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September 6, 2013

Submitted Electronically: www.regulations.gov

Ms. Marilyn Tavenner
Administrator
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Department of Health and Human Services
Attention: CMS-1600-P
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7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Tavenner:

On behalf of the American Society of Transplant Surgeons (ASTS), I am pleased to have the opportunity to submit these comments in response to the 2014 Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule (the "Proposed Rule"), including the proposed modification of the conditions of participation for Organ Procurement Organizations (OPOs). ASTS is a medical specialty society comprised of over 2000 transplant surgeons, physicians, scientists, advanced transplant providers and allied health professionals dedicated to excellence in transplant surgery through education and research with respect to all aspects of organ donation and transplantation so as to save lives and enhance the quality of life of patients with end stage organ failure.

Generally, under current regulations, OPOs must meet **all three** of the following outcome requirements to be certified by CMS:

- The OPO's donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the national mean (counting donation after cardiac death donor and each donor over the age of 70 in both the numerator and in the denominator).
- The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re-certification, as calculated by the SRTR.
- At least 2 out of the 3 following yield measures are no more than 1 standard deviation below the national mean, averaged over the 4 years of the re-certification cycle:
    - The number of organs transplanted per standard criteria donor, including pancreata used for islet cell transplantation;
    - The number of organs transplanted per expanded criteria donor, including pancreata used for islet cell transplantation; and

- The number of organs used for research per donor, including pancreata used for islet cell research.

CMS Proposal

CMS is proposing to modify the regulations so that all of the OPOs must meet **only two out of the three** outcome measures to be recertified. CMS indicates in the Proposed Rule that it has become concerned that requiring all three of the above standards to be met is "unnecessarily stringent." CMS notes that the majority of all of the OPOs are meeting all three of the outcome measures but that many of the OPOs that are failing to meet all three outcome measures are meeting two of the three measures and are in compliance with all of the other process requirements.

In the Proposed Rule, CMS notes the following problems with the current conditions of coverage:

- CMS indicates concern that the determination of "eligible deaths" differs among OPOs, and that this apparent variance may be adversely affecting the performance of some OPOs on the first of the three outcome measures.

- Based on comments received from the OPO community, CMS appears to believe that there is a considerable difference between standard criteria donors (SCDs) in various areas of the country, which may explain at least some of the differences in the OPOs' performance on the "yield" measures (e.g. if a particular area has an older potential donor population or one that is typically not as healthy).

- Based on OPO feedback, CMS also appears to be concerned that at least some OPOs may not pursue certain potential donors with multiple comorbidities because they believe that such donors may adversely impact their performance on the "yield" measure.

For these reasons, and in order to avoid the automatic decertification of OPOs that CMS believes to be operating "satisfactorily", CMS is proposing to hold the OPOs accountable for meeting only two out of the three current outcome measures.

In addition CMS is also soliciting public comments on the current outcome measures for OPOs, and on "any other potential empirically based outcome measures for OPOs that might be used in the future." CMS is specifically soliciting comments on whether it should adopt the new "yield" measure that is now being used by the OPTN. The new yield measure adopted by the OPTN is designed to take into account more extensive risk factors, thereby allowing an OPO's performance to be more accurately measured. Specific details on the risk adjustment models used for this measure are located on the SRTR Web site at: http://www.srtr.org/csr/current/Tech_notes.aspx.

ASTS' Prior Position

ASTS submitted extensive comments on the current OPO conditions of participation when they were initially proposed. At that time, ASTS anticipated a number of the problems that have arisen as the result of the current standards. Specifically, ASTS expressed serious concern about the "disconnect" between certification standards for OPOs, which encourage OPOs to pursue retrieval of organs regardless of whether they are likely to yield positive outcomes for recipients, and the Transplant Center certification

standards, which focus on patient outcomes. Our concerns about this and other problems arising from the OPO and Transplant Center conditions of participation have been the subject of frequent communications with CMS, including most recently a letter submitted to Thomas Hamilton on January 21, 2013 (attached). Generally, **ASTS has taken the position that the OPO certification requirements should be strengthened to encourage the retrieval of higher quality organs rather than loosened, as proposed by CMS in the Proposed Rule.**

Recommendation

As set forth above, ASTS has long recognized that the current OPO conditions of participation need to be modified, and to this extent we agree with the Proposed Rule. We also agree that it would be counterproductive for CMS to apply the current OPO outcomes requirements strictly in a manner that would result in massive decertification of a large number of the current OPOs at the same time. In our view, decertifying a substantial proportion of the current OPOs likely would result in chaos for potential transplant recipients in the areas affected, especially since it is not clear whether and to what extent the OPOs that remain have the staffing and other operational resources necessary to extend their organ retrieval capabilities into additional jurisdictions.

However, we do not believe that it is in the best interests of transplant patients to give the current OPOs a "pass" on poor performance by eliminating one of the three outcomes standards that they are currently required to meet. The variation in performance among OPOs is significant and simply giving the current OPOs an indefinite "pass" does nothing to improve substandard OPO performance. We believe that CMS outcomes requirements could serve as an important role in providing an incentive for improved performance, but this is not the path taken in the Proposed Rule. Rather, the Proposed Rule appears to accept substandard performance indefinitely. In fact, once loosened, we believe that it will be difficult, if not impossible, for CMS to strengthen the OPO outcomes requirements without raising considerable opposition.

We urge that CMS strike a more nuanced balance between the need to avoid the chaos that would result from decertifying a substantial proportion of the current OPOs and the equally important need to provide incentives for poorly performing OPOs to improve their donation rates, yields, and organ quality. We believe that implementing a "mitigating circumstances" process similar to the process that has been made available to transplant centers that do not meet CMS outcomes requirements strikes a more appropriate balance than providing a blanket "pass" for underperforming OPOs by scaling back OPO outcomes requirements by one third. Making available a "mitigating circumstances" process would enable CMS to review the circumstances of underperforming OPOs individually to determine whether certification should be extended and, if so, for how long and under what conditions. Specific benchmarks for improved performance could be set, and CMS would retain the authority to take appropriate action if performance does not improve.

Unfortunately, making such a process available does not address the basic deficiencies in the OPO conditions of participation (or equally serious deficiencies in the current Transplant Center conditions of participation). For this reason, we urge CMS to initiate a negotiated rulemaking or other process involving all stakeholders to address the regulatory changes that should be made in this area. ASTS would

be delighted to participate in such a process, and we look forward to working with CMS to ensure that outcomes requirements for both OPOs and Transplant Centers serve the interests of our patients.

Sincerely yours,

Alan N. Langnas, D.O.
President

American Society of Transplant Surgeons

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January 21, 2013

Thomas E. Hamilton, Director
Survey & Certification Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
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Re: Organ Procurement Organization (OPO) Performance Measures

Dear Mr. Hamilton,

The American Society of Transplant Surgeons (ASTS) appreciates the opportunity to provide input on the CMS requirements for Organ Procurement Organizations (OPOs). As you know, ASTS has a long history of advocating on this subject and remains deeply concerned by the continued disconnect between transplant center (TC) and OPO certification requirements. We applaud ACOT's recent recommendation to Secretary Sebelius (**Appendix A**) and believe that regulatory and policy modifications are needed to reduce organ wastage and decrease the costs of solid organ transplantation.

The misalignment and inconsistencies between CMS outcomes requirements for TCs and OPOs inhibit optimal organ donor strategies and contribute to organ wastage, which is a significant problem in the field of transplantation. More specifically, CMS regulations encourage OPOs to increase the number of all types of organs from all types of donors (from ideal to marginal, brain dead or DCD). These regulations incentivize OPOs to maximize organ retrieval, 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, TCs are required to meet stringent transplant recipient outcomes requirements, regardless of donor organ quality. Risk-adjustment methodologies are grossly imperfect and renal-centric and therefore TCs risk losing Medicare certification for accepting and transplanting organs associated with poor outcomes. In fact, in 2009 44% of kidneys retrieved from Extended Criteria Donors (ECDs) were discarded.

The OPO certification regulations not only reflect performance metrics that are inconsistent with those imposed on TCs, but also result in increased Medicare expenditures and increased overall transplantation costs. By pursuing all organs (good and bad – including marginal organs), the OPOs incur significant expenditures as a result of "dry runs" (donor team deployed, but organs not procured and therefore not transplanted), and "discards" (procured organs that are subsequently discarded, i.e. not transplanted). The costs associated with dry runs and discards are allocated to the Standard Acquisition Charge (SAC) for transplanted organs, driving increases in the SACs for transplanted organs and increasing the cost of transplantation. For Medicare beneficiaries, Medicare pays the full SAC, and therefore it is CMS that ultimately incurs the additional cost. For non-Medicare patients (the majority of non-renal transplant recipients), inflated SACs resulting from dry runs and discards place pressure on case-rates negotiated with third party payers. Moreover, the non-SAC related additional clinical costs of using marginal organs (such as increased recipient length of stay) incurred by TCs result in higher payments by both CMS and other third party payers.

These inconsistencies also have resulted in misaligned incentives and therefore increased conflict between TCs and OPOs, adversely impacting the continued success of the Organ Donation Breakthrough Collaborative and other collaborative efforts.

Potential Solutions:

The current tension between TC and OPO certification requirements (and the resulting organ wastage and increased costs) can be alleviated, at least in part, through modification or reinterpretation of the OPO outcomes requirements and/or TC outcomes requirements included in the Medicare certification regulations.

Modification/Reinterpretation of OPO Outcomes Requirements.

The outcomes requirements included in the OPO certification regulations, set forth at 42 CFR §486.318) require that:

- The OPO's donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the national mean (counting donation after cardiac death donor and each donor over the age of 70 in both the numerator and in the denominator).
- The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re-certification, as calculated by the SRTR.
- At least 2 out of the 3 following yield measures are no more than 1 standard deviation below the national mean, averaged over the 4 years of the re-certification cycle:
    - The number of organs transplanted per standard criteria donor, including pancreata used for islet cell transplantation;
    - The number of organs transplanted per expanded criteria donor, including pancreata used for islet cell transplantation; and
    - The number of organs used for research per donor, including pancreata used for islet cell research.

Thus, under the current outcomes metrics, an OPO could meet Medicare requirements by focusing its efforts virtually exclusively on marginal organs: Specifically, marginal organs "count" the same as standard organs for the purposes of the first two standards set forth above, and an OPO could meet the third standard by ensuring that the number of organs that are used for research and the number of marginal organs that are transplanted (generally kidneys) are not substantially below the national means, without paying any attention whatsoever to transplantation of organs from standard criteria donors.

This problem ideally should be addressed through regulatory change. A number of options should be considered. First, in our comments on the OPO outcomes requirements that were initially proposed in the *Federal Register* (**copy attached**), ASTS suggested that marginal organs be excluded from both the numerator and the denominator of the calculation of an OPO's donation rate. Modifying the OPO outcomes standards to make this change would ensure that OPOs focus their efforts on securing organs from standard criteria donors. Second, the OPO requirement related to the number of organs transplanted per standard criteria donor could be made mandatory rather than optional. Third, also as set forth in ASTS' comments on the OPO requirements that were initially proposed in the *Federal Register*, the regulations could be modified to require OPOs to meet a mandatory performance measure related to the number of extra-renal organs transplanted. Since organs from DCD and ECD donors are generally limited to kidneys, a mandatory performance measure related to extra-renal organs would necessarily increase the incentive for OPOs to seek standard criteria donors. Finally, the OPO regulations could be modified to include some measure of transplant outcomes.

While addressing this issue through modification of the OPO certification regulations would create the greatest clarity, we recognize that regulatory changes necessarily take considerable time and agency resources. For this reason, pending any regulatory change, we urge CMS to consider reinterpreting the OPO outcomes requirements in a manner that may at least partially address the disconnect between the OPO and the TC regulations. Specifically:

- The comparison of an OPO's donation rate as a percentage of eligible deaths required under 42 CFR § 486.318(a)(1) could be calculated separately for standard criteria and marginal (DCD/ECD) organs.
- The OPO's expected donation rate as calculated by the SRTR could be calculated separately for standard criteria and marginal (ECD/DCD) organs.

We believe that reinterpreting the requirements set forth at 42 CFR Section 486.318 in this manner is within the agency's discretion and would not require the lengthy process entailed by regulatory change.

Modification/Reinterpretation of TC Outcomes Requirements

As set forth at 42 CFR §482.80(c), the TC outcomes requirements mandate that , with certain exceptions, a TC's observed patient survival rate and observed graft survival rate be within certain parameters established by the SRTR. Under current SRTR methodology, transplantation of standard criteria and marginal organs are combined in determining whether or not a TC meets the Medicare

outcomes requirements. However, it does not appear that the regulations themselves mandate this methodology. For this reason, it would appear that it may be possible to partially address the current "disconnect" between OPO and TC outcomes requirements through reinterpretation of the current TC outcomes requirements and by tweaking the SRTR methodology.

More specifically, ASTS recommends that CMS consider the following options:

i. Solely for the purpose of determining compliance with Medicare certification requirements and not for other SRTR purposes, CMS may wish to request the SRTR to eliminate transplantation of marginal organs from its calculations of both "expected" and "observed" transplant outcome rates. This would require modification of risk adjustment methodologies and CMS Interpretive Guidelines (IGs), but no regulatory change. One potential downside to this solution would be that TCs might be encouraged (incentivized) to increase marginal organ transplantation, without regard to potential outcomes.

ii. Solely for the purpose of determining compliance with Medicare certification requirements, and not for other SRTR purposes, CMS may wish to consider requesting the SRTR to calculate "expected" and "observed" rates separately for standard and marginal organs. Again, this would require modification of risk adjustment methodologies and CMS Interpretive Guiidelines, but no regulatory change. One potential hurdle to this solution would be establishing the "benchmark" for marginal organs, although this could be achieved initially using retrospective data and tweaked further by prospectively analyzed data. Under this model, TC compliance with outcomes criteria would be applied to both standard criteria and marginal organs, but the disincentive to use marginal organs would be minimized, since a TC's outcomes for marginal organ transplants would be compared to national standards likewise determined based on marginal organ transplants. Over the longer term, funding for research is needed to develop improved risk-adjustment methodologies for both standard and (especially) marginal donor and recipient variables.

iii. CMS may wish to consider modifying its survey and certification procedures to reduce the disincentive for TCs to accept marginal organs. For example, for TCs that are not compliant with CMS outcomes criteria, "expected" and "observed" rates would be separately recalculated to determine whether standard organ outcomes fall in compliance (without consideration of marginal organ outcomes). If so, a condition level determination would not be made by CMS, and the TC would not be publically "flagged" by CMS. Instead, a remediation plan would be provided by the TC to address deficiencies in outcomes for marginal organs. This would result in the application of SRTR data for its intended purpose of remediation, and not the punitive "bright-line" test that it currently serves. Again, no regulatory change and no changes in the Interpretive Guidelines would be needed. Instead, this would constitute a slight modification to the "mitigating circumstances" process and guidelines.

Beyond 42 CFR §486.318, there are other factors that influence OPO performance that should be reexamined and best practices disseminated to the community. For example, 42 CFR §486.322 lays out requirements for written agreements between hospitals and OPOS that must specify the meaning of terms such as "timely referral" and "imminent death." While these are important piece to have in place for checklist/review purposes, successful OPOs have established more meaningful relationships with transplant centers that result in higher conversion rates. Additionally, 42 CFR §486.326 sets forth requirements for human resources that calls for "sufficient number of qualified staff." ASTS believes it would be worthwhile to analyze staffing amongst OPOs and determine if certain staffing levels or staffing composition contribute to improved donation rates. Finally, 42 CFR §486.348 outlines quality assessment and performance improvement (QAPI) requirements that include death record reviews and adverse event processes in addition to objective measures to demonstrate improved performance. Given that donation rates have remained relatively flat in recent years, the identification and dissemination of best practices and other benchmarks and their adoption by other OPOs could positively impact the donor pool and result in more lifesaving transplants.

ASTS would also be interested in better understanding the long term impact of the HRSA sponsored Organ Donation Breakthrough Collaborative. We are familiar with the September 2003 best practices and final report document and think that an analysis of what has occurred in more recent years would be incredibly useful for QAPI purposes.

Thank you for engaging ASTS in these important discussions. We believe that modification of the OPO and TC outcomes requirements would constitute an important step in addressing organ wastage. We look forward to working with CMS on these and other steps intended to increase the availability and successful transplantation of both renal and extra-renal organs.

Best regards,

Kim Olthoff, MD
President

Appendix A

The ACOT recognizes that the current CMS and HRSA/OPTN structure creates unnecessary burdens and inconsistent requirements on transplant centers (TCs) and organ procurement organizations (OPOs) and that the current system lacks responsiveness to advances in TC and OPO performance metrics. The ACOT recommends that the Secretary direct CMS and HRSA to confer with the OPTN, SRTR, the OPO community, and transplant center representatives, to conduct a comprehensive review of regulatory and other requirements, and to promulgate regulatory and policy changes to requirements for OPOs and TCs that unify mutual goals of increasing organ donation, improving recipient outcomes, and reducing organ wastage and administrative burden on transplant centers and OPOs. These revisions should include, but not be limited to, improved risk adjustment methodologies for transplant centers and a statistically sound method for yield measures for OPOs. The ACOT recommends that this review be completed within one year and that action be taken within two years.