



American Society of Transplant Surgeons

June 27, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-5517-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (CMS-5517-P)

Dear Acting Administrator Slavitt:

On behalf of the American Society of Transplant Surgeons (ASTS), I am pleased to have the opportunity to submit these comments on the MACRA Proposed Rule. ASTS is a medical specialty society representing more than 1,500 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through leadership, advocacy, education, and training.

Our comments are divided into a number of sections:

- General Observations
- Comments related to Advanced Alternative Payment Models; and
- Comments related to the Merit-Based Incentive Program (MIPS).

I. General Observations

We share the general concerns that have been expressed by others regarding the extraordinary complexity of the MACRA Proposed Rule. While most transplant surgeons are associated with academic medical centers and hospital systems and bill Medicare under the tax identification numbers (TINs) associated with large faculty practice plans and multi-specialty group practices of the kind most likely to have the resources to understand the new payment system and its implications, we believe that if the new system is to be effective in engaging physicians in quality improvement and resource management, the final rule must be more easily understood. We would encourage CMS to make such modifications in the MACRA final rule as may be necessary to simplify the new system, especially with respect to scoring.

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Recommendation: We urge CMS to simplify the new payment system to the extent practicable by, for example, further limiting the number of measures reportable under each category of MIPS; simplifying the MIPS scoring methodology; and refraining from introducing any new and previously untested measures (e.g., population-based quality measures).

A number of our other general concerns with the Proposed Rule are addressed in depth by other organizations in their comments, and are best addressed in this context.

Recommendation: We urge CMS to modify the Proposed Rule as recommended by the American College of Surgeons and the American Medical Association in their comments. We therefore incorporate these comments by reference.

Accordingly, our comments below focus on transplant-specific concerns.

II. Advanced Alternative Payment Models (AAPMs)

A. Transplant under AAPMs

Like others, we are disappointed that, as the result of the Proposed Rule's narrow definition of AAPMs, MACRA is unlikely to serve the role envisioned for it by Congress, which clearly intended the new physician payment system to strongly incentivize physicians to align their practices with value-driven alternative payment models. Transplant providers are a model for:

- Team-based delivery of multidisciplinary, comprehensive, long-term care;
- Mandated use of a robust clinical data registry that is risk adjusted and publicly reported (see more below on the federally funded Scientific Registry of Transplant Recipients (SRTR));
- Accountability for clinical outcomes, including risk adjusted survival thresholds;
- Specialty-specific regulations encompassing the full spectrum of care including resources, processes, and governance (under the CMS Conditions of Participation (CoPs) and Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS) policies and bylaws);
- A heavy focus on safety, quality, and performance improvement, through the Quality Assessment and Performance Improvement (QAPI) provisions within CMS CoPs and OPTN/UNOS policies;
- Patient and family engagement and satisfaction through, among other activities, federally required education and informed consent processes.

Transplant providers lead the way in value-based care delivery by a team heavily focused on quality and management of a population of end-stage-organ-disease patients and organ transplant recipients. Furthermore, transplant providers already practice under bundled payment programs instituted through private payers. We seek to facilitate entry of transplant programs into AAPMs so that transplant providers can continue to focus on truly meaningful, high-value care that benefits transplant patients.

Recommendation: We strongly urge CMS to clear a path forward for transplant programs to qualify as AAPMs. Possibilities include modifying the criteria for approval of AAPMs or enabling additional demonstration programs that have been funded by the CMS Innovation Center. In

particular, we encourage CMS to modify the Proposed Rule to enable programs based on the Bundled Payment for Care Improvement (BPCI) and similar episode-based care payment models to qualify as AAPMs. In this regard, we note that a number of private payers have instituted transplant bundled payment programs conceptually similar to BPCI models 2 and 4.

B. Comprehensive ESRD Care (CEC) Initiative

MACRA provides substantial financial incentives for physicians to align their practices with, and to derive a substantial portion of their patient revenues from, AAPMs. While the Proposed Rule interprets AAPM requirements narrowly to preclude many of the Innovation Center demonstration projects from qualifying, the Proposed Rule indicates that Large Dialysis Organization (LDO) End Stage Renal Disease (ESRD) Comprehensive Care Organizations (ESCOs) that participate in the Innovation Center CEC initiative would qualify as AAPMs.

As we understand it, the concept underlying the CEC model is that many beneficiaries with ESRD also have multiple comorbidities. The model is intended to encourage dialysis facilities, nephrologists, and other providers to coordinate and manage the complete spectrum of care for their ESRD patients through ESCOs, which are essentially Accountable Care Organizations (ACOs) composed of providers and suppliers who voluntarily come together to form a legal entity that offers coordinated care to beneficiaries with ESRD. LDO ESCOs share in both losses and cost savings (as compared with a baseline), while non-LDO ESCOs only share in savings.

Under both models, a beneficiary loses eligibility by, among other things, receiving a functioning transplant. For this reason, the ESCO initiative has the potential to impact the ESCO-aligned Medicare beneficiaries that both LDO and non-LDO ESCOs refer for transplant evaluation. Specifically, to the extent that ESCOs put in place processes that are generally effective in achieving savings, their interest in referring ESCO-aligned Medicare beneficiaries for transplant evaluation generally decline. They have an incentive to refer for evaluation only those ESCO-aligned Medicare beneficiaries for whom they do not believe savings are achievable (i.e., sicker patients who consume relatively more Part A and Part B medical services). LDO ESCOs, which are at risk for losses, are especially likely to have a strong incentive to refer ESCO-aligned Medicare patients with multiple co-morbidities for transplantation, while continuing to provide dialysis for those ESCO-aligned Medicare beneficiaries who are relatively healthy. It does not appear that the quality metrics used to measure ESCO participants' performance includes any measure of the number of patients referred by the participants for transplantation, or the medical condition of patients referred for transplantation.

The potential impact of the CEC initiative on referrals for transplant evaluation is critically important.

The average kidney transplant recipient lives more than twice as long as he/she would if remaining on dialysis (USRDS data) and enjoys markedly improved quality of life and longevity: Life expectancy after starting dialysis is 5.7 years and after kidney transplantation is 15.8 years. Thus, to the extent that the CEC model disincentivizes the referral of appropriate ESCO-aligned Medicare beneficiaries for transplant evaluation, this model has the potential to significantly and adversely impact the life expectancy and quality of life of these Medicare patients.

In addition, since transplantation is by far the most cost-effective treatment option for patients with ESRD, to the extent that the CEC initiative disincentivizes transplantation, it has the potential to

increase, rather than decrease, ESRD costs of care. Kidney transplantation is associated with a cost savings of as much as \$200,000 per transplant over the first 5 years after transplantation. (Examination of Medicare spending reveals the breakeven point for transplantation vs. dialysis is 2.3 years for patients who undergo living donor transplantation and 3.6 years for recipients of deceased donor transplantation.)

At this stage, there are only 13 ESCOs and these potential incentives and disincentives likely will not impact a large patient population; however, if LDO ESCOs are qualified as AAPMs, this model is likely to attract a significant number of renal physicians and dialysis facilities. Widespread adoption of this model for the provision of care to ESRD patients would have the potential to substantially jeopardize appropriate referrals by dialysis facilities and renal physicians for transplant evaluations.

Recommendation: We strongly urge CMS to refrain from authorizing LDO ESCOs to qualify as AAPMs unless and until strong safeguards are implemented in the CEC program to ensure that LDO ESCOs refer ESRD patients for transplant evaluation as clinically indicated and without regard to financial considerations. Our specific suggestions for ensuring access to transplantation are set forth in correspondence sent to the Innovation Center on this issue (Attachment A).

III. Merit-Based Incentive Program

We have spent considerable time and effort attempting to digest the nearly 1000 page Proposed Rule, especially those provisions related to MIPS, which we anticipate will apply to virtually all of our members. Even so, a number of aspects of this complex program remain unclear to us, and we believe that it is virtually impossible for us to completely determine the implications of the program for our members. Nonetheless, we offer the following observations for CMS' consideration with respect to the potential application of MIPS to transplant surgeons.

A. Virtual Group Reporting

The Proposed Rule indicates that CMS has not yet worked out the operational issues involved in implementing those provisions of MACRA that recognize the application of MIPS to "virtual groups." We urge CMS to implement these provisions as soon as practicable and formulate the rules in a manner that facilitates reporting by a transplant team as a virtual group.

Section 1848(q)(5)(I) of the Act requires the Secretary to establish a process to allow an individual MIPS EP or a group practice of not more than 10 MIPS EPs to elect for a performance period for a year to be a virtual group with other such MIPS EPs or group practices for the purposes of fulfilling the quality and value component of MIPS. Under this provision, the performance of each individual in the virtual group is based on the virtual group's performance: All of those in the virtual group will have the same quality and value "scores" for the purpose of MIPS.

Transplantation is the quintessential "team sport." Without close collaboration and cooperation among all members of the team—including physicians, surgeons, transplant coordinators, nurses, nutritionists, social workers, pharmacists, and others—it would be impossible to achieve positive outcomes, and, conversely, positive outcomes cannot be attributed to any single clinician or other provider. For this

reason, it would appear that the concept of a “virtual group” is well suited to the field of transplantation: clinical results—whether positive or negative—constitute the results of the entire team (which may not coincide with any single group TIN). MIPS reporting and measurement scorecards should reflect this reality. For this reason, we are disappointed that the systems are not in place for transplant teams to form virtual groups, participate in MIPS jointly, and share MIPS performance scores.

Recommendation: ASTS would support issuance of a unique virtual group identifier to be used exclusively for MIPS purposes and that could be used by transplant teams to ensure that patient outcomes are shared by the transplant team, without individual attribution of results.

B. MIPS Quality Component

It appears that the quality component of MIPS will be the most critical for most of our members, at least during the initial phases of MIPS implementation. Not only is the quality component heavily weighted (50% of total score) during the first year of MIPS implementation, but also that weight may be even higher for transplant surgeons. Since transplant surgeons generally perform at least 90% of their services on hospital inpatients, they likely will be exempt from the Advancing Care Information (ACI) component of MIPS and it is unclear whether, and to what extent, transplant surgeons will be scored on the cost/resource component of MIPS. Therefore, we anticipate that many transplant surgeons’ scores will depend on their quality scores and their Clinical Practice Improvement Activities (CPIA) scores.

(1) Quality and Transplantation: Background

Transplantation is among the most heavily regulated health care services provided in the United States.

Not only are Transplant Centers required to comply with comprehensive Medicare conditions of participation in addition to (and operated in conjunction with) hospital conditions of participation, but these centers are also subject to comprehensive regulation by the OPTN, which is funded through the Health Resources and Services Administration (HRSA) of the Department of Health and Human Services. As the result of both sets of regulations, transplant surgeons and other clinicians involved in the transplantation process are required to meet numerous quality requirements that are not applicable to other physicians.

Specifically, CMS CoPs for Transplant Centers and OPTN bylaws and policies (accessible through the website <http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp>) set standards and monitor compliance of transplant program resources, policies, outcomes, governance, and quality improvement. Both agencies mandate site visits for transplant center certification, and both agencies perform additional site visits on an as-needed basis. CMS reviews individual program results biannually and threatens termination for lower than expected clinical outcomes, low volume, or government surveyor cited deficiencies in other CoPs. OPTN/UNOS reviews individual program results quarterly and takes adverse actions against programs, including recommending that the Secretary of Health terminate approval of a center to perform transplants. Both agencies may require that a consistently underperforming center undergo onsite evaluation by a selected peer review team, use the team’s resulting performance improvement recommendations to formulate a corrective action plan, and be held accountable for plan implementation and outcome improvement.

CMS and UNOS (which is under contract with HRSA to operate the OPTN) each require transplant programs to have a formal transplant-focused QAPI enterprise that addresses a broad spectrum of clinical care through processes and outcomes measures for the pre-transplant, perioperative, and post-transplant periods. CMS and OPTN/UNOS mandate that each specific organ transplant program maintain an effective QAPI program with a structure that includes a QAPI plan, leadership, staff, a multidisciplinary committee, meetings, minutes, indicators, improvement projects, monitoring methods, reporting tools, logs, a dashboard or other type of worksheet that summarizes the QAPI activities, team training and education, links to the hospital's overall quality improvement program, and support from hospital administration. The QAPI program must address transplant patient and live donor processes and outcomes for the candidate period (pretransplant), hospitalization (peritransplant), and long-term post-transplant. The QAPI program must incorporate morbidity and mortality discussions, root cause analyses, and adverse event reporting internally and externally. QAPI must be data driven and engaged in a continuous rather than episodic cycle of measurement, reporting, analysis, and action. Quality assessment endeavors include data capture, measurement, and reporting. Performance improvement endeavors include comparison to benchmarks, identification of gaps in care, and corrective action strategizing, implementation, and tracking to assess success of interventions and endurance of change so that negative behaviors are not repeated. QAPI must incorporate use of the SRTR clinical quality improvement spreadsheet calculator to enable programs to assess how subgroups of their patients with particular characteristics fare compared with national risk-adjusted results. Transplant surgeons are integrally involved in Transplant Center QAPI activities.

Patient and graft survival are tracked by the SRTR. Both CMS and UNOS utilize the SRTR program-specific reports (PSRs) to cite programs with 1-year patient or graft survival results that fall below established, risk adjusted thresholds; PSRs are also used by private insurers to identify centers of excellence, by transplant programs to discern improvement opportunities, and by patients to help select centers. The SRTR operates under contract with the Health Resources and Services Administration, a sister agency to CMS within HHS, and SRTR transplant program reports include:

- Reliable transplant information for patients, families, and medical professionals;
- A complete list of U.S. transplant centers;
- Waiting time and organ availability data for each center; and
- Patient and organ survival statistics.

In short, the SRTR provides detailed patient and organ survival and other outcome information for every transplant for each transplant center and each type of organ transplant (i.e., kidney, liver, heart, heart-lung, pancreas, intestine, kidney-pancreas). Each center's performance is risk adjusted and reported against applicable benchmarks. Actual performance is compared to "expected" performance on key measures, taking into account sophisticated (albeit as-yet-imperfect) risk adjustment methodologies.

This information, which is made public, is precisely the type of specific, accessible outcome information that patients and prospective patients want and need.

Recommendation: In light of the extraordinary quality requirements already imposed on transplant surgeons and other members of the transplant team, we believe that clinicians whose primary practices focus on transplantation either should be exempted from MIPS quality requirements or should be given credit in the MIPS quality component for the activities and reporting that are already required through Medicare Transplant Center certification

requirements, OPTN requirements, and SRTR reporting requirements. While it may be possible for transplant surgeons to identify six quality measures among those proposed that may be tangentially relevant to achieving high quality outcomes, reporting of these measures will not meaningfully contribute to the quality of the services provided to transplant donors and recipients.

(2) Quality Performance Measures (Generally)

Generally, under the Proposed Rule, quality measurement under MIPS requires near uniform (80-90% of all patients) reporting on six quality measures. However, the quality measures, which are generally “process” rather than “outcomes” measures, are an imperfect “fit” for transplant surgery and, we believe, many other types of surgery as well. The proposed quality reporting structure, which is built on the PQRS foundation, does not serve the needs of Medicare patients. The proposed multiplicity of measures does not provide the type of actionable transparent quality information that Medicare and other patients need in order to make informed decisions about their providers.

Recommendation: We strongly urge CMS to take the opportunity presented by MACRA to move toward fewer and more meaningful measures, such as those reported in the SRTR. In fact, in our view, SRTR should serve as a model for other surgical specialties. SRTR incorporates a “team” approach to quality assurance, which more realistically reflects how quality in the provision of surgical services is attained and retained; tracks patient outcomes rather than processes of care; provides patients with helpful information in selecting their health care providers; and provides health care providers with clinically useful benchmarking information on their overall performance, without micromanaging processes of care.

(3) Individual Quality Measures Relevant to Transplantation

We are concerned that the proposed quality measures are not well suited to measuring quality in transplantation. Specifically, our review of the proposed measures suggests that transplant surgeons may be in a position to report a number of general perioperative, medication reconciliation, and preventive care and screening measures¹, but these measures are too general as indicators of quality in transplantation and their utility to patients and providers pales in comparison with the utility of the SRTR outcomes measures which provide patients with actionable data on patient and organ survival.

¹Specifically, we believe that the following measures may be reasonably reportable by transplant surgeons:

- 0268/021 Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin
- 0271/022 Perioperative Care: Discontinuation of Prophylactic
- Parenteral Antibiotics (Non-Cardiac Procedures)
- 0239/023 Perioperative Care: Venous Thromboembolism (VTE)
- Prophylaxis (When Indicated in ALL Patients)
- 0097/046 Medication Reconciliation Post-Discharge
- 0326/047 Care Plan
- 0419/130 Documentation of Current Medications in the Medical Record
- 0421/128 Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
- 0028/226 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Recommendation: We believe that it may be useful to consider the addition of a number of transplant-specific outcomes measures to those reportable under the quality component of MIPS and that CMS approve these measures as a specialty measure set:

- *Number of adult (18 or over) [organ][patient/graft] survival at one month/SRTR Expected number of [organ][patient/functioning graft] survival at 1 month(adjusted for patient and donor characteristics)*
- *Number of adult (18 or over) [organ][patient/graft] survival after one year/SRTR Expected number of [organ][patient/functioning graft] survival at one year post transplant (adjusted for patient and donor characteristics)*
- *Number of adult (18 or over) [organ][patient/graft] survival after three years /SRTR Expected number of [organ][patient/functioning graft] survival at three years post transplant (adjusted for patient and donor characteristics)*

We believe that these measures should be approved for Electronic Health Record and registry reporting, and plan to consider submitting them to CMS for approval by the next deadline (June 2017).

(4) Patient Experience of Care Survey Measure

We also note that CAHPS, which is reportable as a quality measure under the Proposed Rule, is not currently useful for transplantation, and even the S-CAHPS (developed for use in the provision of surgical care) is of limited utility. This is primarily because, in the case of transplant surgery, unlike many elective surgical procedures, the patient may have had no prior interaction with the surgeon who ultimately performs the surgery. Furthermore, a major aspect of provider/patient perioperative communication and quality of care focuses on immunosuppressive and other medications, which is not addressed by CAHPS or even S-CAHPS.

Recommendation: We believe that a measure of patient experience of care (CAHPS or other than CAHPS) should be used under the CPIA component of MIPS, rather than as an element of the quality component of the program. Alternatively, we urge CMS to work closely with the transplant community and the American College of Surgeons to adopt a patient experience of care measure that is relevant to all surgeons, including transplant surgeons, and that adequately takes into account the team-based nature of transplantation and other complex surgery.

(5) Population-Based Quality Measures

Finally, we note that the Proposed Rule would determine physicians' quality scores based in part on population-based measures that were developed for use in other contexts. It is our understanding that hospital readmissions are indirectly taken into account in these population-based quality measures. While we appreciate and respect the need to reduce overall readmissions, transplantation is very different. Readmission is not only commonplace for patients receiving transplants, it is frequent and often necessary to ensure that patients do not reject the transplanted organs. Organ rejection is not only a dangerous health condition but it is costly to the Medicare program and wasteful of precious gift

of life, the donated organ. Patients who return to the hospital do so not only related to complications of the transplant or their immunosuppressant medications, but also quite often for issues unrelated to the transplant. It is the transplant physician and team's role to strive to reduce readmissions; however, the reality is that readmission rates are—and, in the interests of patient safety and high quality care, likely should be—disproportionately higher for transplantation than for many other inpatient procedures. In the context of MIPS, then, taking readmissions into account in quality scoring—or in any other context (see discussion below with respect to the MSPB cost/resource measure)—effectively discriminates against transplant surgeons who report individually and groups that include transplant surgeons and other transplant clinicians.

Recommendation: We urge CMS to remove the population-based quality measures from consideration under the quality component of MIPS.

(6) SRTR as a QCDR

We have begun discussions with CMS regarding the potential approval of the SRTR as a Qualified Clinical Data Registry; however, those discussions have been complicated both by the team-based nature of transplantation and by the numerous technical and other requirements that QCDRs are required to meet. At this time, SRTR data is reported to the public on a transplant center level, and ASTS strongly opposes any attribution of transplant outcomes to individual surgeons, physicians, or other clinicians. On the other hand, we recognize that, under the Proposed Rule, MIPS scorecards require that quality measurement take place at the individual (NPI/TIN) or physician group (NPI/TIN) basis and that, for many physicians, evaluation of quality at the individual and group levels makes some amount of sense. We are currently considering whether reporting SRTR data at the group level would be workable for groups that include transplant surgeons and would sufficiently maintain the team concept; however, we believe that the implementation of “virtual groups” comprising the transplant team is likely to be the best long-term solution for this dilemma.

Even assuming the resolution of this issue, we are concerned that some of the technical requirements for QCDRs may make it difficult for the SRTR to obtain and maintain approval. For example, upon request and for oversight purposes a QCDR must:

- Provide CMS access to the QCDR's database to review the beneficiary data on which the QCDR-based submissions are based or provide to CMS a copy of the actual data.
- Submit an acceptable “validation strategy” to CMS. A validation strategy details how the QCDR will determine whether EPs satisfactorily reported measures and that the data submitted to the QCDR is true, accurate, and complete.
- Provide feedback, at least four times per year, on the measures at the individual participant level.
- Be able to collect all needed data elements and transmit the data on quality measures to CMS in one of two formats, either via a CMS-approved XML format or via the QRDA category III format.
- Meet certain timelines for data submission that may not coincide with SRTR deadlines. See http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015_QCDRVendorCriteria.pdf

We look forward to working with CMS to see whether these issues can be resolved in a manner that does not substantially interfere with the operational efficiency and mission of the SRTR.

(7) Adoption of Hospital Quality Measures under MIPS

Section 1848(q)(2)(C)(ii) of the Act, as added by section 101(c) of MACRA, provides that the Secretary may use measures used for a payment system other than for physicians, such as measures for inpatient hospitals, for purposes of the quality and resource use performance categories of MIPS. The Proposed Rule seeks comment on how it might be feasible and when it might be appropriate to incorporate measures from other systems into MIPS for clinicians that work in facilities such as inpatient hospitals. For example, the Proposed Rule suggests that it may be appropriate to use hospital measures when, among other things, strong payment incentives are tied to measure performance, either at the facility level or with employed or affiliated MIPS eligible clinicians.

SRTR outcomes measures are used for quality assessment of hospitals under the Medicare certification regulations applicable to transplant programs, and transplant centers that fail to meet applicable outcomes measures are subject to de-certification. Therefore, hospitals operating transplant centers have the strongest of all possible incentives to meet applicable outcomes requirements.

Recommendation: We urge CMS to adopt a provision that enables a transplant surgeon and other members of the transplant team to elect to use their institution's performance rates under the outcomes requirements set forth at 42 CFR §482.80(c) and §482.82(c) as a proxy for the transplant surgeon or other MIPS eligible clinician's quality score. We believe that a transplant surgeon or other MIPS eligible clinician or group's election should not be automatic. Rather, he or she should elect for transplant center outcomes to be used, through a registration process. For the purposes of scoring, we believe that if a transplant center meets or exceeds the outcomes requirements set forth in the regulations, the transplant surgeon electing to use the transplant center outcomes measures should be accorded 100% credit under the quality component of MIPS.

C. Cost/Resource Component

Transplant surgeons generally do not provide the plurality of primary care services for their patients and there are no transplant episodes proposed for measurement under the Cost/Resource component of MIPS. Since patients are attributed to clinicians based on primary care services for the purposes of the total cost per beneficiary measure and transplant surgeons generally do not perform the plurality of a patient's primary care services, we do not anticipate that transplant surgeons generally will obtain a score for this measure. Moreover, since there are no transplant episodes proposed for resource measurement, we would not anticipate that transplant surgeons will generally be included under this resource measure either.

However, we would anticipate that transplant surgeons may be scored on the cost/resource component of MIPS (if they are scored at all), based on the Medicare Spending per Beneficiary (MSPB) measure and the total spending per beneficiary measure. It is our understanding that, under the Proposed Rule, clinicians with the plurality of claims (as measured by allowable charges) for Medicare Part B services rendered during an inpatient would be assigned the episode. Since transplant surgery charges may

constitute the plurality of charges for transplant admissions, we anticipate that some transplant surgeons may be scored on the cost/resource component of MIPS, to the extent that episodes assigned to them exceed applicable thresholds.

We are concerned about the use of the MSPB measure under MIPS, since physicians whose patients frequently require readmission are likely to score relatively poorly on this measure. For the reasons set forth above with respect to population-based resource measures, readmissions of transplant patients are relatively frequent; the risk adjustment measures used by Medicare in the context of MIPS are too general and do not take into account the special circumstances of the transplant recipient population; and hospital readmissions therefore should not be used directly or indirectly in determining transplant surgeons' (or their groups') MIPS scores.

In this regard, the Proposed Rule acknowledges that CMS only recently finalized a policy that increases the minimum cases for the MSPB measure from 20 to 125 cases (80 FR 71295 through 71296) due to reliability concerns with the measure including the specialty adjustment. The Proposed Rule would retract this change and adopt a 20 episode minimum for the purposes of MIPS scoring, and would eliminate the specialty adjustment in order to address reliability concerns.

ASTS does not support the establishment of a 20-episode minimum for the purposes of scoring the cost/resource component of MIPS, nor do we support the elimination of the specialty adjustment. We believe that it would be imprudent to rely on CMS' current risk adjustment methodology to ensure that cost/resource use is compared fairly across groups, especially since the current risk adjustment methodology is generally acknowledged to underestimate the costs of sickest and most complex patients. We also note that the risk adjustment methodology used for these purposes is not specific to, or necessarily germane to, transplantation. Specifically there is no adjustment for severity of illness at time of transplant (by a transplant specific measure, such as Model for End-stage Liver Disease (MELD)), and there is no adjustment for deceased donor characteristics which have an enormous impact on both the type and the cost of the transplant episode.

Recommendation: For the purposes of cost/resource component scoring under MIPS, we recommend that CMS either eliminate the MSPB measure or, at the very least, retain the 125 case minimum for the MSPB measure that was recently finalized for use in conjunction with the Value-Based Payment Modifier program.

D. MIPS Clinical Practice Improvement Activities (CPIA) Component

In order to get a 100% score for the CPIA component of MIPS, most physicians (including all transplant surgeons) would have to participate in 3-6 CPIAs for 90 days each. We are confident that, in light of the range of population management, care coordination, beneficiary engagement, patient safety and practice assessment, and other practice improvement activities routinely incorporated into transplantation processes of care, these requirements can be met by our members.

However, as indicated above, the SRTR registry—an unparalleled state of the art registry that provides public access to precisely the kind of outcomes measures Congress envisioned—is not currently

approved as a Qualified Clinical Data Registry. SRTR provides quarterly feedback reports that summarize transplant outcomes and access (waitlist statistics).

Recommendation: We strongly urge CMS to make the following change in the Population Management CPIA (High Weight) to provide appropriate recognition of the SRTR (NEW LANGUAGE UNDERSCORED):

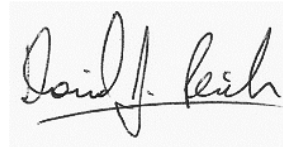
Use of a QCDR or government-funded registry to generate regular feedback reports that summarize local practice patterns and treatment outcomes, including for vulnerable populations.

We hope that these comments are useful in finalizing this important rule. If you have any questions or if we can be of further assistance, please do not hesitate to contact Diane Millman, Washington counsel for ASTS (dmillman@ppsv.com).

Sincerely yours,



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