ASTS
American Society of Transplant Surgeons

April 6, 2012

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

Dear Dr. Lake,

The American Society of Transplant Surgeons (ASTS) appreciates the opportunity to comment on the OPTN bylaws substantive rewrite of Appendix A: Application and Hearing Procedures for Members and Designated Transplant Programs (the "Draft Procedures"). ASTS appreciates the OPTN's efforts to translate the procedures to be used in taking adverse actions against transplant centers into plain language. However, the Draft Procedures not only fail to achieve this objective but also incorporate sweeping and unwarranted changes to the current procedures that we do not support.

The Draft Procedures, if adopted in their present form, have the potential to obfuscate the processes to be used in imposing potentially severe sanctions on transplant centers and to curtail the due process protections to which they are entitled, while substantially expanding the role of the OPTN Executive Director and minimizing the role of the Membership and Professional Standards Committee (MPSC). At the same time, the Draft Procedures fail to address the most important and pressing issue facing transplant centers with regard to adverse actions: the lack of coordination between OPTN/HRSA and CMS processes. For these reasons, and the others set forth in detail below, we respectfully **oppose** adoption of the Draft Procedures in their current form and urge the OPTN to re-examine and revise them prior presenting to the Board of Directors for consideration.

Based on the preamble to the Draft Procedures and other OPTN public statements regarding the Draft Procedures, it appears that a primary objective of this proposal is to rewrite – in plain language – the procedures to be used in investigating potential "adverse actions" and other OPTN sanctions. While this objective is laudable, we believe that it is difficult to utilize plain language in describing due process rights, hearing procedures and notification requirements – each of which carry legalistic overtones. In light of the extraordinary consequences of an adverse OPTN finding , a high priority should be placed on clarity over brevity. Terms should be precisely defined, definitions should be carefully worded, and factors taken into consideration should be clearly articulated. Priority should be placed on precise definitions, clear terminology, and logical sequencing, each of which the Draft Procedures appear to lack.

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On the other hand, to the extent that the Draft Procedures are intended to clarify certain key aspects of adverse actions that are not addressed in the current procedures (e.g., the period within which the Secretary is to be notified of potential violations; the time when potential violations are to be "referred" to the Secretary; and the procedures to be used by the OPTN in conducting special "Secretary-directed" reviews in cases not involving violations of OPTN policies or procedures), a complete re-write of the current procedures is not necessary. To the extent that these specific issues are the focus of the Draft Procedures, we suggest that the OPTN abandon the current Draft Procedures and focus on these more narrow objectives.

Generally, we have two overarching concerns. First, the Draft Procedures appear to vest the OPTN Executive Director with substantial new authority that historically has been within the scope of the MPSC. For example, the Draft Procedures (at L.I.A) direct the Executive Director to conduct ongoing periodic reviews and evaluations of each Transplant Hospital, Histocompatibility Laboratory Member, and OPO Member for compliance with OPTN obligations. All compliance monitoring is to be performed using guidelines developed by the Executive Director.

In contrast, current bylaws provide the Executive Director with general authorization to monitor compliance and refer potential non-compliance to the MPSC. In addition, the Draft Procedures authorize the Executive Director to unilaterally require a transplant center to take "corrective action" including, for example, a root cause analysis, corrective plan, plan for quality improvement, on-site monitoring or the retention of external expert consultants, all apparently without the involvement of the MPSC (L.6.). In cases where the MPSC Chair determines that an "urgent" and severe risk to the public "appears to be" present, it is the Executive Director – and not the MPSC Chair – who determines what action should be taken by the offending transplant center (L.10.B.). At L.15.B, if the Member fails to fulfill the corrective action requirements, the Executive Director may determine what action is to be taken, apparently without a requirement for input from or consultation with the MPSC. The Draft Procedures include numerous other expansions of the Executive Director's responsibility. We are aware of no reason to substantially expand the authority of the Executive Director and recommend that this authority should continue to be vested in the MPSC.

The Draft Procedures fail to address a very critical aspect of the OPTN sanctions process: coordination with the CMS transplant center conditions of participation. While the Draft Procedures include numerous new provisions under which the Secretary is to be notified of a transplant center's alleged deficiencies (in some cases, before the transplant center itself is notified of the potential issue), neither the Draft Procedures nor any other document of which we are aware establishes how any action to be taken by the Secretary with regard to the transplant center's CMS certification status is to be coordinated with OPTN processes. Since the current CMS transplant center conditions of participation were adopted after the current OPTN procedures were developed, coordination of investigations is not addressed in the OPTN's existing policies and procedures. There is a genuine need for established and clear processes for coordination, especially since the failure of a transplant center to notify CMS of its OPTN status may itself subject the center to de-certification under the CMS regulations. Duplicative and potentially conflicting processes waste governmental as well as private resources. While we recognize that the processes to be used by CMS in the context of its certification process are beyond the scope of the OPTN's authority, we believe that this re-write of the OPTN adverse action procedures presents a perfect opportunity for the OPTN to interface with CMS to eliminate duplicative processes or, at the very least, to clarify exactly which OPTN actions are reportable to CMS and the timing requirements of such reporting.

The Draft Procedures also include a number of sweeping changes that require more thorough consideration. For example:

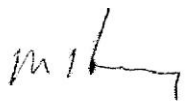
- Under the Draft Procedures, failure of a member to "self report" a violation of OPTN policies and procedures or failure to report another member's alleged violations would constitute a basis for sanctions (L.3).
- The Draft Procedures appear to limit the extent to which the OPTN will keep its deliberations confidential. (L.5).
- The Draft Procedures include extremely vague requirements with regard to the composition of Hearing Panels and appear to include no provisions to preclude participation by individuals who may have a conflict of interest because of their association with a competing transplant center.
- In routine cases, it is unclear precisely when a transplant center would be entitled to an interview. Compare L.14.1 ("Members will be notified of their right to an interview at the time they are informed of the Committee's determination.") and L.14.C ("The Member will be entitled to an interview when the Routine Review Committee is considering making a recommendation for a Letter of Reprimand or an adverse action.").

The bullet points above document only a few of the poorly drafted and potentially overreaching provisions included in the Draft Procedures, none of which are noted in the preamble of the policy proposal.

In summary, the ASTS is opposed to this policy proposal and respectfully urges the OPTN to refrain from adopting the Draft Procedures in their present form.

Thank you for consideration of this request. If we can be of further service, please contact Kim Gifford, ASTS Executive Director, via phone, 703-414-1609, or email, kim.gifford@asts.org, and she will facilitate additional discussions.

Sincerely,



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