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Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program (CMS-1656-P)

Dear Administrator Slavitt:

On behalf of the American Society of Transplant Surgeons (ASTS), I am pleased to have this opportunity to comment on the 2017 Hospital Outpatient Prospective Payment System Rule Proposed Rule ("the Proposed Rule"). ASTS represents more than 1,600 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.

The Proposed Rule includes a number of provisions related to the conditions of participation (CoPs) for both Transplant Centers (TCs) and Organ Procurement Organizations (OPOs). Specifically, CMS is proposing to modify the tolerance range for clinical outcomes set forth in the current TC certification regulations and to modify certain elements of the OPO certification regulations to be more consistent with Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR) standards.

ASTS is proud of our longstanding partnership with CMS to enhance the quality of organ transplantation nationally though enhanced center performance monitoring and process improvement. ASTS would like to commend the agency for the development and implementation of the TC certification regulations in a manner that puts quality improvement first. We were pleased to work cooperatively to develop survey tools that accurately reflect the state of transplant center performance. Furthermore, we strongly support the "mitigating factors" process

established by CMS to address transplant centers which were identified as having outcomes that were significantly less than expected. The mitigating factors process has been extraordinarily successful as it recognizes the complexity of transplant care, the limitations of risk adjustment methods, and the difficulty in rapidly demonstrating performance measurement given the significant time delays inherent in the current SRTR semiannual reports. Through the mitigating factors program, centers in need of improvement have been able to develop and implement internal solutions which improve quality and preserve access. Systems Improvement Agreements (SIAs), too, have played a critical role in ensuring adequate investment in infrastructure and process improvement for centers that were committed to change but unable to accomplish it themselves. In equilibrium with the intended positive improvements from the SIA, this process requires maturation in that it is very threatening and costly to the transplant centers, and specifically to the transplant professionals who are often held personally responsible for center inadequacies. We appreciate the delicate balance involved in ensuring quality while maintaining access, and we look forward to continuing to work with you to achieve our joint objectives.

I. Proposed Modification of Tolerance Range for Transplant Center Outcomes

ASTS applauds CMS for recognizing the need to modify the current O/E tolerance range to restore the performance standards that were originated in 2007. We strongly support increasing the tolerance range for all the reasons set forth in the preamble to the Proposed Rule. One-year post-transplant outcomes have consistently improved since 2007 for all organ types, and the standard deviation has narrowed around a higher mean. This is an expected result. However, as national outcomes have improved, centers with clinically acceptable outcomes appear to out of compliance. These centers often transplant patients whose risks are poorly captured in the current system (socioeconomic status, anatomic complexity) using organs that might otherwise be discarded. We believe that transplant centers' focus on meeting increasingly demanding outcomes requirements contributes to increasingly conservative transplant decision-making that has restrained access for transplant to challenging patients, has also resulted in a significant increase in the discard rate of organs challenging to transplant, and has reduced listing rates for high-risk candidates. These practice changes have helped programs maintain overall outcomes within acceptable parameters to avoid a standard or conditional outcomes violation. Unfortunately, it comes during times when the waiting list of patients for deceased organs is at an all-time high and waiting times are longer and longer. Finally, conservative decision-making has the potential to stifle innovative approaches to transplant that could improve access, increase donor organ usage, and reduce the burden of the need for chronic immunosuppressive medications. We are in agreement that ever-growing waiting lists and the "increased percent of unused adult kidneys, combined with an increase in the number of recovered organs, creates an imperative to action, given the lifesaving benefits of organ transplantation." This is particularly pertinent, as the outcomes standards focus only on post-transplant outcomes and do not reward centers for aggressively using all available organs nor transplanting high-risk patients who would otherwise remain on dialysis for life.

It is significant that organ transplantation is the only procedure for which CMS has used post-surgical outcomes as a condition of participation rather than as a quality measure for payment purposes. While CMS is moving to increase emphasis on outcomes in various quality-related payment programs, in no other field does failure to meet narrowly defined outcomes measures jeopardize Medicare

participation. This creates an alarmist mentality within transplant programs, contributing to risk aversion and reducing access to transplant. For this reason, we believe that the transplant center outcomes standards should be modified to better identify centers that are truly underperforming (increased positive predictive value). This would reduce the rate of transplant center citations for non-clinically significant differences in post-transplant performance. We propose that CMS work with HRSA to ensure that less egregious deviations from expected practice are handled through the Organ Procurement and Transplantation Network (OPTN) review process.

We also believe that the issue of transplant center recipient outcomes requirements should be considered in the context of patient outcomes in the absence of transplantation. The available clinical literature for patients with end stage renal disease (ESRD), for instance, confirms that kidney transplant outcomes even in the "lowest performing" TCs are far superior to ESRD patient outcomes when a patient continues on dialysis. [1] The greatest overall improvements in patient survival and cost reduction could be achieved by increasing access to transplantation. The relatively minor variations in transplant center performance are clinically insignificant when compared with the outcomes of patients who are not transplanted. For this reason, any regulation or standard that has the potential to reduce access to transplantation—whether by increasing TCs' risk aversion or otherwise—warrants careful scrutiny.

The current transplant center certification outcomes standards (at 42 C.F.R. §§ 482.80(c)(2)(ii)(C) and 482.82(c)(2(ii)(C)) specify that outcomes are not acceptable if the ratio of observed patient deaths or graft failures divided by the risk-adjusted expected number, or ''O/E,'' exceeds 1.5. The Proposed Rule would increase the threshold to 1.85 for all organ types. We understand that the proposed 1.85 O/E tolerance range is approximately mid-range between the number that would restore the adult kidney graft tolerance range to the 2007 level (2.02) and the number that would do so for adult kidney patient survival (1.77). Therefore, according to be preamble of the Proposed Rule, CMS' proposal would essentially restore the absolute performance requirements in effect when the TC certification regulations were adopted.

We appreciate the delicate balance that CMS must strike in determining a new O/E threshold, and agree that the pressing need for simplicity suggests that a single new O/E should be established for all organs. We also agree that the new outcomes tolerance threshold should be established based on kidney graft and patient outcomes trends, in light of the proportion of solid organ transplants covered by Medicare that are kidney transplants. However, we propose that the new O/E tolerance threshold be increased to at least 2.0. We note that a tolerance threshold of 2.0 more closely approximates the performance threshold for graft survival in 2007, despite the increased acceptance of higher risk candidates and use of increasingly complex deceased and living donor kidneys.

On the whole, however, we do not believe that the 2007 threshold is necessarily the appropriate reference point. As ASTS commented during the rulemaking proceedings leading up to adoption of the 2007 tolerance threshold, that standard (the 1.5 tolerance threshold) was based on the threshold for OPTN Membership and Professional Standards Committee (MPSC) peer review of potentially underperforming transplant centers and was never intended as a criterion to be used for the initiation of de-certification proceedings. In short, the tolerance threshold reflected in the regulations since 2007

[1] Schold, JD et. al, Association between Kidney Transplant Center Performance and the Survival Benefit of Transplantation, Versus Dialysis. *Clin J Am Soc Nephrol* 9: 1773–1780, 2014.

always has been too stringent, resulting in a high number of false positive citations. The preamble to the Proposed Rule points out the growing evidence that the current Medicare certification standards contribute to the increased organ discard rate. We believe there is now a pressing need for a more flexible tolerance standard than that established in 2007. As noted in the preamble to the Proposed Rule, the organ discard rate spiked when the regulations went into effect and have not returned to pre-2007 rates, even though other factors contributing to the spike (including modifications of the OPTN allocation methodology) have been addressed. This suggests that the O/E threshold adopted in 2007 was too stringent. It follows that it would be appropriate to establish the new tolerance threshold at a point that gives TCs more leeway than the 2007 standard allows, and we believe that a tolerance threshold of at least 2.0 strikes a suitable balance.

Finally, based on CMS' own projections, the increase to 1.85 would result in a relatively minimal change in the number of programs flagged at both the standard and at the condition level. CMS indicates that if the 1.85 O/E tolerance threshold had been in effect for the period covered in the 2015 SRTR reports, the number of transplant programs flagged once would have been reduced from 54 programs (24 adult kidney programs) to 48 programs (21 adult kidney programs). If the proposed new tolerance threshold had been in effect for CY 2015, 27 programs rather than 30 programs (and 13 rather than 15 adult kidney programs) would have been flagged twice (condition level deficiencies). CMS also estimates that four fewer programs each year would be required to complete an SIA under the new proposed standard. In order to appreciably impact transplant center reluctance to accept marginal organs for transplantation, we respectfully suggest that a more significant modification of the current thresholds is needed. We believe that, in light of the overall improvements in transplant outcomes, increasing the O/E threshold to 2.0 will accurately identify transplant programs that are truly underperforming and that could benefit from the additional oversight and guidance available through the "mitigating circumstances" review process, without endangering transplant recipients' lives in TCs that elect to use marginal organs.

II. The Adoption of a "Balancing Measure"

The Proposed Rule notes that CMS may explore other approaches aimed at optimizing the effective use of available organs instead of adjusting the CMS outcomes threshold further, such as the creation of a "balancing measure" that would directly measure a transplant program's effectiveness in using organs. Such a balancing measure could "unflag" a program that had been flagged for substandard outcomes under the existing outcome measures. Along similar lines, the Proposed Rule notes that the OPTN has developed a concept paper to obtain public comment for a similar idea, in which highest risk organs when transplanted into the highest risk recipients might be removed from the outcomes metrics (https://optn.transplant.hrsa.gov/governance/public-comment/performancemetrics-concept-paper/). This concept is slightly different than the formal incorporation of pre-transplant metrics but tracks with a program which has been highly successful in western Europe.

We agree that a multi-year effort would be required to construct, test, and study the effects of both these approaches. This is currently underway through the COIIN project which may answer some of these questions. In the interim, we encourage CMS to continue to consider higher risk organs, higher risk candidates/recipients, and innovative practices in the "mitigating factor" review process. Increasing transplant volume would be more directly enhanced if CMS with the transplant community would

define prospectively groups of organs and/or candidates which would be excluded from standard outcome metrics.

III. Transplant Center Regulations Technical Corrections and Other Issues

ASTS also supports the change in the Proposed Rule that would extend the due date for programs to notify CMS of their intent to request mitigating factors approval from 10 days to 14 calendar days, and to clarify that the time period for submission of the mitigating factors information is calculated in calendar days (that is, 120 calendar days). We also understand CMS' proposal to revise § 488.61(h)(2) to provide that a signed SIA with a transplant program remains in force even if a subsequent SRTR report indicates that the transplant program has restored compliance with the Medicare CoPs, except to the extent that CMS chooses to shorten the SIA timeframe. Finally, for the reasons set forth in the outcomes analysis portion of the Proposed Rule, we strongly support CMS' decision not to adopt the SRTR Bayesian methodology for flagging underperforming transplant centers, as it lacks adequate risk adjustment and clarity.

IV. Coordination of OPO and Transplant Center Outcomes Requirements

The Proposed Rule would modify the OPO outcomes requirements to make technical changes to bring the certification and OPTN outcomes standards for OPOs into better alignment. While we appreciate the need to ensure that SRTR and CMS requirements are consistent and support the proposed changes, we continue to believe that additional attention is needed to the current "disconnect" between OPO and transplant center outcomes measures. CMS regulations indirectly discourage OPOs from increasing the recovery of organs from older, "marginal donors" as this practice reduces Organs Transplanted per Donor. This will reduce the incentive to aggressively pursue all donors. Conversely, these regulations incentivize OPOs to maximize organ retrieval from multi-organ donors, without consideration of whether the organs retrieved are appropriate for transplantation or whether transplantation of these organs will result in positive patient outcomes. By contrast, transplant centers are required to meet stringent post-transplant recipient outcomes requirements, regardless of donor organ quality. Thus, acceptance of these organs resulting in a higher transplant rate, while good for OPOs and patients, may actually hurt the centers if the rate of graft failure is excessive. ASTS is working with the OPO community to formulate a proposal to address this "disconnect"; however, the issue is complex and additional research may be needed to resolve the tensions created by the current approach.

In the interim, we urge CMS to consider modifying the OPO regulations to reduce the concentration on Organs Transplanted per Donor. In addition, CMS should encourage OPOS and transplant centers to work cooperatively to ensure that organs are placed in a timely manner which maximizes the opportunity for transplant. OPOs that underperform on the Organs Transplanted per Donor metric should be allowed to argue for mitigating factors which take into consideration the quality of the organs retrieved by an OPO and the relative transplant rate of these organs. Finally, altering the post-transplant outcome monitoring systems for transplant centers to allow the exclusion of the highest risk organs would align OPO and transplant center performance to focus on the better organs which should have good outcomes. In addition, we believe that the mitigating factors process and the SIAs that underperforming transplant centers have entered into with CMS have had an extremely positive impact in improving transplant center performance, and that instituting a similar process for OPOs could result in the retrieval of a greater number of transplantable organs.

We appreciate the opportunity to submit these comments and look forward to working with CMS to formulate additional policy changes to further improve access to transplantation and to further improve transplant outcomes.

Sincerely yours,

Timothy L. Pruett, MD
ASTS President