March 18, 2011

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President
Organ Procurement and Transplantation Network (OPTN)
United Network for Organ Sharing (UNOS)
700 North 4th Street
Richmond, VA 23219

Dear Mr. Alexander:

On behalf of the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST), we submit the following comments in response to the Organ Procurement Organization (OPO) Committee and the Membership and Professional Standards Committee's (MPSC) proposal for the use of a statistical model to analyze OPO performance.

Philosophically, the proposed approach for assessing OPO performance parallels the methodology for evaluating transplant center performance, and at least tries to build in consideration of the donor characteristics. But it seems unlikely that this new methodology for "flagging" potentially substandard OPOs would solve the underlying issue of misaligned OPO and Transplant Center Conditions of Participation (CoP) for Medicare. Since the model is necessarily populated with historical data, and since individual OPO data is compared with the average, the model at least initially may reflect transplant centers' traditional reluctance to transplant substandard organs where there is potential to negatively impact their CMS certification. Generally, the proposal is a step in the right direction towards "risk adjustment" for OPOs, but a misalignment of OPO and Transplant Center incentives will continue to be a major issue. The following summarizes the issue and was sent to CMS Administrator, Donald Berwick, by ASTS, AST, AOPO and UNOS with a request for a meeting in an effort to elevate the issue within CMS.

Transplant Center (TC) and Organ Procurement Organization (OPO) Certification Requirements Should be Modified to Reduce Organ Wastage:

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. In 2009, 3145 kidneys were procured from Expanded Criteria Donors (ECDs); 44% (1372) were discarded of which 75% were donors under the age of 65. This strongly suggests that a large number of these kidneys were potentially transplantable, with good outcomes. Such wastage is inconsistent with the national objective of increasing rates of transplantation.

This problem is exacerbated by CMS certification regulations for TCs and OPOs. 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. *Also, TCs are penalized for not accepting and transplanting organs procured and offered to their patients, even though the TC deems the organs clinically unsuitable for transplantation into their particular patient(s).*

The OPO certification regulation 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 beneficiaries (the majority of non-renal transplant recipients), case-rates negotiated with third party payers include the SAC paid by the TC to the OPO for the organ, and therefore the additional cost of dry runs and discards affects TC margins directly and may impact the TC's ability to negotiate future case-rates with payers. Moreover, additional clinical costs of using marginal organs (not related to SAC; items such as increased recipient length of stay) incurred by TCs result in higher payments by both CMS and 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 Transplant Collaborative and other collaborative efforts.

Potential Solutions:

Short Term Options:

i) Eliminate marginal organs from 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) Calculate both "expected" and "observed" rates separately for standard and marginal organs. Again, this would require modification of risk adjustment methodologies and CMS IGs, 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 accreditation decisions would be heavily weighted towards standard organs.

iii) 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 "tagged" 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 IGs would be needed. Instead, this would constitute a slight modification to the "mitigating circumstances" process and guidelines, in line with previous suggestions by the ASTS both during and subsequent to the public comment period.

Long term Options:

i) Funding for research to develop improved risk-adjustment methodologies for both standard and (especially) marginal donor and recipient variables.

ii) Improving the informed consent process, including especially improving effective communication with potential recipients regarding the risks and benefits of accepting marginal organs, the performing center's outcomes for both standard and marginal organ transplants, and the outcomes of other area transplant centers.

iii) A unification of the cultures of CMS, HRSA, and the Collaborative that emphasizes a reduction in organ wastage and a focus on linking organ donation initiative metrics (OPO Performance) with transplant outcomes (TC Performance).

iv) Allocation policy reform with a focus on reducing organ wastage and improving transplant outcomes.

v) Revise the OPO outcomes requirements to reflect a risk-adjusted model for yield.

The ASTS and AST would also like to comment on transplant hospital representation on OPO governing boards and are therefore including the following statement.

Joint Statement of the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST) regarding Transplant Surgeon and Transplant Physician Representation on Organ Procurement Organization (OPO) Governing Boards

It has come to the attention of ASTS and AST that some OPOs have reduced or eliminated transplant hospital representation from their governing boards. Neither Medicare regulations nor OPTN requirements limit transplant surgeon or transplant physician representation on OPO governing boards.

The American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST) embrace the inclusion of community leaders, financial experts, and others with diverse content expertise on the governing boards of Organ Procurement Organizations (OPOs). Diverse perspectives on OPO governing boards enable OPOs to be better equipped to deal with a myriad of issues, develop the OPO budget, and to reach a broader sector of the community. A thorough diversity of skills and perspectives makes for a better and more effective governing board.

- There is no proscription of transplant surgeons and physicians serving on OPO governing boards by law (NOTA) or regulation (CMS).

- Transplant surgeons and physicians are an essential constituency and content experts for OPOs, and thus play a legitimate role on their governing boards.

- Conflicts of interest (COI) on boards such as OPO governing boards are inevitable, and they should be handled via robust, transparent, and auditable COI disclosure and management policies.

- ASTS and AST have been made aware of instances where individual OPOs have reduced or eliminated transplant surgeons and physicians from their governing boards, and consider this to be inappropriate and counterproductive to the proper discharge of OPO function.

The National Organ Transplant Act (NOTA) mandates the creation of a broadly diverse board whose responsibilities are limited to establishing procurement and other OPO policies. NOTA specifically requires that this policy-making board include a transplant surgeon from each transplant center in the OPO's service area, other physicians with particular types of expertise, and community and hospital representation.

The current OPO Medicare certification regulations and the preamble to these regulations make it clear that CMS anticipates the establishment of at least two OPO boards: The "Advisory Board", which includes surgeon and other physician representation as mandated by NOTA, and the governing board, which may or may not include transplant surgeon or transplant physician representation. In the preamble to the final OPO certification regulations, CMS specifically rejects the suggestion that representatives of transplant centers, such as transplant surgeons and physicians, be excluded from the governing board, and suggests that transplant surgeon/transplant physician/transplant center representation and community member representation on the governing board be balanced.

Neither Medicare regulations nor OPTN requirements require limitation of transplant surgeon or transplant physician representation on OPO governing boards. ASTS and AST strongly oppose any effort by OPOs to systematically remove transplant surgeons and transplant physicians from OPO governing boards or to otherwise limit their involvement in OPO governance.

Sincerely yours,

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