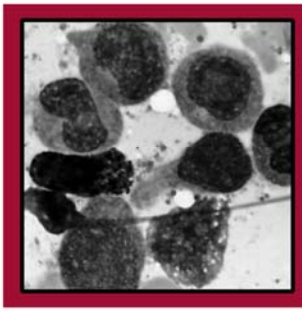

ASBMT™
American Society for Blood and Marrow Transplantation

Executive Office
85 West Algonquin Road, Suite 550
Arlington Heights, IL 60005-4460
Telephone: (847) 427-0224
Fax: (847) 427-9656
Email: mail@asbmt.org
Web: www@asbmt.org

June 24, 2016

Acting Administrator Andrew Slavitt
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-5517-P,
Mail Stop C4-26-05,
CMS-5517-P TLP 4/25/16 3
7500 Security Boulevard,
Baltimore, MD 21244-1850.

Dear Director Slavitt:

We are writing on behalf of the American Society for Blood and Marrow Transplantation (ASBMT) to comment on the proposed MACRA rule. Since 1993, The ASBMT has been the national professional association that promotes education, research and clinical affairs that advance the field of cellular therapy and blood and marrow transplantation.

As regards MACRA, the ASBMT is well positioned to provide insights as many of the ideas contained within the proposed MACRA rule have been integral to the steady improvement of outcomes for blood and marrow transplant recipients over the last 25 years. As background, hematopoietic cellular transplantation (HCT) has been paid for by commercial payers for 25 years, primarily with bundled care payments for episodes of care. As a specialty we have had an outcomes data base in continuous operation since 1972. Many advances in our field as well as issues of disparity, have been led by the appropriate scientific analysis of this data. In 1993, the ASBMT and our sister organization, the International Society of Cellular Therapy (ISCT), put in place an organization for the self-regulation of HCT. Accreditation by the Federation for the Accreditation of Cellular Therapy (FSCT) is recognized as a cornerstone to providing high quality care and is a basic requirement for most payers. Since 2004, all HCT programs in the United States have had to report center specific acuity adjusted 1-year survival of allogeneic (donor) transplant recipients. While many organizations are commenting on the technicalities of payment and global aims of the MACRA program, the ASBMT is particularly well suited to provide commentary to CMS regarding operational issues that likely will arise when using a team-based medical care of complex patients if the MACRA rule is implemented as currently written.

The physician-specific patient-specific outcomes measures assume that physicians in every specialty care for a similar bell shaped curve patient population. Hematopoietic cell transplant physicians, whether classified as hematologists or medical oncologists care for patients with life threatening diseases of bone marrow failure, acute leukemia, chronic leukemia, lymphoma and multiple myeloma. Often we are referred patients failing other therapies. These patients are very different in resource consumption than patients with clotting disorders, hemoglobinopathies, or solid tumors which are the norm for hematologists and medical oncologists. The resources to care for HCT transplant patients is in general far greater than required for the other patient populations. The care of HCT patients includes significant in-patient in addition to out-patient periods of care.

These complex immunocompromised patients often require readmission to the hospital. Nearly all of their care is team based versus solo provider. As our patient population and practice model is quite different than other areas of hematology or medical oncology, in order to evaluate our care fairly, transplant physicians must be evaluated against their peer group. Thus we have urged CMS to designate "Hematopoietic Cell Transplantation and Cellular Therapy" to be a separate specialty as per our request to Director Howe on September 10, 2015.

Recently the NIH sponsored a Late Effects of Blood and Marrow Transplant Survivors Consensus Conference. This conference reviewed all the late effects that our survivors are at risk for, highlighting that their care is more difficult than for other similar age patients. Our HCT survivors are at increased risk for ischemic heart disease, metabolic disorders including diabetes, chronic kidney disease, second malignancies, severe infections due to their immunocompromised status, and mental health problems such as depression, adjustment disorders and survivor's guilt. These patients will have increased resource utilization compared to similar age patients from a primary care practice. In absence of appropriate acuity adjustment, we are concerned our survivors may have care access issues as providers will not want to accept patients who will adversely affect their resource utilization profile. We do see a need and a responsibility for our physicians to be part of the care team for all of our survivors, both short term and long term. Highlighting the importance of long term follow up of patients cured by HCT, FACT is developing standards regarding the need to provide long term care support for patients and payers are interested in discussing ways in which this could be built into their payment models. We would like to work with CMS to develop attribution coding to help in the care and follow-up of our survivors.

As mentioned above, the care of HCT patients is provided by a team that includes multiple transplant physicians. One physician may see the patient for the initial assessment and planning to get the patient into transplant, several may see them as inpatient as we often rotate physicians on inpatient duty every 1-2 weeks and another physician may follow them post admission. Additionally, all of our teams have some of the care delivered by advanced practice professionals. We cannot measure our doctors by individual patient outcomes, but we can measure and accredit team based performance. We do not think HCT is unique in this regard. Consideration of mechanisms to evaluate team care delivery are required in MACRA. Our outcomes registry, run by the Center for International Bone Marrow Transplant Research (CIBMTR) (formerly the International Bone Marrow Transplant Registry, IBMTR) has high quality data on HCT outcomes by teams, but it cannot be a qualified reporting registry for MACRA as currently proposed, because its outcomes are not and could never be physician specific. The CIBMTR has a wealth of experience operationally as an outcomes registry for over 40 years. CMS should take advantage of this CIBMTR experience not only for evaluating team-base quality outcomes for HCT patients but for assistance in helping other specialties with team-based care enhance their outcomes reporting.

We worry the current diagnosis coding system is not granular enough to appropriately measure costs and outcomes for these complex patients. The measurement of outcomes for certain diagnoses is challenging in patients with multi-organ dysfunction. As an example, many HCT patients must be treated with high dose steroids either for leukemia disease control or for management of graft vs. host disease. Steroids cause insulin resistant diabetes. Assessing doctors for management of diabetes in such a context would be problematic as measurement of hemoglobin A1c would be nonsensical. We need to be able to code diabetes in our patient population, but we cannot be assessed for poor control of diabetes as good control is impossible with diabetes when patients are on high dose steroids. Normal diabetic treatment monitoring would be wasteful in our patient population. Outcomes measures used must be relevant to the patient circumstances. In the proposed rule, CMS commented on the need for risk adjustment, but did not state whether those physicians caring for the sicker patient will have risk adjustment to neutrality. We are also concerned the coding system is not refined enough to prevent access issues.

Outcomes reporting in MACRA requires physician providers to document in their notes all factors affecting outcomes, especially factors adversely affecting outcomes. Socioeconomic status, family support systems, cognitive dysfunction and mental health issues affect compliance and outcomes. Coding for some of this is poor, even in the available options for diagnostic coding. We are concerned that open access to all physician notes will jeopardize proper documentation of these issues. While patients own their notes, physicians are the authors. One of the most crucial purposes of a physician note is the communication to the successor physician, the thoughts and concerns of the provider so that there can be a safe transition of care. Any rule that inhibits honest

documentation of issues and concerns will create both a milieu for error and access problems for patients prone to noncompliance or sabotage of care. These types of patients while challenging, must have unimpeded access to care as they will cost more if there are barriers to their timely and comprehensive care. Diagnostic coding must include these concerns so there can be proper acuity adjustment in measuring physician or team performance. We suggest that all charts have certain areas of restricted protected access to allow documentation of such issues. This type of charting must be available to physicians who are not categorized as mental health professionals.

We are concerned about the patient satisfaction surveys, particularly in the context of team based care delivery. Individual scoring of patient satisfaction is prone to misassignment of both good and bad quality. The bad quality is often a problem for the bearer of bad news or very unexpected news. For example, cancer physicians giving a realistic survival chances and a thorough description of the toxicities of therapy, have by our experience had lower scores than physicians just giving optimistic news. A second relevant example is satisfaction surveys of physicians providing pain management in patients with legitimate real pain and simultaneously having addiction issues which occurs all too frequently with cancer patient. Physicians must walk a fine line in managing of such patients. Controlled use of narcotics is an essential component of good care. Good care here dictates physicians setting limits. Yet patients are not appreciative of that need and often critique the good physician harshly in satisfaction surveys. Similar problems occur with physician treatment patients with delirium and early cognitive deficits.

The HCT transplant field has lots of experience with bundled payments for episode based care. Early transplant bundles payments attempted to exclude costs associated with pre-existing conditions. Billing operations staff for both providers and payers could not micromanage a bill to pull out creatinine and glucose blood levels for diabetic hypertensive patients getting a HCT, let alone deciphering whether to attribute it to either the pre-existing diabetes, hypertension or the glucose raising, hypertension causing immunosuppressive drugs needed for the HCT. Specialty practices assuming care management and payment for a time episode must care for all the patient's medical needs, not just the specialty issue. There is no other practical workable solution. HCT doctors have maintained their general medical or general pediatric skills.

There are also many patients diagnosed with a malignancy or requiring HCT with limited resources. Many patients only have time or resources to worry about the immediate issues of daily existence and are not able to incorporate preventative health measures into their daily lives. Sadly, it is the catastrophic cancer diagnosis that brings them into the healthcare system. There have been many middle age patients with new acute leukemia who as we treat their leukemia, we discover they have untreated diabetes, coronary artery disease, sleep apnea and/or hypertension.

These comorbidities increase resource utilization and add to the cost of care, making bundled payment care a challenge to price fairly. Even without comorbidities, HCT patients are prone to complications that can be very costly. The most expensive quartile of patients can have 10 fold the resource consumption of the median. For high risk diseases and complex therapies, while there can be an episode bundle, there must also be outlier clause payment methodologies. If not, there is a risk that a few catastrophic patients could bankrupt a community hospital system and its associated practices. Such a calamity could hurt access to care for an entire community.

Even in a bundled episode based care system, there remains a requirement to measure clinical care services provided. The Medicare fee for service relative value unit (RVU) system will remain the accounting tool for such care measurement. MACRA focuses on population management and disease management over time. Care coordination as part of longitudinal care is an essential service. For physicians in population management roles, we need the fee for service system to recognize and pay for complex care management. The care coordination for HCT patients is more complex and work effort exceeds that captured in the existing chronic care management and transitional care management codes. This non face to face time for complex care management is where the quality of care will happen. For it to happen at the highest level of quality requires time and time requires payment recognition even in the context of a bundled payment. To assist with care delivery for our long term survivors in community setting far from the HCT center, we need payment for telehealth services both for HCT physician to the patient and for HCT physician to the community physician. For HCT bundled payment of physician services, the fee for service division of the professional bundled payment is reflected via RVUs. As outlined above, RVUs need to reflect the work effort for these patients, including complex care coordination.

We are currently preparing a manuscript for publication describing how HCT care delivery offers an example for a patient centered medical home for complex specialty medicine patients. ASBMT recognizes that Merit Based Incentive Payment System (MIPS) is at best a short term solution for its members. Long term HCT is best compensated for physicians and facilities via an alternative payment model. HCT has much experience with bundled payment for episode based care. We will at some point request a meeting with CMS to discuss options to create for CMS beneficiaries an alternative payment model. We look forward to discussing such a proposal with the agency.

ASBMT understands CMS's and Congress's goals with MACRA. We want MACRA to improve care and not be a cause of access issues for patients requiring complex medical care. As written, we are concerned that MACRA poses a health care access risk for complex patients, such as those requiring HCT. ASBMT wishes to partner with CMS to work through issues and find solutions that meet the intent of MACRA and help provide the best care to our patients.

We appreciate your consideration and look forward to fruitful discussion in the future.

With kindest regards,

Christopher Bredeson MD MSc FRCPC
President, ASBMT

James Gajewski, MD
Director

cc: Sean Cavanaugh