are available as a resource for CMS staff when issues associated with HCT and other cellular therapies are raised internally in the future. Please do not hesitate to reach out whenever we may be of assistance.

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